PROJECT MANAGEMENT PRACTICES AND KEY FACTORS FOR SUCCESS IN FDA HUMAN FACTORS VALIDATIONS OF MEDICAL DEVICES AND COMBINATION PRODUCTS

BY

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Abstract

In 2016, the Food and Drug Administration (FDA) issued final guidance entitled "Applying Human Factors and Usability Engineering to Medical Devices" (FDA & CDRH, 2016a), as part of its comprehensive Quality System Regulation (QSR). Human Factors Engineering (HFE) is considered critical in the design of safe medical devices and its application is now a requirement for manufacturers of such products.

Multiple issues and bottlenecks have emerged, involving concerns about the quality and success of the HF validations, as well as about FDA's review process. While there is a significant amount of research looking to improve the quality of the HF validations through improving the HFE methods used, no attention has been given to other important aspects (such as understanding the needs of key stakeholders and the characteristics of FDA HF validation projects) to develop across the board solutions. Key stakeholders lack the necessary tools to adapt successfully to current and future demands of the QSR, and measures that help increase the quality and success of such projects are urgently needed. Upcoming updates to the QSR will place greater emphasis on risk-based management of suppliers of medical device manufacturers, and the FDA has launched initiatives that demand performance-based data to measure excellence.

An industry-focused (human factors service providers) project management (PM) maturity assessment tool was proposed, consisting of two dimensions (HFE and PM). The research questions this work sought to answer include the following: Is PM being applied to manage FDA HF validation projects? What are the main challenges? Why do

these projects fail? What are the drivers of success? What is the average PM maturity level for this industry? What is the ideal PM maturity level for HFSPs? A mixed-methods, exploratory research design was used, including Bruin's framework for maturity models development. This work included two phases. Phase I consisted of a survey which helped to understand the specified projects and inform the design of the tool. To develop the content to populate the model, Phase II included a panel of experts (Delphi Panel). Part 2 of Phase II covered testing the beta version of the tool. Overall, participants found the tool and content useful. In addition, this work contributes to the literature research about the practices and the key factors that influence the quality and success of HF validations for medical devices and combination projects that seek approval from the FDA.

To my one and only.
My dynamic and deep seven years old daughter,
Karisa

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"Ebenezer" (1 Samuel 7:12)

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Chapter 1 - Introduction

1.1 Human Factors Studies Required by the FDA

The FDA is the government agency that regulates medical devices and drug combination products in the United States (U.S.). In 2016, the agency issued final guidance entitled “Applying Human Factors and Usability Engineering to Medical Devices” (FDA & CDRH, 2016a). The Human Factors Pre-Market Evaluation Team (HFPMET) at the Center for Device and Radiological Health (CDRH) led the preparation of the document. Furthermore, between 2016 and 2017, the FDA published three new guidance drafts outlining HF requirements specifically for drug combination products that involve devices (FDA et al., 2016, 2017; FDA & CDER, 2017).

The specified guidance documents come as a result of an ample and evolving quality system regulation (QSR) applicable to medical devices (see Chapter 1.2). Their purpose is to help manufacturers of medical devices and combination products apply suitable human factors engineering (HFE) methods so that their products can prove to be effective and safe for human use before getting to be marketed in the USA. Depending on the level of risk, pre-market submissions for FDA approval must now include an HFE report.

1.2 The Quality System Regulation (QSR) - Basis for the HF Requirement

Title 21 of the Code of Federal Regulations (CFR), Part 820, establishes the process through which the FDA ensures finished devices are safe and effective. This

regulation is also known as Quality System Regulation (QSR) or Current Good Manufacturing Practices (CGMPs). Manufacturers of medical devices are subject to FDA inspections for compliance of the stated FDA 21 CFR 820. The HF requirements are outlined as part of the Design Control of Title 21 CFR 820.30 (a) General. (1): "Each manufacturer of any class III or class II device, and the class I devices listed in paragraph (a)(2) of this section shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met."

Table 1.1: The FDA HFE validation requirement as part of the Design Controls of the QSR (Title 21 CFR Part 820)

FDA 21 CFR Part 820
+ General Provisions
+ Quality Systems Requirements
- **Design Controls:**
a) General
b) Design and Development Planning
c) **Design Input**
d) **Design Output**
e) Design Review
f) Design Verification
g) **Design Validation**
h) Design Transfer
i) Design Changes
j) Design History File
+ Documents Controls
+ Purchasing Controls
+ Identification and Traceability
+ Production and Process Controls
+ Acceptance Activities
+ Nonconforming Product
+ Corrective and Preventive Actions
+ Labeling and Packaging Control
+ Handling, Storage, Distribution, and Installation
+ Records
+ Servicing
+ Statistical Techniques

Source: Developed by the author with information from the Electronic Code of Federal Regulations (https://www.ecfr.gov)

Although, the FDA remarks that HF should be considered through all the Design Controls, specific references to the need for HF data are in the paragraphs c) **Design Inputs**, f) **Design Verification**, and g) **Design Validation** of said Title 21 CFR 820.30 (see Table 1.1). For regulating purposes, medical devices are organized into categories and by the level of control needed, from class I to III. The higher the level of risk of injury or illness, the greater the level of control (FDA & CDRH, 2018b). For instance, most class I devices are exempt from pre-market review by the FDA, while class III must go through rigorous review path before getting approved to market in the USA.

In that same vein, Title 21 CFR Part 4, which was recently published, specifies in details the CGMPs process for combination products to meet the HF requirements, combination products manufacturers can demonstrate compliance with either or both, the drug CGMPs and/or the device QSR previously discussed (see section 1.20), depending on the product's primary mode of action (PMOA). The Center for Drug Evaluation and Research (CDER) will be assigned, for instance, if the PMOA is drug (FDA & OCP, 2017).

1.3 What is 'Human Factors Engineering'?

Also known as usability engineering or ergonomics, HFE seeks to solve problems of how humans interact with machines/computers and even their environments, through the use of scientific methods, experimentation and validation including psychology and engineering. HFE is considered critical in the design of safe medical devices (Weinger et al., 2010). The International Ergonomics Association defines HF as "the scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theories, principles, data, and

methods to design in order to optimize human well-being and overall system performance" (https://www.iea.cc).

1.4 What are HF Studies?

There are two types of HF studies. *Formative*, which comprise a series of usability studies usually during product development, to help inform and optimize the design of the product. The s*ummative* usability study are meant to uncover any use-related hazard in the finished product (FDA, 2016; Kortum, 2016).

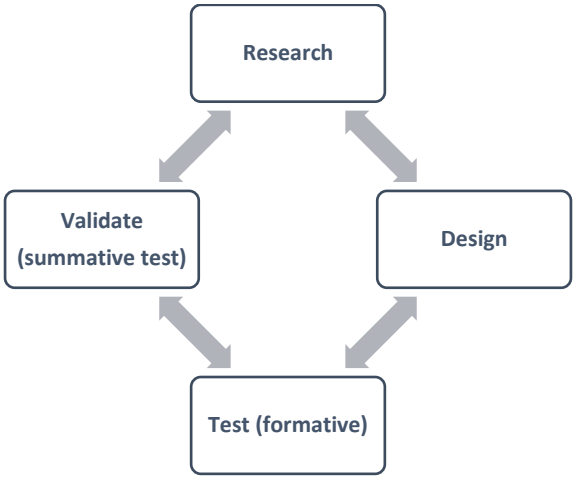


Figure 1.1: Simplified HFE validation process relative to the FDA's HF guidance for medical devices

In contrast with formative usability studies, the HF validation is the final usability study in which the assumptions made during product design receive a last test against the reality of use by the intended end users (usability requirements). As per FDA's guidance on the topic (FDA & CDRH, 2016b), the goal of the HF validation is to demonstrate that

the device can be used by the intended users, under the expected use conditions, and without serious use errors or problems.

1.5 What are Medical Devices?

It could be surprising to know that medical devices are not always complicated pieces of equipment. Essentially, any device which is used to treat or manage patients, and it is not exclusively a drug, would fall into the legal definition of medical device, which could range from a toothbrush to a complex heart valve (FDA & CDRH, 2018b). FDA Title 21 Code of Federal Regulations Part 820, Chapter I, Subchapter H, defines a medical device as an:

"…Instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is

1. recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
2. intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
3. intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and, which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes…"

1.6 What are Combination Products?

Combination products (see Figure 1.2), are those which combine different parts (called "constituents") to include a medical device and/or drug and/or biologic (drugs produced from living organisms using biotechnology). The formal definition of combination products can be found in Title 21 CFR 3.2 (e). Examples of combination products include prefilled syringes, autoinjectors, transdermal patches, pen injectors**,** and a co-package of a syringe with a drug or biological product.

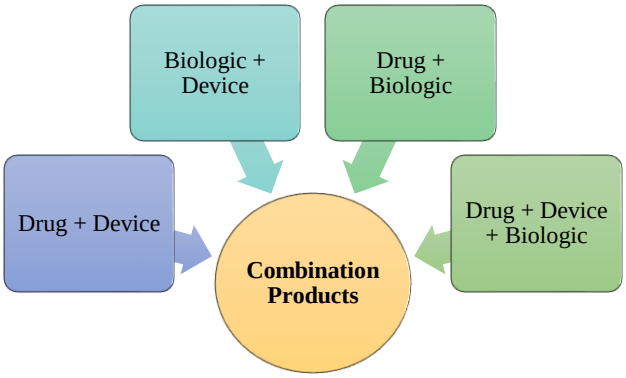


Figure 1.2: Combination Products

1.7 Why Does the QSR Prescribe HF Studies?

1.7.1 The Health System and Need for Minimizing Errors

Since the Institute of Medicine (IOM) reported that medical errors were causing up to 98,000 deaths yearly in the USA, the significance of minimizing the risk of medical errors has gained more attention than ever (IOM, 1999). As per latest estimates, medical errors are now considered to be the third leading cause of death in the US (Anderson & Abrahamson, 2017; Makary & Daniel, 2016).

In this case, the urgency for change was amplified by the rise in the number of errors in the use of medical devices leading to patient harm such as: ventilators, defibrillators, infusion pumps, and drug-device combination products. These devices often have interface-related issues (see Figure 1.3: *Device-user system HF considerations*), resulting in dangers like drug overdose or delay in delivering medical help (Borchers et al., 2007; Ho (Patrick), 2010; Middleton et al., 2013; Zuckerman et al., 2011). Reports of recalled medical devices between the years of 2003 and 2012, suggested the need for interventions, considering that design and labeling failures were the main causes for most of all recalls (Ferriter, 2011; Zuckerman et al., 2011).

1.7.2 The Role of HFE

The trend toward self-care (medical devices and combination products being sold over the counter for home use), consumers self-treating or self-administering medications, has also raised concerns regarding the safety of consumers (Middleton et al., 2013). Therefore, as healthcare continues to transition from traditional to self-care, it is necessary that users with fewer skills, or even unskilled users, can use such devices safely.

As illustrated on Figure 1.3, consumers and healthcare providers often face difficulties understanding poorly designed interfaces or instructions, and errors can occur due to improper use. Other HF considerations include the following: the device use environment (home or hospital?) and the device user (end-user or healthcare provider?). Risks of errors can be reduced through a better understanding of our psychological and physical limitations, to design interfaces and instructions that are clear and easy to use. It was in recognition of the previous that the FDA has required pre-market HF studies for

approval of medical devices and combination products. Manufacturers of medical and drug delivery systems are responsible for providing safe and effective products by ensuring that potential errors are studied and mitigated.

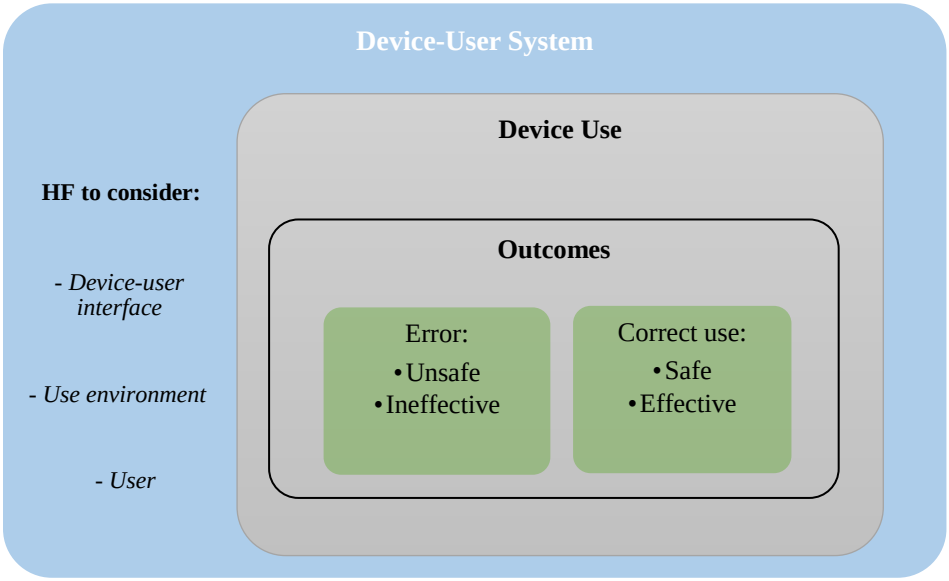


Figure 1.3: Device-user system HF considerations. Adapted from Applying Human Factors and Usability Engineering to Medical Devices - Guidance for Industry and FDA Staff (FDA/CDRH, 2016)

So far, the basic premises of why there is a need to ensure user safety in the context of medical and drug delivery devices have been described. The FDA has remarked the necessity of validating the use of such products in close to real-life conditions, applying HFE, and an HF report must be included with pre-market applications.

The following paragraphs will touch on explaining the main problem, the details and need for improvements, following by a proposed solution to help align stakeholders within an evolving quality system environment.

1.8 The Problem

1.8.1 Implications of Failed HF Validation Projects

Although the FDA has not yet released data [1]regarding the number of failed HF validations or reasons why they failed, to analyze the factors underlying the problem a causal-loop-diagram (CLD) was developed (see details in Rojas, Sharareh, et al., 2019). The resulting CLD is shown on Figure 1.4, with no immediate balancing loops, only reinforcing loops. According to Meadows (1999), reinforcing loops are points where a system can either grow or collapse (Meadows, 1999). Hence, these loops need interventions to ensure the best outcomes possible. Reinforcing loops can push a system out of control because a small issue could quickly turn into a big problem, as the growth may be exponential. These loops can either turn into vicious cycles, where the development of unwanted outcomes gets out of control. For instance, Loop R4, where more failed FDA HF validation projects lead to more need for remedies, represents a vicious cycle. Another clear example of undesirable outcomes that can get out of control is Loop R6: as the system's effectiveness decreases, so do the level of innovation and the benefit for users. On the other hand, reinforcing loops can be leveraged to create virtuous cycles, which would be the opposite, a desirable exponential growth, e.g., referring specifically to Loop R7, could there be a case where patients would be benefiting too much as a result of a highly effective system?

[1] In response to this author's questions, the Center for Devices and Radiological Health (CDRH) shared statistics in 2019 at the HFES Healthcare Symposium, indicating failure rates as high as 93.5% (e.g., pre-market approval applications), and 90% on average for all pre-market submissions through the CDRH.

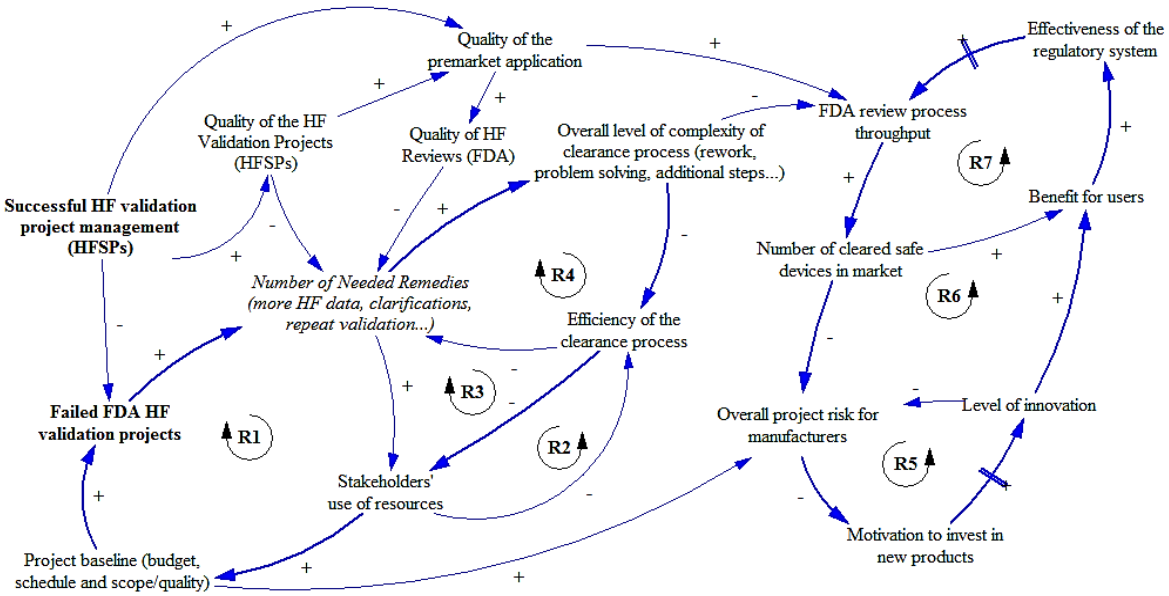


Figure 1.4: CLD illustrating the dynamics of failed FDA validation projects (Rojas et al, 2019)

R6 demonstrates how the lack of effectiveness of the regulatory system has a significant impact on several variables, leading to a reduced opportunity for users or consumers to benefit from medical device and combination products. In some circumstances (depending on the regulatory pathway), patients could lose their lives if a particular product takes a long time to get to market or never makes it.

Overall, the need for strategies that increase the quality of FDA HF validation projects and reduce "remedies" were identified. These "remedies" refer to the requests from the FDA to revise the HF validation (e.g., request for more information or data), and such situation translate into project failure.

It is known that the drug development and medical device industries face a tedious and lengthy regulatory process which is associated with high risks and, hence, high costs (Van Norman, 2016a, 2016b; Williams et al., 2016). All of these may add considerable challenges to for manufacturers to get their products to market. Pharma,

medical device, and biotech industries might be frustrated to find that any seemly small change requested by the FDA (due to a failed HF submission) could imply an array of troubles for them – and of course, increased costs. If a medical device or a combination product fails the HF validation requirement this might mean that the product would need to be redesigned, or even never get to market.

The previous implies lost investments or higher costs, depending on the device classification, complexity of the design process and the required remedies. Moreover, delays in approval due to inefficiencies in the validation process could mean that users/patients would experience delays before they would benefit from the product (Williams et al., 2016). Also, in extreme circumstances, patients may even lose their lives, unable to benefit from a product that takes a long time to get to market. In other words, manufacturers and consumers face severe consequences as a result of an ineffective and inefficient HF validation process.

With the described situation, it is not uncommon to find that the conversation when it comes to FDA HF validations, revolves around strategies for success during the HF validation process (Lemke, 2017; Privitera et al., 2017; Story et al., 2017; Wiklund, 2012).

1.8.2 Why are FDA HF Validations "Projects" (and Often Fail)?

It seems that in many organizations, FDA HF validations are not considered projects in their own right, just a Phase in product development. That is a missed opportunity for the application of available tools and the development of strategies to increase success. In that sense, what is a "project"? A project is described as a temporary

effort carried out for a unique purpose (a unique product, service or result), with a predetermined amount of resources and scope (Project Management Institute, 2017).

Because HF validations for FDA approval should have a specific start and end, they are *temporary*. Since these are temporary efforts, a predetermined amount of work (scope) and resources should be agreed. That is, a budget and people that otherwise would not be working together, entailing multiple internal or external stakeholders such as manufacturers, product developers, HFSPs, and regulators. HF validation projects are also very *unique,* something that the FDA has persistently remarked (FDA & CDRH, 2016a). The FDA deals with each HF validation submission on a case-by-case basis. FDA, HF validations are projects, and as it will be explained next, often fail.

1.8.3 Project Failure vs. Success

Project success has been largely discussed in the PM literature (Ika, 2009), because even in with the application of strategic PM, projects may still fail. For projects to be successful, there are basic and specific criteria that lead to successful PM. In that sense, PM is considered a success when it has met project objectives within time, within cost, at the desired performance level, while utilizing the assigned resources effectively and efficiently, and was accepted by the client (H. Kerzner, 2017). However, to evaluate the impact of failed FDA HF validation projects, it is necessary to observe a "failed" one. That is not observable because, as explained above, the FDA does not directly fail submissions. The notion is that if the FDA finally approves the HF validation, even after having corrected any number of deficiencies, the project was successful.

Unfortunately, the previous is only an illusion. Based on the impact on traditionally and most widely accepted criteria about project success – schedule, costs,

and scope/quality – any need for unexpected remedies during the pre-market review process, certainly means project failure. That is because "the success of a project is measured against its objectives" (Project Management Institute, 2017). Moreover, modern constructs of project success also consider the satisfaction of stakeholder groups as a critical factor to determine if a project has been successful (Albert et al., 2017).

Stakeholders and Different Perceptions of Success

It has been largely studied that different stakeholder groups have different perception of project success (Davis, 2014). The case of HF validation projects that seek approval from the FDA, is an excellent example of that issue (see Table 1.2). As it can be inferred at this point, some stakeholders would like to avoid the use of the term "failure" when a submission is not immediately accepted due to issues with the HFE report (e.g., found deficient). While such a situation would not be viewed as a failure by the FDA or by HFSPs; with no doubt, it would not look like success to manufacturers or project sponsors.

Table 1.2: The situations that translate as failure or success depending on stakeholders' view

The finished product is in fact	**Need for remedies?**	**Failure for?**	**Success for?**
(a) Safe, the FDA finds it is unsafe (false negative by the FDA)	Yes	Manufacturers, FDA, users	HFSPs
(b) Unsafe, the FDA finds it is safe (false positive by the FDA)	Yes (eventually)	HFSPs, manufacturers, FDA, users	No stakeholder
(c) Safe, the FDA finds it is safe (errors successfully avoided)	No	No stakeholder	All stakeholders
(d) Unsafe, the FDA finds it unsafe (false positive by HFSPs)	Yes	HFSPs, manufacturers	FDA, users

Note: Failure = remedies after HF validation submissions (a, b, d)

Therefore, even in the case where the FDA has only asked for clarifications, the project cannot be accepted by the client (the manufacturer) until all issues are resolved. Moreover, despite being able (in some cases) to meet the final objectives as a result of correcting any deficiencies, if a project is late, over budget, and took more than the initially agreed work (scope), it was not successful in meeting its initial objectives; thus, it failed.

In summary, the implications of failing a HF validation could turn out costly, and that is why it is a high-risk component of the medical device and drug/combination products development process.

1.8.4 A Developing Requirement in a Changing Regulatory Environment

While the FDA has a long-standing awareness of the impact of HFE on reducing use-related errors in medical devices (Burlington, 1996; FDA & CDRH, 2000; Sawyer, 2000), it was only until after 2011 that the Agency gave serious attention to the topic, through the publication of a draft guidance and more dedicated HF reviewers (FDA & CDRH, 2011; Kay et al., 2011). While the first HF guidance was final in 2016, it did not address many of the reported concerns. Regarding combination products and biosimilars, the published HF guidance documents are still in the draft stage.

As explained (see Chapter 1), the HF requirement is part of an ample QSR, outlined in Title 21 CFR Part 820 for medical devices and Part 4 for combination products (FDA & OCP, 2017). Among the triggers behind the FDA's increased efforts on the implementation of several medical device safety initiatives, are the upcoming updates to similar international standards. In that sense, an important consideration is the harmonization of the current QSR with ISO 13485:2016, which would classify HFSPs as

critical suppliers. The newest version, ISO 13485:2016 includes control of suppliers based on risk, demanding the need for careful management of suppliers. Clause 7.4 of ISO 13485:2016, remarks, “The organization shall establish criteria for the evaluation and selection of suppliers.” In addition, Clause, 4.2.1, states, "The organization shall apply a risk-based approach to the control of the appropriate processes needed for the quality management system. Anything that affects the quality system (QS) needs to be viewed from that risk perspective.” According to this, and taking into consideration the critical role of HFE in ensuring the safety and quality of medical devices, HFSPs shall be subject to careful management and assessments.

It can then be established that the HF requirement is a developing process in a changing regulatory environment. Proposed solutions must not only be scalable but should also enable the development of the necessary capabilities to ensure success in the future regulatory environment.

1.8.5 Lacking HF Awareness and QS = Disconnect Between Key Parties

A lack of HF awareness is an overwhelming fact for the FDA. Representatives of the Agency are frequently confronted with inquiries about basic HFE principles, which has been evident during knowledge-sharing workshops, and discussion panels witnessed by the lead author (I. Z. Chan, 2017; Horst et al., 2015; Wiyor et al., 2018).

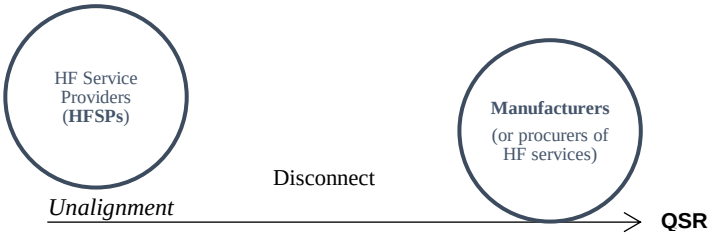


Figure 1.5: Disconnect/unalignment between key parties in FDA HF validation projects

Besides the Design Controls, other requirements of the QSR include Management Responsibility and **Purchasing Controls (**Table 1.3**)**. In that sense, manufacturers must assess and ensure that suppliers can provide quality products or services, and that includes the HF function (QSR Preamble, Comment 46). Still, procurers of HF services often lack a solid understanding of the HF requirement, and are not aware of its impact on overall project success (Rojas, Sharareh, et al., 2019). As such, they are often oblivious of what to ask to HFSPs for their supplier assessments (see Table 1.4).

Table 1.3: High-level outline of Title 21 of the Code of Federal Regulations (CFR), Part 820 – QSR

FDA 21 CFR Part 820:
+ General Provisions
+ Quality Systems Requirements
+ Design Controls
+ Documents Controls
+ **Purchasing Controls**
+ Identification and Traceability
+ Production and Process Controls
+ Acceptance Activities
+ Nonconforming Product
+ Corrective and Preventive Actions
+ Labeling and Packaging Control
+ Handling, Storage, Distribution, and Installation
+ Records
+ Servicing
+ Statistical Techniques

Source: Developed by the author with information from https://www.ecfr.gov

HFSPs, on the other hand, are often frustrated when required to go through what they would consider irrelevant and time-consuming questionnaires that are not aligned with how the HF industry works. The reality is that HFSPs are usually not adept in the concepts of manufacturing quality management. They are experts on HFE methods and usability testing to deliver the HFE validations.

Table 1.4: Partial view of 2 actual questionnaires used by procurers of HF services to assess HFSPs

SUPPLIER QUESTIONNAIRE

QUESTIONS FOR THE DIRECT MANUFACTURER OR SERVICE PROVIDER

1.	Are you a distributor or a sales office for a manufacture	**Yes**	☐	**No**	☒
2.	Do you have a written quality manual?	**Yes**	☐	**No**	☒
3.	Is your facility subject to periodic inspections by U.S. FDA?	**Yes**	☐	**No**	☒
	If yes, list date of last inspection				
4.	Has your quality system been audited by any third parties?	**Yes**	☐	**No**	☒
	Are you willing to provide a copy of the report?	**Yes**	☐	**No**	☐
5.	Are you currently registered to any quality standards (e.g., ISO 13485, ISO 9001, etc.)?	**Yes**	☐	**No**	☒
	If yes, please list them and provide copies of the certifications.				
6.	Do you have internal quality metrics that are reviewed periodically?	**Yes**	☐	**No**	☒
	If yes, please provide recent samples of those metrics.				
7.	Do you have customer satisfaction metrics that are reviewed periodically?	**Yes**	☐	**No**	☒
	If yes, please provide recent samples of those metrics.				

Please provide a list and copy of all accreditations for your company.

REQUEST FOR INFORMATION (RFI)

4. Sustainable Development and Environmental Policy

4.1 Is the company engaged in sustainable development process?

Please tick applicable box

YES	
NO	

Please describe

4.2 Are Quality & Security / Environmental policies compliant with OHSAS 18001 and ISO 14001?

Please tick applicable box

YES	
NO	

5. Human factor studies

5.1 For which parts of design control does the company provide human factor studies?

It seems there are not only significant knowledge-based gaps but also process-based gaps. Key parties (such as the biotech and pharmaceutical industries) are under pressure to develop an understanding of the HF discipline, and HFSPs must implement QS. Thus, such lack of HFE awareness on the side of manufacturers, and of QS on the

side of HFSPs, brings about a sort of disconnect as well as unalignment, illustrated on Figure 1.5.

The aforementioned described weaknesses for each one of the sides suggest a need to align manufacturers and HFSPs to work smoothly within such a regulatory framework, considering their specific needs and capabilities. With such complexities, it is reasonable to wonder whether the necessary conditions are in place to ensure the quality and success in the implementation of the HF requirement.

1.8.6 The Need to Align Manufacturers and HFSPs

Moreover, as part of the QSR, manufacturers of medical devices are subject to inspections by the FDA. The regulation requires that manufacturers of these devices demonstrate objective measures indicative of quality and success regarding how potential HFSPs would deliver HF validation projects. In that sense, they are responsible for selecting only the providers that have the capabilities to provide the required quality (21 CFR 820.50 Preamble, Comment #106).

As an example, let us consider how UX research (user experience research) has become a popular business topic, as it pertains to the design of websites and apps. However, due to stated lack of HF awareness, UX is often mistakenly presented as its mother discipline, HFE. Could that mean that any number of firms, including novice ones, might be offering HF research services? "Would-be HFSPs" could be conducting FDA HF validations without any standards of quality as it applies to the QSR. There is no appropriate tool or system for manufacturers to assess and document the quality of HFSPs as directed by 21 CFR Part 820.50(a)(1)), soon to be harmonized with ISO 13485:2016. Interestingly, a report that led to the "Case for Quality" in the medical

device industry outlined that supplier monitoring and management is widely identified as a continuing source of significant quality risk in the value chain (FDA, 2011).

Considering the paragraphs, a suitable approach is proposed and described, to help bridge the described gap while meeting the independent needs of each stakeholder.

1.9 Problem Statement

From the above discussions, it is clear that medical device use errors are a prevalent and significant issue to address in modern society. Further, it is clear that HFE science, methods, and principle have much to offer towards creating safe and effective medical devices. However, there appears to be a gap between manufacturers of these devices and the consistent and proper application of HFE methods towards successful FDA HF validation submissions.

Furthermore, the following critical considerations could help to develop appropriate solutions:

1) There is no way for manufacturers (or procurers of FDA HF validations) to predict and document the quality and success of FDA HF validation projects.
2) HFSPs are challenged by the lack of suitable and standardized quality systems (QS) to integrate and work smoothly considering the demands of the QSR.
3) The disconnect between HFSPs and manufacturers (or in general, those who procure HF validation services for FDA pre-market submission) also leads to a critical need for alignment. Hence, given the demands of the QSR, suitable solutions should enable alignment and integration.

At this point, it is reasonable to ponder regarding how to enable the delivery of HF validations with consistent (repeatable) quality and success. For that to happen, HF validations must consist of standardized processes that can be documented, measured, and improved.

1.10 The Proposed Intervention

1.10.1 Considering the Flexibility in the Development of Quality Systems

While the QSR/CGMPs makes manufacturers (and their suppliers) responsible for developing quality systems that ensure products meet regulatory requirements, there is an essential mechanism that both, procurers of HF services and HFSPs can use to bridge the described gaps. The QSR/CGMPs (nor the revised ISO 13485:2016) do not prescribe a specific framework to plan and establish a quality system. Instead, the objective is to develop and follow applicable procedures as appropriate, considering the type of operations and products.

Title 21 CFR, section 820.50 (QSR) mandates that each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured, and that meets the requirements of this part. In other words, the essential elements of the regulation must be objectively met, the details, method, and strategy in ensuring so are left to the manufacturers, who can as well require suppliers to implement quality plans that align to meet the requirements (*21 CFR, section 820.50* Preamble, Comment #99). Likewise, ISO 13485:2016 places greater focus on the need to control suppliers based on risk:

"When the organization chooses to outsource any process that affects product conformity to requirements, it shall monitor and ensure control over such processes. The

organization shall retain responsibility of conformity to this International Standard and to customer and applicable regulatory requirements for outsourced processes. The controls shall be proportionate to the risk involved and the ability of the external party to meet the requirements in accordance with 7.4. The controls shall include written quality agreements." (Clause 4.1.5, ISO 13485:2016)

1.10.2 Project Management Maturity as an Indicator of Quality and Success

Project Management (PM) is been considered an organizational innovation that can impact the internal and external systems of an organization, with the introduction of innovative structures and methods (Martinsuo et al., 2005). As per literature, the level of project management maturity is associated with quality and project success (Cooke-Davies & Arzymanow, 2003; Nieto-Rodriguez & Evrard, 2004; Papke-Shields et al., 2010; PM Solutions, 2014; PMI, 2018; PwC, 2012; Sonnekus & Labuschagne, 2004; Thomas & Mullaly, 2009). As such, PM maturity is recognized as an organizational capability and competitive advantage (J K Crawford, 2006; L. Crawford, 2006).

The case has been described to make evident that current times and the evolving regulatory framework for medical and drug combination products demand robust processes which ensure success in meeting requirements (failure is not an option in such environment). To meet goals successfully, there is a need for PM (Miklosik, 2015). Applying systematic PM can help HF organizations, manufacturers, and regulators create more focused competencies and efficiencies to reduce risks and costs while increasing quality in the FDA HF validation process (see Figure 1.4).

The explained need for integration and organization can be improved through project-based management. Martinsuo et al. (2005) found that two critical drivers that

lead to the implementation of project-based management are *external* pressure and *internal* complexities (as it is the case). Improvements in efficiency and project culture were the results of such implementation (Martinsuo et al., 2005).

Now, to conduct successful PM, a certain level of organizational infrastructure and competencies that denote the capability to manage projects successfully is essential (Man, 2007). That leads to the idea of maturity: something *fully developed* (Cooke-Davies & Arzymanow, 2003). As described by Andersen & Jessen (2003), PM maturity entails "perfect conditions to handle projects." This refers to a state of readiness that ensures projects will be delivered successfully. Accordingly, understanding and establishing an ideal level of PM maturity in the described context could help solve several dimensions of the problem (see Figure 1.6).

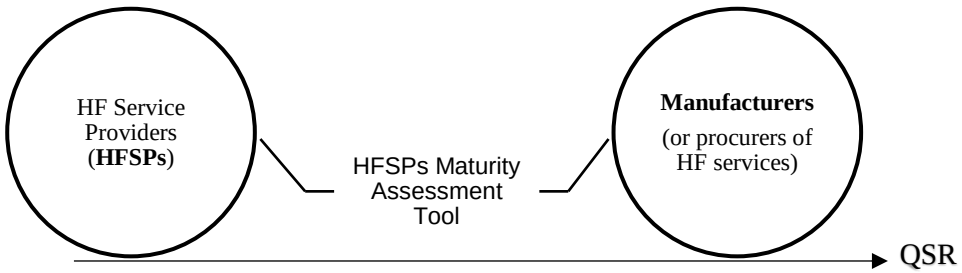


Figure 1.6: How an industry-focused (HFSPs) maturity assessment tool could align and connect key stakeholders of FDA HF validation projects

For an objective and practical model, it becomes necessary that the corresponding HFE processes should be based on:

a) The specified FDA HF guidance: "Applying Human Factors and Usability Engineering to Medical Devices;"
b) Supplemented with the international standard IEC 62366-1: 2015, Medical Devices-Part 1: Application of usability engineering to medical devices.

The PM Dimension will be based on:

a) PM processes aligned with the most widely recognized standard in PM, which is the Project Management Body of Knowledge (PMBOK®)
b) Research on FDA HF validation projects (characteristics, practices, and factors critical to quality/success).

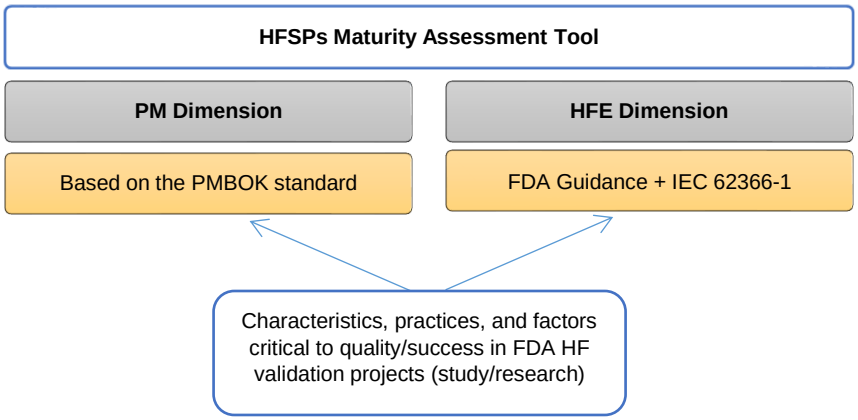


Figure 1.7: Content architecture for the proposed HFSP maturity assessment tool

1.10.3 Assessing PM Maturity in FDA HF Validation Projects

Before any roadmap to improvement can be developed and implemented using PM, there is a need to study and understand capabilities (Mullaly, 2006). Maturity assessment can measure the level of excellence and sophistication managing projects, and help recognize any necessary changes to ensure success. HFSPs themselves need to be able to understand where they stand and what to improve. Maturity assessment can serve to assess and benchmark the status of an organization or business unit, and identify a path toward improvement for the achievement of strategic goals (Mullaly, 2006). PM maturity models were developed within the software development industry, due to the need US Government had to measure and discriminate among competent and incompetent service providers and contractors (W. S. Humphrey, 1999). This type of framework seems very

appropriate to help study and improve the indicated situation, which is explained in detail below.

Why is a Maturity Model Needed?

While several PM maturity models exist, current models would be unable to assess HFE domain processes, considering there is already a lack of HFE awareness. In addition, existing maturity models would be too difficult to implement and sustain for HFSPs, which are usually small organizations or departments (if within a manufacturing organization).

Considering that the regulation of HF application is relatively recent, there is a clear indication that the process per se is *not fully developed.* Furthermore, today, UX Research (another term for HF research) is a trendy topic, and many would-be HF firms have been emerging. Coupled with the previous, manufacturers are required to demonstrate objective measures indicative of quality and success regarding how HFSPs deliver HF validations.

Research has demonstrated that the use of PM maturity assessment tools can bring harmony, stability, and success to organizations (Man, 2007; Houda Tahri & Drissi-Kaitouni, 2015). Although, maturing will take time and efforts, not only on the side of the FDA and corresponding inter-center coordination (MJ Rappel et al., 2017) but also on the side of all other impacted parties. Nonetheless, measuring the level of maturity in the management of FDA human factors validation projects could bring improvements, increasing effectiveness and positively impacting all stakeholders (including regulators, developers, and human factors organizations). Moreover, it is essential to remark how the lack of process maturity converges with a lack of domain knowledge (human factors

engineering). Thus, any measurement of maturity must adequately consider and integrate the applicable le HFE standards, which explain the need for an industry-focused PM maturity assessment.

The previous described why developing a tool to assess and improve the validation process is a practical and timely intervention. An industry-focused project management maturity assessment would help to eliminate risks while increasing quality and efficiency, and this is considered a competitive advantage (Huang, 2017). That sense of competitive advantage could also lead to more quality among HFSPs, impacting the delivery of effective HFE studies.

1.11 The Purpose of this Research

This research will seek to develop and test a PM maturity assessment tool for FDA HF validation projects that could also serve as an HFSP appraisal system. For that purpose, the essential mechanisms that could ensure successful HF validation projects, known as Critical Success Factors (CSFs), the validation process, and the capabilities both in HF and PM techniques, will be studied and described. Good practices and guidelines will be recommended to help human factors organizations, regulators and manufacturers effectively manage their corresponding parts in the HFE validation process.

1.12 The Scope of this Research

This research will focus on understanding FDA HF validation projects, to inform the development of a tool that can assess the maturity (readiness) of HF HFSPs to deliver quality HF validation projects for pre-market applications of medical devices and drug

combination products. Such projects are usually undertaken by third parties or HF consultancies/firms/service providers, who deliver an HF report which is then submitted to the FDA for approval to market the products in the USA.

1.13 The Objectives of This Research

The two high-level objectives of this research are:

a) To study and understand the characteristics, practices and critical success factors of FDA HF validation projects for medical and drug combination products.
b) To develop and test an industry-focused (human factors service providers) project management maturity assessment tool.

1.14 The Research Questions

The research questions to address the objectives above are the following:

1) Is PM being applied to manage FDA HF validation projects?
2) What are the main challenges?
3) Why do these projects fail?
4) What are the drivers of success?
5) What is the average maturity level?
6) What is the ideal (or adequate) PM maturity level for this industry (HFSPs)?

1.15 Potential Gap: Scarce Application of Formal PM

The author presumes that there is little or no formal application of PM in HF validation projects; the maturity will likely be very low, and there will be much room for improvement. Considering that manufacturers of medical and drug delivery devices usually outsource the HF services to consulting firms or agencies, and HF organizations are often small firms with no dedicated PM for FDA HF validations.

On the other side, HF professionals are expected to be subject matter experts regarding user research activities, rather than on the systematic management of the validation projects. Furthermore, even when large manufacturing companies conduct the human factors studies in-house, usually HFE departments are comprised of small teams, sometimes only one person (there may be exceptions). The result is most likely that systematic management of FDA HF validation projects will be scarce and that the application of PM tools and techniques could provide great potential for improvements in the quality and success of these projects.

1.16 Research Uniqueness and Contribution

The importance of the application of HFE to the design of medical devices is an unarguable necessity which has been noticeably advocated by many and also recognized by the FDA. However, it can indeed be stated that the effort is still a work in progress, and there is a significant need for organization, integration/alignment, and standardization to ensure quality and success in a changing and demanding regulatory environment.

Furthermore, this research leverages industrial and systems engineering methods in healthcare systems, to improve and to deliver successful FDA HF validation projects. The gaps remarked suggest a need to create capabilities, harmony, and synchronization considering the weaknesses and needs of the different stakeholders (manufacturers, regulatory agents, HFSPs, and even patients/consumers). Contributions of this research include adding to the literature research that had not been previously conducted (practices and critical success factors) while developing and delivering a much-needed tool to enable improvements and integration between manufacturers, HFSPs and regulators.

Therefore, a domain focused assessment tool that can assess capabilities in FDA HF PM, as well as indicate areas of improvement, could benefit all stakeholders, who can also leverage this to develop a competitive advantage. Also, such an assessment tool could enable efficiency for regulators (FDA), by allowing them to confidently review HF submissions when the level of excellence of the organization conducting the evaluation is known. Furthermore, developing a competitive advantage in the domain of interest will positively impact end-users (patients/consumers) by ensuring timely and safe to use products.

1.17 Summary of Chapter 1

In this chapter, basic concepts and the reasons the HF requirement and the dynamics of failing were described. Basically, as part of its comprehensive Quality System Regulation (QSR) and Good Manufacturing Practices (GMPs), the FDA has recognized the role of HFE for the development of effective and safe medical devices. Numerous issues and bottlenecks have emerged since the publication of the draft guidance in 2011, which sought to help manufacturers meet the HFE. However, identified gaps include the fact that the HF requirement is a developing process in a changing regulatory environment, and there are notorious knowledge-based and process-based gaps that create a need for alignment between key stakeholders, to work effectively considering the demands of a changing QSR.

Upcoming updates to the QSR will demand more control of suppliers from medical device manufacturers, and the FDA has launched initiatives that demand performance-based data to measure excellence. However, currently, manufacturers have no way to assess the capability of HFSPs, in order to meet the demands of the QSR. One

way to improve quality and excellence of projects is through the use of PM maturity models, which can help measure the level of sophistication or the state of the PM practices so that HFSPs can develop improvement plans and leverage the application of project management (PM) to increase quality and success of their projects. Existing maturity models are too generic; thus, the trend is that a growing number of models have been developed to meet the specific needs of their stakeholders. An industry-focused (HFSPs) PM Maturity Assessment Tool was proposed consisting of two dimensions (HFE and PM) and based on applicable industry standards. The proposed solution could enable integration between key stakeholders, including FDA HF reviewers, HFSPs, and manufacturers. The research questions to address the objectives above are the following: Is PM being applied to manage FDA HF validation projects? What are the main challenges? Why do these projects fail? What are the drivers of success? What is the average maturity level? What is the ideal PM maturity level for this industry (HFSPs)?

1.18 Organization of Dissertation Chapters

Chapter 1: The goal of this chapter is to introduce the reader to the topic of this research, including background information, relevant definitions (e.g.: What is HFE? What are medical devices? What are combination products), as well as a review of the issues and concerns around the problem being studied. This chapter also proposes a solution and briefly describes the chosen approach and research questions.

Chapter 2: In this chapter the relevant literature is reviewed. It is divided into two sections: described how the HF requirement developed, the current state of the topic and future interventions. Also, an idea of the overall FDA pre-market review process is presented. In the second section (2.4), the reader is introduced to literature relevant to the

chosen framework (PM Maturity Models) including PM and maturity models. Also, some existing maturity models related to HFE are presented and briefly discussed considering the intent of this work.

Chapter 3 "Methodology": This chapter's goal is to outline and explain the methodology, and the specific methods utilized to meet the purpose of this project and to answer the research questions established in the previous chapters. A sequential (two phases) mixed-methods is used for the development of the PM maturity assessment tool, and described.

Chapter 4 "Results and Discussion": In this chapter the results and discussion are presented as the research questions are answered (considering that a great part of the results involved qualitative data results and discussion are better combined). Likewise, and as explained in Chapter 3, it is organized in two Phases, as follows: Phase I: Understanding the Characteristics and Critical Success Factors of FDA Human Factors Validation Projects; Phase 2 - Part 1: The Delphi Panel (experts feedback) - developing the tool, and Phase II - Part 2: Overview of the HFSP-MAT (resulting tool) and Summary from Testing.

Chapter 5 "Conclusion and Future Research": This section outlines the key points that could be concluded from the findings. Because the limitations of this research are the basis for next steps, future research is made part of this section.

Chapter 2 - Literature Review

2.1 The HF Regulatory Process - Overview of Progress

Despite the fact that the need for harmonization, efficiency, effectiveness and better coordination in the implementation and management of the HF regulatory process has been a widely recognized concern (Combination Products Coalition, 2014; Enriquez, 2015; FDA, 2015; Horst et al., 2015; Michael Rappel & Sherman, 2016; MJ Rappel et al., 2017; Tsourounis et al., 2015), to the author's knowledge, no scientific research has yet addressed such concerns (described in Chapter 1.8).

Research addressing the outlined concerns related to FDA HF validations has focused mostly on the HF methods/techniques to increase the quality of the data (Brand-Schieber et al., 2016; Kappes et al., 2017; Lemke, 2017; Mahony et al., 2015; Samaras, 2006; Schmettow et al., 2017a; Story et al., 2017). Interventions on FDA's side have addressed the problem by focusing on *their* internal processes, such as trying to expedite reviews and reducing overlap in the case of combination products, as well as improving inter-center communication. The guidance documents published so far are also explicitly focused on describing the application of HFE methods and outlining the specific expectations of the agency in that sense. However, there is little focus on other aspects of the HF validation process, considering stakeholders with their weakness, and the need to ensure successful submissions while meeting the applicable regulatory requirements.

The following paragraphs will discuss related progress and relevant interventions in light of achieving improvements/project success in HF validations. A high-level

description of the pre-market review process, as currently described by FDA's literature (and from general knowledge), will also be presented.

2.1.1 Safety of Medical Devices - Early Regulations

The regulation of medical devices is a relatively modern topic. Medical devices mainly began proliferating after the 1960s; before World War II (WWII), the medical device industry practically did not exist (Merrill, 1994). Efforts to control the commercialization of medical devices were mainly focused on avoiding fraud or unrealistic claims (Merrill, 1994), such as selling consumer products that dishonestly advertised "miracle" results or that were meant for professional use.

Also, during the early 1900s, the FDA had zero to little control on existing medical devices, with regulatory jurisdiction limited mainly to drugs through the 1938 ACT (Merrill, 1994). In the 1960s authorities began showing more concern about the safety and quality of a growing number of medical devices. However, the FDA had minimal opportunities through its Bureau of Drugs. To be precise, the injuries reportedly caused by intrauterine devices (IUDs) and a large number of related lawsuits (Burnhill, 1989; Westhoff, 2003; York, 1989), was most likely the compelling argument pointing towards the need to regulate medical devices. It was through the Medical Device Regulation Act of May 28, 1976, that the FDA gained specific power to control the commercialization of medical devices (Merrill, 1994; Pietzsch et al., 2007).

The Amendments of 1976 gave origin to the classification of medical devices by level of risks (Classes I, II, and III) and the need to apply for pre-market approval. Likewise, the FDA prescribed good manufacturing practices for medical devices (GMP) with its higher regulatory power in 1978. The GMP introduced the 510(k) legal pathway

of comparing new medical devices with those already being marketed and proven safe (predicate devices).

2.1.2 Pressure to Enforce the Application of HFE

Evident attention to the need to apply HFE to increase the safety of medical devices can be attributed directly to the deaths caused by the misuse of anesthesia machines (Cooper et al., 1978, 1984). Cooper et al. (1978), pointed out that the application of HF to the design of user interfaces for anesthesia machines could make such devices safer. That recommendation would be validated a few years later (Lin et al., 1998). Furthermore, the FDA's database of devices recalled between the years 1985-1989 confirmed that up to 50% of the recalls were due to poor design (Sawyer et al., 1996). Subsequently, the Safe Medical Device Act of 1990 gave the FDA more jurisdiction and regulatory control over medical device manufacturers.

In 1995, a landmark conference on Human Factors in Medical Devices took place. The conference was co-sponsored by the FDA and the Association for the Advancement of Medical Instrumentation (AAMI). That event led to significant expansions that would promote the application of HFE to the design of medical devices (Burlington, 1996), which could be labeled today as the foundations of FDA's explicit endorsement of the user-centered design process (Sawyer et al., 1996). In 1996, the Quality System Regulation (QSR) for medical devices overhauled the GMP. To go beyond manufacturing practices, the QSR added the subsystem known as Design Controls (21 CFR 820.30).

Another precursor to the FDA's efforts in the safety of medical devices is the famous report by the Institute of Medicine, "To Err is Human" (IOM, 1999), which

disclosed a surprising number of deaths caused by medical errors that can be prevented. Shortly after the IOM's report, the FDA released an HF guidance to reduce medical device use error risk (FDA & CDRH, 2000). Table 2.1 summarizes the main events that led to the HFE requirement.

Table 2.1: *Summary of the main events leading to FDA HF requirement*

Year	**Event**
Before WWII	No medical device industry existed
1938	Few laws for regulating the safety of medical devices (if any, the focus was on avoiding fraud/unrealistic claims)
The late 1960s	Signs of concerns about the safety of medical device (e.g., IUDs), but minimal regulatory power
1976	Medical Device Regulation Act of May 28; Classification by the level of risk; Pre-market Applications
1978	GMPs; 510(k) pathway
The 1980s	Anesthesia machines' deaths; FDA's database of recalls indicated 50% due to poor design; application of HFE suggested to improve the design of anesthesia machines
1990	Safe Medical Device Act of 1990 → increased FDA's authority
1995	Landmark conference on HF in medical devices sponsored by the AAMI and the FDA
1996	Harmonization with ISO/CD 13485:1996; Quality System Regulation (QSR); Design Controls (21 CFR 820.30)
1999	IOM report "To Err is Human".
2000	FDA's guidance Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management
2001-2010	Lack of HF regulatory updates; Growing number of medical device recalls (due to design/manufacturing issues); New technologies/combo products; Advancement of HFE international standards
2011	FDA "Draft Guidance: Applying Human Factors and Usability Engineering to Optimize Medical Device Design"
↓	
2016: Final Guidance "Applying Human Factors and Usability Engineering to Medical Devices"	

2.2 Implementation of the HF Requirement

Close to the start of the new Millennium, half-hearted efforts took place to encourage the integration of HFE into the medical device development process (Burlington, 1996; FDA & CDRH, 2000; Sawyer, 2000; Sawyer et al., 1996). However, between the year 2001 and 2010, there were zero regulatory updates directly related to HFE. Such lack of regulatory revisions began to hinder innovation and the introduction of new technologies (IOM, 2010).

The practice of comparing novel devices with old ones has become inappropriate, as new trends and modern product development methods demand serious focus on usability to promote safety and effectiveness (Ho (Patrick), 2010; IOM, 2010; A. E. Mitchell et al., 2011; Vincent et al., 2015; Williams et al., 2016). Indeed, the 510(k) program has been heavily scrutinized (Ho (Patrick), 2010; IOM, 2010; A. E. Mitchell et al., 2011), but it has been, and still is the legal path through which the highest number of medical devices have obtained clearance to be marketed in the United States (US).

A growing number of medical device recalls, and the progression of international and local industry standards (see Table 2.2) made it evident that existing FDA regulations were inadequate to ensure the effectiveness and safety of medical and drug delivery devices (Ferriter, 2011; A. E. Mitchell et al., 2011; Zuckerman et al., 2011). It was in recognition of the previous points that in 2011, the FDA finally made the application of HFE a requirement for medical devices, and consequently, for combination products (see Table 2.1). However, it is essential to mention that said guidance has been criticized for being merely prescriptive of final validation efforts that seek to avoid unacceptable use

errors. More than the FDA guidance has been deemed necessary to ensure the rigorous application of HFE to the development of device products (Cafazzo & St-Cyr, 2012).

Table 2.2: Progression of standards in the application of HFE to medical devices

Year	Standard
1998	▪ ISO 14971-1:1998, Medical devices -- Risk management -- Part 1: Application of risk analysis.
2000	▪ ISO 14971:2000 Medical devices -- Application of risk management to medical devices
2001	▪ ANSI/AAMI HE74, HF Design Process for Medical Devices
2004	▪ IEC 60601-1-6:2004, Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability
2006	▪ IEC 60601-1-6:2006, General requirements for basic safety and essential performance - Collateral standard: Usability
2007	▪ ANSI/AAMI/ISO 14971:2007, Application of risk management to medical devices ▪ IEC 62366:2007, Application of Usability to Medical Devices
2009	▪ ANSI/AAMI HE75:2009, HF Engineering – Design of Medical Devices
2010	▪ IEC 60601-1-6:2010, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
2013	▪ IEC 60601-1-6:2010+AMD1:2013 CSV, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
2014	▪ IEC 62366:2007/AMD1:2014, - Application of usability engineering to medical devices ▪ AAMI TIR50 Post-market surveillance of use error management ▪ AAMI TIR51 Guidance for contextual enquiry
2015	▪ IEC 62366-1:2015, Medical devices -Part 1: Application of usability engineering to medical devices ▪ IEC 60601-1-11:2015, Medical electrical equipment -Part 1-11: General requirements for basic safety and essential performance --Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
2016	▪ ANSI/AAMI/ISO 14971:2007/(R) 2016, Medical devices - Application of risk management to medical devices ▪ AAMI/IEC TIR62366-2:2016 Medical Devices Part 2: Guidance on the Application of Usability Engineering to Medical Devices
2017	▪ AAMI TIR59:2017, Integrating Human Factors into Design Controls

Source: Developed by the author with information from www.iso.org, www.ansi.org

2.2.1 Some Resulting Challenges and Concerns

2.2.1.1 Inefficient HF Submissions Review Processes

Significant issues have developed after the enforcement of such a high-risk component for medical device manufacturers (Rojas, Sharareh, et al., 2019). Impacted parties have reported that the HF pre-market review process has been characterized by capricious requests, a lack of a rigorous scientific basis, delays, confusion, overlap, and poor coordination (Combination Products Coalition, 2014; FDA, 2015).

The need for improvement and efficiency has been acknowledged by the FDA (Enriquez, 2015; FDA, 2015). As a result, the Agency has launched several internal initiatives. An independent assessment of the combination product review process was conducted in 2015 (FDA, 2015). The study revealed significant inconsistencies in the review process, a lack of standardization, the need for a common language among the centers, and resources to support the increasing workload (FDA/Department of Health and Human Services, 2015).

2.2.1.2 Problems with Combination Products

One central remark is that the integration of pharmaceuticals and medical devices (combination products) could have exposed numerous regulatory issues and overall inefficiency of the pre-market review process. The combination products are a challenge for the FDA as well as for manufacturers. The rapid development of technologies, the need to consider different branches of the applicable regulations, and the need to involve multiple FDA centers are some the challenges that these products present (Baird et al.,

2015; C. C. Chan et al., 2014; Michael Rappel & Sherman, 2016; Vincent et al., 2015; Wechsler, 2017).

2.2.1.3 The Impact of the HF Requirement on FDA Review Process

In 2015, the FDA reported that although the number of annual application submissions had remained the same from 2003 to 2013, there was a notable increase in the number of inter-center consults in the review process for combination products (FDA, 2015). The increase in inter-center consults at the FDA, which was highly significant after 2011, is very likely due to the release of the first draft guidance on the application of HFE to medical devices. That increase is one more indicator of the impact of HF validation projects on the overall review process, and the need to ensure the quality of submissions (Rojas, et al., 2019).

2.2.2 Relevant Progress – Interventions that Have Taken Place

2.2.2.1 FDA's Internal Process Improvement Initiatives

To expedite their review process, the FDA created The Combination Products Policy Council, (Michael Rappel & Sherman, 2016). Moreover, several internal process improvement initiatives have taken place at the FDA (Booz Allen Hamilton, 2016; FDA, 2015). That includes streamlining the synchronization and management among the FDA centers involved in the review of combination products (MJ Rappel et al., 2017), and the modernization of the 510(k) pathway (FDA & CDRH, 2019). Likewise, the FDA has implemented the Total Product Life Cycle (TPLC) methodology (Schmitt, 2017), which will impact the organizational distribution of the CDRH to become "Super Office."

Through the TPLC methodology, the FDA seeks to enable more agile processes and sharing of information across the interrelated centers (FDA, 2018).

2.2.2.2 Consultations with the FDA

Another applicable intervention was the "repackaging" of the pre-IDE program as the pre-submission program (FDA et al., 2018). The program, also known as Q-submission is still in the form of draft and outlines the mechanism to request a consultation with the FDA before submitting a pre-market application. That also includes HFE questions such as reviewing HF tests plan or protocol.

2.2.2.3 Some more HF Guidance Drafts

To address some the stated concerns and bottlenecks related to the HF requirement, the FDA has published several guidance drafts. The documents are meant to clarify FDA's approach and expectations regarding HF validations (FDA et al., 2016, 2017; FDA & CDER, 2017; FDA & CDRH, 2016b; FDA & OCP, 2017; Hodsden, 2016). However, substantial concerns, process-based issues, and knowledge-based issues remain. Some the measures taken and published draft guidance might have even turned out counterproductive. For instance, a list of high priority devices (FDA & CDRH, 2016b) for HF reviews, added more problems to the situation as manufacturers could think that if the product is not on the list, HF validations are not required.

2.2.3 Future Developments Affecting the HF Requirement

2.2.3.1 Harmonization with ISO 13485:2016

Other changes and new guidance documents have been envisioned to improve the overall pre-market review process, which will have a direct impact on the HF requirement. For instance, the Agency has formally announced that it will update the current QSR to be harmonized with ISO 13485:2016 Medical Devices - Quality management systems - Requirements for regulatory purposes (FDA Unified Agenda, 2018). The internationally recognized standard delineates specific requirements for quality management systems (QMS) in the design and manufacturing of medical devices. It was first published in 1996 as the "ISO/CD 13485:1996 Quality Systems Medical Devices Supplementary Requirements to ISO 9001."

A previous harmonization of FDA's QSR with the international QMS went into effect in June 1997 (FDA, 2003; FDA & CDRH, n.d.), due to which the two regulatory documents already have much in common. By harmonizing with international standards, the FDA has tried to stay up to date, and to ensure that manufacturers can smoothly meet both local and foreign requirements (indicated in Section 803 of the Safe Medical Device Act).

2.2.3.2 Impact of a Revised ISO 14971 - Risk Management System

In that same vein, the QMS ISO 13485:2016 is tightly linked to ISO 14971 - Risk Management System (RMS) for medical devices. The RMS is said to be under revision to include future changes that will impact the risk evaluation and control process. Greater emphasis will be placed on risk-benefit analysis and post-market surveillance (IOM,

2011; Parise, 2019). Consequently, updates to the international RMS standard will have a direct impact on the HF regulatory efforts for medical devices.

2.2.3.3 Interventions in the Combination Products Review Process

As per the Agency's representatives, other relevant interventions are taking place between 2018 and 2022, with a particular focus on the combination products review process. The changes will include the development and publication of policies and procedures manuals, as well as standard operating policies and procedures (I. Z. Chan, 2018a; FDA & CDER, 2018). With these interventions, the FDA seeks to clarify expectations regarding the consultation of internal experts outside the designated review center, the definition of critical terms, development of patient/user-oriented labeling, and bridging of data from combination products and devices for the same drug (I. Z. Chan, 2018a).

2.2.3.4 A More "Laissez-fair" Approach (More Flexibility)

To reduce regulatory burdens, the FDA seems to be taking a more collaborative and flexible approach towards medical device manufacturers. In order words, the Agency might have recognized that keeping up with the regulatory demands of the medical industry might be an impossible mission. Thus, the FDA might be willing to give some credibility to manufacturers of medical device products during pre-market applications. However, for that to happen, measures of excellence are essential. In that sense, the FDA has launched a pilot program that involves the implementation of a maturity framework to assess excellence in the medical device industry. The assessments could also substitute FDA's audits (FDA & CDRH, 2018c; MDIC, 2015, 2019). The voluntary program is

making use of the Capability Maturity Model Integration (CMMI) framework to assess manufacturing processes. The pilot is a joint initiative involving the Medical Device Innovation Consortium and the CMM Institute. The pilot program is part of the initiative "Case for Quality" which stresses the need for performance-based data in the medical device industry (MDIC, 2019).

At this point, it can be inferred that the FDA's interventions to address issues involving the HF requirement have been limited to improving internal processes and clarifying the Agency's expectations. Conversely, scientific research has been limited to the study of HFE methods to improve the HF data, including validity and reliability (Campoe, 2013; Chagpar & Cafazzo, 2010; Kappes et al., 2017; Mahony et al., 2015; Schmettow et al., 2017b). However, other critical factors and remaining gaps must be considered for the development of across-the-board strategies.

2.3 The HF Reviews at the FDA

For those expected to comply with the new HF regulatory requirement, understanding the HF review process and the organizational structure of the FDA is often challenging and one possible root cause of many of the discussed concerns (see Chapter 1.8). The following paragraphs will briefly describe some essential aspects of the HF reviews including the current organizational structure of the FDA as it applies to the divisions/centers specifically involved in the HF validation review process. [2]

[2] The FDA has been implementing a harmonization and modernization process including changes to it organizational structure. Some the presented information might have changed by the time this work is published, although only high-level aspects are being described ((FDA Unified Agenda, 2018; Schmitt, 2017).

2.3.1 The Pre-Market Submissions

As established on the QSR, those looking to market medical devices which are intended to be used by humans in the U.S., must go through a submission process (for approval or clearance through the FDA). Also, it is important to understand that the HF requirement is one component of several others in the QSR see (Table 1.1). The complete process, details, and specifications for pre-market submissions can be found on the FDA's website (https://www.fda.gov/medical-devices).

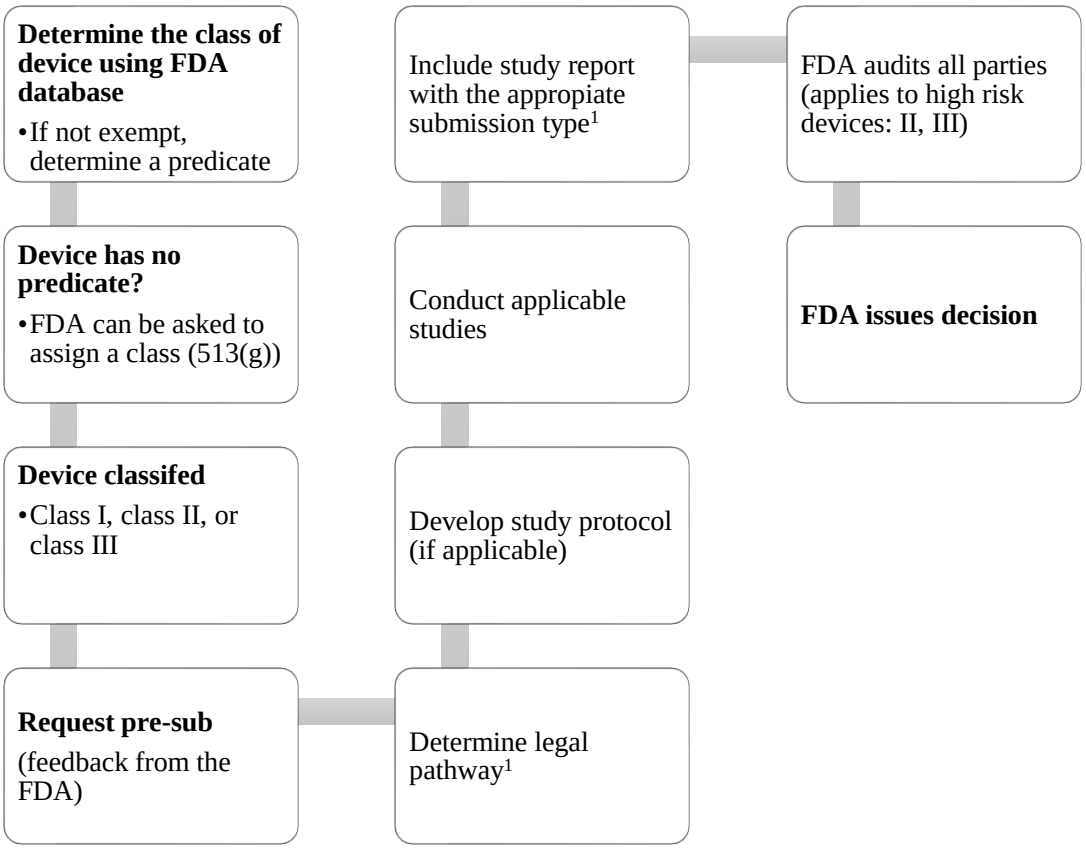


Figure 2.1: Simplified high-level view of the pre-market submission process[3]

[3] See Table 2.3 and Table 2.4 regarding the different regulatory pathways depending on the product classification.

Depending on the classification of the device (low risk or high risk), there are different kinds of submissions. The ones most mentioned are 510(K) and Pre-market approval (PMA). The first cover devices classified as I and II and differ from PMA in that it relies on establishing substantial equivalence to a device already approved to be marketed, while the PMA is a more rigorous process reserved for high risk devices (class III). Table 2.3 and Table 2.4 also contain details of the different types of submission and the corresponding regulatory pathways.

2.3.2 An Output-Oriented Review Process

One important characteristics of the FDA HF validation review process is that it is process output-oriented. All the *outputs* from the HFE process during development and design, should go to the "design history file" (DHF). While the Agency will want to see the details, the reviews start with the process outputs (see Figure 2.2).

2.3.2.1 The HFE Report

The deliverable that the FDA expects to be submitted with a pre-market application is the "Human Factors Engineering Report". Such report must document that HF considerations were implemented during product development, and thus the finished device can be used by the intended users, under the anticipated use environments, without serious issues or use errors.

To conduct the HF validation, a study protocol is first developed. Ideally, an important part is asking the FDA for feedback on the HF validation study protocol. The FDA guidance dictates the following elements in designing an HFE validation protocol:

- Participants are representative users of the device
- The test includes performing all the critical tasks

- The user interface of the device for the study represents the final design.
- The conditions simulate realistic conditions of use

The HF report should include all the items outlined as per the corresponding guidance for industry and staff (FDA & CDRH, 2016a), starting with the conclusion and finalizing with details of the HF validation (the summative usability testing). This report is considered a "living document" (I. Z. Chan, 2018c) and should be kept as part of what the QSR calls "Design History File (DHF)".

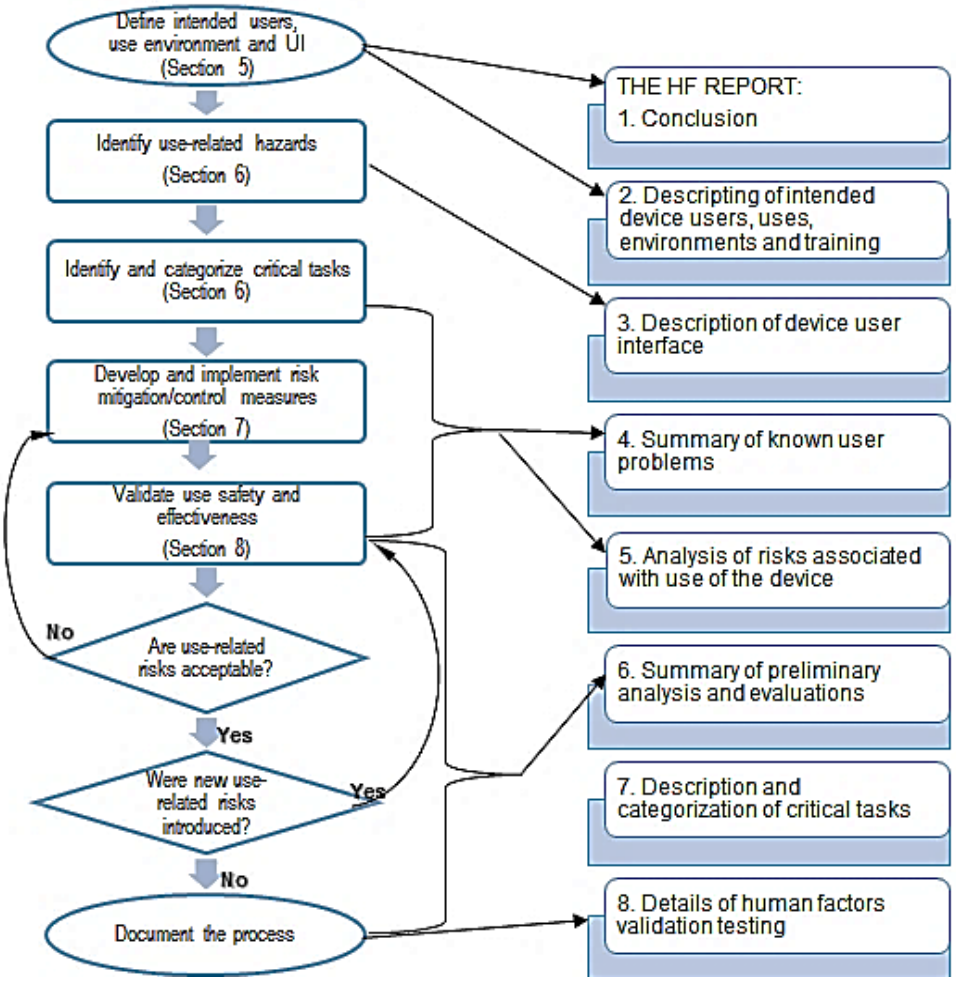


Figure 2.2: The HF validaiton process and resulting HFE Report. Adapted from (FDA & CDRH, 2016a)

2.3.3 Lead Centers in the HF Review Process

As part of the U.S. Department of Health and Human Services, the FDA is composed of a large number of offices and centers, out of which only some are involved in the HF review process. There could be more than one center handling the HF validations, depending on whether the product is a medical device or a combination product. In that sense, the corresponding HF review centers involved, so far, are:

- The Center for *Drug* Evaluation and Research (CDER)
- The Center for *Devices* and Radiological Health (CDRH)
- The Office of *Combination* Products (OCP)

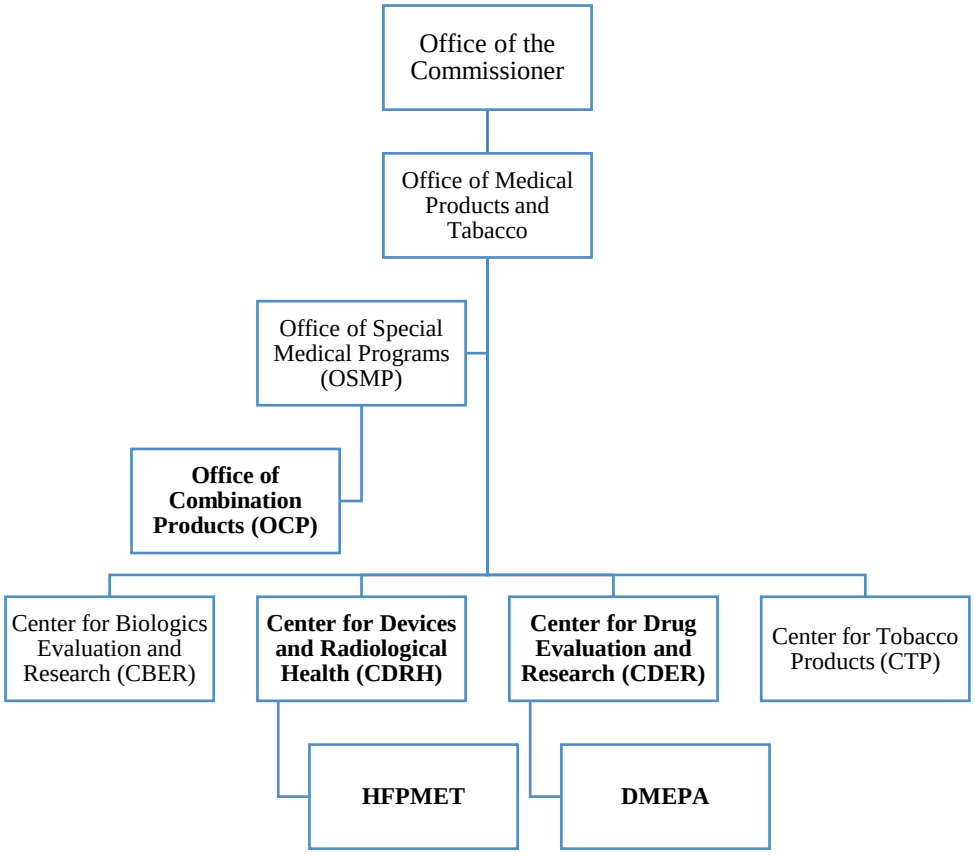


Figure 2.3: Partial view of FDA's organizational structure showing centers involved in HF reviews.

Figure 2.3 illustrates a partial view of the FDA's organizational structure to specify the centers which currently lead the HF reviews for clearance to go to market. The complete FDA organizational structure is available online (FDA/Office of the Commissioner, 2018).

2.3.3.1 The Office of Combination Products (CP)

This office has authority over the regulatory lifecycle of combination products, including deciding the appropriate center for review (depending on the product's primary mode of action). The FDA OCP was established in December 2002, as part of the Medical Device User Fee and Modernization Act. The purpose of the OCP is to enhance the transparency, predictability, and consistency of combination products regulation to ensure timely approval (I. Z. Chan, 2018b; MJ Rappel et al., 2017).

Although OCP decides where a product is reviewed, such activities take place within the corresponding FDA's product center. A combination product is generally assigned to a lead center: either the Center for Drug Evaluation and Research (CDER) or the Center for Devices and Radiological Health (CDRH), which may also seek consultation from other centers overseeing other constituents of the product under review. Thus, a combination product, depending on its primary mode (device, drug, biological), can hence, have the involvement of any FDA center among the ones which are described below.

2.3.3.2 The Center for Drug Evaluation and Research (CDER)

The CDER is a large center comprised of several branches which are organized by therapeutic areas, and consists of a team of over 50 scientists and healthcare professionals (see partial view on Figure 2.4).

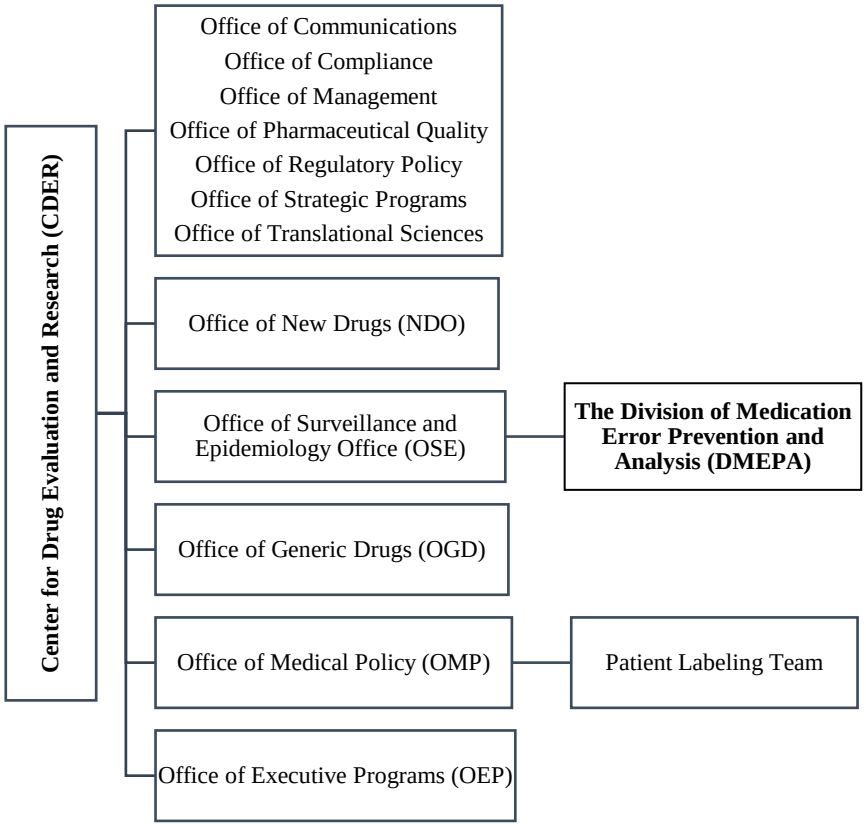


Figure 2.4: The Center for Drug Evaluation and Research (CDER). Adapted from Chan, 2018a

Inside the CDER, the **DMEPA** is the head office leading the HF submissions for *Drug, Biologic, and Combination Products.* However, any necessity for HF reviews can be identified by the OSE/DMEPA, and request inter-center consults to the CDRH Human Factors Team, as needed. The OSE/DMEPA can also consult with the Patient Labeling Team in the Office of Medical Policy, when it comes to reviewing Instructions for Use (IFU) for laypersons in the IND. Created in 1999, the general mission of the Division of

Medication Error Prevention and Analysis (DMEPA) division is "to increase the safe use of drug products by minimizing use error that is related to the naming, labeling, packaging, or design of drug products…" (I. Z. Chan, 2018a).

2.3.3.3 HF Regulatory Pathways through the CDER

"Regulatory pathways" refer to the different ways (depending on the product's class and nature) an organization or sponsor (applicant) will need to use when submitting the necessary documentation to get approval or clearance for marketing. For instance, a product or drug that is being developed for the first time versus a generic would require a different application.

For each type of product submission, there is a guidance document that can be referenced for the HF review/clearance. The current regulatory pathways through the CDER (*Drugs, Biologics, and Combination Products),* are listed in Table 2.3.

Table 2.3: Different Approval Pathways through the CDER. Adapted from Chan, 2018a

Type of Product	**Type of application**	**Regulation (pathway)**	**Applicable FDA HF guidance**
New Drug	NDAs, and BLAs	505(b)(1), 505 (b)(2), 351(a)	Draft Guidance for Industry and FDA Staff: Human Factors Studies and Related Clinical Study Considerations in *Combination* Product Design and Development. **Released: February 2016 (21 pages)**
Biosimilar	BLAs	351(k)	
Generics	ANDAs	505(j)	Draft Guidance for Industry: Comparative Analyses and Related Comparative Use HF studies for a Drug-Device *Combination* Product Submitted in an ANDA. **Released: January 2017 (15 pages)**
Interchangeability	BLAs	351(k)(4)	Draft Guidance for Industry: Considerations in Demonstrating *Interchangeability* with a Reference Product. **Released: January 2017 (30 pages)**

NDA = New Drug Application; ANDA = Abbreviated New Drug Application; BLA = Biologics License Applications. Other types: IND = Investigational New Drug (for research purposes/not to be marketed).

2.3.3.4 The Center for Devices and Radiological Health (CDRH)

The mission of the Center for Devices and Radiological Health (CDRH) is to assure that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products (FDA, 2017).

Currently, this FDA center is said to be undergoing an organizational transformation and pilots are going on to implement a Total Product Life Cycle (TPLC) approach. The goal is becoming more agile internally, integrating and sharing information across the full process and the interrelated centers (FDA, 2018; Schmitt, 2017). However, at the moment this work is being done, the CDRH is presently comprised of the following offices:

- Office of the Director
- Office of In Vitro Diagnostics and Radiological Health
- Office of Science and Engineering Laboratories
- Office of Communication and Education
- Office of Management
- Office of Compliance
- Office of Device Evaluation
- Office of Surveillance and Biometrics

The reorganization based on the TCPL consists on the centralization of the Office of Compliance, the Office of Device Evaluation, and the Office of Surveillance and Biometrics, into a “one-stop” super office.

2.3.3.5 The HF Pre-market Review Team and Regulatory Pathways through the CDRH

At the CDRH, the HF Pre-Market Review Team is composed of 6 members, specialized in the HFE domain (Wiyor et al., 2018). To meet the HF requirement for medical devices, the relevant guidance to reference so far is the final document published in 2016 (FDA & CDRH, 2016a). As explained before (see Chapter 1.1), the guidance is focused on discussing the HFE methods applicable to medical devices and the expectations from the HF report.

Table 2.4: Different Approval Pathways for Medical Devices, CDRH

Type of Device	Pathway	Applicable FDA HF guidance
Predicate Devices	510(k)	"Applying Human Factors and Usability Engineering to Medical Devices. Guidance for Industry and Food and Drug Administration Staff " **Released**: February 2016 (49 pages)
High-risk Medical Devices (Class III)	PMA	
New Devices (innovative)	De Novo	
Humanitarian Device Exemption	HDE	
Investigational Device	IDE	

As shown on Table 2.4, within the CDRH, the paths to market for medical devices are the following (FDA & CDRH, 2018a):

- **510(k)/Pre-market Notification:** this is the most common way of obtaining clearance for devices that have demonstrated to be "substantially equivalent" to other devices already marketed for the same use.
- **Pre-market Approval (PMA):** these include new or high-risk medical devices (Class III). In comparison with the 510(k) pathway, the PMA entails a very rigorous review including FDA audits to all parties involved in the manufacturing process.
- **De Novo Classification**: for devices which are considered innovations, and completely new to the market, but the technology being used has been researched. However, this approval pathway could be the most tedious and resource consuming, also including FDA audits.

- **Humanitarian Device Exemptions (HDE):** devices which are meant to treat or diagnose a disease or condition that affects a relatively low number of people (< 4,000 individuals) in the United States yearly.
- Other types: **Investigational Device Exemption (IDE):** these are devices for investigational study purposes and which are not intended to be marketed.

2.4 Project Management (PM) Brief

The concept of *project* and *project management* are different. A project is a distinctive, transitory assignment for a specific outcome; the PMBOK® Guide describes it as *a temporary endeavor undertaken to create a unique product, service or result* (Project Management Institute, 2017). PM on the other hand "is the application of knowledge, skills, tools, and techniques to project activities to meet the project requirements" (Project Management Institute, 2017). PM helps to meet short- and long-term goals by bringing projects to fruitful completion, while ensuring that in the process all the project stakeholders are satisfied. That is done by expertly juggling the constraint of costs, time, desired quality and scope (Demir & Kocabaş, 2010).

2.4.1 PM History Overview

The form and substance of projects have been managed for millennia, even though the consensus is yet to be arrived at, the Egyptians' pyramids are considered as the first examples of projects (Morris, 2011). PM started to assume a recognizable form towards the latter part of the 20th century. The transformation took place from approximately the 1910s, as undertaken by Henry Gantt the namesake of the Gantt chart. The Gantt chart is a scheduling diagram used to help keep projects on time. The Gantt chart was used to successfully manage the construction of the Hoover Dam in 1931

(Young Hoon Kwak et al., 2014). Likewise, in 1957, the DuPont Corporation created the famous Critical Path Method (CPM), to predict projects duration (Y H Kwak, 2005).

Project Management Today

PM has undergone a paradigm shift from its rudimentary form as crafted by Henry Gantt in the 1920s, and several PM models have been formally developed. Originally, projects did not have a system of management and depended on ad-hoc and unofficial intuitions and unplanned actions. The project owners and managers were responsible for figuring out the means to deliver the project in such a manner that it met its objectives (Y H Kwak, 2005).

Recently, PM processes and methodologies have increasingly adopted technologies that have automation characteristics (Cermak et al., 2011; L. Crawford et al., 2006). Repetitive tasks, like scheduling timetables, timesheets, etc., that often made certain aspects of PM tedious, are now being taken over by computers, enabling optimum and comfortable implementation of PM.

2.4.1.1 The PMBOK® Guide

In 1969, the Project Management Institute (PMI) was formed to govern and promote PM as a profession. In 1987, the PMI published a whitepaper named PMBOK® Guide or the PM Body of Knowledge (Y H Kwak, 2005). It is a set of rules and guides to standardize PM practices and information. The PMBOK® Guide was adopted as **a standard** formal document by the American National Standards Institute (ANSI) in 1998, and has become the most widely recognized PM standard. In 2008, the fourth edition of PMBOK® Guide was published. The most current version of the PMBOK®

Guide is the 6th edition 2017 (plus Agile) with ten Knowledge Areas, five Process Groups and 49 processes (see Appendix A).

2.4.2 Common Project Management Methods

PM methods combine processes, tasks, and tools that guide a new project venture from start to finish. These frameworks help organizations plan, initiate, control, and conclude a new venture. PM methods are known to use either a *traditional* framework or an *agile* framework. Regardless of the method, the main purpose of PM is *scope* definition (how work/deliverables will be achieved), as per the allocated *cost*/resources and a specific *schedule*, while balancing any possible *constraints*, including quality and risks (Cermak et al., 2011).

2.4.2.1 Traditional frameworks, advantages, and weaknesses

The traditional framework is based on having clearly defined boundaries and predictable outcomes (B. Boehm & Turner, 2005; Spundak, 2014). The traditional framework manages predictability with heavy upfront efforts and a linear, step-wise approach to product development. The most widely known example of a traditional framework is **waterfall**, published in 1970, and it is also the oldest approach for software development in the manufacturing and construction industries (B. W. Boehm, 1988). It proposes that new projects be developed linearly, with eight sequential phases of development starting with conceptualizing the project and ending with maintenance. In the waterfall framework, feedback loops exist between stages but are confined to successive stages to limit costly revisions to work completed at earlier stages of the project (B. W. Boehm, 1988).

The advantages of waterfall are that its format is relatively easy to use and understand, it provides a definite start and endpoint for each phase of the project, and it gives a high degree of documentation for each stage of development that makes it easy to review or replicate, as needed (Jurison, 1999). It is best for projects that are straightforward and large projects that require a significant amount of restraints, such as government contracts (Larman & Basili, 2003).

The disadvantages of waterfall stem from its sequential and rigid nature. Because waterfall projects are sequentially developed and seek to minimize a changing environment, any alterations that need to be made at earlier developmental stages may not be realized until later in development where they are costly and difficult to make (Jurison, 1999). Additionally, it can be difficult to accurately define the project requirements at the outset of the project where end-users may not be fully clear on what they need. The lack of flexibility in the process does not allow for iterative collaboration. Instead, it requires that the entire project be conceptualized and completed in sequence before changes can be considered. Other examples of traditional frameworks include Critical Chain PM (CCPM) and Critical Path Method (CPM).

2.4.2.2 Agile Frameworks – Advantages and Weaknesses

The agile framework assumes that unpredictability is natural and seeks to manage it rather than minimizing it (Karlesky & Voord M, 2008). The foundation of agile methodologies is Shewhart's Plan-Do-Check-Act cycle (Sliger, 2008). The idea is to adapt to the existing conditions and provide robust, continuous and rapid product delivery to the client. Unlike traditional linear methods, agile requires no defined end products or deliverables but bears the full marks of a disciplined process. In essence, the process has

non-static requirements that accommodate constant changes to the processes of PM, often relying on constant communication.

Scrum is an agile model, developed by Agile Solutions in 1986, as a process that emphasizes speed and flexibility in new product development (Schwaber, 1997). It is a management, enhancement, and maintenance methodology that can be used to establish the process for product development in a new company or it can be used as an agent of change to inject creative development in older, more rigid organizations (Schwaber, 1997; Takeuchi & Nonaka, 1986). The model uses a six-unit approach that consists of built-in instability, self-organizing project teams, overlapping development phases, "multi-learning," subtle control, and organizational transfer of learning (Takeuchi & Nonaka, 1986).

Two major advantages of Scrum are that it produces greater speed and flexibility in new product development. Scrum enhances shared responsibility and cooperation from team members, stimulates involvement and commitment, sharpens a problem-solving focus, and encourages initiative-taking. The weaknesses of Scrum are that it requires close management of such an intensive process. Issues that arise may include difficulties communicating with an entire project team, maintaining correspondence with suppliers, handling surprises, and preparing contingencies. Additionally, the Scrum model is not appropriate in these situations: for organizations whose development is spearheaded by a single individual who specifies instructions for subordinates; for large projects, like those in aerospace, that have limited face-to-face discussions; or for projects that require a revolutionary innovation, such as those in biotechnology or chemistry (Takeuchi & Nonaka, 1986). Other methods considered agile (although these might precede the term

"agile") are Extreme PM (XPM), Kanban, Adaptive Project Framework, and Projects in Controlled Environments (PRINCE2).

2.5 Project Management Maturity Assessment Models

PM maturity assessment models are benchmark tools that help the modern enterprise determine where it stands relative to other organizations that manage projects within the same industry or among others (Grant & Pennypacker, 2006). They contain a systematic way of improving project development, business processes, and work by identifying the weaknesses and potential benefits, as well as the stages that the organization must progress through before reaching maturity.

2.5.1 The Origins - Crosby's Quality Management Grid (QMMG)

The foundation of maturity assessment models is based on long-standing frameworks (Total Quality Management) of process improvement and statistical process control (B. Pasian, 2018). Perhaps the earliest example of a maturity assessment model is Crosby's Quality Management Maturity Grid (QMMG), a significant precursor that has served as a foundation for many current maturity models is the Capability Maturity Model (CMM) (W. S. Humphrey, 1999), which has evolved to be known today as CMMI. The CMMI framework was developed within the software development industry, as a response to the US government's need to measure and discriminate among competent and incompetent service providers and contractors (W. S. Humphrey, 1999).

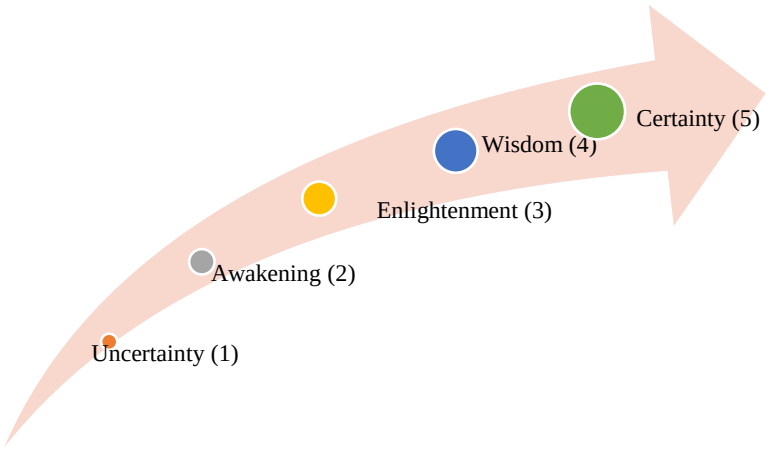


Figure 2.5: Levels of Crosby's Quality Management Maturity Grid (QMMG)

2.5.2 The Capability Maturity Model (CMM)

PM maturity assessment models started in the eighties when projects seemed not to be achieving objectives within the required constraints. The Software Engineering Institute was the first organization that developed a maturity model in PM, known as the Capability Maturity Model (CMM). The model was originally developed to fill the Department of Defense's need for identifying capable software contractors who could best deliver projects (Grobler & Andsteyn, 2006; W. Humphrey, 1989).

The focus of the CMM was on describing what was needed to improve the ability to deliver what the customers want at the specified time and cost. The model later evolved into a PM maturity model which provides a platform to evaluate the maturity of the management process (M.C. Paulk et al., 1993). The CMM has served as a foundation to most of the maturity models that have been emerging since then (Silvius, 2018), and has been consistently applied in management processes, to support change and continuous improvement initiatives (Andersen & Jessen, 2003; Ibbs & Kwak, 2002; B. Pasian, 2018).

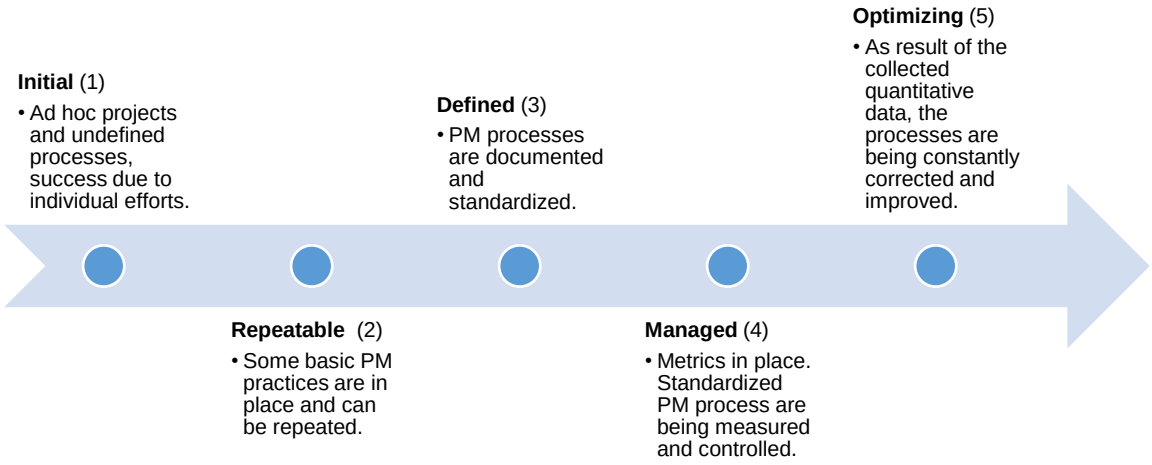


Figure 2.6: The CMM process areas by maturity levels (Adapted from Paul et al., 1993)

2.5.3 Characteristics and Components of Maturity Models

Although, through the literature, it is difficult to find agreement regarding the components and constructs of PM maturity frameworks, there are some common features found in maturity models in general (Albrecht & Spang, 2016). A study conducted by Fraser et al. (2002) identified these features: levels, descriptors and descriptions for each level; dimensions, process areas and activities for each area with description of each activity at each maturity level (Fraser et al., 2002).

In that sense, a maturity model will consist of *levels* that indicate maturity by numbers or stages; as well as *areas* or the processes and practices to be studied and improved. In fact, the operational definition of the CMM outlined its components and structure as consisting of *maturity levels* that indicate *process capabilities*; which contain *key process areas* to achieve goals; organized by common features that help address implementation, formed by key practices to describe activities (M.C. Paulk et al., 1993). The key areas are often based on specific content (e.g., standards), but can also be

developed considering the specific processes and practices that would determine maturity for the context of interest. Several authors have described the development of industry/area-specific PM maturity assessment models (Cooke-Davies & Arzymanow, 2003; Maier et al., 2012). Examples of industry-specific maturity models are the construction and software management industries (Backlund et al., 2014; Mark C. Paulk, 2009).

Generally, it is regarding organizational dimensions and the number of maturity levels that most authors will introduce different components of the PM maturity models. One good example of this is a recent model known as Duplex PM Maturity Model (DPM3) which addresses four dimensions of maturity categorized as Hard-skills, Soft-skills, Environmental, and Facilitators (Chee Choong Gan & May May Chin, 2018). Another example is the model by the International Project Management Association (IPMA) which organizes competences in 3 categories or modules: people, practice, and perspective.

Nevertheless, as it was indicated, most maturity models are inspired on the CMM principles which will consist on describing the level at which an organization can *manage and continually optimize* their project processes (see Figure 2.6). At the same time, the model is not prescriptive, instead it describes the characteristics of each level of maturity for any given organization, and it does not indicate how to get there (M.C. Paulk et al., 1993).

2.5.4 Common PM Maturity Assessment Models

Maturity assessment models can be used to evaluate project quality management (i.e., Quality Management Maturity Grid), process management (i.e., Process Maturity

Model, Business Process Maturity Model), or overall PM (Capability Maturity Model Integration). Such existing PM maturity models have been largely discussed in the literature (Backlund et al., 2014; Brookes et al., 2014; Cooke-Davies & Arzymanow, 2003; J. Kent Crawford, 2015; De Souza & Gomes, 2015; Farrokh & Mansur, 2013; Görög, 2016; Grant & Pennypacker, 2006; Grobler & Andsteyn, 2006; Huang, 2017; Iqbal, 2005; Jugdev, Kam; Thomas, 2002; Khoshgoftar & Osman, 2009; Man, 2007; Mullaly, 2006; B. Pasian et al., 2012; Sargent, 2016; Silvius, 2018; Wendler, 2012). Some the more widely discussed known PM maturity assessment models are presented below, based on whether or not models could be found in journal articles published within the last five years.

Furthermore, this section organizes project maturity models as hierarchical or process-based. Hierarchical models follow a staged representation of maturity and are based on a philosophy of incremental maturity using some capacities (Farrokh & Mansur, 2013; H Tahri & Kaitouni, 2017). Process-based models define maturity based on the processes being implemented (Tahiri & Kaitouni, 2017).

2.5.5 Capability Maturity Model Integration (CMMI)

CMMI is an improved version of the CMM (see Figure 2.6). The original model was developed by the Software Engineering Institute (SEI) at Carnegie Mellon University and released in 2002 (CMMI Product Team, 2002; M.C. Paulk et al., 1993). The CMM described the key elements of an active software development process by using five levels of maturity.

The levels (see Figure 2.6) begin with an initial or chaotic level of maturity and end with a fully optimized product development process (Paulk et al., 1993). The model

worked by first conducting a maturity assessment survey to determine the maturity of current PM processes and capability practices within an organization. Then, the assessment would function as the basis for comparison with different organizations. As it was mentioned, the CMM was intended as a method to assess the capabilities of government contractors for delivery of software projects (W. S. Humphrey, 1999). However, the CMM was poor at applying multiple models that were not integrated across the organization (M.C. Paulk et al., 1993). Thus, the *CMMI was created to satisfy this purpose*—to integrate traditionally separate organizational functions (CMMI Product Team, 2002). As such, the CMMI focuses on improving performance through the organizational processes. It does so by addressing three areas: product and service development (CMMI-DEV), service establishment and management (CMMI-SVC), and product and service acquisition (CMMI-ACQ).

2.5.5.1 Advantages and disadvantages of the CMMI

Its advantages are that it integrates traditionally separate areas of development, service, and acquisition. Furthermore, the CMMI sets process improvement goals and priorities, guides quality processes, and provides a point of reference for appraising current processes (CMMI Product Team, 2002; Majumdar et al., 2011).

In contrast, the disadvantages of the CMMI is that it is geared toward long-term strategic management, with processes that may actually hinder development. It allows management to circumvent accountability by claiming that unsuccessful projects are due to a lower maturity level. While it defines what processes and activities need to be implemented, it does not describe how they should be carried out. Moreover, the CMMI

may not be suitable for every organization and may require additional financial and time resources to implement the method in smaller organizations (Majumdar et al., 2011).

2.5.6 PM Maturity Model (PMMM)

The PMMM was first released by PM Solutions in 2002 (J K Crawford, 2006). Like many of its contemporaries, it follows the CMM previously developed by SEI (Crawford, 2006). PMMM made itself different from the CMM by focusing specifically on the assessment of PM capabilities (J K Crawford, 2006).

Based on the content of the PMBOK® and the CMM architecture, the PMMM assess project maturity using the familiar five-level maturity spectrum (see Table 2.3). Its levels are labeled as “Initial Process”, “Structured Process and Standards”, “Organizational Standards and Institutional Process”, “Managed Process”, and “Optimizing Process” (Demir & Kocabaş, 2010; Kent Crawford & Crawford, 2006).

The assessment approach is simple, consisting of listing the specific processes of each PM Knowledge Area of the PMBOK® for the user to indicate from the five options provided. Each process area has a structure that describes the project’s functional achievement as per the processes in the PMBOK® (see Table 2.5).

The PMMM tries to indicate how key process areas can be hierarchically structured to provide transition states for an organization wishing to set practical goals for improvement (Demir & Kocabas, 2010). The model seeks to help organizations address the fundamental aspects of managing projects and improve the likelihood of a quality result.

Table 2.5: PM Maturity Model (PMMM) adapted from Crawford, 2002

PMBOK® Knowledge Area	Level 1: Initial Process	Level 2: Structured process and standards	Level 3: Organizational Standards and Institutionalized Process	Level 4: Managed Process	Level 5: Optimizing Process
Integration Management					
Scope Management					
Time Management					
Cost Management					
Quality Management					
Human Resources Management					
Communications Management					
Risk Management					
Procurement Management					
Stakeholder Management					

2.5.6.1 Advantages and disadvantages of the PMMM

The main advantage of this model is that, just as any other maturity model, can help an organization reduce the likelihood of risks that adversely impact projects without direct costs (Demir & Kocabas, 2010). A disadvantage of the PMMM is that it relies on a self-assessment which can produce biased or inaccurate data. Also, the simple process of PMMM may serve as a guide for improvement but it takes for granted that all organizations must follow all the content of the PMBOK. However, depending on the type of business and projects, it may need to be combined with other methods to ensure robustness.

2.5.7 Organizational PM Maturity Model (OPM3)

OPM3 started to be developed in 1998 and formally published in 2003 by the Project Management Institute (PMI), with the goal of being a global standard for organizational PM maturity (Grant & Pennypacker, 2006). It was created by analyzing existing maturity assessment models and soliciting input on best practices from over 30,000 PM professionals (PMI, 2003). The OPM3 is a process-oriented framework, which seeks to identify an organization's level of maturity by using a list of best practices and capabilities. The third edition of OPM3 is the latest model being used by the PMI, expanded to align with the PMBOK® (PMI, 2013).

OPM3 is a process-oriented framework, which identifies an organization's level of maturity by using a list of best practices and capabilities (Project Management Institute, 2003). The model allows organizational project managers to evaluate and compare their companies' practices to the industry best practices. The narrative text of the best practices presents the OPM3 foundational concepts. Then, the self-assessment method (SAM) consists of hundreds of questions (practices) and four process improvement stages are reported: Standardization, Measurement, Control and Continuous Improvement (Mateen, 2015), although it has a level "0" which means the practice does not exist. The other component of the assessment is by domain (project, portfolio and program). Reporting is delivered in percentages for the stages and domains, and one total percentage.

2.5.7.1 Advantages and Disadvantages of the OPM3

Its primary strength is that it allows an organization to compare its PM practices against industry best standards or its competitors (Pennypacker & Grant, 2006). The

scoring approach is binary (1=practice exist, 0=practice does not exist), while the resulting maturity levels are based on the typical 5-point scale, across the PMBOK Knowledge Areas (Mateen, 2015). However, this model comprises hundreds of practices and questions, which could seem extremely complex for some organizations, especially small ones. The OPM3 could turn out to be resource-consuming, requiring significant time investment, training and use of external consultants in order to implement and sustain. Also, some authors consider the binary scoring approach too simple, easily leaving out important partially existing practices (Mateen, 2015)

2.5.8 Portfolio, Program, and PM Maturity Model (P3M3)

The P3M3 model was introduced in 2006 by the Office of Government Commerce (OGC), an office of Her Majesty's Treasury within the UK Government (OGC, 2010). It was originally meant to be an enhancement to the OGC's PM Maturity Model, which was based on the framework found in the CMM. As a result, P3M3 follows the familiar five-level maturity framework of the CMM, but with some differences (see Figure 2.7). Content-wise, it follows the PRINCE2 methodology. Also, it covers portfolio, program, and PM allowing to measure each separately. The model claims to be written in a straightforward format that makes it user-friendly (OGC, 2010).

P3M3 is a process-oriented framework that seeks to offer a holistic view of an organization's performance, using "generic attributes" to represent each level. A total of 32 processes are assessed across the five levels, and seven "process perspectives": management control, benefits management, financial management, stakeholder engagement, risk management, organizational governance, and resource management

(Young Young & Zapata, J. R., R, 2011). The perspectives are more like process categories, while the attributes are simply the description of each level.

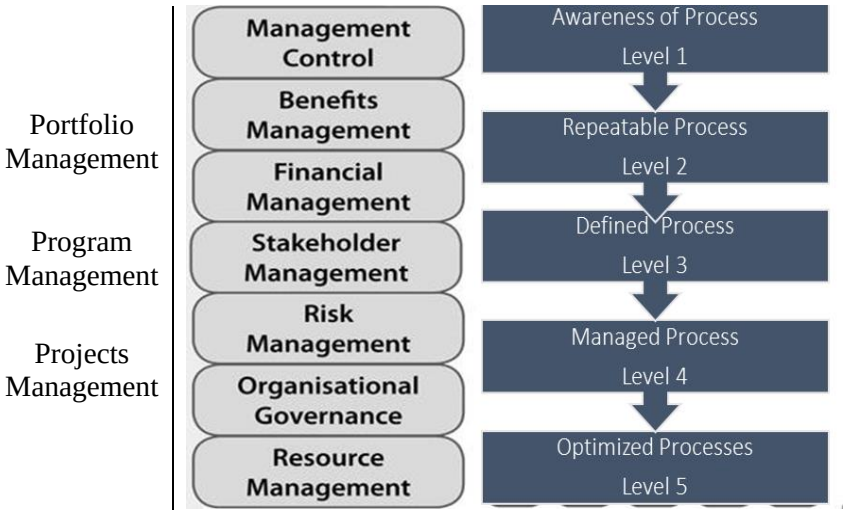


Figure 2.7: The P3M3 Structure - adapted from OGC, 2010

2.5.8.1 Advantages and Disadvantages of the P3M3

Some attributes are embedded within the process perspectives. P3M3 is designed to identify the attribute and perspective weaknesses. This allows organizations to understand the key practices that need to be embedded within the organization for it to achieve the next maturity level. Additionally, P3M3 indicates it has the flexibility to be refined as best practices evolve within each management area.

In contrast, the P3M3 model has some disadvantages. The model does not differentiate between PM and project success. Its focus is on processes that are not equally effective in increasing the chances of project success and can have different impact on efficiency (Young Young & Zapata, J. R., R, 2011). Secondly, while the model allows portfolio, program, and PM to be separately assessed, these areas are

inherently linked (but should not be assessed using the same generic attributes) — programs are composed of projects and portfolios are composed of both programs and projects. Therefore, the assessments may be less independent than the model assumes, resulting in erroneous indicators, including consideration of the lowest score across processes, to report total maturity (Young, Young, & Zapata, 2011).

2.5.9 Kerzner's PM Maturity Model

Another famous model is the one developed by Harold Kerzner, published 2001 (Beukers, 2011; H. R. Kerzner, 2005), with focus on strategic principles and organizational behavior as basis for success in PM. The model claims to be adaptable to any type of business.

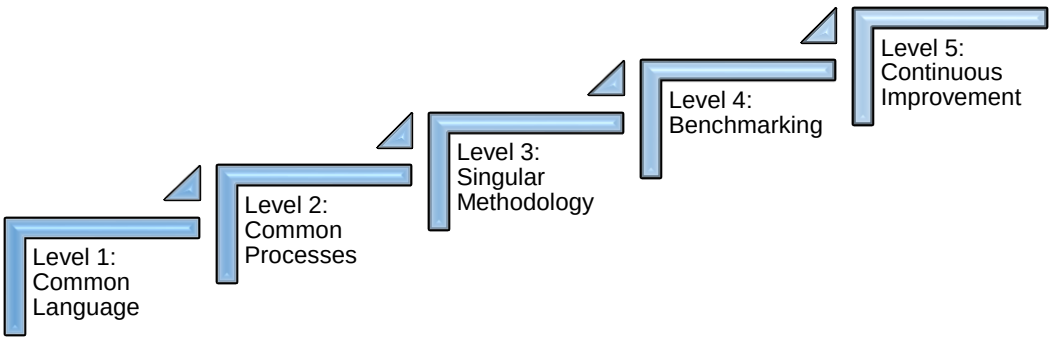


Figure 2.8: Levels of Kerzner's PM Maturity Model (adapted from H Kerzner, 2005)

Kerzner's PM Maturity Model is also based on the PMBOK® and the CMM. As such, it utilizes the described five levels of maturity (see Figure 2.8). This model consists of multiple questionnaires for each level. For instance, level 1 is a questionnaire on PM knowledge, based on the PMBOK®, while Level 3 consists of measuring the formality of the PM processes in the organization (in sublevels from "embryonic" to "maturity").

2.5.9.1 Advantages and Disadvantages of Kerzner's PM Maturity Model

The advantage of Kerzner's model is that it takes a deeper approach to understanding the PM situation of an organization (compared to other models such as the PMMM by Crawford, and the P3M3P by the UK Government). However, the model is rather long with almost multiple exams totaling around 200 questions. While it claims to be applicable to all industries, the need for customization for that purpose is also a disadvantage, making this model a generic one, and takes for granted that all organizations must need and should be assessed against the full content of the PMBOK.

Also, the results of such long assessment only provide percentages achieved for each level, without any final notes. For that reason, Kerzner's model is resource-consuming, it requires third party's support to interpret results and to plan improvements.

2.5.10 PM Process Maturity $(PM)^2$ Model

The $(PM)^2$ model was developed by Young Hoon Kwak and C. William Ibbs in the early 2000s. It is a 5-level PM maturity model intended to be a reference point for organizations seeking to adapt and implement PM (PM) tools and processes (Ibbs & Kwak, 2002). The $(PM)^2$ model breaks the processes and practices of PM into the nine Knowledge Areas and processes of the then available version of the PMBOK®.

The $(PM)^2$ model is a process-oriented framework with five PM maturity levels (Ibbs & Kwak, 2002; Y H Kwak & Ibbs, 2002). Each maturity level contains key PM processes, organizational characteristics, and focus areas as per the PMBOK®. These levels are meant to allow the organization to determine the strengths and weaknesses of its practices and improve on weaker ones to reach a greater level of maturity (Kwak & Ibbs, 2002).

Level 1 of the $(PM)^2$ model establishes and creates an understanding of basic PM processes. Level 2 focuses on individual project planning. Level 3 creates systematic, structured project planning and control for individual projects. At Level 4, organizations integrate multi-project planning and control. Finally, at Level 5, organizations are incorporating innovative ideas to improve PM processes and practices on a continual basis.

2.5.10.1 Advantages and Disadvantages of the (PM)2

Its advantages are that it provides a means for identifying and measuring different PM levels by combining Knowledge Areas with project processes, and it offers an orderly and disciplined method for achieving a higher level of PM maturity; and it applies to a wide range of companies and industries (Ibbs & Kwak, 2002). No specific statements of the disadvantages of this model were found. Although the model is cited extensively in the literature, it has not been applied since early 2002 (when the authors developed it). Most likely because other similar models emerged which built upon it and are more up-to-date concerning the PMBOK®.

2.5.11 Important Criteria in the Selection and Use of Maturity Models

Organizations that wish to measure and improve quality of projects through the use of PM maturity evaluate existing maturity models, such as the CMMI and OPM3 (Bourne, 2016), or identify criteria to determine which model better suits their needs. There are various processes and criteria used to ultimately select the correct maturity model, which could be technical and complex (Söylemez & Tarhan, 2016). However,

implementing the appropriate model increases the chances that the investment will be worth it. Some the criteria considered to do so include:

- **Integration: Can we implement it?** This has to do with the ability to implement a maturity model in the organization. According to Guédria, Naudet & Chen (2015), determining if a particular maturity model fits into the needs, goals, and objectives of the organization is an important consideration. In this context, factors such as resource requirements, costs, and the strain of strategic alignment are some the considerations that an organization should include in its criteria to assess maturity levels. A maturity model that does not fit into the organization's business profile, missions, visions, operational functions, and its strategies should not be selected. For instance, in a retail environment, OPM3 may be a bad fit. While CMMI is suited to a service environment and thus enhances service delivery and customer support (Guédria et al., 2015). Bourne (2016) argues that in many instances, budgetary allocations limit any project.

- **Design and Functionality: How does the model work**? Man (2007) points out the nature and functionality of the maturity model as compared to the organization's objectives should be considered to implement a maturity model. Maturity is manifested in levels, and thus models have criteria to test different levels. For instance, in data collection and processing to determine an organization's maturity level, OPM3 framework has four levels while CMMI assesses five levels. Implicitly, one may assume the CMMI takes a long time. Also, the need for a certified assessor and related costs could make the model unsuitable for certain types of organizations.

- **Purpose of Use: Is it useful for the organization?** Pöppelbuß & Röglinger (2011) state that different maturity levels are designed with different purposes, such as descriptive, prescriptive or comparative purposes. If the goal of the organization is to find out how it compares to other organizations in the industry, it must select/design a model that allows benchmarking. If the objective is to improve PM practices, the selected/designed model should have prescriptive

functionality. The organization also bears in mind that a single iteration of assessment and implementation is never enough. The proposed model should be useful, fluid and robust enough (Bourne, 2016).

- **Sustainability: Can we sustain it?** The maturity model has to be sustained and should anticipate further development and improvements that will be required bearing in mind that some the models' elements will become obsolete (Silvius & Schipper, 2015). A common feature is that new constructs emerge on divergent levels of maturity. A maturity model has to be able to assimilate these new constructs. Otherwise, it may result in copious costs and time. Therefore, even at infancy, it is critical also to understand how to take care of changes in the model deployment and design. Assessors have to consider a certain degree of model sustainability. In this respect, the maturity models should be gradually developed over a stretched time horizon (Silvius & Schipper, 2015).

- **Organizational/Senior Management Support**. Considering the way maturity models work, the most probable limitations on the success of a chosen model are typical restraining factors of improvement initiative, such as a lack of senior management buy-in, organizational complacency, and so on. In that sense, it is necessary to evaluate which model will have the least impact on the organization as to ensure support (Bourne, 2016).

2.5.12 Flaws of PM Maturity Assessment Models

Table 2.6 shows a summary of the PM maturity models reviewed and their main weaknesses. To any story, there are always two sides, and the PM maturity assessment framework is not an exception. As a relatively new discipline, PM maturity models' evidential literature is said to lack a solid scientific foundation, making them prone to misapplication (Cândido & Santos, 2015; Mettler, 2011). Criticism exists concerning the need for more bodies of work to support their functionality in different paradigms and situations (Grobler & Andsteyn, 2006; Khoshgoftar & Osman, 2009; Wendler, 2012).

Table 2.6: Summary of the models reviewed and main weaknesses.

Model	Developed by	Based on	Assessment Approach	Main Weaknesses
Kerzner's PM Maturity Model (K-PMMM)	Dr. Harold Kerzner in 2001	CMM architecture Levels from 1-5 Pass/fail score PMBOK® content	Multiple exams Self-assessment	Generic Long, point-less questions Medium difficulty Assumes all PMBOK® is applicable
Crawford's PM Maturity Model (PMMM)	J. Kent Crawford in 2002	CMM architecture Levels from 1-5 Lowest rating assigned PMBOK® content	Quiz-like Self-assessment	Generic Short, low difficulty (too simple/not robust) Assumes all PMBOK® is applicable
Organizational Project Management Maturity Model (OPM3)	PMI, published in 2003	4 stages Levels, Levels from 0-4 Binary (yes/no) score PMBOK® content	Quiz-like Self-assessment (3^{rd}. Ed.)	Generic Very long (almost 600 practices), overwhelming Assumes all PMBOK® is applicable
Portfolio, Program, and PM Maturity Model (P3M3)	By the UK's Office of Government Commerce, in 2006	CMM architecture Levels from 1-5 Average/lowest score PRINCE2® content	Quiz-like Self-assessment	Very generic 32 processes, medium difficulty Same attributes for all dimensions (unrealistic) PRINCE2® method dependent

Several authors have suggested that the multiplicity of project management maturity models conveys one common flaw: that is, the inability of such project management maturity models to meet all project management needs and objectives, saliently and pragmatically (Grobler & Andsteyn, 2006; Silvius, 2018). Besides this, in many respects, PM maturity models have been labeled as impractical, overly disciplinary, challenging to apply, and mostly addressing processes and hard-soft elements which leave out human factors (Chee Choong Gan & May May Chin, 2018; Rincon, 2018).

These assertions are supported by several authors, including Kerzner (2017) and Grobler et al. (2009). In particular, Kerzner's work revealed that the majority of the PM maturity models failed first, due to the complexities of some models, and secondly, due

to the incompetence of some project managers in dealing with maturity models. The application of some PM maturity models may require the acquisition of new skills and knowledge, making them expensive to implement, for instance, OPM3 and CMM (Hillson, 2003). Perhaps a more comprehensive list of flaws, criticisms, and disadvantages of PM maturity models is provided by Jugdev and Thomas (2002). They also stated that most of these models are inflexible to deal with changes and improvements when they are needed most, and provide problem description rather than problem-solving processes.

2.5.12.1 Why PM Maturity Assessment Models Serve a Useful Purpose

Despite the remarked flaws, PM maturity assessment models serve a genuine purpose by filling a need that would not be satisfied if such frameworks were unavailable. They constitute a formal methodology for organizations to get an idea of their current PM state. Also, they can help organizations to gain comprehensive knowledge regarding what constitutes good PM practices, and provide guidance on prioritizing and planning towards improvements that can result in competitive advantage (Chui, 2008; Fazio, 2017; Jugdev, Kam; Thomas, 2002; Pennypacker & Grant, 2003).

2.5.13 Maturity Models in the HFE Domain

There is currently no work related to the assessment of human factors service providers in the context of FDA HF validations for medical devices and combination products. However, to differentiate the focus and scope of this research, it is important to briefly mention the use of maturity models in the HF literature. In that sense, it applies to say that some HF (including the words “usability” and “UX”) maturity assessment

models have been developed (Carvajal & Moreno, 2017; Del Giudice et al., 2015; Jokela & Lalli, 2003; J. Mitchell, 2015; Nickleby HFE Ltd, 2002; Sherwood-Jones et al., 1999). However, in one way or another, these models seek to measure how well a system integrates the HF principles in order to avoid accidents, ensure safety or enhance user experience (e.g., a hospital environment, a nursery home, software or product). To put this into perspective, existing HF maturity models try to measure HF readiness, by assigning a level to indicate how safe and effective for human-use, a system or product is. For instance, Nielsen's Corporate UX Maturity Model goes from "Hostility Towards Usability to User-Driven Corporation" (Nielsen, 2006). Another framework is the Human Factors Maturity® model developed by the Keil Centre (Mitchell, 2015), which is a modification of an earlier model called HF Capability Framework and based on the CMM (J. Mitchell, 2015). The Keil Centre arrived at a five steps card-sort method for measuring HF maturity.

In the same way, Del Giudice, Hale, & Johnston (2015) developed the SHARE-Human Factors Assessment and Readiness Evaluation process that seeks to quantify the HF readiness of a system. They suggested that a project will incur delays and extra cost if organizations do not carry out an assessment of HF readiness. The authors proposed a supporting metric in Human Factors Readiness Level (HFRLs) scale to accurately determine field-readiness of the entire system awarding a scientific score. Earlier, Sherwood-Jones et al. (1999) proposed the need to evaluate the capability and process models in HF within the contemporary world. They evaluated the UK Ministry of Defense (MoD) HF requirements, development, integration and implementation strategy and offered recommendations using the model called Human Factors Integration

Capability Maturity Model (Sherwood-Jones et al., 1999). According to the authors, it would guarantee those complex systems are operational when required. Therefore, the Human Factors Integration Capability Maturity Model is as well similar to an HF validation of a given system.

2.6 Summary of Chapter 2

Chapter 2 is a review of literature relevant to this research, starting with a review of how the HFE requirement developed as well as describing a changing regulatory environment. Most noticeably issues discussed include the difficulty that drug/device combination product represents (involving multiple stakeholders), the lack of HFE awareness/knowledge, and the increase in the number of consultations at the FDA due to the HF requirement. Progress to address the issues so far were also reviewed, such as FDA's internal initiatives involving process improvement and adding consultations with the Agency. Future changes are in the horizon as well, most importantly for his research are: implementation of maturity model for the medical device industry which will extent to their suppliers, and the harmonization and modernization of FDA's quality system regulation (QSR), which will impact HFSPs. In additions, literature about the selected framework, PM maturity models, was discussed including reviewing existing models and their limitations.

Chapter 3 – Methodology

3.1 A Mixed-Methods Exploratory Research Design

As it can be determined from Chapter 2, there is a growing number of maturity assessment models. However, there are also reasons for the variety of maturity models. While some researchers would love to come up with a model that could apply to all situations, some authors have appropriately pointed out it is unlikely for one single maturity model to fit for all purposes (domains, and industries). Instead, it is essential to consider the specific needs of each problem (Grobler & Andsteyn, 2006) and projects in their own context or industry.

In this case, the idea of PM maturity has not been applied to the described problem. Thus, an industry-focused tool will be developed considering the prerequisites specific to FDA HF validation projects including the freshness of the topic, the regulatory nature of the process, the needs of the different stakeholders and the domain (human factors engineering). This approach is consistent with design principles and phases in the development of maturity models (de Bruin et al., 2005; B. L. Pasian et al., 2011; Pöppelbuß & Röglinger, 2011; Silvius & Schipper, 2015).

In that tone, effective PM maturity models must account for criteria linked to specific project practices and needs (Khoshgoftar & Osman, 2009), in order to define criteria of project performance. However, projects vary in value, size, and complexity, impacting such criteria regarding project performance from one context to another (Müller & Jugdev, 2012; Müller & Turner, 2007).

Accordingly, projects must be studied considering their specific context and practices (Blomquist et al., 2010; Cicmil et al., 2006), which is also among the reasons for the growing number of industry-focused PM maturity models (Grobler & Andsteyn, 2006; B. Pasian et al., 2012). Nevertheless, there is little or no research about FDA HF validation projects for medical devices and combination products.

3.1.1 Two-Phase Study Design

As it was described in Chapter 2 the proposed tool involves two dimensions (PM and HFE). Given the lack of literature on the projects of interest, this research is exploratory and involved mixed-methods for the collection of the vital qualitative and quantitative data. Specifically, this research used a two-phased mixed methods design methodology including triangulation (Carter et al., 2014), which consists of using various methods and data to better understand FDA HF validation projects as well as to ensure validity of the findings.

3.1.1.1 The Proposed Tool

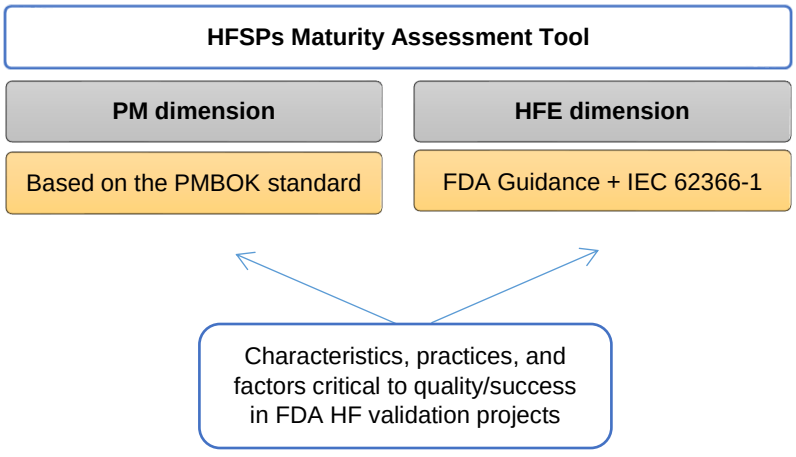


Figure 3.1: Content architecture for the proposed HFSPs maturity assessment tool

For an objective and practical model, it becomes necessary that the corresponding HFE content is based on:

a) The specified FDA HF guidance: "Applying Human Factors and Usability Engineering to Medical Devices;"
b) Supplemented with the international standard "IEC 62366-1: 2015, Medical Devices, Part 1: Application of Usability Engineering to Medical Devices."

The PM Dimension will be based on:

a) PM processes aligned with the most widely recognized standard in PM, which is the Project Management Body of Knowledge (PMBOK)
b) Research on FDA HF validation projects (characteristics, practices, and factors critical to quality/success).

To accomplish the previous, two main studies were devised. First study sought to understand and describe FDA HF validation projects within its specific context and answering some specific research questions (Phase I). Phase II entails developing the and testing the tool through the application of de Bruin's model.

- **Phase I:** Understanding the Characteristics and Critical Success Factors (CSFs) of FDA Human Factors Validation Projects

  Objective: To explore and understand the characteristics, critical success factors and project management practices of FDA HF validation projects to inform the development of a PM maturity assessment tool.

- **Phase II:** Developing and Testing an Industry-focused (Human Factors Service Provider) Project Management Maturity Assessment Tool

Objective: To develop (Part 1) and test (Part 2) an industry-focused project management maturity assessment tool that can help assess HFSPs who manage and deliver FDA HF validation projects.

3.1.2 Development Phases of a Maturity Model

The general objective is to develop an industry-focused PM maturity assessment instrument to measure the capability of those organizations (or units) which conduct HF validations for medical devices and combination products and which seek FDA's approval. De Bruin et al. (2005) outlined the phases in the development of a maturity assessment model (see Figure 3.2) and it will be used to organize the general method for this research.

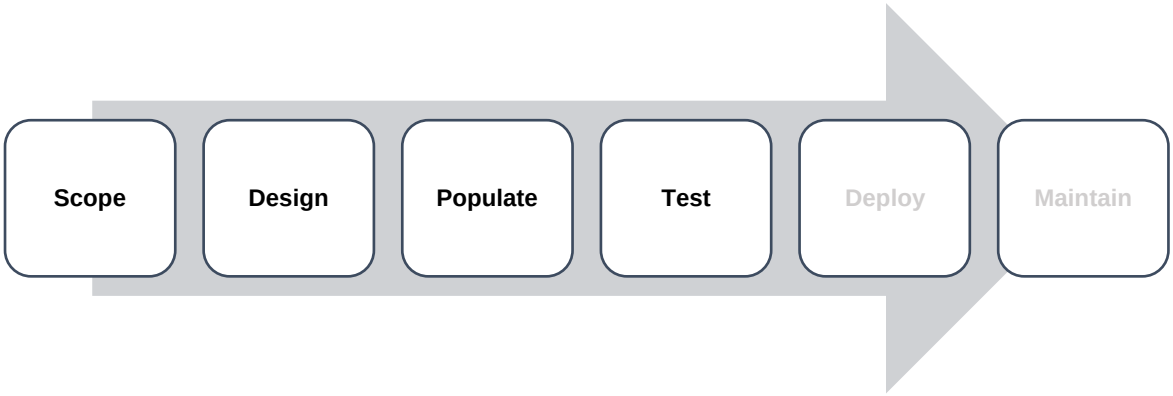


Figure 3.2: Model Development Phases, adapted from de Bruin et al. (2005)

- **Scope**: The objective of this Phase is to determine the scope of the model. The decisions made in this phase should determine the *focus of the model*, the *domain and stakeholders*.
- **Design**: During this phase the *architecture* of the model is determined. This could include the target audience, method of application (e.g.: self-assessment), type of application and respondents (those that fill out the assessment) and operational definitions (how maturity will be measured).
- **Populate**: This phase consists of adding the content to the defined "skeleton" or architecture of the model, including conceptual definitions (or what to measure). De Bruin et al. (2005) identified several methods typically used during this phase. For this research, the Delphi technique, in combination with the reviewed literature and findings from a previous study (phase 1 of this research) were considered appropriate to develop the desired content to populate the tool.
    - The **Delphi technique** is a consensus development approach ideal for topics where there is very limited or imprecise research (Avella, 2016). Although Delphi designs vary, it generally works by forming a reduced group (ideally, of stakeholders of the problem being researched). Members of the panel only interact with a facilitator (in this case, the researcher) who collects feedback in rounds of questions while their specific feedback remains anonymous to the rest of the group. Results are analyzed by and rounds are repeated until outcomes are positively accepted by at least 70% in the panel (Avella, 2016).
- **Test**: the goal of this Phase is, of course, to test the developed tool to ensure relevancy and usability, also for validity. De Bruin's model states that the way maturity models have been tested varied between models, but one way of doing this was by seeking feedback from a select group of domain experts, and using pilot testing. In this research, testing is addressed as Part 2 of Phase II.
- **Deploy** and **maintain:** once the tool has been tested, it is then made available (deployed) to the interested audience, and maintain as needed for continuous relevance and used. Deployment and maintaining will be part of future research, hence not addressed for this dissertation project.

3.1.3 Bruin's Maturity Model Development Process Applied to this Research

Each phase of de Bruin's phases is concerned with the decisions needed to develop the model. Figure 3.1 illustrates how such phases are developed for this research and to meet objectives. This work will report up to the testing Phase in two parts. The first part addresses the phases *scope, design, populate*, while the phase *Testing* takes place as a Part 2 of this research. Deploy and maintain have been planned as part of future work.

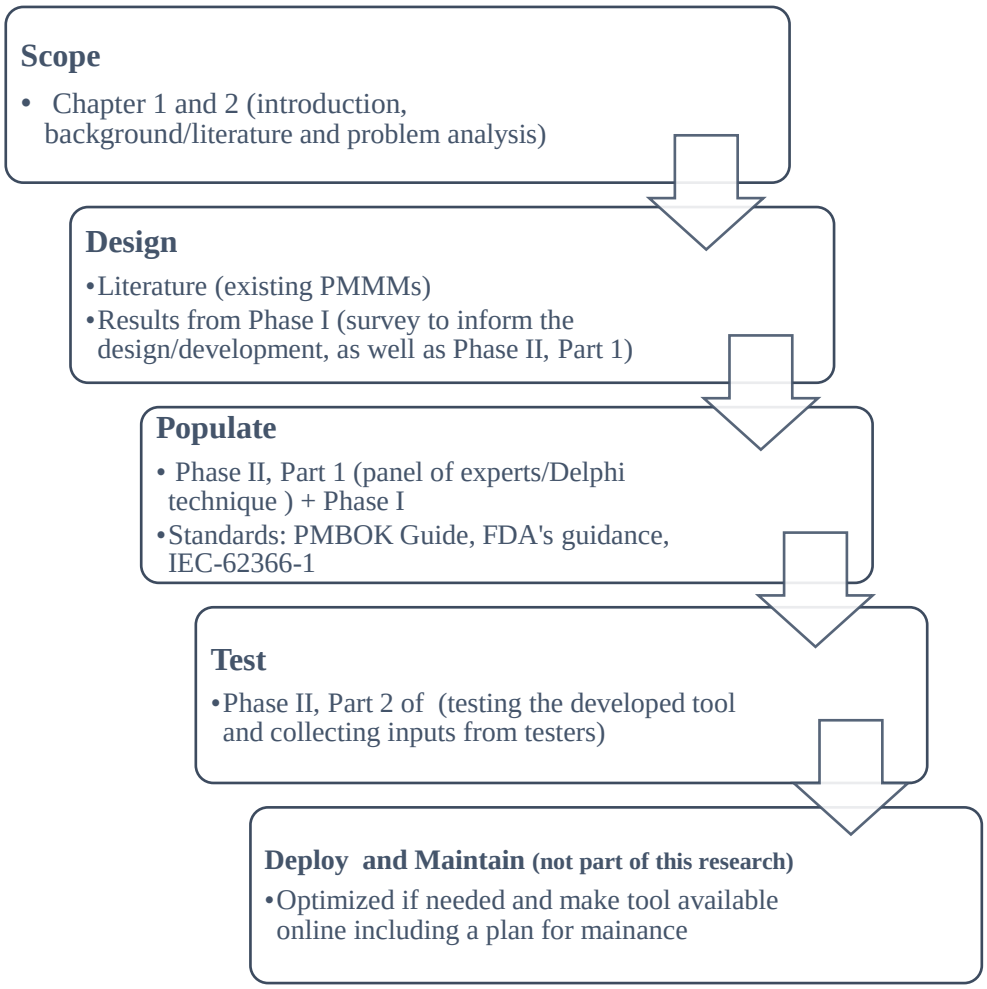


Figure 3.3: Maturity assessment model development (Bruin et al., 2005) applied to this research

3.1.4 Participants and Data Collection

All participants were recruited online and by word of mouth. A publication of this study was made available online through relevant LinkedIn groups (e.g.: Combination Products Coalition, Medical Device groups, etc.), the HFES healthcare technical group and other related online forums (e.g.: AAMI and RAPS). The invitation described the study protocol and requested inputs from individuals with experience leading FDA HF validation projects (a requirement to participate). In addition, the HF review team at the FDA were also invited to provide inputs, specifically as part of the panel of experts of Phase II (however, the team did not respond to the invitation).

During Phase 1, a total of 18 organizations/individuals responded requesting more information about the study, which was provided to them. Afterwards, twelve participants agreed to take the survey and were provided an anonymous link via email for that purpose. At the same time, they were asked to kindly share the link within their network. With that approach, a total of twenty (20) responses were collected (Phase I).

In Phase II, Part 1 (Delphi Panel), eleven (11) individuals met the criteria to be part of a panel of experts (senior level experience managing HF validations that seek approval from the FDA). The purpose of this panel was to provide inputs to generate the content (populate) the maturity model using the Delphi technique (Avella, 2016).

For Part 2 of Phase II, which consisted of testing the tool, all organizations/individuals that had responded to the initial invitations published online since Phase 1, were contacted via email. They were made aware that a beta version of the tool was ready for testing. With that approach, fourteen (14) organizations tested the tool. For that purpose and to motivate participation, no demographics information was requested.

3.1.4.1 Ethics

The research protocol was submitted to the IRB at Binghamton University for initial review, and it was classified as exempt. Also, to ensure privacy and confidentiality of participants, informed consent was secured before participation by providing the necessary details of this research. Furthermore, the collection of demographic information was kept to a minimum or not collected where possible (for that reason, Phase II, Part 2 – Testing the too) did not require any demographic information from participants to complete the self-assessment, in order to motivate participation.

For the panel of experts (Phase II, Part 1 of this research), each expert was asked for and provided permission to disclose their names to acknowledge their kind participation and valuable inputs as part of the Delphi Panel. All the data analysis and reporting of results were conducted at the group level (e.g., "participants" "experts", "individuals").

Participants in this research did not receive any monetary incentives. To encourage participation, all participants were informed that the beta tool would offer a free report as result of a self-assessment.

3.1.5 Data Analysis

Qualtrics online survey software platform was used to collect data for both Phases. The majority of the data collected in the process of developing the tool were qualitative in nature. Multiple techniques can be used to analyze qualitative data; for this study, thematic coding was used (Braun & Clarke, 2006) to identify the patterns and themes from the data collected. This type of analysis works by first getting engaged with the data to then extract initial pieces of texts by converting into shorter sentences (the

codes). These codes are grouped based on their meaning. At this point the codes are refined by further understanding and analyzing any patterns, renaming and merging themes as needed. The last part consisted of organizing by themes to produce a report, enabling discussions and theorization. The quantitative data collected were mostly nominal and ordinal, and were analyzed and reported using descriptive statistics. For Phase II – Part 2 (Testing), IBM Statistical Package for the Social Sciences (SPSS) was also used to perform statistical analysis on the collected data, including Cronbach Alpha coefficient, correlation, Principal Component Analysis with Factor Analysis and Confirmatory Factor Analysis (IBM® SPSS® Amos).

3.2 Summary of Chapter 3

This chapter described the methodology used for this research. Bruin's framework outlines the stages to develop a maturity model, which are: Scope, Design, Populate, Test, Deploy and Maintain. A mixed-methods methodology of two phases was used to execute the stages of maturity model development (from Scope to Testing). For Phase I, a survey tailored to this context was designed, as recommended by the literature. The survey provides understanding about PM performance criteria, which change significantly depending on industry or context. Considering also there was no research about HF validation project characteristics. Phase II consisted of 2 parts. Part 1 entailed of determining the key factors for success in FDA HF validation projects, and a panel of experts (Delphi Panel) as well as the use of FDA HF guidance and other applicable standards, helped for that purpose. The identified factors for success served to populate the two dimensions of the model, HFE and PM. Part 2 covered the testing of the beta version of the developed maturity model.

Chapter 4 – Results & Discussion

Considering that most of the collected data were qualitative and that thematic analysis (Braun & Clarke, 2006) was necessary to understand key concepts, this chapter blends the results and discussion in one section. As explained in Chapter 3, this research involves two Phases, the first one consists of an exploratory survey meant to understand more about FDA HF validation projects. Phase II includes two parts, the development of an industry-focused project management (PM) assessment tool and testing (Part 2) of the tool. The results from the survey of Phase I and the inputs from a panel of experts (Phase II) make up the content to populate the tool based on factors critical to quality and success of the projects being studied. The resulting tool (beta) is described and tested in Part 2 of Phase II.

4.1 Phase I: Understanding the Characteristics and Critical Success Factors of FDA Human Factors Validation Projects

The study aimed to understand HF validation projects of medical devices and combination projects that seek FDA's approval. Gaining a deep understanding of these projects was necessary to inform the development of an industry-focused PM maturity assessment tool. A context-focused survey instrument was created using variables identified and described through a causal-loop-diagram (CLD) which had been developed to analyze the problem of study (Rojas, Sharareh, et al., 2019). The instrument was pilot-tested and refined.

The final, pilot-tested instrument resulted in an online (Qualtrics) survey-questionnaire of 39 open and closed-ended questions (Appendix L), developed to collect data about the characteristics of HF Validations projects of the organizations represented, that would help answer specific research questions.

The primary questions of this Phase I study are the following:

1. Is PM being applied to manage FDA HF validation projects?
2. What are the main challenges?
3. Why do these projects fail?
4. What are the drivers of success?

4.1.1 Participants

The survey was completed by 20 individuals experienced leading HF projects that seek FDA approval. Participants were senior managers who had directly completed an average of 28 FDA HF validation full-cycle projects. Regarding the level of education, 90% had a graduate degree, while the remaining 10% had an undergraduate degree.

4.1.1.1 Types of Organizations

Individuals who completed the survey (N=20) were either providers of HF services (80%, 16) or procurers (20%, 4), at manufacturing organization (50%, 10) or at agency/consultancy firms (50%, 10). There was much variation depending on the type of organization where participating HF leads worked, for that reason, results are shared separately by “manufacturing organizations” and by “agencies/consultancy firms” (when necessary. e.g.: variation).

Most of the participating manufacturing organizations (90%) had been in business for more than 21 years; the other 10% had been in business from 11 to 16 years.

Similarly, 20% of agency/consultancy firms that participated had been in business for 11 to 16 years, 20% 17 to 20 years and 60% for more than 21 years. Table 4.1 shows that the number of employees at 100% of agencies/consultancies was below 200 (with 50% 11 to 50 employees, and 30% 6 to 10 employees), while 70% of manufacturers had > 41,000 employees.

Table 4.1: Number of employees of participating organizations (N=20)

Number of Employees	Manufacturers (n=10)		Agencies/Consultancies (n=10)	
1 - 5	0.00%	0	10.00%	1
6 - 10	0.00%	0	30.00%	3
11 - 50	0.00%	0	50.00%	5
51- 200	10.00%	1	10.00%	1
201-1000	10.00%	1	0.00%	0
5001- 20,000	10.00%	1	0.00%	0
> 41,000	70.00%	7	0.00%	0

4.1.1.2 Primary Business

The primary business (product) of the participating organizations included medical devices (55%), followed by drug/pharmaceutical products (35%) and combination products (30%).

Table 4.2: Summary primary business of participating organizations (N=20)

Answer	%	N
Medical devices	**55.00%**	11
Combination products	30.00%	6
Drug/Pharmaceutical products	35.00%	7
Biotechnology products	5.00%	1
All of the above	20.00%	4

4.1.1.3 Primary Type of Submission

Among all participating organizations (N=20), "predicates" were the most common type of submission (65%), while combination products involving a device + biosimilar and a device + generics were the least common.

Table 4.3: Summary primary type of submissions, N=20

Answer	%	N
Combo (New Drug)	35.00%	7
Combo (Bio-similar)	10.00%	2
Combo (Generics)	0.00%	0
Combo (Interchangeability)	15.00%	3
Medical device (predicates)	65.00%	13
Medical device (high risk)	35.00%	7
Medical device (De Novo)	15.00%	3
All equally common	15.00%	3

4.1.1.4 Geography of Project Sponsors

In terms of geography, most organizations sponsoring FDA HF validation projects are both local and international (70%, 14). However, when broken by type of organization, agency/consultancy firms (60%, 12) said they conduct HF validation projects for "both local and international" sponsors, while only 10% from international. As per manufacturers, 80% (16) are "both local and international."

4.1.2 Project Size Based on Budget and Duration

Project size is often something relative, depending much on duration, cost and scope (also, these often interrelated, e.g.: for a project with a large scope, duration and

cost increase). However, in the case of HF validation projects there is no literature about project size. What is a short-term or large HF validation project?

To have an idea of how one would determine an HF validation project to be large or small, respondents were asked to arrange by themselves a classification in terms of project duration and budget (see Table 4.5 and Table 4.4).

Table 4.4: Size of FDA HF validation projects based on budget and duration

		Agencies/Consultancy firms (n=10)				**Manufacturers/developers (n=10)**			
		Min	**Max**	**Mean**	**Std Dev**	**Min**	**Max**	**Mean**	**Std Dev**
Budget ($000's)	Small	26	151	74.4	37.51	10	428	125.2	120.34
	Medium	98	350	**195.6**	89.28	75	855	**344.5**	244.61
	Large	100	599	345.8	164.92	125	1604	676.4	518.53
Duration (months)	Small	1	12	4.4	3.07	3	24	9.9	7.76
	Medium	5	24	**10**	5.25	6	36	**17.5**	11.06
	Large	6	36	18.1	8.01	12	50	27.9	15.1

Although both types of organizations indicated that "medium-term/medium-size" projects were the most frequent (Table 4.5) one interesting finding is that the idea of project size varied significantly depending on the type of organization. Manufacturing organizations had very different definitions compared to agencies where a "medium-term" and "medium-size" project can last significantly longer and cost significantly more (see Table 4.4). Also, manufacturers experience more variation than agencies/consultancies (see 'standard deviation' in Table 4.4). The previous also applies to the number of HF validation projects per year (see Table 4.6). There seem to be a significant difference between mean number of HF validation projects per year at agencies/consultancies versus manufacturers.

Table 4.5: Frequency of FDA HF validation projects (greater % of frequency is in bold)

	Short-Term/Small			Medium-Term/Medium			Long-term/Large		
Type of organization	**Most Freq**	**Less Freq**	**Least Freq**	**Most Freq**	**Less Freq**	**Least Freq**	**Most Freq**	**Less Freq**	**Least Freq**
Manufacturer/developer (n=10)	10%	30%	60%	**50%**	30%	20%	**40%**	40%	20%
Agency/consultancy firm (n=10)	30%	**60%**	10%	**70%**	30%	0%	0%	10%	90%

Table 4.6: Number of FDA HF validation projects per year

Type of Organization	Min	Max	Mean	Std Dev.	Variance	N
Manufacturer/Developer	4.00	20.00	8.40	5.87	34.44	10
Agency/Consultancy	4.00	65.00	19.80	21.77	473.76	10

As per those surveyed, FDA HF validation projects of manufacturers are mostly medium term (50%, 5), with a mean duration of 17.5 months (±11.06 SD). Similarly, 70% (7) of the agency/consultancy firms described their HF validation projects to be mostly medium-term (10 months, ±5.25 SD). Interestingly, long-term/large projects are very rare for agencies/consultancy firms (90%, 9) said these are the "least frequent type of projects, but they are the second most frequent for manufacturers (40%, 4).

4.1.3 Is PM being Applied to Manage FDA HF Validation Projects?

In general, 50% (10) of participants indicated they do use PM (see Figure 4.1). However, in this specific context formal PM seems limited, as much as 50% might not be using any tool or method to apply PM in the management of FDA HF validation projects. That is, 40% (8) of all participants directly indicated "No" while 10% said they did not know, as shown on Figure 4.1.

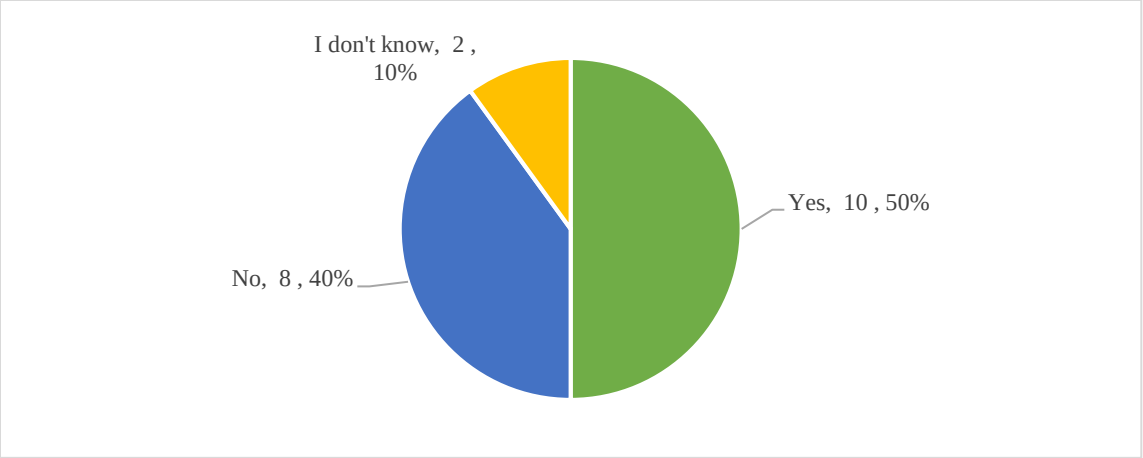


Figure 4.1: Is a PM Methodology/Tool used in your organization? (N=20)

4.1.3.1 Who does the PM Work?

Altogether, from the 50% (10) who indicated they use PM, notice on Table 4.7 that only 40% (4) is done by formal PM professionals. Most of that PM is handle by HFE personnel or other personnel including senior management.

Table 4.7: Who does the PM work by use of PM (N=20)

Use of PM	Product Engineers	n	Sr. Mgmt.	n	Project Managers	n	Human Factors personnel	n	Other	n
We use PM	0%	0	0%	0	40%	4	50%	5	10%	1
We do not use PM	0%	0	13%	1	0%	0	75%	6	13%	1
I do not know	50%	1	0%	0	0%	0	50%	1	0%	0

Hours on PM Tasks per Project

Most participants indicated that the number of hours spent *weekly* on PM tasks is a minimum of 5 to 10 hours per project (see Figure 4.2). Considering that the workweek is commonly 40 hours, if most individuals are assigned 2 to 3 projects (Figure 4.3), and they spend a minimum of 5 to 10 hours per project per week, this could add up to 30 hours per week only on PM tasks. What happens to the HFE work?

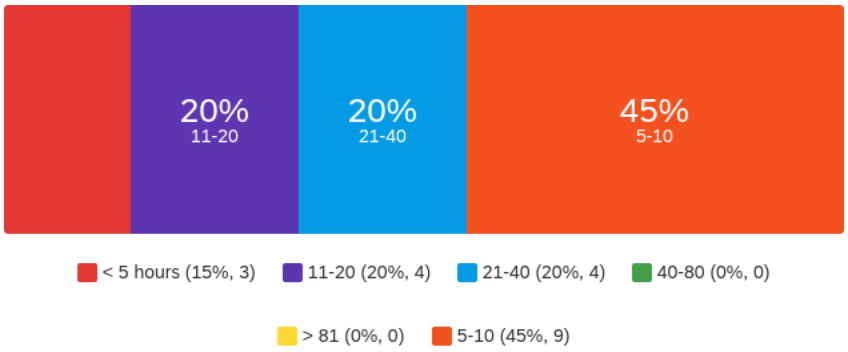


Figure 4.2: Number of hours spent weekly on PM work (N=20)

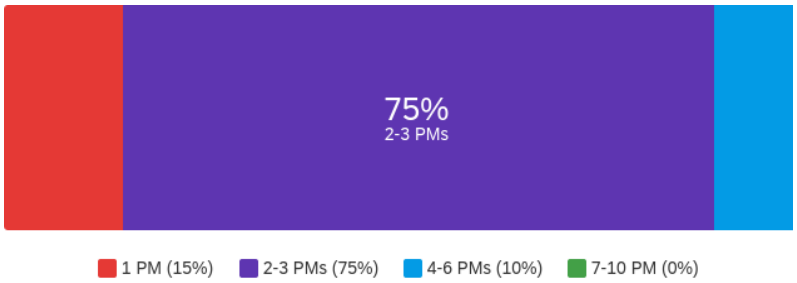


Figure 4.3. Number of projects assigned per employee (N=20)

4.1.3.2 Quality Systems (QS)

All the participating *manufacturing* organizations (10) had a quality system (QS) in place, while 50% (10) of the agency/consultancy firms did not. The questions remain if the QS of manufacturing organizations considers specifically the HFE PM practices, or only manufacturing processes.

Figure 4.4, shows only the agencies/consultancy firms which indicated they had no QS (5). When asked if they had plans to implement a QS in the future, 80% (4) said they had no plans to implement one, and the rest (1) did not know.

Figure 4.4: Do you have plans to implement a QS? (Organizations that indicated "no QS in place")

4.1.3.3 Scarce Application of Formal PM

The use of formal PM in HF projects for medical devices seems limited, and the majority of HF service providers do not even have any kind of QS in place. It is possible that one reason for the scarce application of formal PM methodologies/tools in FDA HF validation projects is a lack of awareness about the need to manage them as projects, and this was discussed in details before (Rojas, Sharareh, et al., 2019). Even though HF validations are required as part of the FDA's QSR, HF service providers (HFSPs) are not yet directly mandated to comply with such requirements (ensuring project quality). However, as explained by Rojas, et al. (2019), that is just a matter of time. The ongoing and future interventions (including harmonization of the QSR with international standards) will impact HFSPs so that they will be required to comply with the QSR and provide measures of excellence.

4.1.4 What are the Main Challenges?

"The FDA does not always understand Human Factors work, and sometimes documents in the DHF [design history file] between groups are not traced appropriately." (From participants' quotes)

Participants were asked to specify the top challenges they face conducting FDA HF validation projects, and the resulting list of codes was rather long (see Table 4.9). Summarizing the initial list of codes, the top challenges are:

- Unreasonable demands and inconsistencies on the side of the FDA
- Sponsors' unrealistic expectations,
- Sponsor's lack of awareness and commitment to the HFE work-stream of product design and development
- Access to representative users
- Uncertainty about the need for HF data
- Differing with FDA about ideal training approach, and
- Coordinating work with sponsors

To understand the situation better, the initial list was further summarized by grouping the codes based on root-cause and results, as well as source of the challenge (see Table 4.8).

Table 4.8: Grouping challenges by root-cause

Top challenges (bold) and sub-categories	Codes
Reviewers' lack of understanding of HFE (FDA) Results in inconsistencies, unreasonable demands/timelines	**21**
Sponsor's lack of HFE awareness and commitment Results in unrealistic demands and late HFE integration in product development	**15**
Planning/coordinating the HF work Results in difficulties working with sponsors	**7**

One main root-case seems to be the 'lack of HFE awareness" considering it could be stemming from both, the FDA's and sponsors' sides. On FDA's side it could be causing inconsistencies, unreasonable demands/timelines. Likewise, sponsors' lack of HFE awareness/commitment could be the reason for late integration of the HF considerations in product design and development, as well as for unrealistic expectations

in obtaining approval from the FDA (as a HFSP commented for instance: “fixing a bad design with training”, would be unrealistic).

Concerning to challenges that pertain directly to HFSPs, they stated difficulties when planning/coordinating the HFE work with sponsors as well as with the FDA. Still, if the challenges summarized in Table 4.8 are considered together (a, b and c), it is noticeable that “a” and “b” will cause “c” (difficulties coordinating with sponsors and the FDA). Then “c” could lead to further questions such as what can HFSPs do to avoid difficulties planning and organizing work with sponsors and the FDA. Interestingly, HFSPs reported that *advising and educating sponsors* was among the top key factors to work successfully with sponsors of FDA HF validation projects (see section a)4.1.6).

Table 4.9: Codes for “top challenges”

Top Challenges	Code Freq.	Remarkable Quotes
Unrealistic sponsor's demands	7	“Aggressive and unrealistic client timelines when HF is not prioritized from the start of product development, starting HF too late, trying to "fix" a bad design with labeling/training.”
Coordinating with sponsor	7	“Logistical issues such as scheduling sites, delivery of product.”
FDA's reviewers/inconsistencies	5	“HFE feedback from FDA is often vague. A more informal relationship with FDA during planning of HFE strategy is discouraged due to rigor of 1-hr FDA meetings.”
FDA's unreasonable demands and timelines	5	“Post-validation changes by FDA without providing rationales and/or ignoring HF data.”
Access to representative users	5	“Challenges accessing the right participants, concerning use errors that should have been addressed and mitigated prior to HF validation.”
Late HFE in product development	4	“Client timelines. clients unwilling to change device design or finding us too late to do that.”
Lack of sponsors, commitment/awareness	4	“Gaining the initial management commitment, counterproductive participation of managers without human factors experience.”

		"lack of preparation by clients, recruiting typical users when they are medical personnel"
FDA's labeling/IFU changes requests	2	Feedback from FDA very late in the process requiring labeling changes.
Access to realistic use-environment	2	"Getting a sufficient number of participants from the various user groups, getting a good simulation environment to represent actual field conditions"
Need to retest	2	"User Groups and need for retesting."
Uncertainty about the need for HF data	1	"Not sure whether HF validation is required or not."
Denied challenges	1	"It's not challenging."
Agreeing with FDA about ideal training approach	1	"Allowing participants to familiarize themselves with product materials including IFU without the FDA considering this to be a form of training."

4.1.5 Why do these Projects Fail?

As shown on Figure 4.5, when it comes to how often participants experience the FDA rejecting their HF validations, 35% (7) indicated they "never" do. On the other hand, 60% (12) said they "sometimes" experience the FDA rejecting their HF validations, while said 5% "most of the time".

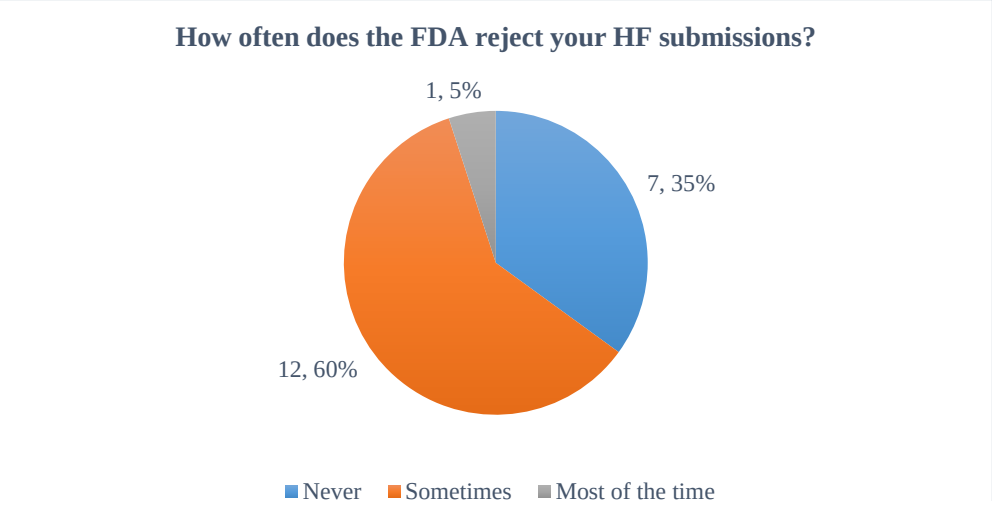


Figure 4.5: Failure in HF validation projects (N=20)

While those who indicated they “never” fail, where not presented the question to specify the reasons for failure, the other 65% (13) was able to specify the reasons. Themes resulting from grouping the list of reasons regarding why the FDA has rejected their validations, are shown on Table 4.10.

Table 4.10: Summary of codes with reasons the FDA rejected HF validations

Top Reasons	Code Freq	Remarkable Quotes
Minimized/denied failing	6	"Deficiencies because of misunderstanding or because of other companies’ HF Studies."
Clarifications/Level of details	4	"Generally, when the FDA is looking for more information on a product or submission"
Incorrect critical tasks/risk analysis	3	"Definitions of Critical Tasks based on Risk Analysis…"
Additional data/retesting	3	"More user groups, Need for retesting."
Missing or inappropriate user groups	3	"We find our clients get pushed back most often if they did not assess all user groups, did not perform an HF validation test, or did not perform a complete risk analysis.”
Protocol/Methodology	3	"Protocol is reviewed and agreed by FDA that minimize the risk"
Inappropriate training approach	2	"Letting participants familiarize themselves with the product and IFU when there is no training given."
Need to change design	2	"It has only happened once or twice when we originated the work. Once they wanted more people with less education. Another time they wanted a change in the design of the device due to a close call."
Need to change labeling/IFU	1	"Updates to labeling (especially the instructions for use)."

4.1.5.1 Formative Studies: Not Standardized

As explained in Chapter 2.3, HF studies can be *formative*, involving a series of usability studies normally during product development for optimum design. HF studies

can also be *summative*, one single usability study to uncover use-related hazard to determine if the finished product meets usability requirements.

Formative studies could be considered "Phase I" of HF validation studies. Without appropriate formative studies, the latter (HF validation) will surely fail. Respondent were asked how often they do formative studies, and a shown on Table 4.11, these essential studies for effective HF validations are not standardized. Specially in manufacturing organizations, they are not as consistent compared as the agencies/consulting firms.

Table 4.11: Frequency of formative studies as part of HF validation projects (N=20)

How often do you do formative studies?	***Manufacturers (n=10)***	***Agencies/Consultancies (n=10)***
Always	40.00%	30.00%
Most of the time	40.00%	60.00%
About half the time	20.00%	0.00%
Sometimes	0.00%	10.00%
Never	0.00%	0.00%

Perhaps one reason for the lack of standardization of formative studies is the already remarked lack of commitment and HFE awareness on the side of manufacturers/sponsors (Table 4.9). While agencies/consulting firms are more consistent in conducting formative studies, they are limited by manufacturers (the sponsors). Many times, manufacturers do not give them the opportunity to plan with them early before product design and development starts. Instead, they come to them when the product has already been developed. This is a serious issue that should not be taken lightly by manufacturers, to avoid "losing more for less" (see the dynamics of FDA's HF validation requirement by Rojas et al., 2019). If HF are considered too late, there is a high risk that the HF validation will not be successful.

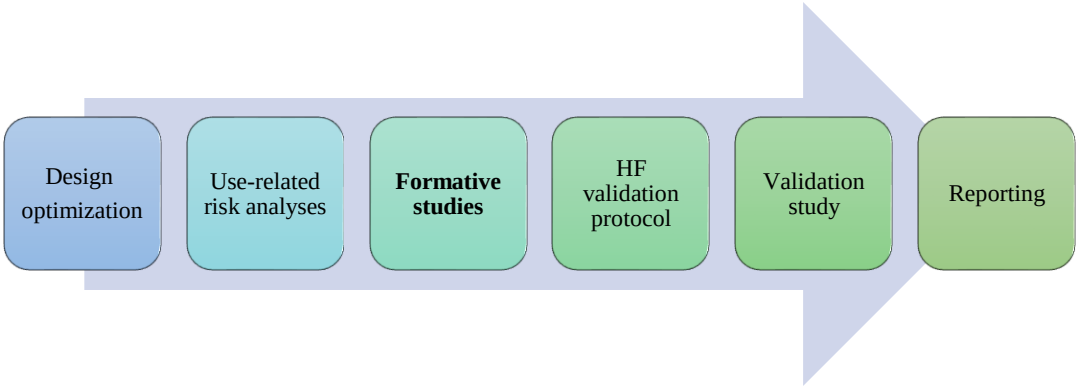


Figure 4.6: High-level phases of an HF validation project plan, and should include formative studies (developed by the author)

4.1.5.2 Denial about Project Failure

"Deficiencies because of misunderstanding or because of other companies' HF Studies."
(From participants' quotes)

Although 60% confirmed they "sometimes" get their HF validation submissions rejected by the FDA, there could be more behind the fact that some respondents (35%) denied ever failing (see Figure 4.5). It is simply a matter of perspective. As discussed in previous work (Rojas, et al., 2019), issues such as having to do extra work to re-deliver an HF validation is not considered a failure by HFSPs, or even by the FDA (Rojas, et al., 2019).

In addition, while a great number of respondents specified that they communicate with the FDA only when they had any problems with their HF submission (30%, 6). However, when asked to specify those problems, responses seemed to minimize or even retract, e.g.: "no issues, just misunderstandings" (see Table 4.12). This is a major issue that should be addressed by stakeholders. Inability to recognize failure will certainly be a

block to achieve improvements in the quality of HF validations and overall review process.

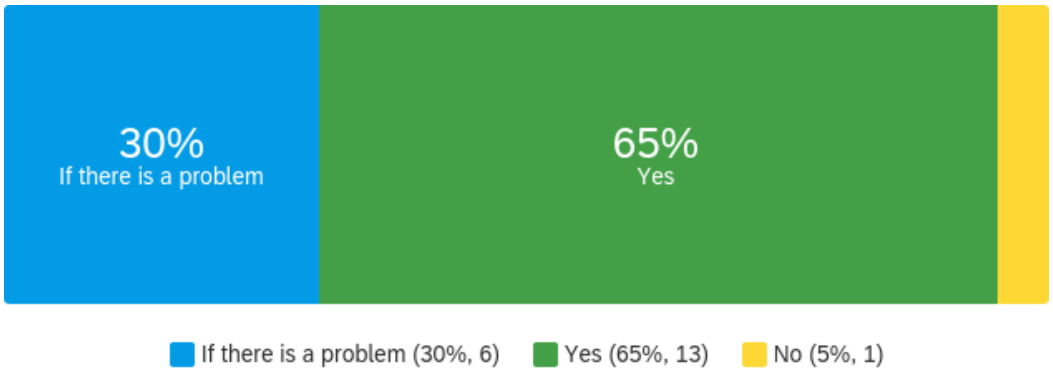


Figure 4.7: Do you communicate with the FDA?

Table 4.12: Problems due to which participants communicate with the FDA

Problems	Code Freq.	Remarkable Quotes
Clarifications/level of details	2	No issues, sometimes clarifications.
Missing or inappropriate user groups	2	Proper identification of **user groups**
Protocol/methodology	2	"…research methodology…"
Additional data or retesting	1	"Requests for additional data, or additional subgroups."
Incorrect critical tasks/risk analysis	1	"How critical tasks are defined and alignment on HFE strategy."
Inappropriate training approach	1	"Discussion of justifications for training, etc."
FDA's Timelines	1	**"…Timing** of FDA review process."

Denial vs. Facts

As identified before (Rojas et. al, 2019), some stakeholders seem to have difficulties when it comes to recognizing project failure (e.g.: the FDA rejecting their HFE report). This situation is inconsistent, not only with the persisting concerns about the

HF review process (see Chapters 1 and 2) but with the statistics on the topic. In 2019, during the HFES Healthcare Symposium, the FDA released relevant statistics indicative of a failure rate of more than 90% of HF validations submissions (Wiyor et al., 2019). There are obvious difficulties recognizing failure, probably due to the regulatory aspect of these type of projects, which hinders the application of appropriate strategies (see details in Rojas, Sharareh, et al., 2019).

4.1.5.3 Traditional Indicators of Project Success (Scope, Schedule, Budget)

As explained by Rojas, et al. (2019), per PM literature, the traditional indicators of project success involve delivering such project while staying within the originally planned scope, schedule, and budget (Rojas, et al., 2019). Among those surveyed, running behind schedule seems to be a general issue (see Table 4.13). All participants at manufacturing organizations (n=10) indicated they usually run behind schedule, in contrast with 70% (7) at agency/consultancy firms.

Table 4.13: At project completion, what is normally the case regarding original schedule? (N=20)

Response	Manufacturer/Developer (n=10)		Agency/Consultancy (n=10)	
Far behind the schedule baseline	0%	0	0%	0
Moderately behind the schedule baseline	100%	10	70%	7
Exactly as the schedule baseline	0%	0	20%	2
Moderately ahead of the schedule baseline	0%	0	10%	1
Far ahead of the schedule baseline	0%	0	0%	0

Typically, running behind schedule will have an impact on the project budget. In this case, 50% of respondents indicated they usually go over budget while the remaining 45% indicated they normally do as per the plan or better (5%). Table 4.14 shows responses by type of organization.

Table 4.14: At project completion, what is normally the case regarding original budget? (N=20)

Response	Manufacturer/Developer (n=10)		Agency/Consultancy (n=10)	
Far above the budget baseline	0.00%	0	0.00%	0
Moderately above the budget baseline	50.00%	5	50.00%	5
Exactly as the budget baseline	50.00%	5	40.00%	4
Moderately under the budget baseline	0.00%	0	10.00%	1
Far under the budget baseline	0.00%	0	0.00%	0

Regarding scope (Figure 4.8)there was little variation by type of organization. In general, 45% (9) indicated they usually end up doing more work than originally scoped, and 5% (1) "much more." In contrast, 45% meet objectives or do less than originally scoped (5%).

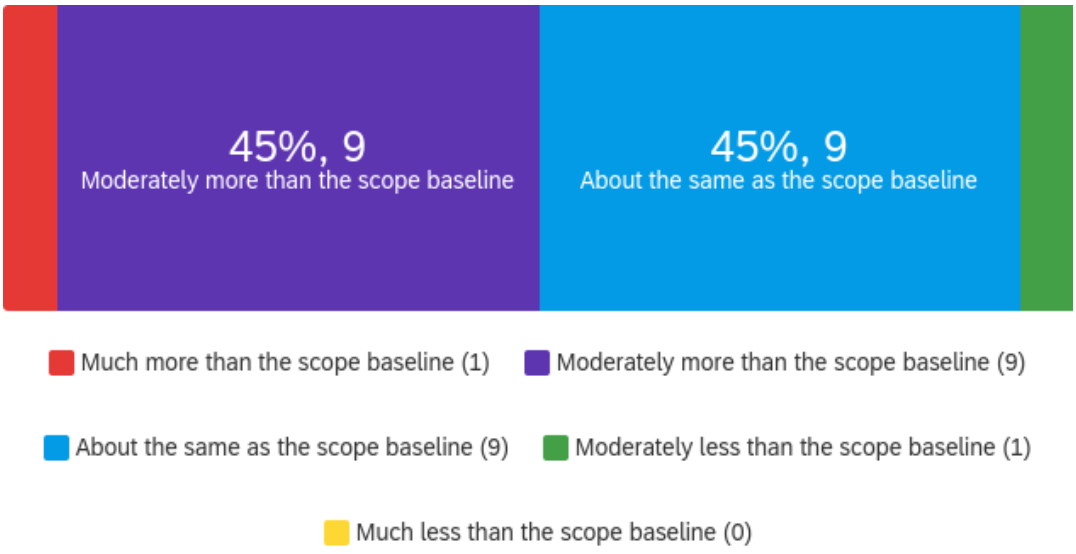


Figure 4.8: At project completion, what is normally the case regarding original scope?

Considering the type of product or submission

As indicated on Table 4.3: Summary primary type of submissions, N=20Table 4.3, most participants described their FDA HF validation projects are for "predicate"

devices. In that sense, the type of submission could have a direct impact on project complexity including cost, duration, scope and even the types of challenges.

4.1.5.4 Quality of the HF work and the need for better PM

At first glance, the discussed challenges and reasons for failure could lead to think directly about the quality of the HFE work (not a wrong interpretation). However, considering the dynamics of FDA HF validation projects as previously analyzed and discussed by Rojas, et al. (2019), it is very likely that careful planning, execution, monitoring/control and appropriate delivery of the HF validation project could have avoided all of them. In doing so, it would be mandatory to include formative studies as part of the HF validation project plan.

Table 4.15: How successful are your FDA HF validation projects vs. competitors? (N=20)

Use of PM	Much more successful		Moderately more successful		About the same as competitors		No way to know it		Total
We use PM	50.00%	5	0.00%	0	10.00%	1	40.00%	4	10
We do not use PM	25.00%	2	25.00%	2	37.50%	3	12.50%	1	8
I do not know	50.00%	1	0.00%	0	50.00%	1	0.00%	0	2

Moreover, we learned from the previous questions that the application of formal PM is scarce and most of the HF personnel is doing the PM work, which clearly could impact the quality and success of these projects. As a matter of fact, from those organizations which indicated not to be using a PM methodology or tool, only 25% considered themselves “much more successful” than competitors in having their validations approved by the FDA. In contrast, up to 50% of the participants who had indicated their organization is using a PM methodology/tool considered themselves to be “much more successful” (see Table 4.15). Drivers of success are discussed next.

4.1.6 What are the Drivers of Success (critical success factors)?

Concerning the identification of critical success factors, there were three questions in the survey to gather insight for that purpose:

a) What are the key factors working with sponsors? (asked to HFSPs)
b) What are key factors working with HFSP? (asked to procures)
c) What are the key factors for project success? (asked to all)

a) What are the Key Factors Working with Sponsors (asked to HFSPs)?

Overall, the top factors critical to working successfully with procurers/sponsors of FDA HF validation projects were (see Table 4.16):

- Ensuring HFE awareness (engaging sponsors)
- Accurate planning
- Communication and early involvement of the HFE work-stream in product design and development

Table 4.16: Summary of key factors working with sponsors (specified by HFSPs)

Factors for Success	Codes	Remarkable Quotes
People: Engaging (advising/educating) sponsors Clear roles/expectations Sustained expertise/knowledge in HF	10	"Rigor and experience" ".. being a trusted advisor, being friendly and professional, gaining and maintaining expertise" "Clarity of expectations regarding who does what" "Clear roles…" "Helping them understand how the process works" "Education up front…"
Accurate Planning: Effective and detailed proposals/plans	7	"Strong proposals, high-quality work…" "All prep/upfront work (task analysis, use error analysis, critical task identification, hazard-related use scenario analysis, formative studies, user-centered design approach) required to ensure successful outcome of summative study."

		"Detailed outline of preparatory steps and timeline; detailed budget…" "Project planning and coordination with Sponsor or CROW"
Communicating with stakeholders	5	"Constant communication. Educating them on the process." "Communication with the stakeholders." ".. Face-to-face meeting with FDA" "… Clear communication about the HF process and need for solid documentation and trace-ability."
Timely integration of HFE (e.g.: formative studies)	4	"Involve HFE early in the product development process." "Awareness trainings at beginning of projects, early HF involvement"

b) What are key factors selecting HFSP (asked to procures)

Procurers of HF services (n = 4) had two main concerns when selecting HFSPs (see Table 4.17), which included the theme people (*qualifications/expertise)* and process *quality*. Increased project quality can result by implementing and developing PM capabilities which is a main remark of this research.

Table 4.17: Summary of the key factors selecting/working with HFSPs (asked to procures)

Factors selecting/working with HFSPs	Codes	Remarkable Quotes
People - Level of experience (senior) - Size of staff - History of success - Product expertise	4	**Availability of internal experience** Experience level, size of staff, "Using senior staff" "Previous experience and success with FDA HF submissions/type of products we work on (e.g. combination products as opposed to pure medical or surgical devices)."
Quality	1	"…Having a good quality process."

c) What are the Key Factors for Project Success?

As for key factors to quality and success, mindfulness about FDA's expectations/standards, strict constraints/consistency, and sustained expertise/knowledge in HFE (staff development) were the top ones mentioned (among others see Table 4.18).

In general, the themes in the identification of factors for success considering the three above questions, could be grouped as shown on Table 4.18.

Table 4.18: Summary of key factors for project success (asked to all)

Factors for Success	Codes	Remarkable Quotes
People: Roles and qualifications of the people involved (sponsors, participants, FDA, dedicated/experienced HFE personnel)	31	"…Ongoing professional development for staff, highly skilled and qualified staff." "A good HFE process and dedicated HFE team in the organization." "Clear roles and face-to-face meeting with FDA"
Accurate plans/quality HFE process: Rigorous HFE, appropriate methods, protocol, detailed and accurate scheduling/budgeting	27	"Rigor and consistent process with changes based on the latest FDA trends" "High-quality deliverables, staying on time and on budget" "FDA validation protocol review, extensive internal HF SOP's."
Mindfulness about FDA's expectations/use of resources: Standards, tools, databases, getting in touch with the FDA	16	"We're tenacious when it comes to following the guidance and 62366!" "Staying in touch with FDA's current thinking…" "Deep knowledge of HF principles and FDA expectations"
Communicating with stakeholders: Sponsor, project team, FDA	9	"Be conservative. Communicate with FDA beforehand" "Knowledge and effective FDA communications" "Planning of activities and communicating needs up front." "…Client-centered approach, thought leadership (speaking, books, articles)"
Timely integration: Early HFE, product development, formative studies	8	"Usability/HF studies during early development and incorporating risk assessment to evaluate mitigations of identified use errors"

		"Tight integration of HF into overall project + rigorous pilot testing of our summative tests" "Early HF involvement, extensive formative studies."
Risk traceability/documentation: Robust risk management, error analysis	7	"Team work, documentation practices, and open communication with FDA." "Integrating HF with Design Control and Risk Management" "… Robust usability risk assessment process and linkage to the HF work stream"
Thoroughness/completeness of the HFE work: Detailed descriptions, justifications, effective detailed reporting	6	"Thoroughness, transparency, detailed description of HF problems based on observed behavior and comments." "Attention to detail and expertise in medical devices"
Sponsor/management commitment	3	"Management commitment, budgeting/scheduling, use of standards"

4.1.6.1 Accurate Planning (Achievable through formal PM)

When looking at how frequently participants experienced failure vs. the use of PM (see Table 4.19) using PM seems to be a driver of success. Notice that as much as 70% (7) of those who said their organization is using PM to manage FDA HF factors validation projects, had indicated they "never" fail (vs. 0% of those who said they are not using PM, who for the most part chose "sometimes or most of the time"). This is definitely an interesting contrast.

Moreover, as recommended by participants (Table 4.18), "Accurate plans and proposals" is a leading factor for success. Considering the PMBOK Guide, "Planning" is the largest Process Group, implying its significance for project success. In line with the previous, a scarce application of formal PM in the management of FDA HF validation projects could be a root-cause of the identified challenges and reasons for failure. From a

high-level perspective, each theme identified, including the specified factors for success, can be allocated under some relevant facets of PM.

Table 4.19: Use of PM vs. How often does the FDA reject your submissions?

Use of PM	**Never**		**Sometimes**		**Most of the time**		Total
We use PM	70.00%	7	30.00%	3	0.00%	0	10
We do not use PM	0.00%	0	87.50%	7	12.50%	1	8
I do not know	0.00%	0	100.00%	2	0.00%	0	2

For instance, to implement PM practices that enable the key factor for success of dealing with sponsors and the FDA, would use the PM Knowledge Area "Stakeholders Management," and "Communications Management." Likewise, the PM Knowledge Area "Resource Management" would deal with the practices about people (setting clear roles, responsibilities, as per the needs of the project).

4.1.6.2 Timing (a gray area in FDA HF validation projects)

"Aggressive and unrealistic client timelines when HF is not prioritized from the start of product development, starting HF too late, trying to "fix" a bad design with labeling/training."
(From participants' quotes)

Throughout this study, it was interesting to notice that there seems to be a gray area about the time to start the HF work. Some key stakeholders, especially sponsors, tend to believe that the HF validation project is just one validation study. That is a serious misconception that can lead to project failure. Because the HF process is iterative, for any particular device or product there could be need for multiple HF studies. HF should not be considered late in product design and development (e.g. once the product has been

developed), but as early as possible in order to properly optimize the design, address and mitigate any critical failures before submitting to the FDA.

4.2 Phase II: Developing and Testing an Industry-focused (Human Factors Service Provider) Project Management Maturity Assessment Tool

For this phase, the goal was to develop a PM maturity assessment tool for FDA HF validation projects (HF service providers) following de Bruin's phases of maturity model development as explained in Chapter 3 (see Figure 4.9). The corresponding stage of de Bruin's model consists of developing the content to populate the tool, and for that some the critical factors for success of FDA HF validation projects are identified with the feedback of a panel of subject matter experts (Delphi Panel) and with the use of applicable proposed standards both in HFE and PM. Such factors for success make up the categories or key areas of assessment for the tool, and the identification process as well as the results are discussed and presented next.

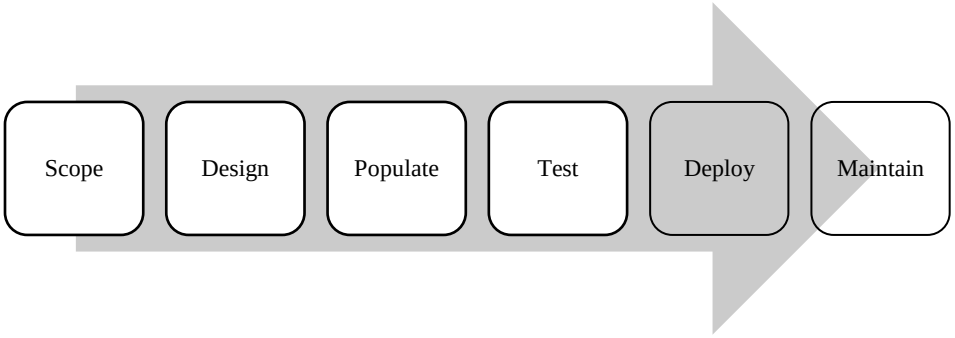


Figure 4.9: Model Development Phases, adapted from de Bruin et al. (2005)

4.2.1 Scoping

The scope of the model was outlined through the literature review (chapters 1 and 2). Besides literature and research from study 1, the remaining decisions for the design and content (populating) involved data collection through Delphi technique (or anonymous expert feedback).

- **Focus of the model**: FDA HF validation projects for medical devices and combination products.
- **Stakeholders' domain**: human factors service providers and manufacturers of medical devices and combination products, and those directly involved in managing HF projects for FDA pre-market review of medical devices and drug combination products**.**

Furthermore, due to the specific needs, the tool comprises two dimensions: one is based on the established PM processes/practices (PMBOK Guide), and the other seeks to assess HF capability in regard to the required processes as it relates to the applicable guidelines and standards (e.g., FDA's HF guidance). This is considered a stage-gate approach, which allows for separate layers of details to assess maturity (de Bruin et al., 2005), while Fraser et al. 2002 call it multi-dimensional.

4.2.2 Designing

The PM maturity assessment tool is meant to ensure integration between HFSPs and manufacturers of medical devices and combination products. Considering that for the medical device industry the FDA has started a pilot program using the CMMI framework (CMMI Institute, 2018; Rojas, Cosler, et al., 2019), the decision was made to follow the structure of the CMMI with its five levels tailored to the HF industry/context. While tailored to the HF industry/context, the model is bound to have five levels of maturity.

Likewise, two key dimensions will be populated with content determined through this research, these are: PM Dimension and human factors engineering (HFE) dimension.

- **Audience**: management and staff (internal), regulators (external)
- **Method of Application:** self-assessment and/or third party assisted
- **Driver of Application:** external requirement - FDA's Quality System Regulation (QSR)
- **Respondents:** leads of FDA HF validation projects
- **Application:**
    - One entity–HF service providers, which can be an organization (agency) or a department/unit inside a larger organization (e.g., manufacturers), and
    - One region–USA.
- **Levels**: five, adapted from the CMMI, but tailored to the context.

4.2.3 The Delphi Panel (Anonymous Expert Feedback)

4.2.3.1 The Experts

The criterion to participate was management level experience in leading FDA HF projects. A total of 11 experts (see Table 4.20) volunteered to join the Delphi Panel. The group included academic and industry practitioners with an average of 18.55 years of experience (±6.50 SD) in the field HFE for medical devices.

Each individual provided authorization to disclose their names as part of the Delphi Panel. Likewise, each one was provided information regarding the purpose of the research and the expectations, including how the Delphi technique works and he approximate number of rounds that gathering inputs would take. In addition, all data were analyzed at the group level, keeping confidentiality regarding the person who provided the inputs.

4.2.3.2 The Rounds of Feedback

As illustrated on Figure 4.10, there were two main objectives that would provide the information for the Design and Populating Phases. In that sense, Round 1 had the objective of determining the HFE categories (factors critical to quality and success). Round 2 consisted of gathering inputs to make the decisions incorporating important key aspects from the applicable international standard. In each round, a short summary of a preliminary analysis was shared.

Table 4.20: HFE for medical devices experts in the Delphi Panel

Full Name	Organization	Role	Years of Experience
Andrea Dwyer, MS, CHFP	Emergo by UL	Associate Research Director	10-15
Anthony Andre, PhD, CPE	Interface Analysis Associates, San Jose State University	Principal/Founder, Professor	20+
Dick Horst, PhD, CPE	UserWorks	President & Principal User Experience Specialist	20+
Don Tumminelli	HIGHPOWER Validation Testing & Lab Services	Sr., Technical Manager, Client Services	15-20
Ed Israelski, PhD	AbbVie/Independent Consultant	Retired Director of Human Factors	20+
Gerard Torenvliet	Medtronic	Sr. Manager, Human Factors & User Experience	10-15
Kathy K. Smith	SoftwareCPR/Medical Device USE Consulting LLC	HFE Expert	20+
Melissa Lemke, MS	Agilis Consulting	Managing Director, Human Factors Engineering	15-20
Morten Purup Andersen, MS	Technolution A/S	Senior R&D Engineer, Human Factors Specialist	5-9
Ronald Pollack	Janssen Research and Development	Senior Principal Engineer, Human Factors Engineering	15-20
Shannon Halgran, PhD	Sage Research and Design, Inc	Founder & Chief UX/HF Consultant	20+

Each round would close as soon as the objectives of the round were met. For instance, Round 1 took three rounds to gather satisfactory information. In contrast,

Round 2 started with the notion that at least two sub-rounds would be needed, but the first one provided enough insights.

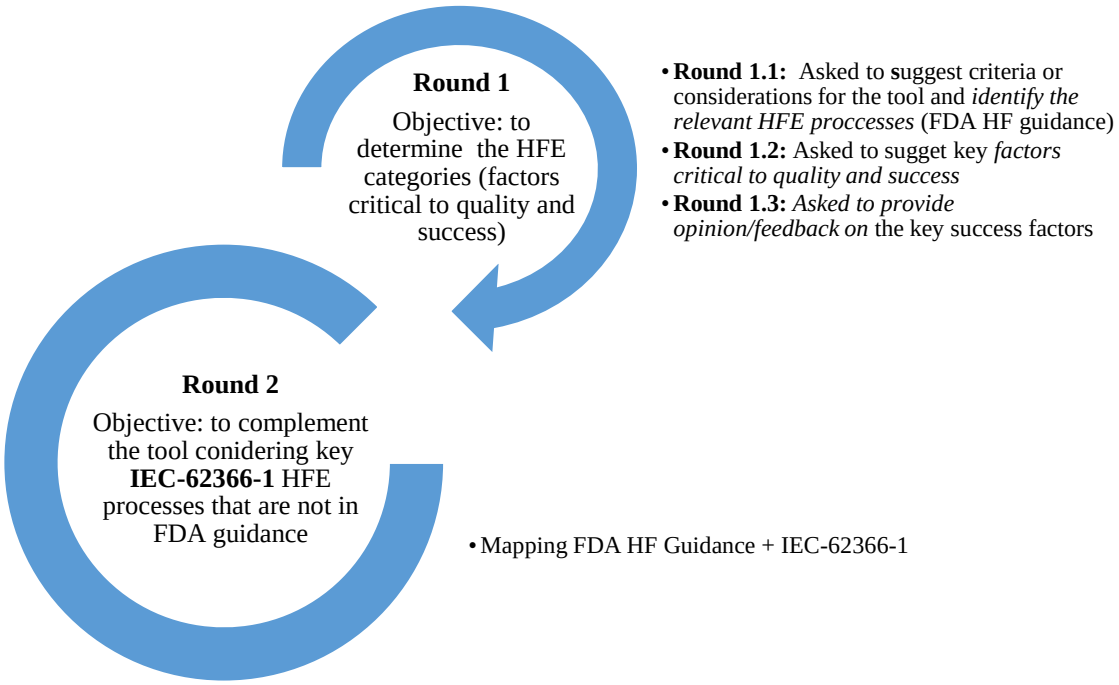


Figure 4.10: Rounds of feedback with a panel of experts (Delphi technique)

4.2.4 Populating

The inputs from a panel of experts together with the results of the previous study (Phase I), helped determine the categories and content/subcategories of the two key dimensions (that is, PM and HFE). Based on the key practices and critical success factors of FDA HF validation projects, themes were created which became the categories of the model. The following paragraphs detail the process through which data to populate the tool were collected and analyzed.

4.2.4.1 Round 1.1 and 1.2: Factors Critical to Quality and Success

To start ("warm-up"), experts were given the opportunity to bring up attributes and/or considerations important to develop the appropriate tool (Round 1.1). The key criteria in which they all agreed included: usable, scalable, prescriptive (helps improve their HFE projects), sustainable/scalable (useful for all size orgs.), process-driven (integration with product design and development), and benchmarking. These were considered in the development of the tool.

During Round 1.2 experts were then asked to provide three key factors to quality and success in FDA HF validation projects, based on the relevant activities of the HFE process prescribed by FDA's guidance (FDA & CDRH, 2016a). Some examples of how experts provided their inputs are share on Table 4.21. The full list based on the FDA HF guidance included the following activities:

- ✓ Definition of Intended device users, uses, use environments
- ✓ Definition of training for users
- ✓ Description of device user interface
- ✓ Identification of known use-related problems
- ✓ Identification of use-related risk
- ✓ Categorization of critical tasks
- ✓ Formative testing
- ✓ Human Factors Testing
- ✓ Analysis of Human Factors Validation Test Results
- ✓ Elimination or Reduction of Use-Related Hazards
- ✓ Residual use-related risk
- ✓ Labeling and IFU
- ✓ Selection HF evaluation methods
- ✓ Documentation of the HFE process

Table 4.21: How experts provided "factors to quality and success" (by section in FDA HF guidance)

HFE Validation Activities (FDA's Guidance)	Remarkable Quotes
Definition of intended device users, uses, use environments	"Complete list, robust definitions, justifications for any excluded user groups that would typically be included"
Definition of training for users	"documentation of process, systematic and consistent delivery, ability to "certify" users as trained"
Description of device user interface	"Include pictures/illustrations/graphics. Make these illustrations realistic. Translate descriptions into user-appropriate languages"

Experts' inputs were coded into shorter texts and considered based on relevance. The resulting list of codes was analyzed for patterns to organize the texts by themes or categories. The first **relevant** categories for the HFE Dimension, based on key factors to quality and success are shown on Table 4.22. The inputs were coded with focus on what the experts referred to from a high-level approach. In that sense, their inputs regarding factors key to quality and success in FDA HF validations could be initially grouped as referring to: People, Tools & Methods, Linkage/Traceability, Format & Language, Completeness, and Timing & Synchronization.

About Combination Products

In the first rounds, it was noticed that experts provided the same input for both device and combo products. Though, in the following sub-rounds, a separate box to enter inputs about combo products was not provided. It was clear that the HF process is applied to the device component of the combination product, which leads back to the application of HFE to medical devices. In that sense, the findings of this work apply likely to combination products which involve a device.

Table 4.22: Initial categories after thematic coding (factors for success provided by experts)

Themes	Codes (what experts referred to in short)	Remarkable Quotes
People	HF personnel, participants/users, moderators, product team and executives	"Experienced personnel done by HF professionals only" "Test moderator should not dialog with participant to avoid biasing task performance" "Test participants (Subjects) including inclusion/exclusion criteria, IRB/Human Subjects Protection, Participant training, Training Decay period and that it reflects the range of time that is likely to pass between when users receive training and when they first use the system"
Tools & Methods	Root-cause analysis, FMEA, MAUDE	"Where was the identification performed (MAUDE, PM surveillance), How comparable are these problems to the UI in question, what has been made design-wise to mitigate these? "Use of root cause analysis to reduce risk." "Follows FDA guidance and latest expectations, use scenarios well selected and not leading, correct users included" "Methodologically sound, representative users, accurate data analysis"
Traceability	Link to standards, overall risk management, UI changes, near misses, failures, measures of success	"…Describe the UI tested (it may undergo tons of changes from formative to summative) so traceability or a thorough description/illustration is of importance. Have the results feed back into the Risk Management Activities" "…Thorough root cause analysis, integrated with risk management,"
Format & Language	User-written, table-format, graphic, clear, accurate, realistic	"…Table-format including prompt, description of acceptable performance, potential use error (risk analysis / failure criteria), subjective feedback/exit interview, data captured and why, how to record data,

		knowledge tasks, USABLE WRITTEN (Easy to read by the FDA reviewer)" "...Photos, statements/paraphrased utterances," "Results in table format…" "Clear, graphical, easy to consume" "Include pictures/illustrations/graphics. Make these illustrations realistic. Translate descriptions into user-appropriate languages"
Completeness	Covering required components (rationales, descriptions, mitigating actions) comprehensive, detailed, complete	"Comprehensive, accurate, based on analysis of all relevant cognitive / physical / affective states" "Results in table format, complete descriptions of critical findings, deep root cause analysis" "Detailed accounting of use errors, close calls and operational difficulties. Comprehensive subjective questions Detailed root cause analysis" "Complete descriptions of critical findings, deep root cause analysis…"
Timing & Synchronization	Early, through design process, end of product design, consider dependencies, milestones	"Including in your UI Evaluation Plan including dependencies to other activities, use the planning to ensure stakeholder handshake/contract to ensure budget/resource for these activities…" "Be thorough, consider *during* design of UI to mitigate known use problems, document process"

4.2.4.2 Round 1.3: Refining the categories of the HFE Dimension

The next step consisted of ensuring validity and relevance of the initial, high-level categories. The panel of experts was provided the resulting list of the initial categories

and asked for their thoughts as well as a proposed definition of each category (that would be used to develop the final descriptions).

Table 4.23 summarizes the feedback provided by the panel of experts, and any needed changes to refine the categories (also considering findings from previous work (Phase I). In addition, this round included providing inputs to formalize the descriptions and the subcategories of the high-level themes (discussed in Section 4.2.5). In that sense, the HFE Dimension is constructed based on the key practices to quality and success in FDA HF validation projects, and it comprises the high-level categories as well as its sub-categories and descriptions that were informed by this research (combined).

Table 4.23: Summary of experts' feedback and changes made to refine the categories and subcategories of the HFE Dimension

Themes	**Remarkable Quotes**	**Overall Feedback**	**Changes**
People	"It's all about the people. So yes, this is a good category. People refers to many things. WHO are the participants and true end users? who moderates the study? who is involved in developing the design and validating the product? what are their skills, experiences, etc.?" "This category is at the core of the FDA HF Validation process. The HP process is focused on the user of the device and making the technology safe and effective for him or her. Another essential component of the HF process is that trained HF professionals lead the HF process to ensure it is performed as intended. Finally, it takes a well-educated product team and execs to support (time, money) an effective HF process." "The people category should constitute the individuals in an organization who will need to play a lead or supporting role to successful HF validation. For	Full consensus	**Stays as is**

	instance, the roles of the lead people and key stakeholders."		
Tools & Methods	"Tools & Methods are another essential component of the FDA HF validation process. The FDA guidance provides a standard approach to the validation process, which in itself, is a high-level methodology. Within this methodology is a process involving numerous widely accepted tools and methods which contribute to the validity of the greater FDA HF process." "Very relevant to HF validation. Picking the right tools, using the right method based on the submission type. Sometimes a validation is not the right method. Which methods you choose to iterate and evaluate a design is important as well." "The key tools and methods used for successful HF validation - e.g., URRA, KPA, HF design principles, formative evaluations, HF validation testing techniques, RCA, RRA"	Full consensus	**The term methodology was considered a better word (overall approach used during the HF validation, including the different methods used).**
Traceability	"I see value in this category" "Not as important" "Traceability is the key to a well-organized HF validation effort. Without a good trace effort, important use errors may be overlooked, and the safety of the device may suffer. "Extremely important" "FDA just spoke about the importance of traceability at the HFES Healthcare Symposium. In order for FDA to make a determination of use related safety and effectiveness from a validation study (and during audits), sponsors must provide adequate documentation that has clear traceability." "Traceability is the process of connecting the various Tools & Methods	Some mixed inputs, possible due to misconceptions, as the category was considered strongly relevant by most.	**Going under a high-level category "Documenting" as "traceability management"**

	to each other through numbering and references in order to tell a clean, consistent story of the HF validation effort."		
Data Presentation	"Very important for successful HFE report" "Perhaps "Documenting Process and Findings" or "Communicating Process and Findings" instead of "Data Presentation." "I think presentation of data has a lot to do with the format used to collect the data. So, I'd change this category to Data collection, analysis and presentation." "Data presentation refers to the reporting of results derived from the various Tools & Methods used and performed within the validation effort. The reports should be well-organized, include proper traceability, and be easy to understand." "The FDA loves to have data presented in their format…HFE report should follow format defined in FDA HFE guidance. FDA likes to see tables and table help map critical tasks to both acceptable performance and identified risk (unacceptable task performance) for instance."	Full consensus, but some made relevant observations	**Will be accounted for under a high-level category "Communicating and Reporting"**
Completeness	"A complete summary report would allow another researcher to completely replicate the results. Can the FDA reviewer find everything they want and not need to file a request for more information. Is the information described in successive layers, so a reviewer can read the high-level summary and then through appendixes dig deeper into the data as needed." "It overlaps a lot with traceability and may not warrant a category of its own." "This means providing all the required information for submitting the HF validation study results to the FDA."	In consensus but some made relevant observations	**Going under a high-level category "Documenting"**

	"If an HFE report is not complete, it is hard for the FDA to review and understand." "Completeness is the concept that all steps of the FDA HF Validation effort must be addressed either by performing the step or thoughtfully justifying why it is not needed."		
Timing & Synchronization	"Can the sponsor show the HF work is coordinated with the flow of the iterative design work and *overall product design validation*?" "I feel that this is the biggest problem in industry. Companies to understand when to invoke human factors and what activity to do at what Phase of product development everyone wants to just jump into validation." "Timing is everything. When you start human factors, when you submit a protocol, when you run studies or do analyses" "In terms of FDA HF validations, this would apply to supplying all information per the FDA requirements, per the FDA guidance, in accordance with expected response times from the FDA with their comments that fits within the timing for product development and expected launch date for the product."	In consensus but some made relevant observations	**Changing the word "synchronization" to "Integration"**

4.2.4.3 Round 2: Mapping FDA's HF Guidance and IEC-62366-1

To complement the HFE Dimension, this round consisted of mapping the activities outline in FDA's HF guidance and the international HF standard IEC-62366-1 (see Table 4.25 and Table 4.24). The latter, IEC-62366-1, outlines a process to apply HFE to medical devices and it is largely used by manufacturers to meet such

requirements internationally. In this round, experts were asked to map the activities of FDA's guidance to those of the IEC-62366 (

Table 4.26) and to mention the main difference between the two documents (Table 4.27).

Table 4.24: Activities HFE process applied to medical devices (FDA's HF guidance)

FDA's HF Guidance (by chapter)
5. Device Users, Use Environments and User Interface
6. Preliminary Analyses and Evaluations
6.1 Critical Task Identification and Categorization
6.2 Identification of Known Use-Related Problems
7. Elimination or Reduction of Use-Related Hazards
8. Human Factors Validation Testing

Table 4.25: Activities HFE process applied to medical devices (IEC-62366-1)

IEC 62366-1 Content (by chapter)
5.1 Prepare Use Specification
5.2 Identify User Interface Characteristics Related to Safety and Potential Use Errors
5.3 Identify Known or Foreseeable Hazards and Hazardous Situations
5.4 Identify and Describe Hazard-Related Use Scenarios
5.5 Select the Hazard-Related Use Scenarios for Summative Evaluation
5.6 Establish User Interface Specification
5.7 Establish User Interface Evaluation Plan
5.8 Perform User Interface Design, Implementation and Formative Evaluation
5.9 Perform Summative Evaluation of The Usability of the User Interface

Table 4.26: How respondents mapped FDA's HF guidance and IEC62366-1 (% of responses)

	FDA Guidance Chapters						
IEC62366-1 Chapters	**5**	**6**	**6.1**	**6.2**	**7**	**8**	**N/E**
5.1	100%	0%	0%	0%	0%	0%	0%
5.2	40%	0%	20%	20%	10%	0%	10%
5.3	10%	10%	10%	60%	10%	0%	0%
5.4	0%	10%	50%	20%	20%	0%	0%
5.5	0%	0%	60%	0%	10%	30%	0%
5.6	50%	0%	0%	0%	10%	0%	40%
5.7	10%	40%	0%	0%	0%	20%	30%
5.8	0%	40%	0%	10%	30%	10%	10%

5.9	0%	0%	0%	0%	0%	100%	0%

N/E: no equivalence in the FDA guidance; n: 10

Table 4.27: Experts feedback on main difference between FDA's HF guidance and IE-C62366-1

IEC 62366-1	Remarkable Quotes
5.1 Prepare USE SPECIFICATION	"The Use Specification does not describe User Interface description but may contain Intended Operating Principle" "FDA equivalent of "intended use"
5.2 Identify USER INTERFACE characteristics related to SAFETY and potential USE ERRORS	"FDA discusses user interfaces in general here, gets to risk aspects in Ch 6" "This is basically about performing risk analysis, and section 6.1 in FDA guidance is about risk analysis. Same fundamental principles for both."
5.3 Identify known or foreseeable HAZARDS and HAZARDOUS SITUATIONS	"FDA (Known use-related problems) typically relate to similar devices, database searches as well as looking at complaints and adverse events… IEC 62366-1 section 5.3 may also refer to foreseeable hazardous situation."
5.4 Identify and describe HAZARD-RELATED USE SCENARIOS	"FDA has more prescriptive traceability requests" "Known use problems are not necessarily a hazardous situation"
5.5 Select the HAZARD-RELATED USE SCENARIOS for SUMMATIVE EVALUATION	"Terminology" "IEC only asks for selection and not testing at this point."
5.6 Establish USER INTERFACE SPECIFICATION	"FDA guidance is not about design" "62366 focuses on the specification - FDA focuses on the result"
5.7 Establish USER INTERFACE EVALUATION plan	"FDA does not describe a plan for UI Evaluations - but focuses on the results (summary) of your preliminary evaluations and analysis. The UI Evaluation plan is often a list of planned activities - whereas many US HFSP refers to the test protocol as the 'plan's:

	"An oversight in the FDA guidance - this is such a helpful document which forces team alignment on the test plan early on."
5.8 Perform USER INTERFACE design, implementation and FORMATIVE EVALUATION	"62366 combines formative evaluation with risk mitigation/UI design. " "The FDA guidance category is only about formative evaluations."
5.9 Perform SUMMATIVE EVALUATION of the USABILITY of the USER INTERFACE	"FDA focuses on testing of critical tasks and asks for 15 people per group, all US." "FDA requires US residents and has an expectation of min 15 participants per user groups."

4.2.5 The Resulting Content for the HFE Dimension

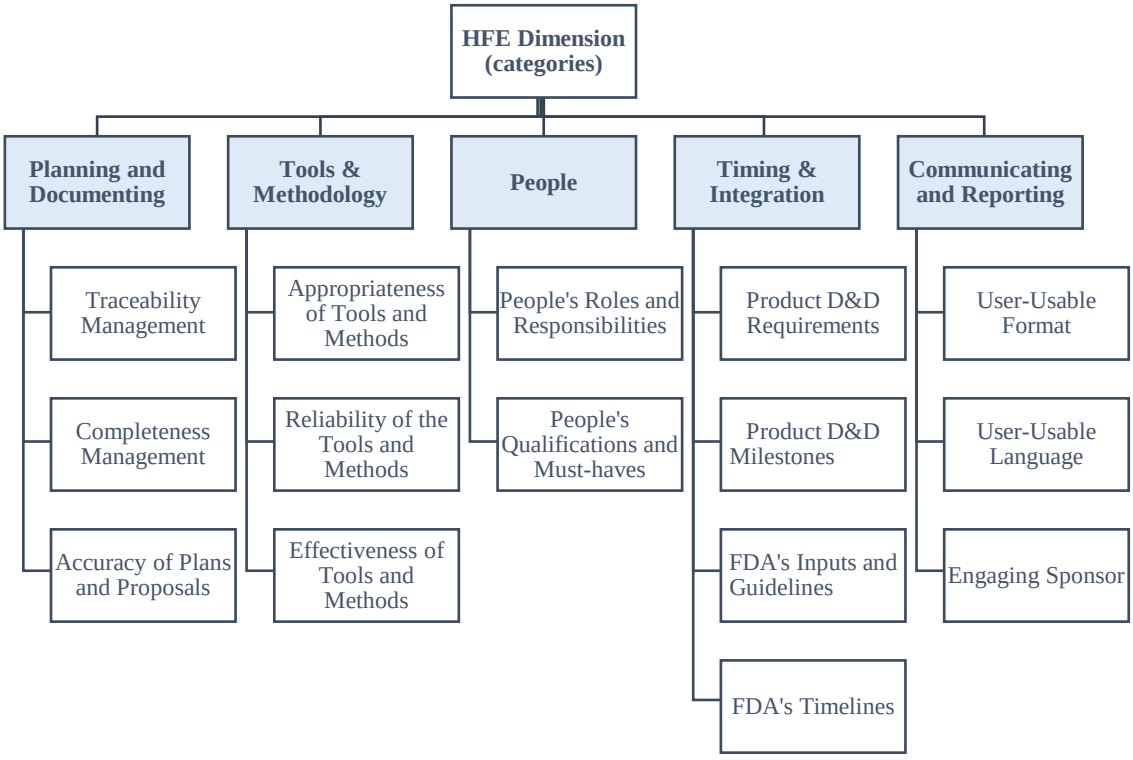


Figure 4.11: The final categories of the HFE Dimension for the tool (factors critical to quality and success in FDA HF validation projects)

4.2.5.1 Planning & Documenting

This category of the HFE Dimension accounts for the following key practices as critical to quality and success in FDA HF validation projects:

- Accuracy of Plans and Proposals
- Traceability Management
- Completeness Management

There was need to create a high-level category to include completeness and traceability, because it became obvious that these factors apply across multiple components of the HF validation process as these were consistently referenced together. Most experts felt intensely about this category, remarking it as definitely critical for successful validations. However, as shown on the process, a minority seemed confused, while some thought of this as documentation and completeness. Due to the mixed opinions, it seems the category must be presented and described in a way that can be perceived and integrated clearly for success as part of this tool. For that reason, it was placed under a major category as part of "Documenting." Moreover, it is early in the HFE process that there must be a definition of what will be addressed (completeness) and how it will be documented (traceability). Then again, the importance of plans and proposals was made evident both throughout this study and Phase I ("accuracy of plans and proposals" was remarked as key).

4.2.5.2 Communicating and Reporting

For this category, the following were the identified key practices:

- User-Usable Format
- User-Usable Language
- Engaging Sponsor

This category started first as “data presentation.” While opinions were very positive and there was consensus that “data presentation” is another key factor, the feedback received also conveyed not only the presentation of the data, but more specifically, the category should consider how to communicate and report results in general during the HF validation process from initiation to completion. For that, the key factors include formatting, writing, language style (user usable, e.g.: FDA, sponsor, executives) in such a way that it is effective to engage sponsors (e.g., keeping them updated and informed) and also to meet FDA’s expectations.

Thus, communicating and reporting can include not only results, also updates, which would be directed to sponsors (as well as the FDA if applicable) helping to ensure sponsor commitment (a key factor for success also identified in survey 1, Phase 1).

4.2.5.3 People

When it comes to people in FDA HF validation projects, the key practices are:

- People’s Roles & Responsibilities
- People’s Qualifications & Must-Haves

Experts were totally in consensus with this category and consistently pointed out “People” are a key factor in successful HF validations. They suggested that this category applies to the different roles (users, moderators, HFE), and requisites such as skills, experiences of the HF personnel, moderators, users/participants different states, and overall people or stakeholders that should support the development, design and validation of the product. Importance of making clear definitions of roles and expectations was also

remarked as essential. People can be divided as pertaining to: HF personnel, device users, and device/product team.

4.2.5.4 Tools & Methodology

The following are the key practices in this category:

- Appropriateness of Tools and Methods
- Reliability of the Tools and Methods
- Effectiveness of Tools and Methods

Experts felt strongly about this one. For the quality of the HF validations, it is essential to define well which tools and methods are appropriate depending on different factors such as type of product, type of submission and timing and purpose of the HF work - formative vs. final validation. Experts listed examples of methods and tools. There is a wide variety of methods, and "reliability" as well as "effectiveness" of the methods and tools used are other key factors. Accordingly, the category refers to the different approaches, activities and supporting tools used to deliver the HF validations successfully, including the methods used for risk analysis and usability testing. Overall, the term "methodology" for the main category fit better, because the category involves demonstrating that the overall approach (including tools and methods used) in the HF process has been methodical, objective, and data driven.

4.2.5.5 Timing & Integration

The key practices in this category look at:

- Product Design and Development Milestones
- Product Design and Development Requirements
- FDA's Inputs and Guidelines
- FDA's Timelines

4.2.5.6 "Timing" of HF integration with product design and development

Besides the inputs provided by experts pointing to the importance of timing and alignment of the HFE considerations in product design and development milestones, it was also identified in a previous study (Phase I of this research) that the factor "timing" or when to start integrating HF, appears to be a confusing area for stakeholders of HF validation projects, especially manufacturers and developers. However, such determination is largely part of product design and development plans, and it cannot be directly controlled by the HFSPs. As such, product developers/manufacturers or sponsors bear great responsibility for ensuring timely integration of the HFE work into the product design and development plans.

The need for emphasis on product design and development when it comes to "Timing & Integration" of the HF work, accounts also for the areas where IEC-62366-1 and the FDA's HF guidance differ. This means, the emphasis on design and timing of the HFE work, compensates those areas where the FDA's guidance lacks compared to the IEC-62366-1, and this is discussed next.

4.2.5.7 Considering International HF standards: mapping IEC-62366-1 and FDA's HF guidance

Manufacturers of medical devices often must meet regulatory burdens in a global market and need to optimize time and resources while doing so. To ensure a complete maturity assessment tool that would eliminate the need for multiple assessments, it was mandatory to consider an important international HF standard for medical devices and combination products.

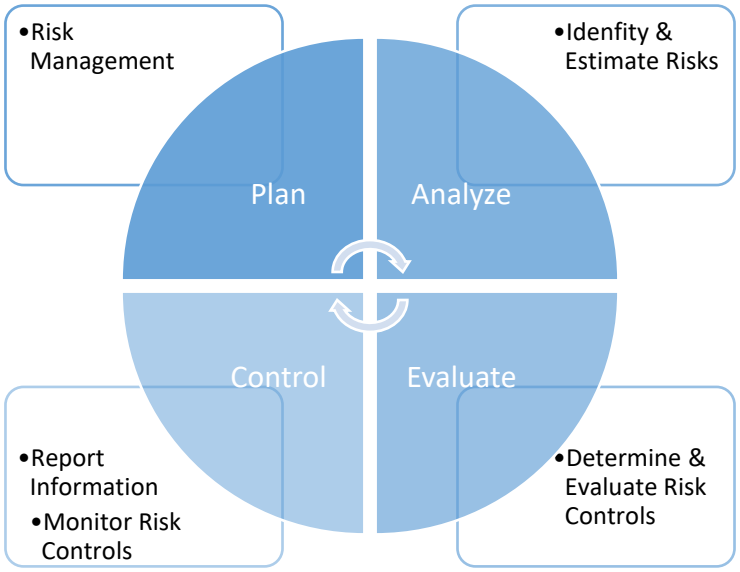


Figure 4.12: ISO 14971 Risk Management Process

ISO 14971 is the overall international standard when it comes to risk management for medical devices. The standard prescribes an iterative risk control process, that should be repeated until risks are properly mitigated. Likewise, the HFE process is iterative (Figure 1.1). In fact, section 8 of the FDA guidance requires validating "as needed." Which means that if any use-related risks have been introduced, there is need for validation unless such risks are acceptable. This process must be documented and reported.

4.2.5.8 The Overlap Between FDA's HF Guidance and IEC-62366-1

Although there were divided opinions regarding how each HFE activities could be mapped (Table 4.27 and

Table 4.26), experts' inputs served to guide the identification of main differences or areas of overlap between the two documents, as it is explained next. Another important consideration to understand these two documents is that, the **IEC-62366-1,** like the FDA HF guidance, is based on **ISO 14971 Risk Management Process** (see Figure 4.12). In that sense, the main differences between these documents are the followings:

- **Approach to Planning**. FDA guidance does not specify a need to develop **formative and summative evaluation plans**. However, in practice, it can be acknowledged that such plan has been partially supplemented by the "HF validation protocol". Of course, an improvement would be not only an HFE study protocol, but an HF validation project management plan (a reason the present work proposed the development of PM capabilities for FDA HF validations).
- **Integration with Design.** One apparent difference is that the international standard makes more emphasis on the terms "design" and "formative testing" by clearly requiring integration of HFE during product design and development. However, this might be only an apparent difference, because both documents contain risk reduction and mitigation process through formative studies and formative studies take part during product design.
- **Foreseeable Hazards.** FDA guidance seeks to address "known" use related risks while the international standard does go further and includes "foreseeable" hazards. Although some might reference that this is just a matter of using different terminologies, it is a point that the FDA guidance could make-up for in a future revision of the guidance when it comes to identification of critical tasks.
- **Post-Production and Post-Market HFE data**. FDA guidance does not get into post-market HF data collection as the international standard does, but this is likely just a matter of time before the FDA publishes a revised version. However, a post-production and post-market effort would need to be addressed as part of the manufacturer's *operations* strategic plan. For this research, projects are temporary and would conclude when the HFE report is delivered, thus operations strategic plan are out of scope here.

Considering the previous paragraphs and based on how the documents overlap, the differences serve to confirm a theme already identified (Timing & Integration) as critical to quality and success. Thus, in this tool the capability to meet IEC-62366-1 is accounted for in the practices that ensure timely integration with product design and development as well as accurate planning. An HFSP that is able to plan and integrate HFE early in product design and development would increase success in meeting FDA requirements. And, that is not only a key factor for success in FDA validation, it determines IEC-62366-1 capability. Simply put, for risks management in de the development of medical devices, the IEC-62366-1 could be described as a general prescription to apply HFE. The FDA's guidance is just specifically (vs. general) developed for application in the US.

Therefore, when an HFSP is conducting the HF validation process focusing on the FDA specific requirements, by default is also meeting the IEC-62366-1. Why? For instance, even though the international standard does not specify a sample size or geographic location of participants, it asks for "intended user profile." The geographic location of participants would be part of the user profile. That is, for a product that will be marketed in the USA, the intended user profile as required by the IEC 62366-1, will necessarily need the description of actual users, which would be in the US. More than that, section 4.3 ("tailoring the usability engineering effort") is clear that depending on certain aspects, the level of effort, the tools, and methods to perform the HFE process may vary.

In summary, mapping IEC-62366-1 and FDA's HF guidance reinforce factors for success that experts had referred to during the Delphi Panel, namely planning as well as timing and alignment of the HFE considerations in product design and development milestones (e.g., market research, UI design and development, and IFU testing). For that reason, "IEC-62366-1 Capability" of the tool can be broken-down to the average score in the corresponding subcategories of the tool (Accuracy of Plans & Proposals, Product Design & Dev. Requirements, Product Design & Dev. Milestones).

4.2.6 The PM Dimension – Tailoring PM to FDA HF Validation Projects

Now that the resulting components of the HFE Dimension have been developed, and we know the key practices for successful FDA HF validation projects, we are ready to configure the PM Dimension. For equivalent reasons as the FDA's HF guidance was used to develop the HFE Dimension, the PMBOK Guide was proposed to develop the PM Dimension (Chapter 1). Before anything, there it is necessary to remark that the PMBOK is a broad guide of PM proven best practices, currently composed of 49 standardized PM processes, 10 PM knowledge, as well as tools and techniques recommended to manage projects successfully.

However, we have discussed before that projects differ depending on context, and not all PM processes contained in the PMBOK are equally useful for all projects and industries. Therefore, we are developing an industry-focused PM maturity model and for that purpose, the content of the HFE Dimension is dictating what to use from the PMBOK Guide, and this is known as "tailoring."

The PMBOK Guide indicates that the management approach including the Knowledge Areas can be tailored depending on characteristics and needs of the project.

The project team should identify the best approach, and what project life cycle best adapts for the type of project (e.g., agile life cycle or hybrid), depending on the Phases must take place: sequentially, iteratively, or overlapping. Selecting the appropriate approach depends on the PM processes needed as well as the Phases.

4.2.6.1 An Output-Oriented Approach (as per Industry Practice)

The standards used to inform the design and the content of the tool inspected the application of HFE to medical devices through the outputs of the HFE process using the two mandatory documents for industry: FDA HF guidance and IEC-62366-1 (see the Delphi Panel in section 4.2.4 and 4.2.4.3). It was also explained in section 2.3.2, that the FDA HF guidance involves an output-oriented process, as it is also the case for the international standard IEC-62366-1, both refer to a "Design History File" (DHF) where all outputs of the HFE process are stored. For instance, the IEC-62366-1 constantly instructs that "compliance is checked" by verifying if each *output* of the HFE process in the DHF.

Consequently, considering that the PMBOK contains a standardized list of PM process outputs, it is very appropriate and useful to employ the same approach for the PM process of an HF validation project (also to ensure integration with industry). Furthermore, by focusing on the PM Process Groups outputs, the tool can be useful *regardless* of the specific PM process that HFSPs want to use in order to get these exact or similar outputs (which means, no specific PM methods or tools are required, the focus is on the outputs). Thus, we can think of a "PM History File" that would contain the outputs of the PM efforts for the corresponding HF validation project.

4.2.6.2 PM Process Groups Outputs – What to Apply?

With the previous considerations in mind, we need to briefly describe the PMBOK Guide (also discussed in section 2.4.1.1). The PM standard outlines 49 standardized PM processes, organized in two different categories. One is by Process Group and the other by Knowledge Area. Not to be confused with the project life cycle (a series of Phases that a project passes through from start to finish), the PMBOK Guide defines a Process Group as "a logical grouping of project management inputs, tools, techniques and outputs." The project management Knowledge Areas are defined by its knowledge requirements and described in terms of the processes that comprise each area.

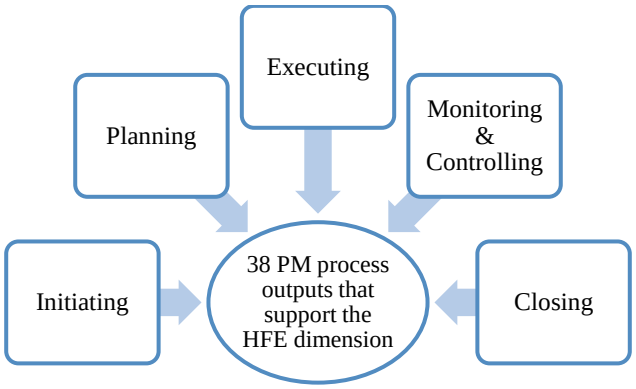


Figure 4.13: This tool's PM Dimension is based on 38 industry-focused outputs of the PM Process Groups

Along with 49 standardized PM processes, the PMBOK Guide also outlines **72 outputs** or results from the Process Groups. For this industry-focused maturity assessment tool, 38 outputs (out of 72) were extracted based on how they support the HFE Dimension, and to ensure simplification. The definitions (as per the PMBOK Guide) of each one of the 38 PM outputs are included in Appendix I. These are listed in

the following paragraphs under each PM Process Group, along with a short definition of the purpose of each Process Group.

Initiating processes. This Process Group comprises the specific processes that result in the definition of the reason for the project as well as the expectations considering the organization's strategic goals. The goal is to decide what we want to achieve and obtain endorsements from the authorized sponsor. Key outputs from the initiating Process Group that support the HFE Dimension:

- Assumption Log
- Project Charter
- Project Management Plan Updates
- Stakeholder Register

Planning processes. With 24 processes, planning is the most time-consuming part of a project, and it entails devising and scheduling the activities required to deliver the project. As per this research, specific outputs to support the HFE Dimension for quality and success of FDA HF validation projects are listed next. Key outputs from the planning Process Group that support the HFE Dimension:

- ✓ Activity List
- ✓ Procurement Management Plan
- ✓ Change Management Plan
- ✓ Communications Management Plan
- ✓ Configuration (Product Version) Management Plan
- ✓ Cost Baseline
- ✓ Cost Estimates
- ✓ Cost Management Plan
- ✓ Duration Estimates
- ✓ Milestone List
- ✓ Project Calendars
- ✓ Project Management Plan Updates
- ✓ Project Schedule
- ✓ Project Scope Statement

- ✓ Quality Management Plan
- ✓ Quality Metrics
- ✓ Requirements Documentation
- ✓ Requirements Traceability Matrix
- ✓ Resource Management Plan
- ✓ Project Risk Management Plan (risk = project failure)
- ✓ Risk Reports
- ✓ Schedule Baseline
- ✓ Scope Baseline
- ✓ Stakeholder Engagement Plan
- ✓ Team Charter

Executing Processes. The 8 executing processes consist of this Phase consist of ensuring that the project runs smoothly, and most of the expenses are incurred while executing what was planned, managing teams, keeping stakeholders updated, managing procurement if needed. Key outputs from the executing Process Group that support the HFE Dimension:

- ✓ Issue Log
- ✓ Lessons Learned Register
- ✓ Procurement Agreements
- ✓ Project Management Plan Updates
- ✓ Project Team Assignments
- ✓ Test and Evaluation Documents

Monitoring & Controlling processes. This group of processes include those which enable the tracking of planned project actions and implementing changes as needed, to ensure that the project is performing as planned to meet the agreed objectives. It includes ten (10) processes to monitor and control project performance. Key outputs from the monitoring and controlling Process Group that support the HFE Dimension:

- ✓ Accepted Deliverables
- ✓ Project Management Plan Updates

- ✓ Verified Deliverables
- ✓ Work Performance Reports

Closing processes. This Process Group is straightforward but of significant importance. The goal here is to ensures that the project is correctly wrapped up and formally closed. Key outputs from the closing Process Group that support the HFE Dimension:

- ✓ End of Project Report
- ✓ Transition of Final Results

4.2.6.3 How the Selected PM Outputs Support the HFE Dimension

It is specified by the PMBOK Guide (and also in the PM literature) that PM needs change depending on the type of project, organization and industry. There lies the reason for an "industry-focused" approach. Considering the key factors for success in the HFE Dimension, we can focus on the essential PM process outputs that would support/enable the HFE Dimension. That is, for instance, the "People" category of the HFE Dimension can be mapped to the PM Process Group outputs of Resource Management and Stakeholders Management. Why? These are the PM processes to manage the project team as well as stakeholders.

Table 4.28: Output "Stakeholder Management Plan" of the HFE Dimension

Output	Stakeholder Engagement Plan
Process Group	Planning
Knowledge Area	Stakeholder Management

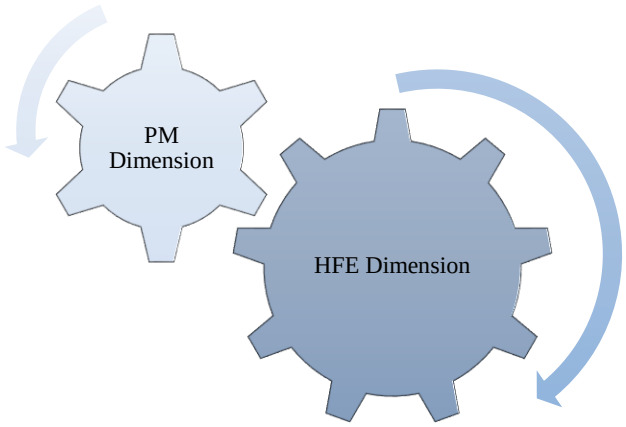


Figure 4.14: The PM Dimension supports the implementation of key HFE practices critical to quality and success

To continue with this example, the stakeholder engagement plan is an output of the Planning Process Group and it utilizes the "Stakeholder Management" Knowledge Area (Table 4.28). By not having the corresponding process and policies to consistently produce a stakeholder engagement plan for your FDA HF validation projects, would influence your results in following categories and sub-categories of the HFE Dimension:

Table 4.29: Output "Stakeholder Engagement Plan" mapped to the HFE Dimension

	PM Output: Stakeholder Engagement Plan	
PM Dimension	**Process Group**	Planning
	Knowledge Area	Stakeholders Management
HFE Dimension	**People**	Roles and Responsibilities
	Planning & Documenting	Accuracy of Plans and Proposals
	Communicating & Reporting	Engaging Sponsors
	Timing & Integration	FDA's Inputs and Guidelines

Subsequently, the PM Dimension for this industry-focused PM maturity assessment tool has been tailored by mapping the outputs of the PM Process Groups

(Figure 4.13) that directly apply and support the HFE Dimension, as illustrated on Figure 4.14. It is through the implementation of the indicated PM Dimension that the related categories of the HFE Dimension can be accomplished; for success and quality of the corresponding projects as the model intends.

The PM processes outputs from the PMBOK® Guide were organized by Process Groups and then matched to the key factors for success in HFE Dimension (see Table 4.30). Tailoring the PM Dimension to FDA HF projects was mainly done by looking for the PM outputs that would enable the applicable HFE practice successfully (or what is the same, based on the impact of each PM process output on the HFE Dimension's categories).

Table 4.30: The PM output "Accepted Deliverables" mapped to the HFE Dimension.

PM Dimension	**PM Output: Accepted Deliverables**	
	Process Group	Monitoring & Controlling
	Knowledge Area	Scope Management
HFE Dimension	**Planning and Documenting**	Completeness Management
		Accuracy of Plans and Proposals
	Communicating & Reporting	Engaging Sponsors
	Timing and Integration	Product Design & Dev. Requirements
		FDA's Inputs and Guidelines

These categories (both under the HFE and PM Dimensions) are meant to be the backbone of the maturity tool, which ultimately are also the metrics based on which HFSPs can be assessed. Appendix A contains the complete mapping between the PM Process Groups outputs and the HFE Dimension categories and subcategories.

4.3 Phase II - Part 2: Overview of the HFSP-MAT and Summary from Testing

In the previous paragraphs, the process to develop the architecture and content of the intended PM maturity assessment tool was described. This session comprises an overview of the developed tool as well as the results from the first evaluation of the beta tool. With that, we get to enter into answering the remaining research question: what is the average and an ideal PM maturity level for this industry? Subsequently, the finalized assessment tool is described including architecture, categories, levels and scoring approach, followed by a brief presentation of the online site for the tool (beta) as a short discussion of the testing results.

4.3.1 Overview of the HFSP-MAT

The following paragraphs explain in detail the resulting architecture, design and full content of the HFSP-MAT. However, Appendix M shows a summarized and precise blueprint that can be helpful for a straightforward implementation by industry.

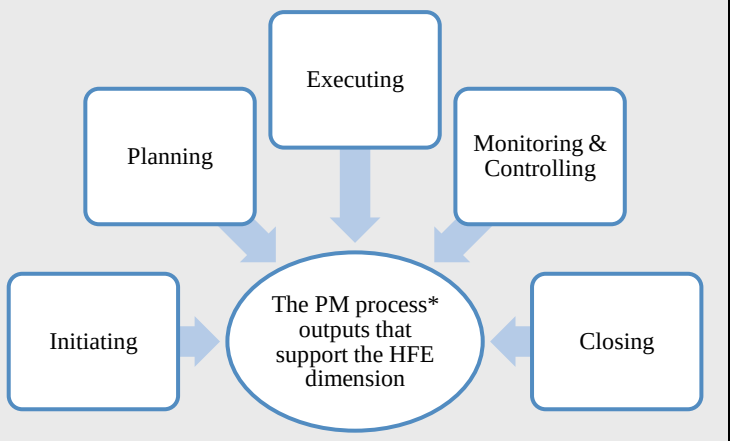
With that said, Table 4.31 shows a summarized architecture of the Human Factors Service Provider Maturity Assessment Tool (HFSP-MAT). It consists of two key dimensions, the HFE Dimension, which was developed through this research and the PM Dimension is based on practices from the PMBOK® tailored to the context and the industry to support the HFE Dimension.

When it comes to ensuring quality and success, HF validation projects that seek FDA approval involve much more than HFE methods. For that reason, the HFSP-MAT targets two key dimensions, the Project Management (PM) dimension and the Human Factors Engineering (HFE) dimension.

Each dimension focuses on specific categories (based on key practices for success) that should be implemented in combination in order to facilitate the successful delivery of FDA HF validation projects. Accordingly, the PM Dimension has been tailored to support the implementation of the key factors for success in the HFE Dimension (Rojas, et al., 2019).

Table 4.31: Architecture of the HFSP-MAT

HFE Dimension (Critical Success Factors)	**State of the Practices by Levels (Maturity)**				
	1 Infancy	**2 Childhood**	**3 Adolescence**	**4 Adulthood**	**5 Maturity**
Planning & Documenting					
Traceability Management					
Completeness Management					
Accuracy of Plans and Proposals*					
Tools & Methodology					
Appropriateness of Tools and Methods					
Reliability of the Tools and Methods					
Effectiveness of Tools and Methods					
People					
People's Roles and Responsibilities					
People's Qualifications and Must-haves					
Timing & Integration					
Product Design & Dev. Requirements*					
Product Design & Dev. Milestones*					
FDA's Inputs and Guidelines					
FDA's Timelines					
Communicating & Reporting					
User-Usable Format					
User-Usable Language					
Engaging Sponsor					



*Breakdown of key factors for success that align with **IEC 62366-1 Capability**.
**Based on PM Process Groups Outputs - PMBOK® 6th Ed.

4.3.2 The HFE Dimension Described (Categories and Subcategories)

The HFE Dimension is based on key factors critical to quality of HF validation projects that have been identified through research including expert feedback and the applicable HFE guidance and standards (Rojas, 2019; Rojas, et al. 2019a).

- **Planning & Documenting.** FDA HF validation projects come with their own nuts and bolts regarding what to document and how. Such *documenting* prerequisites should be strategically determined during planning. Thus, within this category ***Use-Related Risk Traceability and Completeness Management, Accuracy of Plans and Proposals,*** have been identified as necessary practices.
    - **Use-Related Risk Traceability**: a subset of the "Planning & Doc." Category in the HFE Dimension that prescribe how the HFE work must show that any critical task has been addressed/verified and must be easily "traced" back (has been documented) from where it originated to where it has been resolved/addressed. This also includes tracing/linking all elements of the HF validation to the overall risk management strategy and presenting it this way to the FDA.
    - **Completeness Management**: sub-category in the "Planning & Doc." Category of the HFE Dimension, that entails covering all FDA's required steps as per the applicable guidance and standards, as well as addressing any provided inputs while making sure no loose ends remain. This includes coverage in all required topics, failure debriefs root-cause of all, mitigation, or rationales when no mitigation took place. The rationales are also descriptions such as the used approach, the reason for selected groups, tasks, mitigation strategies, UI. All components should be addressed and if not, there must be justifications (including for residual risks).
    - **Accuracy of Plans and Proposals:** a subset of the "Planning & Doc." category in the HFE Dimension that remarks on the critical practice of

ensuring all HFE validation plans and proposals have been developed utilizing a systematic and proven project management planning process. Accurate plans and proposals will not only ensure the success of the validation project, but it is a key factor that sponsors of FDA HF validation projects consider essential when partnering with HFSPs.

- **People.** This category refers to the people that should support the development, design, and validation of the medical device/combination product involved in FDA HF validation projects. In includes HF personnel, device users, and device/product team. The category includes careful consideration of the different ***roles and responsibilities, as well as the requisites, skills, and expertise required*** of the HF personnel, moderators, and users/participants. Likewise, outlining the expectations from each role, from HFE personnel to sponsor, senior management as well as product design and development team and sponsor of the FDA HF validation projects.
    - **Roles and Responsibilities:** a subset of the People category in the HFE Dimension that consists of outlining the expectations from each role, including HFE personnel, senior management as well as product design and development team and sponsor of the FDA HF validation projects.
    - **Qualifications and Must-Haves:** a subset of the People category in the HFE Dimension that looks at the ***requisites, skills, and expertise (or training) required*** of the HF personnel, moderators, as well as users/participants.
- **Tools & Methodology.** The type of product, type of submission, timing and purpose of the HF work (e.g. formative vs. final validation), are some the considerations when determining tools and methodology for the FDA HF validation project. In that sense, a*ppropriate*, *reliable* and *effective* 'tools and methods' in the overall approach (methodology) are critical factors for success.

Choosing the wrong approach will likely result in deficiencies remarked by the FDA when the validation project is delivered.

  - **Appropriateness of Tools and Methods:** a subset of the "Tools & Methodology" category in the HFE Dimension that remarks on the importance of ensuring the tools and methods or overall methodological approach for the HF validation work have been suitable considering the specific requirements of the product.
  - **Reliability of Tools and Methods:** a subset practice of the "Tools & Methodology" category in the HFE Dimension that remarks on the importance of ensuring the tools and methods or overall methodological approach for the HF validation work were accurate and reliable so that the resulting data can be considered valid.
  - **Effectiveness of Tools and Methods:** a subset practice of the "Tools & Methodology" category in the HFE Dimension that remarks on the importance of ensuring the tools and methods or overall methodological approach for the HF validation work could effectively lead to address and mitigate the user-related risks.

- **Timing & Integration.** Sponsors need to demonstrate timely integration of the HFE work with product design and development. As such, this category does not only remark integration of the HFE work, but brings attention to the importance of timing (when in product design and development) to consider HFE. The key components in Timing & Integration are the following:

  - **Product Design & Dev. Requirements:** the subset of the "Timing & Integration" category in the HFE Dimension seeks to integrate the requirements of product design and development with every phase of the HFE work (e.g.: formative usability testing and design optimization), that will end with the HF validation project.
  - **Product Design & Dev. Milestones:** the subset of the "Timing & Integration" category in the HFE Dimension that looks to align the HFE

work with the different milestones of product design and development (e.g.: market research, usability testing, HF test protocol review by FDA, risk mitigation, IF testing, design validation) as necessary component for successful FDA HF validation

- **Alignment with FDA's Timelines:** category in the HFE Dimension involving practices that align the HFE work with FDA's timelines as a critical factor for successful FDA HF validation projects.
- **Integration of FDA's Inputs and Guidelines:** A subset of the "Timing and Integration" category in the HFE Dimension that remarks on carefully and rigorously integrating inputs and HF guidance from the FDA as well as keeping up with any updates.

- **Communicating & Reporting.** What to document and how is not enough for successful FDA HF validation projects. How results or findings will be communicated and presented is as critical to quality and success. This category seeks to focus on the practices that ensure ***format*** and ***language*** used in preparing and communicating results, meet FDA's expectations, and also is helpful to ensure ***sponsor commitment*** (involvement, support) to the HF validation project.
  - **User-Usable Format:** the subset practice of the "**Comm. & Reporting**" category in the HFE Dimension that prescribes the user-focused format (table, descriptions, graphics) to prepare and communicate the results of the HF work, considering FDA's expectations.
  - **User-Usable Language:** the subset practice of the "**Comm. & Reporting**" category in the HFE Dimension that prescribes the user-focused language and terminologies that should be used to prepare and communicate the results of the HF work, considering FDA's expectations.
  - **Engaging Sponsors:** the subset practice of the "**Comm. & Reporting**" category in the HFE Dimension that recognizes that sponsors of HF validations for FDA approval have difficulties committing to and understanding these projects. As such, HFSP must be proactive in

communicating and updating sponsors to ensures and keep their commitment.

- About **IEC 62366-1 Capability**. Manufacturers need to optimize time and resources while meeting regulatory burdens in a global market. In that sense, in the HFE Dimension **IEC 62366-1 Capability** are taken into consideration. Because the FDA's HF guidance and the international standard IEC 62366-1 are based on ISO 14971, the HFSP-MAT considers how the two documents overlap and complement (see Chapter 4.2.4.3). In that sense, **IEC 62366-1 Capability** is reflected in "Accuracy of Plans & Proposals" and integration with "Product D&D" (Timelines and Milestones). In that sense, the tool reports the maturity level in such "**IEC 62366-1 Capability"** by factoring such subcategories.

4.3.3 The PM Dimension

As described in a previous section, this dimension is tailored to contained only the exact PM process outputs that can enable the implementation of the HFE Dimension. For that, the *PMBOK*® was used as the standard, and consists of carefully mapped industry-focused PM practices intended to support the HFE Dimension.

However, the PM Dimension does not require any specific PM methodology, but it looks for the standard PM outputs that must exist to ensure successful project delivery (regardless of the PM methodology or processes in place to produce such outputs), e.g. PM outputs: project scope, project schedule, team assignments, etc. The details of each Process Group and all PM outputs can be found on the PMBOK. Nevertheless, a brief description of the specific PM practices for the model is included in Appendix I.

4.3.4 The Content of the Assessment: 53 Industry-Specific Practices

Appendix D to Appendix H contain the mapping between the key factors for quality and success in FDA HF validations (HFE Dimension), as well as the PM outputs

related to the practices that can help achieve such success factors. The outputs of the processes and/or practices are factored into each corresponding category of both dimensions (PM and HFE) as shown by the way they are mapped.

The HFSP-MAT online self-assessment consists of **53 industry-specific** practices that have been identified as critical factors for success in FDA HF validation projects (as described in detail in the previous sections). These 53 practices are presented through the online self-assessment as follows:

- Practices **from 1 to 15** are exclusively about the HFE Dimension and its *five categories*, which were developed based on research of key factors for quality and success.
- Practices from **16 to 53** correspond to the *PM Dimension* and are based on the *PMBOK® Guide*, carefully tailored to support the HFE Dimension.

4.3.5 The Levels and Scoring Approach

The tool entails five levels aligned with the complex CMMI® framework to ensure consistency with the medical device industry (considering that the FDA has already launched a pilot program using the CMMI® for medical devices manufacturers).

The levels of the HFSP-MAT were adapted from the CMMI® to be easy to understand and implement using the numerical scale from 1 to 5. Also, to enable more integration with the HF field, each level has been analogically named after the Piaget's cognitive stages of human development: Infancy, Childhood, Adolescence, Adulthood and Maturity (Piaget, 1969).

4.3.5.1 Not About Years in Business

Although the number of years that a HFSP has been in business might impact the resulting level of maturity and ability to achieve success in FDA HF validation projects, the stages described here are not referring to years in business or old age. While it could be expected that a novice HFSP might have a low maturity level, this should not be generalized and might not be always true. The same applies to a company that has been a long time in business, there should not be an expectation that such business will have a high maturity level because of the years in business. A company that has been in business for 3 years could as well be performing at Level 4, while another in business for 20 + could be at Level 2. Maturity here refers to the presence and development of the outlined practices (see Table 4.31) to achieve success in FDA HF validation projects. The state of the practice on a scale of 1 to 5 has to do with the level of documentation, and standardization of such practices.

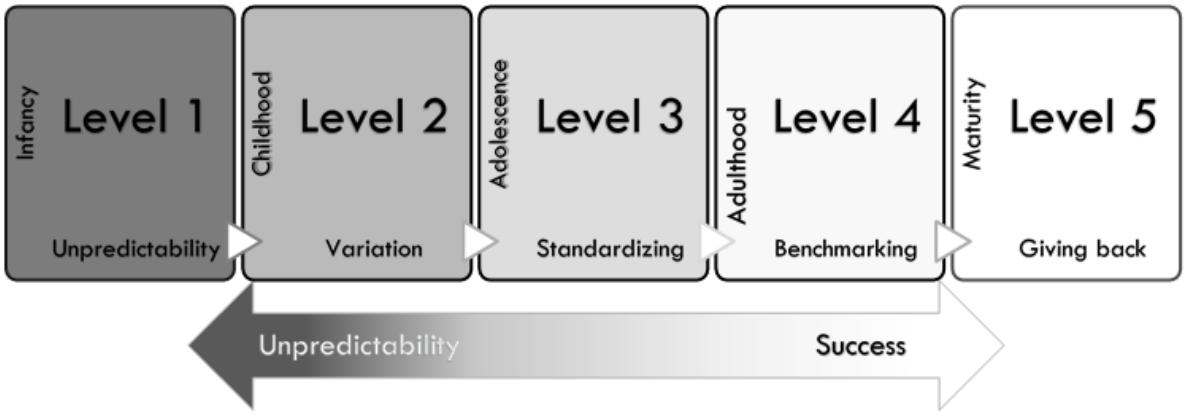


Figure 4.15: The five HFSP-MAT levels (adapted from the CMMI) - as maturity increases project success is clearer

Table 4.32: Summarized description of each level

Levels	State of the Key Practices (HFSP-MAT)
Level 1 – Infancy	Informal practice = unpredictability. Unpredictable, undocumented processes, and informal PM. The success of FDA HF validation projects depends on individual efforts (e.g.: an experienced and overworked manager).
Level 2 – Childhood	Documented practice = variation. General HFE/PM processes are defined and thus repeatable, but not standardized for FDA HF validation projects.
Level 3 – Adolescence	Standardized practice = standardizing. The corresponding HFE/PM processes are defined and standardized specifically for FDA HF validation projects.
Level 4 – Adulthood	Measured practice = benchmarking. Processes are measured and controlled (special causes of variation are addressed). Project success is reasonably certain
Level 5 – Maturity	Perfected practice = giving back. Process control enables process optimization enough to innovate and contribute in the industry (giving back!).

4.3.5.2 Scoring Approach

Every maturity model can calculate the maturity score differently. Some assign a level based on having passed with a certain score, e.g.: 70% of questions asked. An example of that approach is Kerzner's model, which uses a passing score for each level based on a series of quiz-like sections (H. R. Kerzner, 2005). Other maturity models assign the lowest level resulting from the different categories of the assessment, using an average score, as per instance the P3M3 (Giff & Jackson, 2013; OGC, 2010). The OPM3's (the maturity model from the PMI) rates each practice using a binary approach.

That is, 1 for fully implemented practices, and 0 if the practice is not fully implemented to produce the expected outcomes (Mateen, 2015; PMI, 2013).

For the HFSP-MAT, the goal is to assess the different components of each dimension, so that an HFSP can determine where there is need for improvement, and concentrate on critical areas. For that purpose, the score of each item of the instrument is included into the corresponding subcategory and the average score is taken for the subcategory.

Table 4.33: Level determined by mean scores

$1.00 \leq$ Level 1 < 1.80
$1.80 \geq$ Level 2 < 2.80
$2.80 \leq$ Level 3 < 3.80
$3.80 \leq$ Level 4 < 4.80
$4.80 \leq$ Level 5 ≤ 5.00

The overall maturity level is the grand average, which is used to determine into what level the HFSP falls, as shown on Table 4.33. That is, for instance, Level 2 is determined by a total average score of at least 1.80 or up to 2.79. Likewise, in order to be at Level 3, the score needs to be at a total average of at least 2.80 or up to 3.79, and so on. Again, the idea is that the organization can focus on the breakdown per area (e.g.: People, Tools & Methodology) to understand areas of improvement and be able to develop improvement plans as necessary. If the organization is operating at Level 2 in a key area and at Level 5 in another area, there is no need to waste efforts and resources to improve the five categories, only those areas where performance is undesirable, as there might be areas more critical than others and becomes necessary that the HFSP can identify where there is need for improvement.

Nevertheless, the overall level of maturity is impacted by the lowest performing subcategories, even if some areas are at Level 5, the lowest ones will pull the overall maturity level down. That is so the organization is able to look at the components of the HFSP-MAT to analyze the lowest areas and develop specific plans to improve them. The amount of effort to improve should correspond with continuous improvement plans towards specific areas or categories as described in the HFSP-MAT (see Chapter 4.3.2).

4.3.6 PM File for the HF Validation Project

Keep in mind that the HFSP-MAT is "output-oriented" just like the FDA HF guidance and the IEC-62366-1. Thus, to be consistent and organized, think of a "PM History File" when it comes to the key PM outputs for quality and success (e.g.: "Stakeholder Management Plan", "Accepted Deliverables", etc., see Appendix I). These PM outputs serve to show there is process and policies in place to produce them and the HFSP is quality-oriented. Another example is having a documented process to ensure the "Reliability of the Tools & Methods" (the HFE Dimension) and the resulting outputs of the relevant project in the "PM history file".

4.3.7 How the Assessment Works

The assessment works in the same way as a "self-audit," through which we check whether the presented practices exist and how developed they are based on the 5 levels presented (e.g.: documented, standardized, optimized), as described in Chapter 4.3.5.2. For that purpose, five options are given during the beta version of the assessment (a, b, c, d, e), which represent the state of the practice in the organization (this will be only numbers, 1 to 5, for the published online version).

Please consider that the provided answers are progressive, which means for instance, that answer “c” should not be selected if criteria for answer “a” and “b” are not met in the organization in regard to *FDA HF validation projects* (if the processes, policies and procedures do exist as described for the presented practice).

a) Activities related to this practice could take place if needed, but the process is not documented
b) This practice is documented, although not always applied to our FDA HF validation projects
c) Our policies and procedures ensure we apply this practice in our FDA HF validation projects
d) We track quantitative data of the relevant process to ensure consistent quality of the stated practice
e) Through process control and improvement, this practice has been optimized in our organization

4.3.8 An Overview of the Online HFSP-MAT (beta)

The resulting model and content were converted into an online assessment tool at www.hfsp-mat.online using the popular content management system WordPress, and a commercial plugin (Modal Survey) was slightly customized to load the assessment into the WordPress site for the tool.

The website for the tool (beta, subject to modifications) contains the following menu:

- Home
- HFSP Assessment
    - About
    - Features
    - How to use
    - Start assessment

- How it works
    - 3 steps
    - FAQs
- Directory
    - Find HFSPs
    - Find Projects
- Publications
- Dashboard
    - HFSP-MAT Report
    - HFSP-MAT Benchmark
    - Profile
    - Manage Listing
    - Community

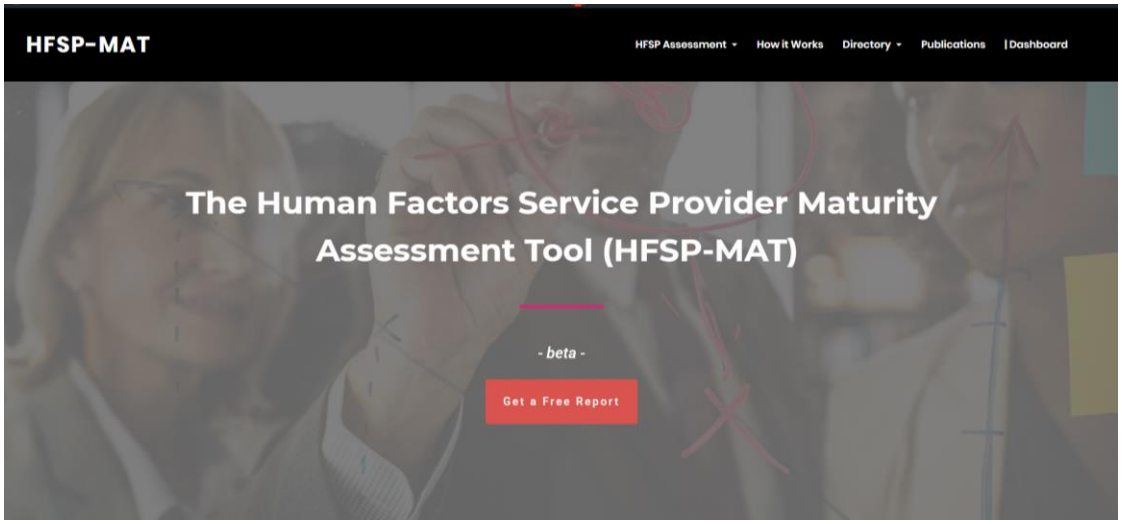


Figure 4.16: Landing page for the online tool

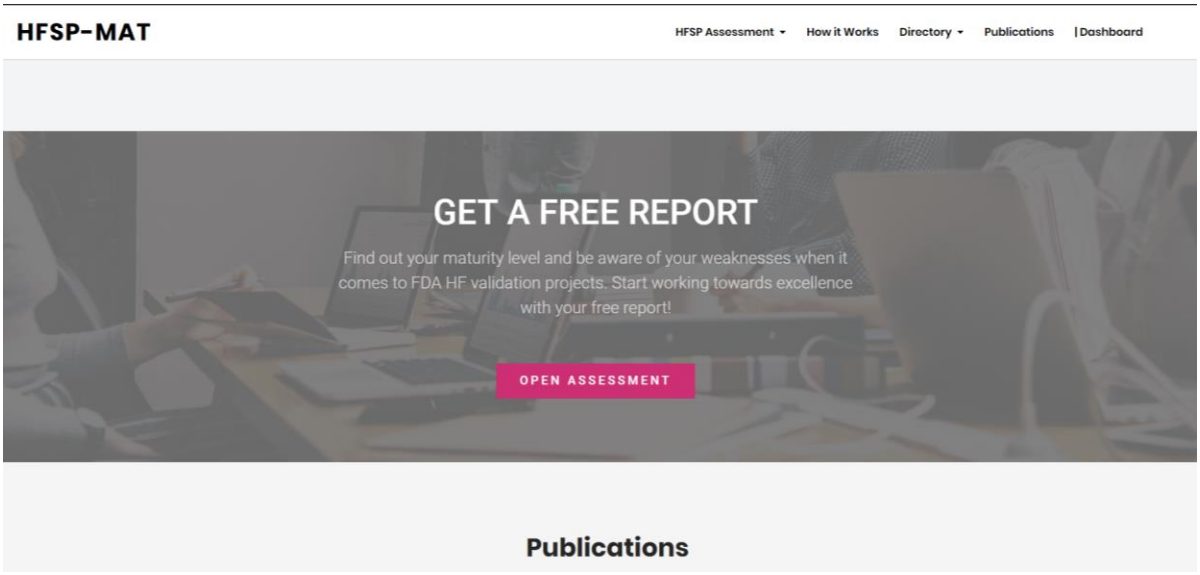


Figure 4.17: Call to action on the landing page of the tool's site

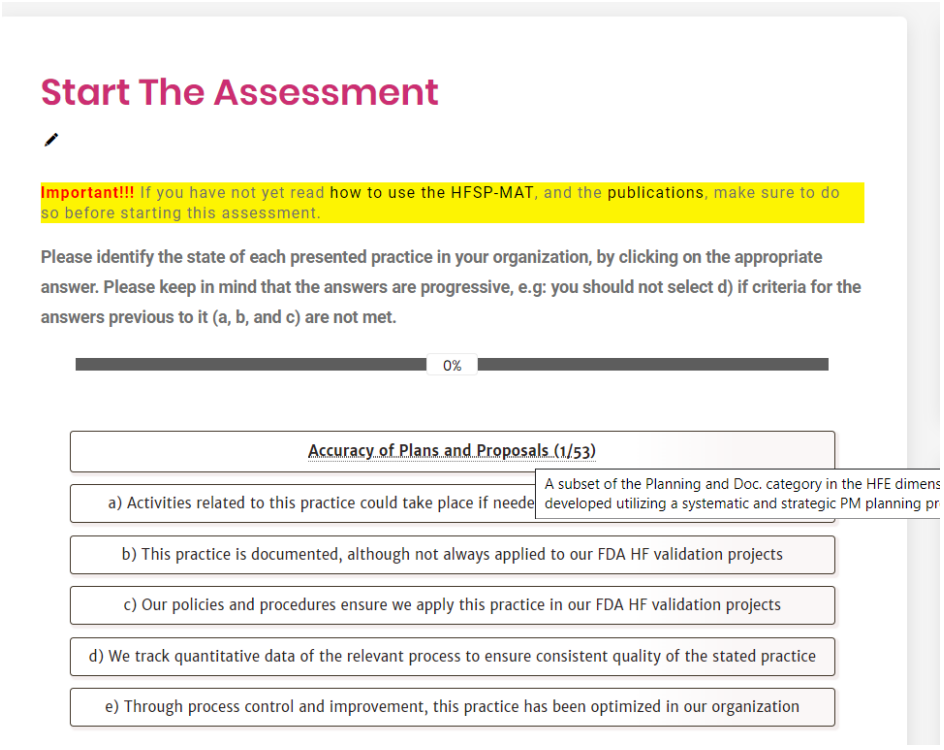


Figure 4.18: First page of the assessment

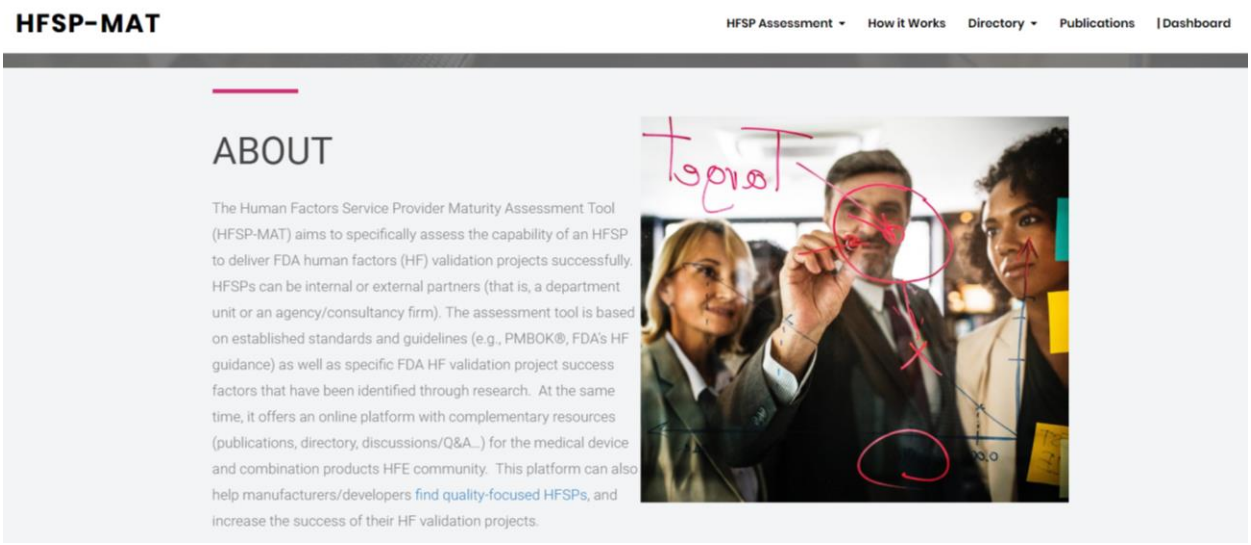


Figure 4.19: A section of the website briefly explains what the tool is about and how to use it

The Home section contains a synopsis of all content available by scrolling down, and invites to get a free report about your maturity level (see Figure 4.17). The section HFSP Assessment explains what the tool is about, its features and how to use the assessment (see Figure 4.19).

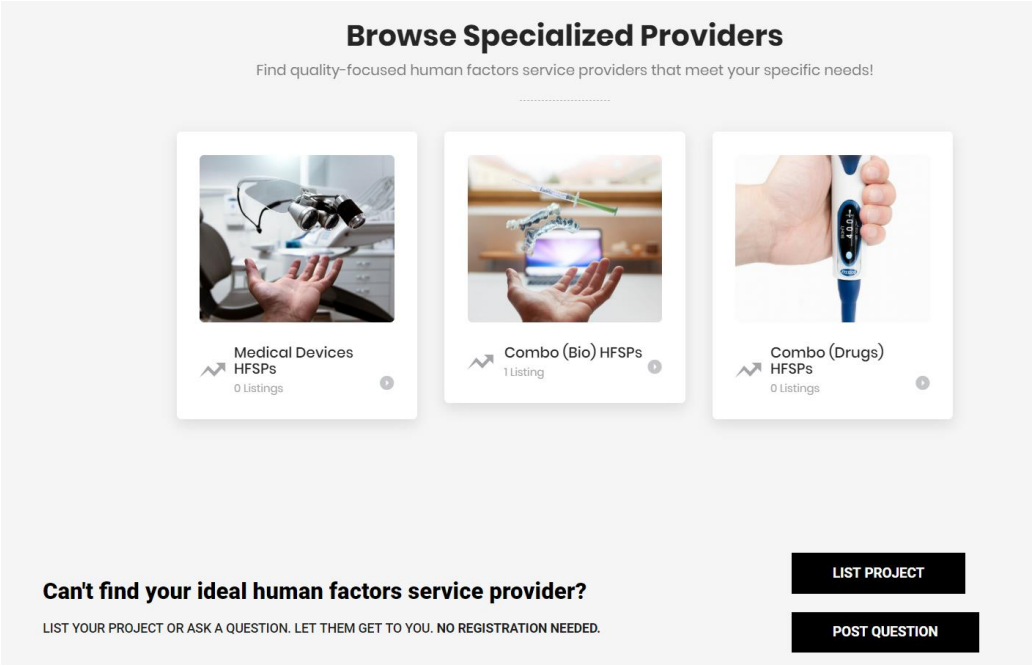


Figure 4.20: The HFSP-MAT site contains a complementary directory

As shown on Figure 4.24, the directory provides an opportunity for HFSPs to list their services showing the important criteria interesting to procurers, as determined during this research. Procurers of HF services indicated the following factors are key in selecting HFSPs (see Chapter Table 4.17): Level of experience, Size of staff, History of success, Product expertise and Quality (which is indicated by the level achieved during the assessment). However, listing the maturity level is up to the HFSP.

There is also a link to "How it Works" which directs to a quick overview of what the whole HFSP-MAT platform comprises. A complimentary directory (see as well as forums/community section (Figure 4.22) with questions and answers so that both HFSPs and procurers can interact and make the best out the tool.

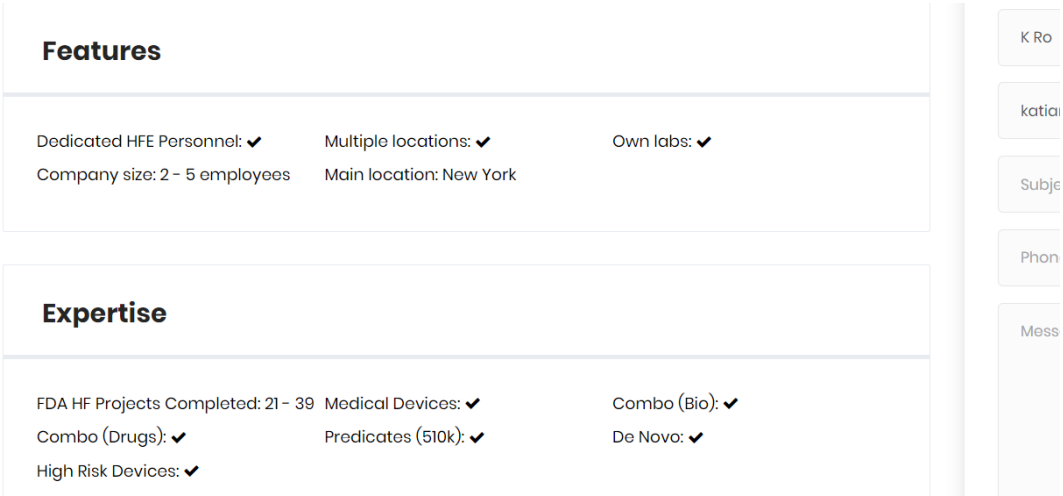


Figure 4.21: Partial view a sample listing of an HFSP using the directory of the HFSP-MAT as sought by procurers

After the user has taken the assessment (see Figure 4.18), a report is generated which details the average level of maturity in general and for each component of both dimensions, the HFE and PM (see Figure 4.24 and Figure 4.25). Also, if the user has chosen to register, the report can later be accessed through the "Dashboard" (see Figure 4.23). The "Dashboard" is also where users can manage their profiles see the *benchmark* page with industry maturity data. There is also a "Publications" section where documentation about the tool and any relevant research or important industry news can be found.

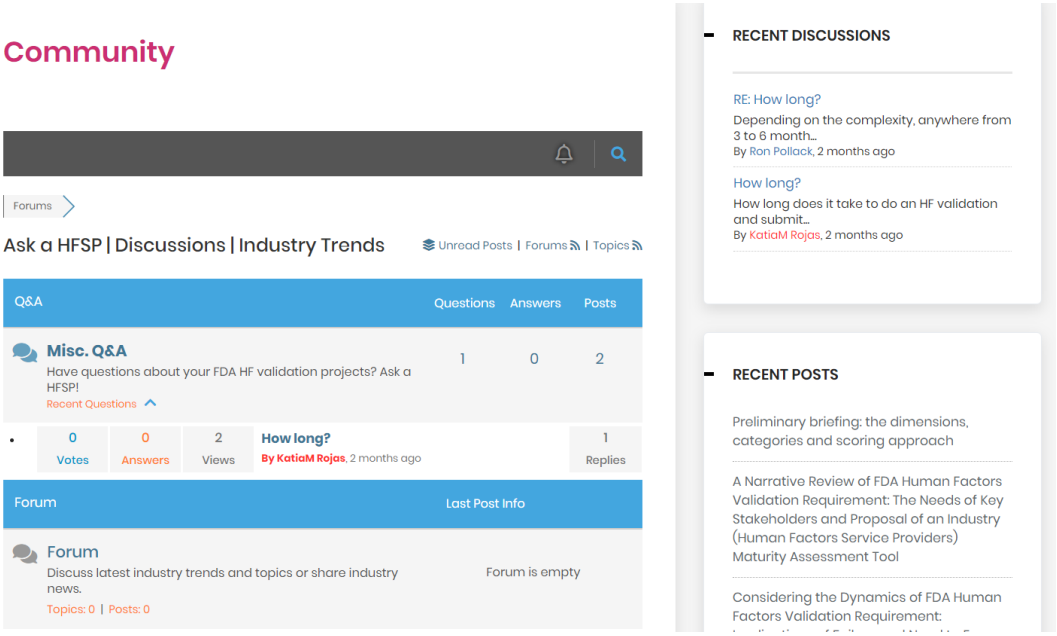


Figure 4.22:Online community section including forum/Q&A

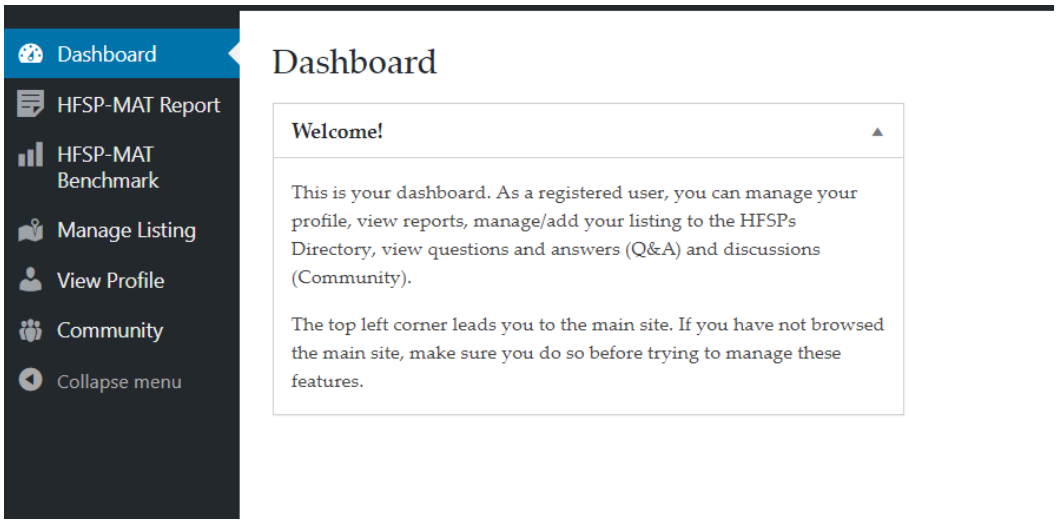


Figure 4.23: Tool's dashboard for HFSP

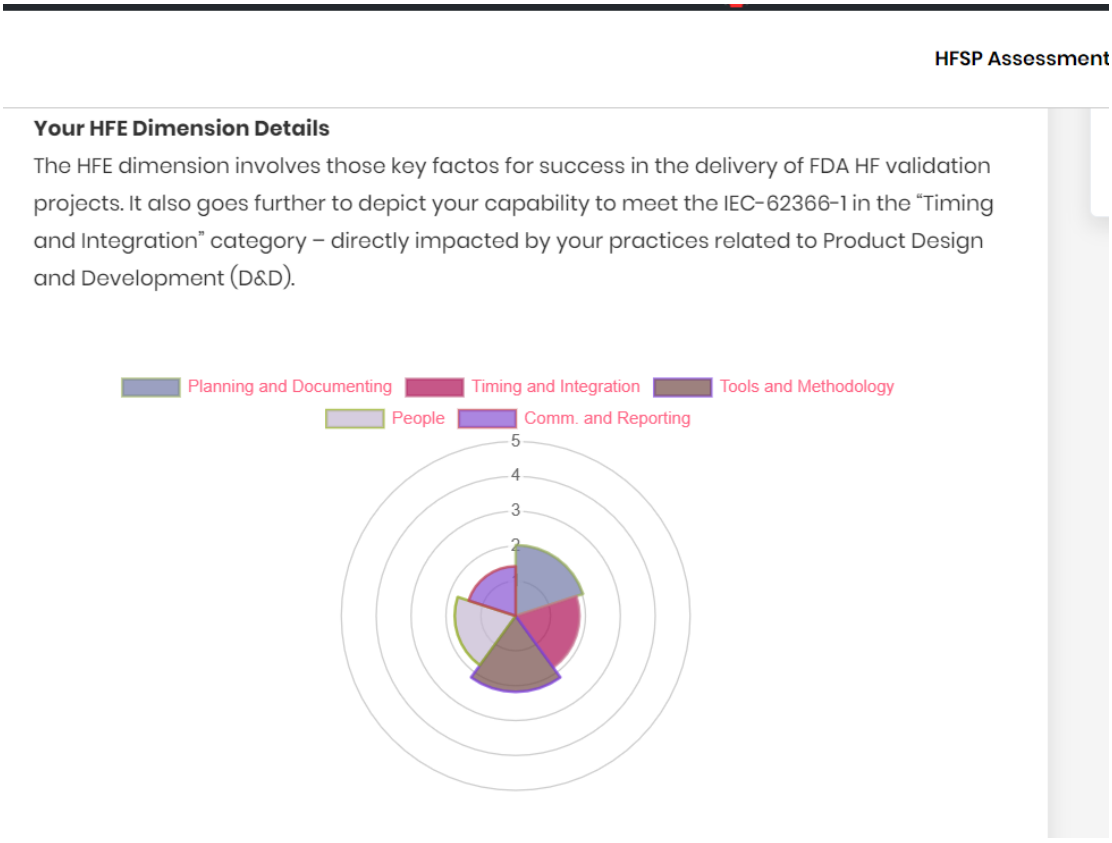


Figure 4.24: Partial view of a sample HFSP-MAT report containing maturity details of the HFE Dimension

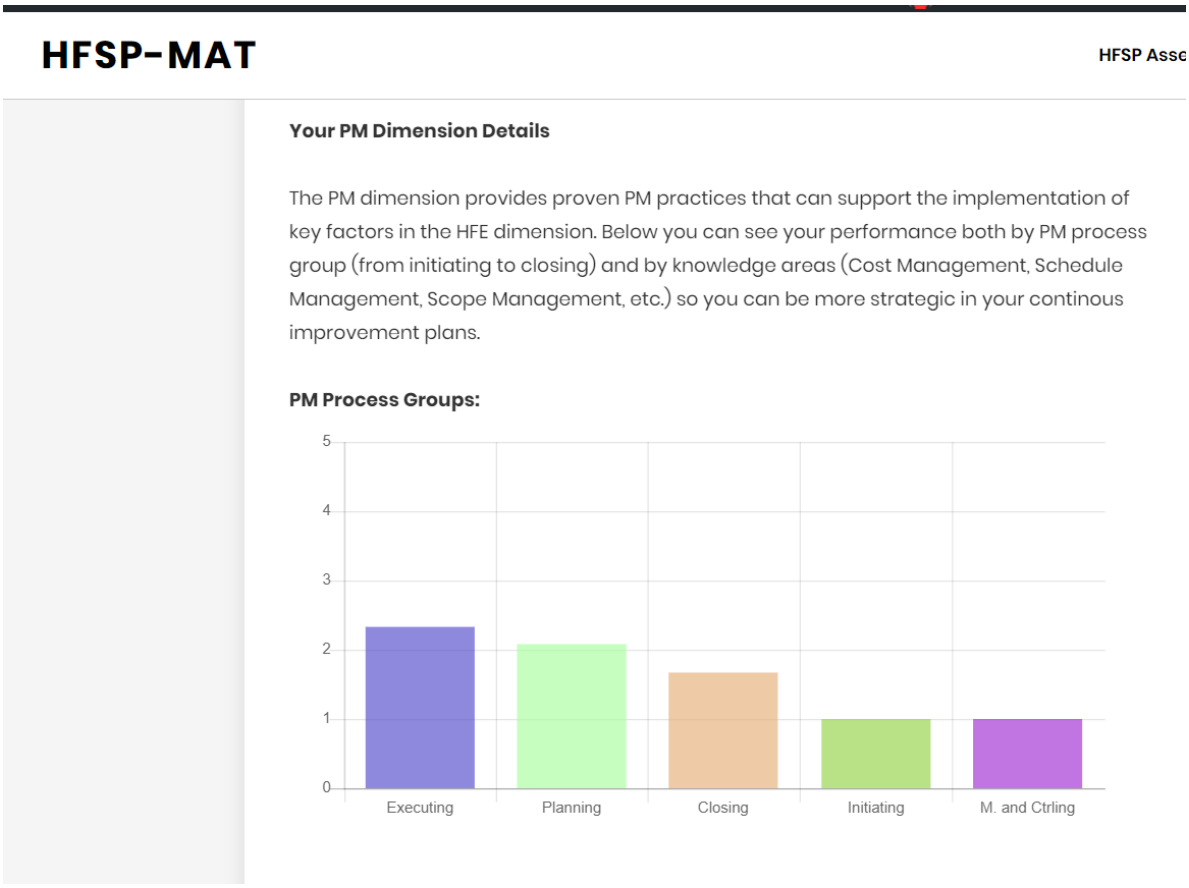


Figure 4.25: Partial view of the HFSP-MAT report (details PM Dimension)

4.4 Testing the HFSP-MAT (beta) - Preliminary Results

4.4.1 Data Collection

After finalizing a beta version of the tool, organizations (22) that had responded to the online posts expressing interest in participating, were informed that a beta version was available to test. 17 organizations responded back and were sent the link to access the tool. The email also included a short survey on Qualtrics intended to collect feedback on specific important criteria of a maturity model (see Appendix K and Chapter 2.5.11). The total number of assessments submitted was 15, out of which 1 was deleted as it was not submitted correctly (the same score was selected across the assessment). Regarding

the feedback survey, one was deleted as it indicated it was submitted without having actually tested the assessment tool. The collected data were analyzed as follows.

4.4.2 Data Analysis

Summary of the Data and Objective of the Analysis

As explained in the previous section, the HFSP-MAT has two dimensions (the HFE Dimension and the PM Dimension) each one has categories and subcategories which are computed through the assessment (see Chapter 4.2.6.3 and 4.3.5.2). A total of 14 observations were collected using a primary set of 53 items on a 5-point scoring scale (see Appendix J). The processed dataset for this analysis contains no missing values (see Table 4.34), with a total of 36 variables and 14 observations. The independent variables are in continuous form and include the 5 high-level categories and 15 subcategories that form the HFE Dimension (Table 4.35). In the same way, the PM Dimension consists of a total of 15 variables (see Table 4.36). The dependent variable, Total Maturity, is in continuous form and also in nominal (the name of the corresponding Level 1 – Infancy, Level 2 – Childhood, etc., as described in section 4.3.5).

Distribution and probability plots for and results of statistical tests (Shapiro-Wilk, Kolmogorov-Smirnov, Cramer-von Mises Anderson-Darling), showed that most variables appear to be rather normally distributed (Table 4.34), since their p-values are greater than 0.05 (with very few exceptions). The focus of the analysis is on the research questions (see Chapter 1.14). Specifically, for this section, the remaining research questions to focus on are the following:

- **What is the average maturity level?**
- **What is the ideal maturity level for this industry?**

Table 4.34: Normality check of all the variables for the analysis

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
Traceability Mgmt	0.12	14.00	0.20*	0.96	14.00	0.80
Completeness Mgmt	0.17	14.00	0.20*	0.95	14.00	0.53
Accuracy of Plans and Proposals	0.16	14.00	0.20*	0.94	14.00	0.37
User-Usable Format	0.13	14.00	0.20*	0.95	14.00	0.51
User-Usable Language	0.17	14.00	0.20*	0.92	14.00	0.19
Engaging Sponsors	0.17	14.00	0.20*	0.91	14.00	0.18
Roles and Responsibilities	0.15	14.00	0.20*	0.95	14.00	0.55
Qualifications and Must-Haves	0.21	14.00	0.10	0.90	14.00	0.12
Product D&D Requirements	0.18	14.00	0.20*	0.95	14.00	0.49
Product D&D Milestones	0.22	14.00	0.07	0.94	14.00	0.43
FDA's Inputs and Guidelines	0.13	14.00	0.20*	0.97	14.00	0.91
FDA's Timelines	0.15	14.00	0.20*	0.97	14.00	0.87
Appropriateness of Tools and Method	0.16	14.00	0.20*	0.95	14.00	0.56
Reliability of Tools and Methods	0.15	14.00	0.20*	0.97	14.00	0.93
Effectiveness of Tools and Methods	0.20	14.00	0.14	0.93	14.00	0.32
Planning & Doc	0.17	14.00	0.20*	0.96	14.00	0.74
Comm. & Reporting	0.16	14.00	0.20*	0.94	14.00	0.39
Tools & Methodology	0.11	14.00	0.20*	0.98	14.00	0.96
People	0.28	14.00	0.00	0.87	14.00	0.04
Timing & Integration	0.15	14.00	0.20*	0.96	14.00	0.66
Initiating	0.14	14.00	0.20*	0.94	14.00	0.38
Planning	0.13	14.00	0.20*	0.94	14.00	0.45
Executing	0.15	14.00	0.20*	0.94	14.00	0.47
M&C	0.21	14.00	0.10	0.93	14.00	0.31
Closing	0.31	14.00	0.00	0.88	14.00	0.06
Integration	0.22	14.00	0.06	0.88	14.00	0.07
Scope	0.12	14.00	0.20*	0.95	14.00	0.64
Schedule	0.11	14.00	0.20*	0.96	14.00	0.65
Quality	0.12	14.00	0.20*	0.96	14.00	0.67
Cost	0.20	14.00	0.14	0.91	14.00	0.18
Resource	0.18	14.00	0.20*	0.95	14.00	0.57
Communications	0.19	14.00	0.19	0.91	14.00	0.16
Risk	0.14	14.00	0.20*	0.94	14.00	0.38
Procurement	0.27	14.00	0.01	0.88	14.00	0.05
Stakeholders	0.25	14.00	0.02	0.88	14.00	0.06
Total MAT	0.26	14.00	0.01	0.90	14.00	0.11

*. This is a lower bound of the true significance.

a. Lilliefors Significance Correction

Table 4.35: Descriptive Statistics of the HFE Dimension (including high-level categories), N =14

	Min	Max	Sum	Mean	Std. D.	Skewness	Std. Error	Kurtosis	Std. Error
Planning & Doc	**1.86**	**3.40**	**38.18**	**2.73**	**0.42**	**-0.52**	**0.60**	**0.45**	**1.15**
Traceability Mgmt	1.83	3.50	39.00	2.79	0.45	-0.54	0.60	0.04	1.15
Completeness Mgmt	1.88	3.41	37.89	2.71	0.45	-0.25	0.60	-0.28	1.15
Accuracy of Plans & Proposals	1.86	3.29	37.65	2.69	0.38	-0.76	0.60	0.87	1.15
Comm. & Reporting	**1.48**	**3.33**	**36.63**	**2.62**	**0.50**	**-0.82**	**0.60**	**0.63**	**1.15**
User-Usable Format	1.44	3.33	36.21	2.59	0.56	-0.56	0.60	-0.53	1.15
User-Usable Language	1.44	3.33	36.76	2.63	0.59	-0.58	0.60	-0.77	1.15
Engaging Sponsors	1.56	3.31	36.88	2.63	0.41	-1.14	0.60	3.14	1.15
People	**2.07**	**3.41**	**37.48**	**2.68**	**0.36**	**0.43**	**0.60**	**0.89**	**1.15**
Roles and Responsibilities	2.14	3.43	39.29	2.81	0.36	0.09	0.60	0.37	1.15
Qualifications & Must-Haves	2.00	3.40	35.70	2.55	0.40	0.68	0.60	0.78	1.15
Timing & Integration	**2.01**	**3.53**	**38.93**	**2.78**	**0.46**	**-0.17**	**0.60**	**-0.53**	**1.15**
Product D&D Requirements	1.84	3.42	38.42	2.74	0.46	-0.33	0.60	-0.04	1.15
Product D&D Milestones	2.00	3.75	40.01	2.86	0.52	0.19	0.60	-0.99	1.15
FDA's Inputs & Guidelines	1.82	3.35	37.35	2.67	0.42	-0.29	0.60	0.07	1.15
FDA's Timelines	1.93	3.73	39.94	2.85	0.51	-0.06	0.60	-0.64	1.15
Tools & Methodology	**1.64**	**3.22**	**35.42**	**2.53**	**0.40**	**-0.52**	**0.60**	**1.00**	**1.15**
Appropriateness of Tools & Methods	1.75	3.25	35.91	2.57	0.36	-0.33	0.60	1.30	1.15
Reliability of Tools & Methods	1.67	3.17	34.00	2.43	0.42	-0.09	0.60	-0.24	1.15
Effectiveness of Tools & Methods	1.50	3.25	36.39	2.60	0.47	-0.96	0.60	1.00	1.15

4.4.3 What is the Average Maturity Level?

As shown on Table 4.37, the average Total Maturity of participants was 2.65 (±0.40 SD) which corresponds to the Level 2 - Childhood (depicted on Figure 4.26). The Level 2 of the HFSP-MAT, implies a lack of standardization of the assessed practices

(see section 4.3.5 about levels and their descriptions). However, given the small sample and also the fact that this was a self-assessment (room for too much optimism), the average HFSP could be at Level 1.

Table 4.36: Descriptive Statistics PM Dimension (N=14)

					Skewness		Kurtosis	
	Min	**Max**	**Mean**	**Std. D.**	**Stat**	**Std. Error**	**Stat**	**Std. Error**
Initiating	1.75	3.50	2.66	0.56	-0.24	0.60	-0.94	1.15
Planning	2.04	3.48	2.78	0.45	-0.05	0.60	-0.25	1.15
Executing	1.83	3.50	2.82	0.44	-0.48	0.60	1.12	1.15
M&C	1.50	3.50	2.59	0.62	0.09	0.60	-0.92	1.15
Closing	1.33	3.00	2.31	0.42	-0.89	0.60	1.37	1.15
Integration	1.90	3.50	2.89	0.43	-0.92	0.60	1.32	1.15
Scope	1.50	3.63	2.49	0.58	-0.15	0.60	0.37	1.15
Schedule	2.33	3.50	2.90	0.36	-0.06	0.60	-0.63	1.15
Quality	1.40	3.40	2.37	0.64	0.04	0.60	-1.13	1.15
Cost	2.25	3.50	2.89	0.35	-0.47	0.60	0.35	1.15
Resource	1.50	4.00	2.68	0.66	0.51	0.60	0.46	1.15
Communications	1.00	3.50	2.50	0.71	-0.38	0.60	-0.11	1.15
Risk	1.00	3.67	2.33	0.84	0.11	0.60	-0.37	1.15
Procurement	1.33	3.67	2.90	0.63	-1.17	0.60	1.64	1.15
Stakeholders	1.67	3.00	2.22	0.46	0.56	0.60	-0.87	1.15

Figure 4.26: The Maturity Level Corresponding to the average "Total Maturity" (MAT).

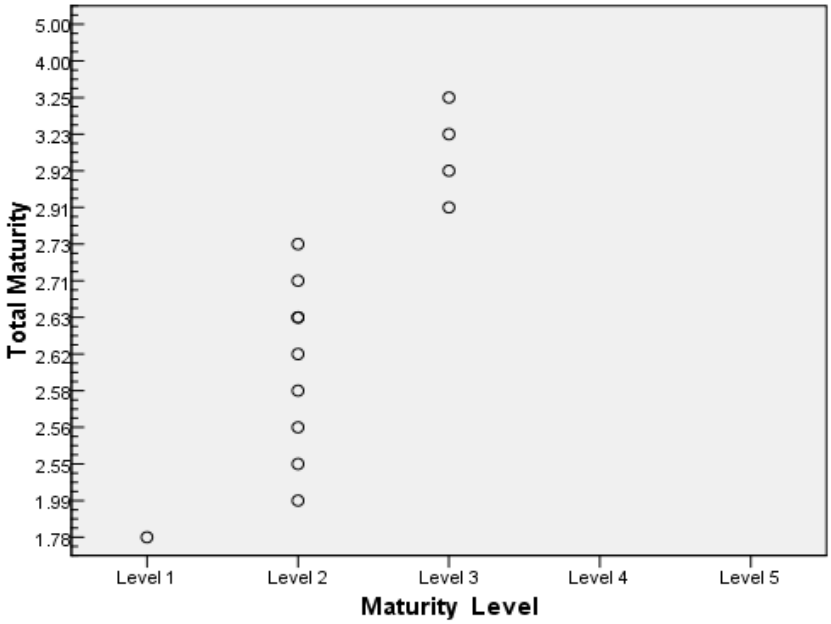


Table 4.37: Descriptive statistics of the variable "Total Maturity" (Maturity Level).

N		**Mean**	Median	Mode	Std.D	Range	**Percentiles**		
Valid	Missing						**25**	**75**	**90**
14	0	**2.65**	2.63	2.63	0.40	1.47	2.56	2.91	3.23

Table 4.35 contains the descriptive statistics of the HFE dimension, and shows the average score detailed by subcategories. The highest average score is 2.86, which corresponds to "Product D&D Milestones," a subcategory of "Timing & Integration." The lowest average score is 2.43, which corresponds to the subcategory "Reliability of Tools & Methods" in the category "Tools & Methodology". The high-level categories of the HFE Dimension are shown on Figure 4.27.

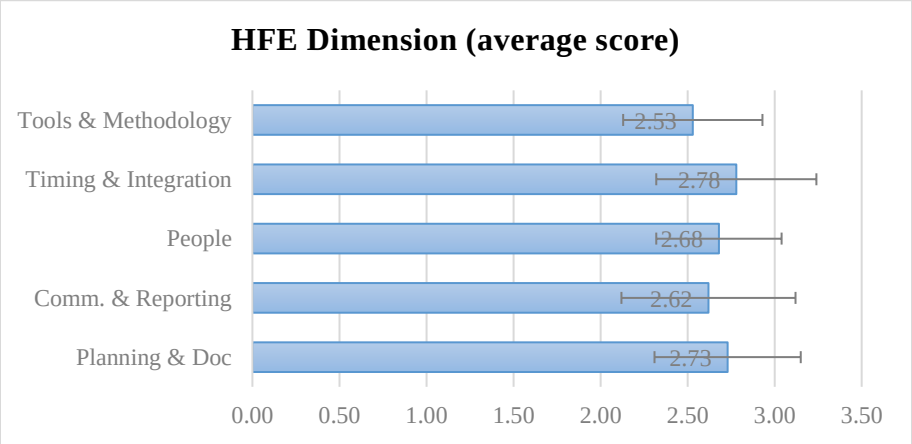


Figure 4.27: Average score in the five high-level categories of HFE Dimension

In the PM Dimension, which is based on the PMBOK Guide, there are two categories (see 4.2.6). One PM category is the PM Process Groups, and the other is PM Knowledge Areas. As shown on Figure 4.28, the lowest average score in the PM Process

Groups is found in “Closing” processes while the highest average score is found in “Executing” process.

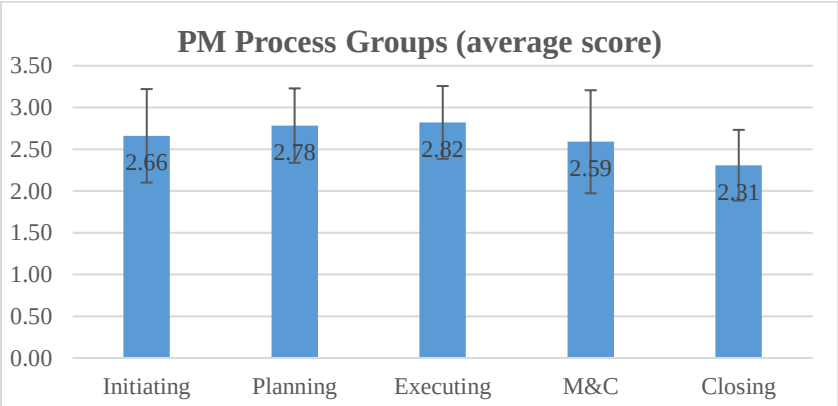


Figure 4.28: Average score in the PM Process Groups

Table 4.36 contains the full descriptive statistics of the PM dimension, including the PM Knowledge Areas. The lowest score in the PM Knowledge Areas was “Stakeholders Management” (2.22, ±0.46 SD) while the highest average score corresponds to the “Schedule Management” Knowledge Area (2.90, ±0.36 SD).

4.4.4 Validity and Reliability

It is known that all measurements have some room for errors, either due to external factors such as those originating on participants’ side (e.g., not knowing the content) or from the instrument itself due to being badly designed (Nunnally & Bernstein, 1994). There are multiple methods used to quantify acceptable amount of errors as to ensure validity and reliability of the instrument. In this case, content and face validity of the HFSP-MAT have been achieved through the previous phases, which included the use

of standardized content (e.g.: FDA's HF guidance, PMBOK) and experts feedback (see the Delphi Panel in section 4.2.4). Next, scale reliability will be explored.

To test reliability, there are several approaches, such as Kuder Richardson (KR) for dichotomous data, Spilt-half for test and retest, and Cronbach Coefficient Alpha for a single test and scaled data (Crocker & Algina, 1986; Cronbach, 1951). Consequently, the most appropriate formula is the last one, the **Cronbach Alpha Coefficient** which measures common variance among items in an assessment. The higher the coefficient, the more reliable the assessment is, and a coefficient of at least 0.70 is recommended (Nunnally & Bernstein, 1994).

SPSS software was used to calculate the desired coefficients and correlations, both on the initial (Table 4.38) 53 raw items and also the processed variables as discussed previously. Overall, the results of Cronbach Coefficient Alpha were greater than 0.90, suggesting optimal internal consistency and reliability.

Table 4.38: Cronbach Coefficient Alpha of the 35 items of the HFSP-MAT

Cronbach's Alpha	0.98
Cronbach's Alpha Based on Standardized Items	0.99
N of Items	35

The inter-item correlation matrix showed significant correlation between items indicating good convergent validity (Campbell & Fiske, 1959). Likewise, the items of each dimension were correlated with the dependent variable "Total Maturity." The full correlation matrix is not included due to size. The correlation matrix of the high-level items of each dimension are shown on (Table 4.39). In general, the mean inter-item correlation was 0.66 (min. -0.37, max, 0.98).

Table 4.39: Correlation matrix of high-level category of the HFSP-MAT

	1	2	3	4	5	6	7	8	9	10	11
1. Planning & Doc	1.00	0.84	0.90	0.88	0.91	0.81	0.92	0.59	0.55	0.65	0.96
		0.00	0.00	0.00	0.00	0.00	0.00	0.03	0.04	0.01	0.00
2. Comm. & Rep.	0.84	1.00	0.94	0.80	0.92	0.62	0.80	0.40	0.55	0.51	0.89
	0.00		0.00	0.00	0.00	0.02	0.00	0.16	0.04	0.06	0.00
3. Tools & Methodology	0.90	0.94	1.00	0.86	0.89	0.66	0.80	0.55	0.61	0.54	0.93
	0.00	0.00		0.00	0.00	0.01	0.00	0.04	0.02	0.05	0.00
4. People	0.88	0.80	0.86	1.00	0.86	0.61	0.92	0.53	0.53	0.47	0.89
	0.00	0.00	0.00		0.00	0.02	0.00	0.05	0.05	0.09	0.00
5. Timing & Integration	0.91	0.92	0.89	0.86	1.00	0.77	0.90	0.33	0.56	0.58	0.94
	0.00	0.00	0.00	0.00		0.00	0.00	0.25	0.04	0.03	0.00
6. Initiating	0.81	0.62	0.66	0.61	0.77	1.00	0.70	0.43	0.66	0.64	0.83
	0.00	0.02	0.01	0.02	0.00		0.01	0.13	0.01	0.01	0.00
7. Planning	0.92	0.80	0.80	0.92	0.90	0.70	1.00	0.40	0.35	0.56	0.89
	0.00	0.00	0.00	0.00	0.00	0.01		0.16	0.22	0.04	0.00
8. Executing	0.59	0.40	0.55	0.53	0.33	0.43	0.40	1.00	0.56	0.37	0.59
	0.03	0.16	0.04	0.05	0.25	0.13	0.16		0.04	0.20	0.03
9. M&C	0.55	0.55	0.61	0.53	0.56	0.66	0.35	0.56	1.00	0.53	0.70
	0.04	0.04	0.02	0.05	0.04	0.01	0.22	0.04		0.05	0.01
10. Closing	0.65	0.51	0.54	0.47	0.58	0.64	0.56	0.37	0.53	1.00	0.68
	0.01	0.06	0.05	0.09	0.03	0.01	0.04	0.20	0.05		0.01
11. Total MAT	0.96	0.89	0.93	0.89	0.94	0.83	0.89	0.59	0.70	0.68	1.00
	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.03	0.01	0.01	

4.4.4.1 Exploratory Factor Analysis (EFA) and Confirmatory Factor Analysis (CFA)

Exploratory Factor Analysis (EFA) is a procedure within factor analysis, frequently used to validate new measured variables (Fabrigar et al., 1999). The goal is to identify the latent underlying constructs among the measured variables (factors), which should be represented by several of the measured variables.

As per literature, EFA applies best to large samples, and 300 observations are usually suggested (Gerbing & Hamilton, 1996; Tabachnick & Fidell, 2012). Such sample size might not be feasible in this case in the near future, considering that the HF requirement is still a fresh topic. The Measure of Sampling Adequacy (MSA) was below

0.50, which confirmed that the sample size is not suitable. That can happen also due to that the number of variables is greater than the sample size (Stevens, 1992). On the other hand, construct validity through EFA is not practical in this case because there is enough theoretical foundation (Suhr, 2006; Thompson, 2004). The constructs of the assessment tool were developed based on standard documents (e.g.: the FDA HF guidance and the PMBOK Guide). The items used to assess PM maturity are standard PM practices well described in the PMBOK Guide (see the selected PM process outputs in section 4.2.6.3). Also, the HFE Dimension was shaped based on the corresponding FDA HF guidance and expert feedback.

Furthermore, we already know that the selected PM practices (process outputs) are related to PM Process Groups and how they related (as per the PMBOK). Conducting an EFA would not lead to eliminating items (we cannot change the fact that for instance, "Planning" is always part of any project and the expected outputs are known). For that reason, it can be said that there is enough theoretical knowledge about the constructs and the inter-items relationship in the instrument (Suhr, 2006; Thompson, 2004).

Consequently, in this case, a confirmatory factor analysis (CFA) would be the rule of thumb, as it can help find a model that describes the latent constructs of the data. While the sample size is not ideal to test a full model that includes all the variables, a CFA was attempted using Factor Analysis with Principal Component Analysis (PCA), which would be an analysis of the "Principal Factors". The author believes this approach can provide enough insight regarding the underlying constructs of the HFSP-MAT with the available data.

4.4.4.2 Principal Factor Analysis

While it is the idea that the variables are correlated, it is also important to identify the main components. Doing so will help answer the research question regarding the ideal maturity level (which will close this analysis). In that sense, Principal Component (PCA) is a dimensionality reduction technique that can help eliminate unclear variables during analysis (Sharma, 1996; Widaman, 1993). When used in combination with Factor Analysis, is it is considered a "Principal Factor Analysis" (Suhr, 2005).

In order to conduct PCA, fewer variables need to be included as to improve the MSA value (see Table 4.40). Likewise, several authors have demonstrated that if large loadings are chosen (e.g.: 0.50 is considered large enough) with at least 3 variables in each component, the findings are reliable even with a small sample size (de Winter et al., 2009; Thompson, 2004).

Table 4.40: MSA results using fewer variables for PCA

KMO and Bartlett's Test		
Kaiser-Meyer-Olkin Measure of Sampling Adequacy.		0.612
Bartlett's Test of Sphericity	Approx. Chi-Square	157.278
	Df	45
	Sig.	0.000

The High-Level Components of the HFSP-MAT

PCA was conducted using only the high-level components of the HFE Dimension and the PM Knowledge Areas. Three principal components are automatically retained as per the Eigenvalue greater than 1, which can explain 80% of the variance (Table 4.41).

Table 4.42 is showing the components of PCA organized from largest to smallest. Component 1 consists of mainly large loadings for the HFE Dimension, and smaller

loadings for the PM Knowledge Areas (except for Risk Management). Likewise, Component 2 does not have many high loadings but the higher ones show a pattern of a slight difference between the two dimensions, since it is more correlated to the PM Dimension while negatively correlated to the HFE Dimension (maybe pointing to the different purpose of each dimension). Component 3 does not account for a lot of the variance, but shows the same pattern as Component 2 (a slight difference between the items of the two represented dimensions).

Table 4.41: Initial Eigenvalues and total variance explained for the PCA

Component	Initial Eigenvalues			Extraction Sums of Squared Loadings		
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1.0	9.4	62.9	62.9	9.4	62.9	62.9
2.0	1.5	10.3	73.2	1.5	10.3	73.2
3.0	**1.0**	**6.8**	**80.0**	**1.0**	**6.8**	**80.0**

Table 4.42: Components loadings PCA PM Knowledge Areas and HFE Dimension

	Component		
	1	2	3
Planning & Doc	0.96		0.12
Timing & Integration	0.93	-0.19	0.21
Tools & Methodology	0.92	-0.17	
People	0.91		
Risk	0.91	-0.16	0.15
Comm. & Rep.	0.87	-0.39	
Scope	0.87	0.21	-0.15
Procurement	0.79		
Quality	0.77	0.36	-0.22
Resource	0.77	0.12	-0.48
Integration	0.73	-0.30	
Stakeholders	0.66	0.59	-0.21
Communications	0.61	-0.50	
Cost	0.38	0.61	0.19
Schedule	0.57	0.23	0.73

Extraction Method: PCA
a. 3 components extracted.

Since Component 1 contains all variables with significant loadings (hard to interpret), Equamax rotation is used with the 3 components to try to find optimal loadings of both variables and components (Stevens, 1992). The results are shown on Table 4.43, where loadings with absolute values smaller than 0.50 have been eliminated. In this case, after rotation, we can continue referring to the components as "components" (Suhr, 2005).

Table 4.43: Rotated components of PM Knowledge Areas(bold) and HFE Dimension

	Component		
	1	2	3
Comm. & Rep.	0.88		
Communications	0.78		
Tools & Methodology	0.76		
Timing & Integration	**0.76**		**0.52**
Risk	**0.73**		
Integration	0.73		
Planning & Doc	0.72		
People	0.59	**0.53**	
Stakeholders		**0.85**	
Quality		0.78	
Resource		**0.78**	
Scope		0.71	
Procurement			
Schedule			**0.94**
Cost			0.53

Extraction Method: PCA, Rotation
Method: Equamax with Kaiser Normalization.

While Component 1 is loading the full HFE Dimension with the largest numbers, the pattern seems to illustrate how the PM Dimension supports the HFE Dimension (main component), considering the highest loadings, we can describe the following:

- **Component 1**: PM Knowledge Areas that support the HFE Dimension as a whole (let us shorten this to: "PMKA for HFD"), and these are: Communications Management, Risk Management, and Integration Management.
- **Component 2**: shows how PM Knowledge Areas support the HFE Dimension's category "People" (e.g.: Resource Management, Stakeholders Management). This will be "PMKA for People").

- **Component 3**: similarly, this shows that "Timing & Integration" is supported by the PM Knowledge Area "Schedule Management". This will be called "PMKA for T&I."

After understanding this pattern, it was interesting to check how the loadings of the identified PM Knowledge Areas in relation with the PM Process Groups (Initiating, Planning, Executing, M&C, and Closing). The scores of each component were saved to obtain the correlation matrix (see Table 4.44). As it can be noticed, these components are not correlated, which is intended to improve interpretation.

Table 4.44: Correlation matrix using the 3 variables created from the Principal Factor Analysis

	1	2	3	4	5	**6**	**7**	**8**
1. Initiating	1.00	0.70	0.43	0.66	0.64	0.49	0.52	0.42
		0.01	0.13	0.01	0.01	0.07	0.05	0.14
2. Planning	0.70	1.00	0.40	0.35	0.56	**0.68**	0.31	**0.57**
	0.01		0.16	0.22	0.04	0.01	0.28	0.03
3. Executing	0.43	0.40	1.00	0.56	0.37	0.22	**0.70**	0.13
	0.13	0.16		0.04	0.20	0.46	0.01	0.66
4. **M&C**	0.66	0.35	0.56	1.00	0.53	0.39	**0.78**	-0.07
	0.01	0.22	0.04		0.05	0.17	0.00	0.82
5. Closing	0.64	0.56	0.37	0.53	1.00	0.51	0.39	0.20
	0.01	0.04	0.20	0.05		0.06	0.16	0.50
6. PMKAd4HFD	0.49	0.68	0.22	0.39	0.51	1.00	0.00	0.00
	0.07	0.01	0.46	0.17	0.06		1.00	1.00
7. PMKA4P	0.52	0.31	0.70	0.78	0.39	0.00	1.00	0.00
	0.05	0.28	0.01	0.00	0.16	1.00		1.00
8. PMKA4TnI	0.42	0.57	0.13	-0.07	0.20	0.00	0.00	1.00
	0.14	0.03	0.66	0.82	0.50	1.00	1.00	

Component 1 "**PMKAd4HFD**" ("PM Knowledge Areas for the HFE Dimension, that is: combination of key PM Knowledge Areas that support the HFE Dimension as a whole) is significantly correlated with the PM Process Group "Planning." Component 2 "**PMKA4P"** (PM Knowledge Areas for the subcategory "People" of the HFE

Dimension) most significantly correlates with the "Monitoring & Controlling" and "Executing" Process Group. Component 3 "**PMKA4TnI"**, the PM Knowledge Areas that most support "Timing & Integration" are most highly correlated with "Planning" Process Group. From this, we can see that the most significant PM Knowledge Areas supporting the HFE Dimension, are the ones used during project *planning*, as it is significant for two of the components.

4.4.4.3 PM Process Groups and the Categories of the HFE Dimension

The same procedure was followed now using the PM Process Groups (instead of the PM Knowledge Areas). Two components are automatically retained which can explain 80% of the variance (see Table 4.45).

Table 4.45: PCA of the PM Process Groups and the high-level categories of the HFE Dimension

	Component	
	1	2
Planning & Doc	.971	
Timing & Integration	.940	-.255
Tools & Methodology	.937	
People	.903	-.182
Comm. & Rep.	.898	-.215
Planning	.896	-.337
Initiating	.822	.174
Closing	.684	.251
M&C	.683	.573
Executing	.587	.566

Extraction Method: Principal Component Analysis.
a. 2 components extracted.

The first component is loading all HFE Dimension categories first, and second is the PM Process Groups (supporting role). Component 2 is most related to PM Dimension. Since both components are loading almost all the variables, Varimax is used for rotation to maximize variance (Kaiser, 1958). Showing on Table 4.46, the HFE

Dimension is fully loading in Component 1, and "Planning" from the PM progress groups.

Table 4.46: Rotated Component Matrix

	Component	
	1	2
Planning	.936	
Timing & Integration	.928	
Comm. & Rep.	.872	
People	.858	
Planning & Doc	.849	
Tools & Methodology	.832	
Initiating		
M&C		.851
Executing		.794
Closing		

Extraction Method: Principal Component Analysis.
Rotation Method: Varimax with Kaiser Normalization.
a. Rotation converged in 3 iterations.

In line with the pattern from the previous analysis, Component 1 confirms that "Planning" (in bold) is an essential supporting component for the HFE Dimension, as it is very correlated with its items (italicized). The second component can lead us to know that if we were to continue with this pattern, there must be other items from the HFE Dimension it relates to (but not loading high enough). However, we learned about the correlation of Executing and M&C when looking at Table 4.44. Overall, this analysis can be summarized as shown on next on Table 4.47.

Table 4.47: Summary of the PCA analysis

	PM Process Group	**PM Knowledge Area**	**For**
Comp 1	Planning	Communications Mgmt., Risk Mgmt. and Integration Mgmt.	HFE Dimension
Comp 2	Executing, M&C	Resource Mgmt., Stakeholders Mgmt., Quality Mgmt., Scope Mgmt.	People
Comp 3	Planning	Schedule Mgmt., Cost Mgmt.,	Timing & Integration

4.4.4.4 Confirmatory Factor Analysis

CFA was conducted using AMOS (SPSS). The variables in the three components identified in the previous analysis were used (Table 4.46). A first attempt returned an error as the number of variables were still too many in relation with the sample size. Thus, only Component 2 (PM Knowledge Areas for "People") and Component 3 (PM Knowledge Areas for "Timing & Integration") were used. The PM Knowledge Area "Cost Management" was deleted from "PM Knowledge Areas for Timing & Integration" as the loading was not high enough.

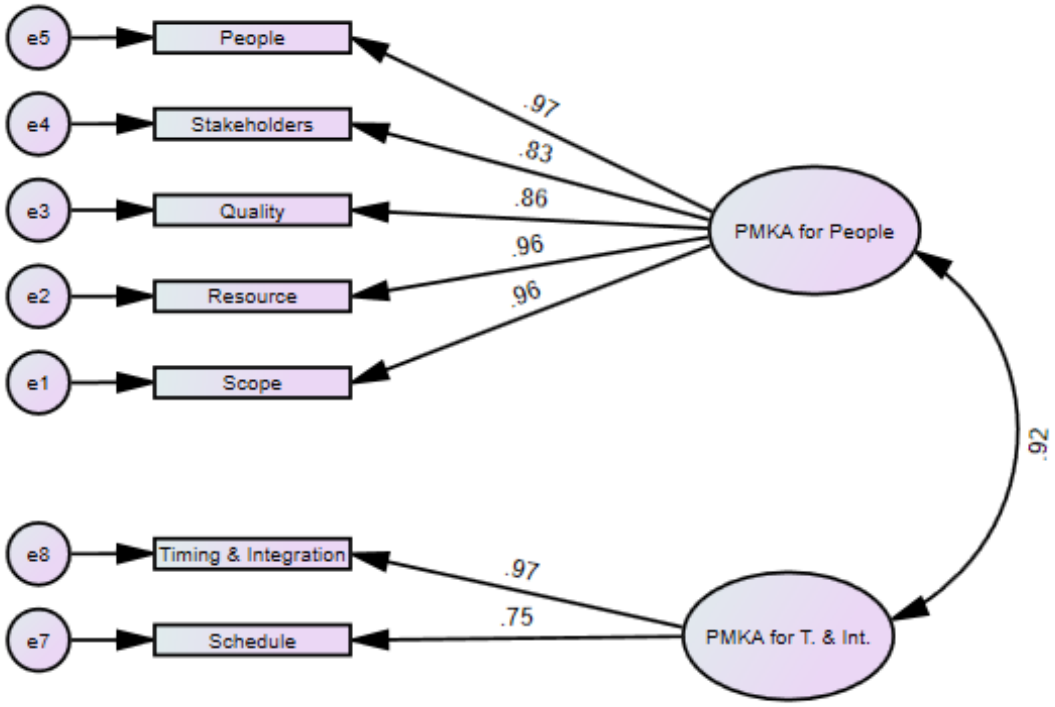


Figure 4.29: Diagram of the two principal factors model for CFA created using SPSS® Amos

After optimizing, the final two factors model is shown on Figure 4.29. The model is useful to explain two principal underlying factors (PM Knowledge Areas for the HFE Dimension category "People" and "M Knowledge Areas for the HFE Dimension

category Timing & Integration"), with excellent statistics: $\chi 2$ (13, N=14) =10.76, p=0.63. Considering that the p-value is non-significant, the model is an excellent fit for the data. That is confirmed by a low RMR = 0.034 and RMSEA = 0.000.

At this time, we were able to confirm the PM Knowledge Areas that support certain categories or factors for success of the HFE dimension. With that, we could explain the main construct of the model, which is that the HFSP-MAT involves two dimensions (the PM Dimension which supports the HFE Dimension). Overall, with a larger sample, it is likely we would be able to build a full model that describes how the different PM Knowledge Areas and the corresponding PM Process Groups, support each category of the HFE Dimension.

4.4.5 What Would be the Adequate Maturity Level for this Industry?

4.4.5.1 The State of 'Generic PM Maturity' Across Industries

According to related research on the global state of "generic" PM maturity, a significant increase has been observed in the last decade. Back in 2004, a global survey by PricewaterhouseCoopers LLP reported that the average PM maturity level was 2.6, conveying a lack of standardization of PM processes (PwC, 2012), and most organizations were between level 1 and Level 3 (in a 5 point-scale aligned to CMMI). The same survey was conducted in 2012 and found 65% of organizations at levels 4 and 5. That is, PM processes already standardized, while measuring and optimizing PM practices (PwC, 2012).

In a more recent study by PM Solutions (PM Solutions, 2014), the reported results confirmed the same trend, and 76% of organizations had improved their PM maturity

level shifting from Level 1 to Level 2 (33%). Likewise, most of the organizations were at Level 3 (PM Solutions, 2014). The use of PM model has surely contributed to such improvements. Companies are implementing and using more PM technologies and tools, to mature their PM practices. Now more than before it has been recognized that sophistication in PM is directly related to high performance and project success for the organization (PM Solutions, 2014; PMI, 2018, 2020; PwC, 2012; Silvius & Karayaz, 2018).

4.4.5.2 Industry-Focused PM Maturity (Focusing on what Matters)

Although organizations are more than ever determined to achieve optimum PM maturity level, it has been also recognized that PM needs vary across industries and organizations (Müller & Turner, 2007; Project Management Institute, 2017; PwC, 2012). The same could be said about PM maturity, it is directly related with the PM needs of the organization, thus it will vary as well across industries. Consequently, it is possible to discuss the same regarding HFSPs, now that the results of this research have helped us understand HF validation projects within the context of FDA requirement for medical devices and combination products.

Crawford (2006), recommends that each organization should determine at which level it is achieving the desired value whether in satisfying clients or ROI. As remarked by Kerzner (2017), another perspective is by identifying the essential PM Knowledge Areas for the business. For instance, a company dealing with many suppliers in order to deliver projects, might need a high maturity in the Procurement Management Knowledge Area, whereas a lower maturity in a different Knowledge Area might not impact the organization as much as low maturity in Procurement Management. For instance, IT

organizations tend to have high PM maturity in Integration Management (PM Solutions, 2014), because IT projects usually comprise multidisciplinary teams with different workstreams and competing interests, where integration management plays an essential role for project success. In that same line, the following are industry-focused PM maturity needs for HFSPs.

4.4.5.3 Using the Components of each Dimension to Develop Key Processes and Metrics

From the findings of this research, Level 2 ("Childhood") is the average level, which corresponds to a need for standardization. It seems HFSPs are currently dealing with too much variation. To achieve more consistent results, HFSPs should strive to develop and standardize processes (Level 3 – Adolescence) and place focus key components of each dimension (see Chapter 4.4.4.2), which were identified as principal factors:

- PM Knowledge Areas to support the HFE Dimension: Communications Management, Risk Management, and Integration Management.
- Essential HFE Dimension categories to pay attention to: "People" and "Timing & Integration."
    - Specific PM Knowledge Areas that can support the HFE key factor for success "People": Resource Management, Stakeholders Management.
    - Specific PM Knowledge Areas to support "Timing & Integration": Schedule Management".
- One essential PM Process Group: Planning.

That means, while all the components of the HFSP-MAT are key factors for success, just as the example of the software development industry (which requires high maturity in "Integration Management" due the nature of such projects), these are areas

that an HFSPs cannot neglect and should try to standardize at a minimum. Processes and policies corresponding to the outputs of the HFSP-MAT should be put in place, and by doing so (standardizing) an HFSPs would be at Level 3.

4.4.5.4 Developing Maturity Beyond Needs – A Competitive Advantage

While organizations want to achieve high maturity levels, that requires investments such as in HR and quality assurance (PwC, 2012). The required investments might force some organizations to stay at a minimum required level. However, as explained so far, the general trend is that organizations are increasingly working towards higher levels of PM maturity, where optimizing (Level 4 – Adulthood "benchmarking") and innovating (Level 5 – Maturity "giving back") are no longer optional, but mandatory in order to stay competitive. Moreover, while HFSPs are not yet experiencing the impact of the QSR, as critical suppliers, it is only a matter of time before they are demanded measures of excellence to stay in the game.

Ideally, HFSPs should use all the components of the HFSP-MAT to develop not only processes and policies that ensure standardization (Level 3), but also metrics that help measure and control performance according to established goals (Level 4). The HFE Dimension contains the direction for HFSPs to develop critical metrics, and ensuring that key factors for success of FDA HF validation projects are implemented and controlled. For example, metrics relative to the "People" categories would include having an established process and policies to understand and meet the needs of the project regarding people's qualifications, roles, responsibilities One essential source for that purpose is the PMBOK Guide, and that is why the HFE Dimension is mapped with essential PM Process Groups outputs. However, the HFSPs are not limited to the

PMBOK, other resources can be used to implement, measure and control the HFE Dimension's key factors for successes.

4.4.6 Participants Feedback After Testing the Tool

After testing the tool, participants were asked to answer a short survey to provide feedback, which consisted of five criteria relevant to use of maturity models (2.5.11) to be rated about the tool on a Likert-scale of 1 to 5 (Appendix K). The results are shown on Figure 4.30.

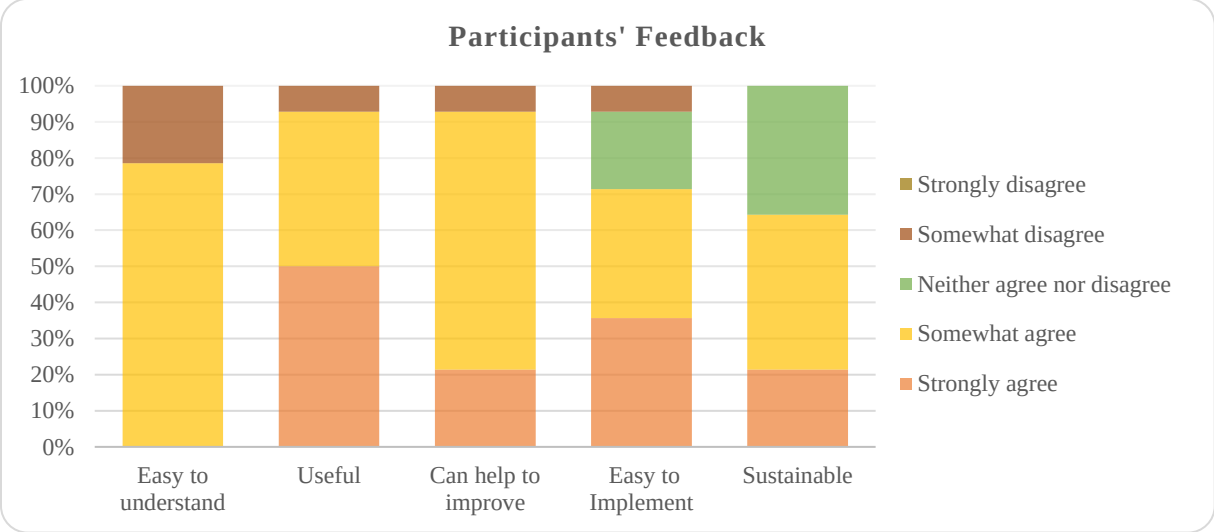


Figure 4.30: Results of how participants (N=14) rated the tool on a Likert-Scale of 1 to 5.

Table 4.48: Participants'' feedback after testing the tool (Likert-Scale 1-5, 5 = highest rating)

Criteria	Mean	SD	Max	Min
Easy to understand	3.57	0.85	4	2
Useful	4.36	0.84	5	2
Can help us improve	4.07	0.73	5	2
Easy to Implement	4.00	0.96	5	2
Sustainable	3.86	0.77	5	3
Average	**3.97**			

Table 4.48 shows the total average score, which was 3.97 out of a Liker-scale of 1 to 5, and can be translated as an overall feedback of "Somewhat Agree." Likewise, participants were asked if they had suggestions to improve the tool.

Also, from the total number of participants which completed the testing phase (N=14), six participants provided additional comments by answering the open-ended question which requested so (comments are shown on Table 4.49). Likewise, discussion on these comments is next.

Table 4.49: Participants' feedback: Do you have any suggestions to improve the tool? (n=6)

Comments/Feedback After Testing the HFSP-MAT
• "I believe the user should have the option to select not applicable and skip a question."
• "The survey questions were somewhat difficult to read and follow - recommend at least removing the box outline from the topic (boxes around ABCDE responses may be fine) and left-justifying all text. Also, any way to simplify or shorten the ABCDE responses? I would think maintaining a directory will be effort-intensive & difficult to assess accuracy/truth in self-reported capabilities; although latter may not matter."
• "When entering the address, the drop-down box for state should be in alphabetical order to make it easier to find. Also provide the ability to select more than one category--for example, we procure services for both a medical device combo product for bio and drugs."
• "Here are few things to consider: * Concepts in the HFSP-MAT seem applicable to manufacturers that use HFSPs and not the HFSP. * Better definition of "HF validation project". Is it the HF validation study and what is needed to make it successful or is it the whole product development project for a product that requires a HF validation? * for the 53 criteria, use screen to show the "dimensional" context instead of the 5 rating levels that do not change * suggest not using "infant", "child" analogy - My manager is not a HFE person and I think he would find it odd to be told that his organization has the maturity level of a 'child'."

• "1. Each of the 53 questions covers a specific area. It would be useful for each of the 53 areas to have more descriptive info for those who need it. Or maybe I missed it. 2. Not sure I understood the improvement recommendations. Needed to have more detail."
• " It was tedious to hover over each item to see its definition, show definitions by default - Remove the ""A subset of the X category"" text from each description and just list the category as a header for faster reading - The 5 options didn't seem to apply to each practice, (i.e., some don't make sense to quantify) - Avoid use of abbreviations for clarity (e.g. ""dev"") - An interesting and helpful tool! I learned a lot taking it."

4.4.6.1 About Participants' Comments

As shown Figure 4.30, the majority of participants found the tool easy to understand (79%) and useful (43% "Somewhat Agree" while 50% "Strongly Agree") help them improve their FDA HF validation projects (71% "Somewhat Agree" and 21% "Strongly Agree").

However, participants lacked experience with a maturity model. Having no point of reference to compare, could also translate into an inability to value/see how the tool can help its stakeholders. Therefore, some participants were neutral (36%) about how sustainable the tool would be. The corresponding industry is not familiar with maturity assessments or any kind of process quality improvement tool for HF validation projects within the context of FDA approval.

For instance, most of the models available (some described in Chapter 2.4), besides not being industry-focused, are extremely complex to understand, entailing hundreds of questions, and requiring training prior to implementing. Other limitations of maturity assessment tools in the market are high-cost and third-party managed, which would be reasons to make a maturity model difficult implement and sustain.

Similarly, two participants had the notion that some the practices did not apply to them For that reason, one suggested adding "N/A" to the five available responses in the assessment (see Chapter 4.3.5). In this case, the tool is carefully using the applicable PM practices that can support the HFE Dimension. The "N/A" option would contradict the essence of the tool (industry-focused, which means the practices to apply to the industry) and the assessment would not distinguish areas of improvement if they can only select the ones they understand and which they have already optimized. It is not the goal to avoid that the user runs into practices the organization has not applied. Instead of the notion that "this practice does not apply to me" an HFSP using the assessment should select the first option (out of the five provided), which means the practice is informal or not recognized at all. Of course, choosing that option probably makes the user uncomfortable, but the goal is to improve.

Another participant suggested not using "infant" or "child" analogies regarding each level because an HFSP would be put-off or management would not be happy by knowing they have an "Infant" or "Child" maturity level. While such analogies to remark what each level means are common – e.g.: Kerzner's, uses analogy of human physical development such as "Embryonic" within his sublevels of PM life cycle (H. R. Kerzner, 2005), it is actually good that management would react negatively to a low level of maturity ("Infancy") and they would want to advance to "Adulthood" or "Maturity." This could have a positive effect on getting support from management who obviously will not want to view themselves as "infants" in doing FDA HF validation projects, but will push harder towards improvement.

Participants could have been expected too much from a self-assessment. For instance, regarding report that is automatically generated after submitting the assessment, one participant expected more details. Usually, self-assessment can only provide limited feedback and a more direct look into the situation of the organization would be needed for personalized and detailed report. That is probably the reason most maturity assessment models only provide the numeric results (average maturity level or percentage achieved for each level). In this case, the report of the HFSP-MAT goes further and describes the current maturity level for dimensions (HFE and the PM Dimension) including each subcategory (see Figure 4.25 and Figure 4.30 and). It also provides the logical next steps to get to the next level. With that information, the organization is responsible for the development of a plan to improve based on strategic goals and areas of improvements detailed on the report.

Another example reflective of the participants' expectations is the directory, meant to provide a forum for quality-oriented stakeholders. It is a fact that HFSPs can promote and advertise themselves as having a higher maturity level than they actually do. As in any other kind setting, the procurers of HF services are responsible for ensuring they are partnering with providers that can deliver as advertised. That could be achieved through multiple strategies (e.g.: auditing the HFSP based on the components of HFSP-MAT, either directly or through third-parties). However, currently, such strategies are out of the scope of this research.

In general, after testing the tool, participants recognized it as useful. Some of them provided observations about the online interface, e.g.: position and organization of

the items, how the descriptions are shown during the assessment, etc., which will be considered before deployment of the site.

4.5 Summary of Chapter 4

This chapter consisted of presenting the results of the two phases comprising the methodology outlined in Chapter 3, with focus on answering the research questions. Phase I (a survey), helped understand FDA HF validation projects and characteristics, including main challenges, reason for failure and key factors for success. Overall, the survey indicated that formal PM was scarce and challenges and reason for failure could all be improved with better PM. In Phase II, Part 1, de Bruin's framework to develop maturity models was executed, involving a detail process to develop the content of the tool ("Populate") with the help of a panel of experts (Delphi Panel). The resulting content was based on the FDA HF guidance document, the IEC 62366-1 and the PMBOK Guide. Last, in Part 2 of Phase II the resulting tool was tested and the remaining research questions about the average maturity level were answered.

Chapter 5 Conclusion & Future Research

5.1.1 Contributions of this Research

This novel exploratory research started with a main objective, the develop an industry-focused maturity assessment tool as a way of helping measure capabilities of HFSP in the delivery of FDA HF validation projects. At the same time and to accomplish the previous, this dissertation also set out to explore and understand FDA HF validation projects. Considering that research of this kind is relatively new, in addition to the provision of some directions for further research, my work has made three significant contributions to the literature on HF validations for medical devices that seek FDA approval:

1. Identification of important areas of improvements, including delineation of key factors for success in the delivery of HF validation projects that seek FDA approval, which can be the foundation for further research.
2. Industry-focused validated constructs based on applicable standards, that industry can use to develop processes, policies, procedures and metrics for success in FDA HF validations.
3. A usable, implementable and sustainable tool is now available to measure maturity and help develop improvement plans for stakeholders of FDA HF validation projects.

In general, besides the tool, this work contributes literature about the current practices and factors that influence the quality and success of HF validation projects of medical devices and combination projects that seek FDA's approval. In this research the HFE Dimension was developed as part of an industry-focused PM maturity assessment tool. The existing FDA HF guidance as well as applicable international HF standards were considered in the identification of key PM factors or practices for success. The following is a summary outlining each one of the key findings. Afterwards, the focus is on the initial research questions and objectives.

5.1.2 Summary of Key Findings

5.1.2.1 Phase I: Understand FDA HF Validation Projects (Survey)

Within this specific context, the use of formal PM methodology is limited, and improvised. HFE personnel or senior management is doing most of the PM work. In the same vein, up to 50% of HFSPs (agency/consulting firms) do not have a QS in place and no plans to implement one. There also seems to be overwork in relation to the amount of PM and the HFE work. Issues with quality that lead to project failure should not be surprising, considering the lack of formal PM skills combined with overwork (HFE personnel already having the HFE work to do). Reasons for failing the validations, challenges and factors for success were identified. It is very likely that careful PM of HF validations could avoid the stated challenges and issues.

5.1.2.2 Phase II, part 1: Developing the Tool (Delphi Panel)

The Delphi technique, a consensus development approach ideal for topics where there is very limited or imprecise research, was applied with the help of a panel of experts

on the topic. The goal was to determine the content to populate the model and the focus was on key factors for success in FDA HF validation projects. The process also made use of relevant standards such as the PMBOK® concerning the PM Dimension, and the FDA's HF guidance plus the international HFE standard IEC-62366-1 for the HFE Dimension. The resulting themes or categories define the design of the model and populate the tool, with the 2 high-level dimensions. The high-level themes for the HFE Dimension encompass the key practices for quality and success of FDA HF validation projects, and these are: **Planning & Documenting** (what to document and how to document), **Timing and Integration** (when to start the HF work, as well as integration with key aspects such as product design and development and FDA guidelines), **Tools and Methodology (**e.g.: appropriateness and effectiveness), **People** (qualifications and must-haves) and **Reporting Results** (e.g.: presentation, format, language). For the PM Dimension, carefully selected practices are part of the tool (based on process outputs) from the PMBOK® that can ensure the successful implementation of the outlined HFE Dimension.

5.1.2.3 Phase II, Part 2: Overview and Testing of the Tool

In this section, an overview of the beta tool "Human Factors Service Providers Maturity Assessment Tool" (HFSP-MAT) was presented, including the online website. The goal of this second part of Phase I, is to test the described tool and provide light regarding the average maturity level, as well as the ideal maturity level for this industry (remaining research questions). In that sense, the collected data were analyzed and checked for reliability and validity, which included Confirmatory Factor Analysis (CFA). The remaining research questions were answered. The resulting average "Total Maturity

Level" was 2.65, which corresponds to Level 2 – Childhood, and indicates a lack of standardization of the practices assessed. The ideal level of maturity, considering literature about PM maturity trends, should be Level 3 – Adulthood, which means practices are standardized, at least in the principal components of the tool which mainly pointed to the "Planning" Process Groups, as most important to enable the HFE Dimension (Planning & Doc, Tools & Methodology, People, Communicating and Reporting, Timing & Integration). These categories can help determine specific metrics for HFSPs to improve the quality and success of their FDA HF validation projects. In general, after testing the tool, participants recognized it as useful. The collected suggestions to improve the tool consisted on recommendations about the look, position, organization of the items and descriptions in the assessment. All feasible suggestions will be considered before deployment of the site.

5.1.3 The Research Questions

The research questions this work set out to answer are summarized below, including interesting findings, are the following:

1. Is PM being applied to manage FDA HF validation projects?
2. What are the main challenges?
3. Why do these projects fail?
4. What are the drivers (critical factors) for success?
5. What is the average maturity level?
6. What is the ideal/adequate PM maturity level for this industry (HFSPs)?

5.1.3.1 Is PM Being Applied to Manage FDA HF Validation Projects?

This question was addressed in Chapter 4, section 4.1.3, as a result the survey in Phase I of this research. In summary, it was found that the use of PM methods/tools is

rather scarce and more formal application to manage their FDA HF validation project, would probably result in significant improvements. In general, 50% of participants said their organizations were using some PM method or tool, but this could be labeled as 'impromptu PM" because such work is not actually done by actual PM professionals but the same HFE personnel. In the same vein, up to 50% agencies/consultancy firms do not have a quality system (QS) in place and further indicated they had no plans to implement one.

5.1.3.2 What are the Main Challenges?

This question was addressed in Chapter 4, section 4.1.4 and 4.1.3 , as a result the survey in Phase I of this research. After coding and summarizing participant's responses to this question, it was found that some of the main challenges HFSPs face, among others issues are the following:

- Sponsors' unrealistic demands
- FDA's seemingly unreasonable demands and timelines
- Access to representative users
- Coordinating with sponsors
- FDA's (reviewers) inconsistencies/lack of HFE knowledge
- Late integration of HFE in product development
- Lack of sponsors commitment/awareness
- FDA's requests for changes to labeling/IFU (instructions for use)
- Difficulties agreeing with the FDA about approach to training (participants)

5.1.3.3 Why do These Projects Fail?

This question was addressed as part of the survey in Phase I, section 0. When asked how often their FDA HF validation projects fail, 30% of manufacturing organizations said they "never" fail, 10% said "most of the time" and 60% said

"sometimes." As per 40% of agency/consultancy firms, failed HF validations do not happen to them, while 60% indicated they "sometimes" do fail. Those who provided the reasons for failure, indicated failing is mostly due to the following:

- Need for clarifications/details
- Inappropriate training approach
- Incorrect critical tasks/risk analysis
- Inappropriate/missing user groups
- Issues with the protocol/methodology
- Additional data or need for retesting
- Need to change product design, and
- Need to change labeling/IFU (instructions for use)

The following are also interesting findings that complement the challenges and reasons for failure:

Issues meeting project schedule, budget and scope. Also, running behind schedule seems to be a general issue among those surveyed. All manufacturing organizations indicated they usually run behind schedule, in contrast with 70% of agency/consultancy firms. Although not as drastic, similar results were found regarding project budget and scope.

Lack of formative studies as part of HF validation plan. Another interesting finding is that the formative studies are not considered a standard and essential part of the HF validation, more so at manufacturing organizations, where only 40% said they consistently conduct formative studies (Table 4.11). While the formative studies are meant to inform the design of the product, and the HF validation is the summative usability study (Kortum, 2016), formative usability studies are a *required basis* for a successful HF validation project.

Denial about project failure. Although 60% of the participating organizations confirmed that they "sometimes" get their HF validation submissions rejected by the FDA, there could be more behind the fact that some respondents (35%) denied ever failing (see Figure 4.5). It is simply a matter of perspective, issues such as having to do extra work to re-deliver an HF validation is not considered a failure by HFSPs, or even by the FDA (Rojas, et al., 2019). On the other hand, the regulatory aspect of these projects, could be a reason for stakeholders to be in defensive mode about failure. However, the previous is inconsistent with the persisting concerns about the HF review process (see chapters 1 and 2) and FDA's statistics on the topic. In 2019, during the HFES Healthcare Symposium, the FDA released relevant statistics revealing failure rates of more than 90% in HF validations submissions (Wiyor et al., 2019). As discussed in previous work (Rojas, et al., 2019), "failure to recognized failure" is a blocking stone in the road to improvement.

Overwork and lack of formal PM. On the other hand, it is important to note that most of the organizations reported they assign 2 to 3 projects per employee. Similarly, a minimum of 5 to 10 hours weekly are spent *per project* on PM tasks, which may add up to at least 30 hours weekly on PM tasks, prompting the question: what happens to the HFE work? Issues with quality that lead to project failure should not be surprising, considering the lack of formal PM skills combined with overwork. In such situation, there is ample room for issues not only with quality, but with integration, communication, scheduling, etc. (key Knowledge Areas in PM).

Improvisation in conducting FDA HF validation projects could have a direct impact on project quality and success. With that said, from a continuous improvement

point of view, HFSPs have much to explode from the use of PM to increase quality and hence, success in the delivery of FDA HF validation projects. The use of the HFSP-MAT could help to identify areas of improvement and serves as guide in the application of industry-focused PM practices.

In fact, from those organization not using a PM methodology or tool, only 25% considered themselves "much more successful" than competitors (having their validations approved by the FDA). In contrast, up to 50% of the participants who had indicated their organizations do use a PM methodology/tool considered themselves to be "much more successful." Also, those who said they use PM seemed to do much better (vs. those who do not) when it comes to having their submissions failed by the FDA (see Table 4.19).

5.1.3.4 What are the Drivers (Critical Factors) for Success?

This question was addressed as part of the survey of Phase I (see section c)). There were three questions in the survey intended to identify critical factors for success, as follows: a) What are the key factors for success working with sponsors (asked only to HFSPs)? b) What are the factors considered by procurers in selecting HFSPs (asked only to procurers)? And in general, c) what are the key factors for success? (Asked to all). Whereas the specific results from these three questions were presented in section 4.1.6, the general themes in the identification of factors for success considering the corresponding questions, could be grouped as referring to:

- People's roles and qualifications,
- Accurate planning,
- Mindfulness about FDA's expectations and use of resources

- Communicating with stakeholders and engaging sponsors, and
- Thoroughness/completeness in all HFE work

Consolidating the Critical Factors for Success (Delphi Panel, Phase II, Part 1)

Likewise, the findings from Phase II, helped consolidate the key factors for success in FDA HF validation projects found during Phase I (survey). Thee critical factors for success are the core components the HFE Dimension, described in detail in sections 4.2.5 and 4.3.2.

5.1.3.5 What is the Average Maturity Level?

This question was addressed as Part 2 of Phase II, after developing the tool (see section 0). Upon testing the tool and analyzing the results, the average Total Maturity of participating organizations was **2.65**, which corresponds to the "Level 2 – Childhood – Variation" (see Table 4.32, description of maturity levels as per the HFSP-MAT). The Level 2 of the HFSP-MAT implies a lack of standardization of the assessed practices (see Chapter section 4.3.5 about levels and their descriptions). In the PM Dimension, the lowest average score is found in "Closing" processes while the highest average score is found in "Executing" process (which is shown on Figure 4.28). The PM Knowledge Area with the lowest score is "Stakeholders Management" while the highest average score corresponds to the "Schedule Management" Knowledge Area (see

Table 4.36). In the HFE Dimension, the best performance was found in "Product D&D Milestones" (2.86), a subcategory of "Timing & Integration." The lowest average

score is 2.43 in “Reliability of Tools & Methods” and pertains to the “Tools & Methodology” category (see Figure 4.27.)

5.1.3.6 What is the Ideal PM Maturity Level for this Industry (HFSPs)?

This question was addressed as Part 2 of Phase II (see section 5.1.3.6). This question was answered considering, both data analysis from testing the tool as well as applicable literature regarding the trends in PM maturity in general. Thus, from the findings of this research, HFSPs are currently dealing with too much variation (see 5.1.3.6), as it was identified the average maturity to be at Level 2 (“Childhood”), which corresponds to a need for standardization. To achieve more consistent results (and get to Level 3 – Adolescence), HFSPs should strive to develop and standardize processes by focusing at least on the essential components of each dimension of the HFSP-MAT. Such components were identified during the PCA (see Chapter 4.4.4.2), indicating that following areas accounted for the most variation and thus have the highest impact:

- Essential PM Knowledge Areas to support the HFE Dimension: Communications Management, Risk Management, and Integration Management.
- Essential HFE Dimension categories to pay attention to: “People” and “Timing & Integration.”
    - Specific PM Knowledge Areas that support the “People” category: Resource Management, Stakeholders Management).
    - Specific PM Knowledge Areas that support “Timing & Integration”: Schedule Management”.
- Essential PM Process Group overall: **Planning**.

5.1.4 PM Maturity Above and Beyond – Mandatory to Stay Competitive

Organizations are always interested in developing maturity, but one limitation has to do with the investments it might require. Research indicates that developing PM maturity demands investments in HR and quality assurance (PwC, 2012). The required investments might force some organizations to stay at a minimum level. However, as explained so far, the general trend is that organizations are increasingly working towards higher levels of PM maturity, where optimizing (Level 4 – Adulthood "benchmarking") and innovating (Level 5 – Maturity "giving back") are no longer optional, but mandatory in order to stay competitive.

Ideally, HFSPs should also use all the components of the HFSP-MAT to develop not only processes and policies that ensure standardization, but also metrics that help measure and control performance according to established goals (that would place a HFSP at Level 4 – Adulthood). The HFE Dimension contains the direction for HFSPs to develop critical metrics, and ensuring that key factors for success of FDA HF validation projects are applied.

5.1.5 The Advantages of the Tool

The HFSP-MAT aims to specifically assess the capability of an HFSP to deliver FDA human factors (HF) validation projects successfully. HFSPs can be internal or external partners (that is, a department unit or an agency/consultancy firm). The assessment tool is based on established standards and guidelines (e.g., PMBOK®, FDA's HF guidance) as well as specific FDA HF validation project success factors that have been identified through research. At the same time, it offers an online platform with complementary resources (publications, directory, discussions/Q&A…) for the medical

device and combination products HFE community. This platform can also help manufacturers/developers find quality-focused HFSPs, and increase the success of their HF validation projects.

Besides generic, existing maturity assessments are hard to implement and resource-consuming. In contrast, the HFSP-MAT features an easy to use and stain self-assessment that stakeholders can truly implement. Beyond assessing maturity level, the HFSP-MAT provides a graphical report that is not only descriptive, but can show weak areas and enable continuous improvement plans! HFSPs, procurers of HF services and regulators need to know in what areas organizations are struggling and how each one compare. Benchmarking is an important need for this industry, and the tool can provide that.

As the industry heads towards the use of maturity models, the HFSP-MAT is aligned with the complex CMMI® framework yet carefully adapted to the needs and context of the HFE industry. The website has a user-friendly interface, a dashboard, and informational resources, to make of the HFSP-MAT a practical option. Unlike other maturity assessment tools, it does not require any investment of resources, expensive training or certifications in order to use it.

5.1.6 Limitations and Future Research

Some difficulties made data collection challenging resulting in one main limitation of this research, probably the size of the samples in Phase I (survey), and last part of Phase II (testing). However, when the context of the research is understood, a small sample is like “gold” because it can provide some insights, leading to more possibilities for future research. It had been identified earlier (Rojas, Cosler, et al., 2019)

that key stakeholders are still learning about how to meet the HF validation requirements, thus a large sample size of experienced participants in FDA HF validation projects does not exist at this point in time (the final HFE guidance was published in 2016, and several guidance documents are still in the drafting phase). Moreover, some stakeholders had no interest in participating, including the HF team at the FDA, and procurers of HF services (or sponsors). It is likely that due to the regulatory side of this topic, some stakeholders are defensive about participating in research to improve the situation.

Another interesting limitation is that the findings in this research (precisely Phase I), could be more about a specific type of project ("predicates") considering that the majority of participants indicated that 510(k) were the most common type of submission for them. Also, a few limitations could impact robustness of results in Phase II, Part 2 (testing the tool). As it was a beta-tool, it is possible that some participants went randomly through the items, just revising the tool. In addition, self-assessments also have limitations, because participants might provide optimistic responses, due to "social desirability biases" (Kimberlin & Winterstein, 2008), especially in this case, stakeholders might want to look much more successful and quality-oriented than they actually are, considering the regulatory aspect of it. Therefore, it is possible that the average HFSP could be at Level 1.

Another limitation is that the assessment was formatted for online delivery using a "prepacked" plugin which turned out limited. For that reason, some functionalities that would have been ideal, could not be implemented due to the limitations of the plugin. To mention some: the assessment's options would be better presented using a scale approach similar to Likert-Scale instead of multiple choices ABCDE (and this was also reported by

users). However, the plugin does not support such functionality (for that reason, a different plugin will be used when deploying the tool online). Also, the reasonable suggestions from participants such as improving the online user interface, will be integrated prior to deployment of the tool. At that point, it will be made public and the hope is that organizations who can benefit from it will use it and enough that will be collected for benchmarking. As described in the tool's overview, there is a section for HFSPs to keep track of current trends and compared themselves to others in industry.

Another limitation is that participants in this research had no experience with maturity models, combined with the scarce application of PM to manage HF validation projects. As a result, the ability of stakeholders to find value and see the benefit of the tool could be limited. Although most participants found the tool useful and easy to implement (see Table 4.48 and Table 4.49), some seemed to have unfeasible expectations for a self-assessment tool which returns an automatic free report. That could be due to the lack of reference and understanding about existing PM maturity models. As described in Chapter 2, the options available to HFSPs (which are usually small organizations), besides generic, are not suitable to their needs and demand considerable use of resources that HFSPs would likely view as major investments.

Furthermore, most maturity assessment models only provide the numeric results (the plain average maturity level or percentage achieved). In this case, the report of the HFSP-MAT goes further and describes the current maturity level for dimensions (HFE and the PM Dimension) including each subcategory (see Figure 4.25 and Figure 4.30 and). In addition, the tool provides directions to develop improvement plans based on the logical next steps to get to the next level (e.g.: at Level 2 there is need for

standardization). With that information, the organization is responsible for the development of a plan to improve based on strategic goals and areas of improvements detailed on the report.

5.1.6.1 Recommendations for Practice

Companies are implementing and using more PM technologies and tools, to mature their PM practices. Now more than before it has been recognized that sophistication in PM is directly related to high performance and project success for the organization. HFSPs can now achieve the same. And there are specific ways in which HFSPs and procures of HF services can use this work to make the best of it. For instance, the HFSP can develop improvement plans, processes and metrics based on the HFE Dimension. Ensuring the implementation of each item such as: “Planning & Documenting”, “Roles & Responsibilities”, etc., during each FDA HF validation. By implementing the factors outlined in the tool, and controlling performance, the HFSP will be able to benchmark performance regarding how it compares to others in this industry, and improve the areas that really matter for success in FDA HF validation projects. Likewise, procurers (sponsors, manufacturers) can audit the HFSPs based on the components of the HFSP-MAT (and the use of a “PM History File” was recommended to facilitate the audits by sponsors/procurers). Keep in mind, HFSPs can be external (an agency) or internal (a department), and the HFSP-MAT can be used in the same way.

Moreover, while HFSPs are not really experiencing the impact of the QSR, as critical suppliers in the development of safe and effective medical device products, it is only a matter of time before they are directly required to provide measures of excellence. The medical device industry is headed towards the use of maturity models. The FDA has

been piloting the use of the CMMI® framework to measure excellence in the medical device industry. The good thing is, that HFSPs can make the best out of this research and improve without major investments.

5.1.6.2 Recommendations for Future Research

Although exploratory research is ideal for novel problems, it only provides the initial variables. In that sense, the identified variables (including key factors for success and areas of improvements), offer much potential for descriptive and causal research. The following are some suggestions about how the findings of this work can be framed for that purpose:

- What is the impact of the category "Timing & Integration" or "Tools & Methodology" on success in FDA HF validation projects? Is one more important than the other?
- Is the category "People" really key to success in FDA HF validations? (As per this research, it is).
- What specific metrics can HFSPs used to control and improve "Accuracy of Plans & Proposals" (or any other item of the HFSP Dimension)?
- Why is there denial about failure during FDA HF validations? What is the impact on the overall review process and on the healthcare system?
- Why is there lack of HFE awareness, especially on the side of sponsors/procurers of HF services? What can be done to improve the situation?
- Do formative studies as part of an HF validation project plan improves success?
- Is it true that "Communicating & Reporting" or "Engaging Sponsors" (or any other subcategory of the HFSP-MAT) is a factor for the quality and success of HF validation projects that seek approval from the FDA?

- Is there improvement in HF validation project duration/scheduling when using the key factors for success outlined by the HFSP-MAT?

Another subject of study could be measuring if overall success in FDA approvals improves as maturity levels do. For instance, cases that involve assessing the current or initial maturity level of HFSPs and measuring again after certain amount of time (consider the duration of FDA HF validation projects, see Table 4.4). For that stakeholders' satisfaction and success with the FDA can be compared to the maturity level of the organization at the initial time, and after implementing the components of the tool. In that same line, the number of FDA's requests for remedies (increased or decreased in relation to the level of PM application?), can also be studied.

Although collecting organizations' demographic information was not part of the last part of this research (when testing the tool), to avoid discouraging participation, it would be very useful to add in the future. Demographics would provide more effective benchmarking, such as: are large organizations doing better than smaller ones?

Also, as indicated in the discussion of the limitations, considering that the majority of participants indicated their most common type of submission was 510(k), also known as "predicates", there is potential in researching the difference in FDA HF validation projects when it comes to the type of submission/device (e.g.: more complexity, duration, cost).

Furthermore, at the time this exploratory research is concluding, the world is experiencing the impact of COVID-19. The FDA is rushing to provide Emergency Use Authorization (EUA) of medical devices, to ensure (above all) the benefit for users. That is a great illustration of why anything that delays or prevents users from benefiting from

much-needed medical devices and combination products can have an exponential and disastrous impact on the healthcare system. As shown on the CLD developed as part of this work (see Figure 1.4), that is because the situation is a dynamic problem involving reinforcing loops that can quickly turn a seemingly small issue into a major disaster, pushing a system to collapse.

That is why interventions that ensure medical devices get to market timely and effectively are necessary (as explained in Chapter 1.8.1). In that sense, the CLD can be used to understand and further study the dynamics of medical devices and combination products in regards to any other situation where the benefit for users is the common goal, such as the case of COVID-19. Consequently, so much can be done to follow-up on this work. This can be considered only the foundation, where others are welcome to build upon and improve.

Appendices

Appendix A: The Knowledge Areas and Process Groups from the PMBOK® 6th. E.

Knowledge Areas	Project Management Process Groups				
	Initialing	Planning	Executing	Monitoring and Controlling	Closing
Project Integration Management	4.1 Develop Project Charter	4.2 Develop Project Management Plan	4.3 Direct and Manage Project Work 4.4 Manage Project Knowledge	4.5 Monitor and Control Project Work 4.6 Perform Integrated Change Control	4.7 Close Project or Phase
Project Scope Management		5.1 Plan Scope Management 5.2 Collect Requirements 5.3 Define Scope 5.4 Create WBS		5.5 Validate Scope 5.6 Control Scope	
Project Schedule Management		6.1 Plan Schedule Management 6.2 Define Activities 6.3 Sequence Activities 6.4 Estimate Activity Durations 6.5 Develop Schedule		6.6 Control Schedule	
Project Cost Management		7.1 Plan Cost Management 7.2 Estimate Costs 7.3 Determine Budget		7.4 Control Costs	
Project Quality Management		8.1 Plan Quality Management	8.2 Manage Quality	8.3 Control Quality	
Project Resource Management		9.1 Plan Resource Management 9.2 Estimate Activity Resources	9.3 Acquired Resources 9.4 Develop Team 9.5 Manage Team	9.6 Control Resources	
Project Communications Management		10.1 Plan Communications Management	10.2 Manage Communications	10.3 Monitor Communications	
Project Risk Management		11.1 Plan Risk Management 11.2 Identify Risks 11.3 Perform Qualitative Risk Analysis 11.4 Perform Quantitative Risk Analysis 11.5 Plan Risk Responses	11.6 Implement Risk Responses	11.7 MonitorRisks	
Project Procurement Management		12.1 Plan Procurement Management	12.2 Conduct Procurements	12.3 Control Procurements	
Project Stakeholder Management	13.1 Identify Stakeholders	13.2 Plan Stakeholder Engagement	13.3 Manage Stakeholder Engagement	13.4 MonitorStakeholder Engagement	

Appendix B: PM Dimension outputs mapped to Process Groups (based on the PMBOK®)

Process outputs (practice)	Initiating	Planning	Executing	M&C	Closing
Accepted Deliverables				x	
Activity Duration Estimates		x			
Activity List		x			
Assumption Log	x				
Change Mgmt. Plan		x			
Communications Mgmt. Plan		x			
Configuration (Product Version) Mgmt. Plan		x			
Cost Baseline		x			
Cost Estimates		x			
Cost Mgmt. Plan		x			
Final Project Report					x
Issue Log			x		
Lessons Learned Register			x		
Milestone List		**x**			
Procurement Agreements			x		
Procurement Mgmt. Plan		x			
Project Calendars		x			
Project Charter	x				
Project Mgmt. Plan Updates	x	x	x	x	x
Project Quality Metrics		x			
Project Risk Mgmt. Plan		x			
Project Risk Reports		x			
Project Schedule		x			
Project Scope Statement		x			
Project Team Assignments			x		
Quality Mgmt. Plan		x			
Requirements Documentation		x			
Requirements Traceability Matrix		x			
Resource Mgmt. Plan		x			
Schedule Baseline		x			
Scope Baseline		x			
Stakeholder Engagement Plan		x			
Stakeholder Register	x				
Team Charter		x			
Test and Evaluation Documents			x		
Transition of Final Results					x
Verified Deliverables				x	
Work Performance Reports				x	

Appendix C: PM Dimension outputs mapped to Knowledge Areas (based on the PMBOK®)

Process outputs (practice)	Integration	Scope	Schedule	Quality	Cost	Resource	Communications	Risk	Procurement	Stakeholders
Accepted Deliverables		x								
Activity Duration Estimates			x							
Activity List			x							
Assumption Log	x									
Change Mgmt. Plan	x									
Communications Mgmt. Plan							x			
Configuration (Product Version) Mgmt. Plan	x									
Cost Baseline					x					
Cost Estimates					x					
Cost Mgmt. Plan					x					
Final Project Report	x									
Issue Log	x									
Lessons Learned Register	x									
Milestone List			**x**							
Procurement Agreements									x	
Procurement Mgmt. Plan									x	
Project Calendars			x							
Project Charter	x									
Project Mgmt. Plan Updates	x	x	x	x	x	x	x	x	x	x
Project Quality Metrics				x						

Project Risk Mgmt. Plan								x		
Project Risk Reports								x		
Project Schedule		x								
Project Scope Statement		x								
Project Team Assignments				x		x				
Quality Mgmt. Plan		x								
Requirements Documentation		x								
Requirements Traceability Matrix		x								
Resource Mgmt. Plan						x				
Schedule Baseline			x							
Scope Baseline		x								
Stakeholder Engagement Plan										x
Stakeholder Register										x
Team Charter						x				
Test and Evaluation Documents				x						
Transition of Final Results	x									
Verified Deliverables				x						
Work Performance Reports	x									

Appendix D: "Planning & Documenting" category (HFE Dimension) mapped to the recommended/supporting PM outputs

PM Process Outputs	Planning and Documenting		
	Risk Traceability Mgmt	Completeness Mgmt	Accuracy of Plans and Proposals
Accepted Deliverables		x	x
Activity List		x	
Assumption Log	x		x
Procurement Management Plan			x
Change Mgmt Plan	x		x
Communications Mgmt Plan*		x	x
Configuration (Product Version) Mgmt Plan	x		
Cost Baseline			x
Cost Estimates			x
Cost Mgmt Plan*			x
Duration Estimates			x
End of Project Report	x	x	x
Issue Log	x		
Lessons Learned Register			x
Milestone List		x	
Procurement Agreements			x
Project Calendars			
Project Charter		x	x
Project Mgmt Plan Updates		x	x
Project Schedule			
Project Scope Statement		x	x
Project Team Assignments			
Quality Mgmt Plan	x	x	x
Quality Metrics	x	x	x
Requirements Documentation	x	x	
Requirements Traceability Matrix	x		

Resource Mgmt Plan			x
Project Risk Mgmt Plan (risk = project failure)	x	x	x
Risk Reports			x
Schedule Baseline			x
Scope Baseline		x	x
Stakeholder Engagement Plan			x
Stakeholder Register			
Team Charter			
Test and Evaluation Documents	x	x	x
Transition of Final Results		x	x
Verified Deliverables		x	x
Work Performance Reports			x

Appendix E: "Communicating and Reporting" category (HFE Dimension) mapped to the recommended/supporting PM outputs

PM Process Outputs	Communicating and Reporting		
	User- Usable Format	User- Usable Language	Engaging Sponsors
Accepted Deliverables			x
Activity List			
Assumption Log			
Procurement Management Plan			
Change Mgmt Plan			
Communications Mgmt Plan*	x	x	x
Configuration (Product Version) Mgmt Plan			
Cost Baseline			
Cost Estimates			
Cost Mgmt Plan*			
Duration Estimates			
End of Project Report	x	x	x
Issue Log			
Lessons Learned Register			x
Milestone List			
Procurement Agreements			x
Project Calendars			
Project Charter			

Project Mgmt Plan Updates			
Project Schedule			
Project Scope Statement			
Project Team Assignments			
Quality Mgmt Plan	x	x	x
Quality Metrics	x	x	x
Requirements Documentation			
Requirements Traceability Matrix	x	x	
Resource Mgmt Plan			
Project Risk Mgmt Plan (risk = project failure)	x	x	
Risk Reports	x	x	x
Schedule Baseline			
Scope Baseline			
Stakeholder Engagement Plan			x
Stakeholder Register			x
Team Charter			x
Test and Evaluation Documents	x	x	x
Transition of Final Results			x
Verified Deliverables			x
Work Performance Reports	x	x	x

Appendix F: "Tools and Methodology" category (HFE Dimension) mapped to recommended/supporting PM outputs from the PMBOK

PM Process Outputs	Tools and Methodology		
	Appropriateness of Tools and Methods	Reliability of Tools and Methods	Effectiveness of Tools and Methods
Accepted Deliverables			
Activity List			
Assumption Log			
Procurement Management Plan			
Change Mgmt Plan			
Communications Mgmt Plan*			
Configuration (Product Version) Mgmt Plan	x		
Cost Baseline			
Cost Estimates			
Cost Mgmt Plan*			
Duration Estimates			
End of Project Report	x	x	x
Issue Log			
Lessons Learned Register	x		x
Milestone List			
Procurement Agreements			

Project Calendars			
Project Charter			
Project Mgmt Plan Updates			
Project Schedule			
Project Scope Statement			
Project Team Assignments			
Quality Mgmt Plan	x	x	x
Quality Metrics	x	x	x
Requirements Documentation			
Requirements Traceability Matrix			
Resource Mgmt Plan			
Project Risk Mgmt Plan (risk = project failure)	x	x	x
Risk Reports			
Schedule Baseline			
Scope Baseline			
Stakeholder Engagement Plan			
Stakeholder Register			
Team Charter			
Test and Evaluation Documents	x	x	x
Transition of Final Results			
Verified Deliverables			
Work Performance Reports			x

Appendix G: "People" category (HFE Dimension) mapped to recommended/supporting PM outputs from the PMBOK

PM Process Outputs	People	
	Roles and Responsibilities	Qualifications and Must-Haves
Accepted Deliverables		
Activity List	x	
Assumption Log		
Procurement Management Plan		
Change Mgmt Plan	x	
Communications Mgmt Plan*	x	
Configuration (Product Version) Mgmt Plan		
Cost Baseline		
Cost Estimates		
Cost Mgmt Plan*		
Duration Estimates		
End of Project Report	x	x
Issue Log		
Lessons Learned Register		
Milestone List		
Procurement Agreements		
Project Calendars	x	
Project Charter	x	
Project Mgmt Plan Updates		

Project Schedule		
Project Scope Statement		
Project Team Assignments	x	x
Quality Mgmt Plan	x	x
Quality Metrics		x
Requirements Documentation		
Requirements Traceability Matrix		
Resource Mgmt Plan	x	x
Project Risk Mgmt Plan (risk = project failure)	x	x
Risk Reports		
Schedule Baseline		
Scope Baseline		
Stakeholder Engagement Plan	x	
Stakeholder Register	x	
Team Charter	x	x
Test and Evaluation Documents	x	x
Transition of Final Results		
Verified Deliverables		
Work Performance Reports		

Appendix H: "Timing and Integration" category (HFE Dimension) mapped to the recommended PM outputs from the PMBOK

PM Process Outputs	Timing & Integration			
	Product Design & Dev. Requirements	**Product Design & Dev. Milestones**	**FDA's Inputs and Guidelines**	**FDA's Timelines**
Accepted Deliverables				
Activity List	x	x	x	x
Assumption Log	x			
Procurement Management Plan				
Change Mgmt Plan	x			
Communications Mgmt Plan*			x	
Configuration (Product Version) Mgmt Plan	x			
Cost Baseline				
Cost Estimates				
Cost Mgmt Plan*				
Duration Estimates		x		x
End of Project Report	x	x	x	x
Issue Log	x		x	
Lessons Learned Register				
Milestone List		x		x
Procurement Agreements				
Project Calendars		x		x
Project Charter	x	x	x	x

Project Mgmt Plan Updates	x	x	x	x
Project Schedule		x		x
Project Scope Statement				
Project Team Assignments				
Quality Mgmt Plan	x	x	x	x
Quality Metrics	x	x	x	x
Requirements Documentation	x			
Requirements Traceability Matrix	x		x	
Resource Mgmt Plan				
Project Risk Mgmt Plan (risk = project failure)	x	x	x	x
Risk Reports	x	x	x	x
Schedule Baseline		x		x
Scope Baseline				
Stakeholder Engagement Plan			x	
Stakeholder Register			x	
Team Charter				
Test and Evaluation Documents	x		x	
Transition of Final Results	x	x		
Verified Deliverables	x		x	
Work Performance Reports	x	x	x	x

Appendix I: The PM Process Outputs Definitions as per the PMBOK Guide (that support the HFE Dimension)

1. Accepted Deliverables: Products, results, or capabilities produced by a project and validated by the project customer or sponsors as meeting their specified acceptance criteria.
2. Activity List: A documented tabulation of schedule activities that shows the activity description, activity identifier, and a sufficiently detailed scope of work description so project team members understand what work is to be performed.
3. Assumption Log: A project document used to record all assumptions and constraints throughout the project life cycle.
4. Procurement Management Plan: A component of the project or program management plan that describes how a project team will acquire goods and services from outside of the performing organization
5. Change Management Plan: A component of the project management plan that establishes the change control board, documents the extent of its authority, and describes how the change control system will be implemented.
6. Communications Management Plan: A component of the project, program, or portfolio management plan that describes how, when, and by whom information about the project will be administered and disseminated
7. Configuration (Product Version) Mgmt. Plan: A component of the project management plan that describes how to identify and account for project artifacts under configuration control, and how to record and report changes to them.
8. Cost Baseline: The approved version of the time-phased project budget, excluding any management reserves, which can be changed only through formal change control procedures and is used as a basis for comparison to actual results.
9. Cost Estimates: The assessments of the probable costs required to complete project work, as well as contingency amounts to account for identified risks, and management reserve to cover unplanned work.

10. Cost Mgmt. Plan: A component of a project or program management plan that describes how costs will be planned, structured, and controlled.
11. Activity Duration Estimates: An estimation of the number of work periods (activity duration) needed to complete the activity using the appropriate project and resource calendars.
12. Final Project Report: The final report provides a summary of the project performance (including a summary of how the criteria for scope, quality, schedule, costs and business needs were met as well as how any project risks encountered were addressed).
13. Issue Log: A project document where information about issues is recorded and monitored.
14. Lessons Learned Register: A project document used to record knowledge gained during a project so that it can be used in the current project and entered into the lessons learned repository.
15. Milestone List: A significant point or event in a project, program, or portfolio.
16. Procurement Agreements: The documentation of mutual obligations, usually: a) The obligations of the seller to provide the specified products, services, or results and b) The obligations of the buyer to compensate the seller.
17. Project Calendars: A calendar that identifies working days and shifts that are available for scheduled activities.
18. Project Charter: A document issued by the project initiator or sponsor that formally authorizes the existence of a project and provides the project manager with the authority to apply organizational resources to project activities.
19. Project Mgmt. Plan Updates: Any change to the project management plan goes through the organization's change control process via a change request. Any component of the project management plan may be updated as a result of this process.
20. Project Risk Management includes the processes of conducting risk management planning, identification, analysis, response planning, response implementation, and monitoring risk on a project.

21. Project Schedule: An output of a schedule model that presents linked activities with planned dates, durations, milestones, and resources.
22. Project Scope Statement: The description of the project scope, major deliverables, assumptions, and constraints.
23. Project Team Assignments: Documentation recording the team members and their roles and responsibilities for the project.
24. Project Quality Metrics: A description of a project or product attribute and how to measure it.
25. Quality Mgmt. Plan: A component of the project or program management plan that describes how applicable policies, procedures, and guidelines will be implemented to achieve the quality objectives.
26. Requirements Documentation: A description of how individual requirements meet the business need for the project.
27. Requirements Traceability Matrix: A grid that links product requirements from their origin to the deliverables that satisfy them.
28. Resource Mgmt. Plan: A component of the project management plan that describes how project resources are acquired, allocated, monitored, and controlled.
29. Project Risk Reports: A project document developed progressively throughout the Project Risk Management processes, which summarizes information on individual project risks and the level of overall project risk.
30. Schedule Baseline: The approved version of a schedule model that can be changed using formal change control procedures and is used as the basis for comparison to actual results.
31. Scope Baseline: A specific, approved version of the detailed project scope statement, work breakdown structure (WBS), and its associated WBS dictionary.
32. Stakeholder Engagement Plan: A component of the project management plan that identifies the strategies and actions required to promote productive involvement of stakeholders in project or program decision making and execution.

33. Stakeholder Register: A project document including the identification, assessment, and classification of project stakeholders.
34. Team Charter: A document that records the team values, agreements, and operating guidelines, as well as establishing clear expectations regarding acceptable behavior by project team members.
35. Test and Evaluation Documents: Project documents that describe the activities used to determine if the product meets the quality objectives stated in the quality management plan.
36. Transition of Final Results: The final product, service, or result that the project was authorized to produce (or in the case of phase closure, the intermediate product, service, or result of that phase).
37. Verified Deliverables: Completed project deliverables that have been checked and confirmed for correctness through the Control Quality process.
38. Work Performance Reports: The physical or electronic representation of work performance information compiled in project documents, intended to generate decisions, actions, or awareness.

Appendix J: Descriptive Statistics of the raw variables in the assessment (53 items)

	N	Range	Minimum	Maximum	Mean	Std. Deviation	Variance
Use-Related Risk Traceability	14	2.00	2.00	4.00	2.8571	0.53452	0.286
Completeness Mgmt	14	2.00	1.00	3.00	2.4286	0.85163	0.725
Accuracy of Plans and Proposals	14	4.00	1.00	5.00	3.1429	1.35062	1.824
User- Usable Format	14	3.00	1.00	4.00	2.9286	0.99725	0.995
User- Usable Language	14	4.00	1.00	5.00	2.7857	0.89258	0.797
Engaging Sponsors	14	4.00	1.00	5.00	3.0000	1.35873	1.846
Appropriateness of Tools and Methods	14	2.00	2.00	4.00	3.0000	0.67937	0.462
Reliability of Tools and Methods	14	3.00	2.00	5.00	3.3571	0.74495	0.555
Effectiveness of Tools and Methods	14	3.00	2.00	5.00	3.4286	0.85163	0.725
Roles and Responsibilities	14	3.00	1.00	4.00	2.7857	0.69929	0.489
Qualifications and Must-Haves	14	3.00	1.00	4.00	2.6429	0.84190	0.709
Product D&D Requirements	14	2.00	2.00	4.00	3.1429	0.66299	0.440
Product D&D Milestones	14	4.00	1.00	5.00	3.1429	1.02711	1.055
FDA's Inputs and Guidelines	14	2.00	2.00	4.00	3.0000	0.55470	0.308
FDA's Timelines	14	2.00	2.00	4.00	2.9286	0.73005	0.533
Accepted Deliverables	14	4.00	1.00	5.00	3.6429	1.59842	2.555
Activity Duration Estimates	14	2.00	3.00	5.00	3.9286	0.73005	0.533
Activity List	14	2.00	3.00	5.00	3.8571	0.86444	0.747
Assumption Log	14	2.00	1.00	3.00	2.0000	0.87706	0.769
Change Mgmt. Plan	14	2.00	1.00	3.00	2.0000	0.87706	0.769
Communications Mgmt. Plan	14	4.00	1.00	5.00	2.8571	1.56191	2.440
Configuration (Product Version) Mgmt. Plan	14	3.00	1.00	4.00	2.4286	1.28388	1.648
Cost Baseline	14	3.00	1.00	4.00	2.5714	1.08941	1.187
Cost Estimates	14	2.00	3.00	5.00	3.8571	0.94926	0.901
Cost Mgmt. Plan	14	2.00	3.00	5.00	3.7143	0.82542	0.681
Final Project Report	14	4.00	1.00	5.00	3.2857	1.48989	2.220
Issue Log	14	2.00	1.00	3.00	2.1429	0.86444	0.747
Lessons Learned Register	14	2.00	1.00	3.00	1.4286	0.75593	0.571
Milestone List	14	2.00	1.00	3.00	2.0714	0.82874	0.687
Procurement Agreements	14	4.00	1.00	5.00	2.9286	1.49174	2.225
Procurement Management Plan	14	2.00	1.00	3.00	1.7857	0.89258	0.797
Project Calendars	14	1.00	2.00	3.00	2.7857	0.42582	0.181
Project Charter	14	2.00	1.00	3.00	1.8571	0.86444	0.747
Project Mgmt. Plan Updates	14	4.00	1.00	5.00	2.9286	1.32806	1.764
Project Quality Metrics	14	2.00	1.00	3.00	2.0000	0.87706	0.769
Project Risk Mgmt. Plan	14	2.00	1.00	3.00	2.2857	0.82542	0.681
Project Risk Reports	14	2.00	1.00	3.00	2.1429	0.77033	0.593
Project Schedule	14	4.00	1.00	5.00	3.3571	1.44686	2.093
Project Scope Statement	14	3.00	2.00	5.00	3.7143	1.26665	1.604
Project Team Assignments	14	3.00	2.00	5.00	3.6429	1.15073	1.324
Quality Mgmt. Plan	14	2.00	1.00	3.00	2.0000	0.87706	0.769
Requirements Documentation	14	2.00	1.00	3.00	2.0714	0.82874	0.687
Requirements Traceability Matrix	14	2.00	1.00	3.00	2.4286	0.75593	0.571
Resource Mgmt. Plan	14	2.00	1.00	3.00	2.0714	0.82874	0.687
Schedule Baseline	14	2.00	1.00	3.00	1.9286	0.99725	0.995
Scope Baseline	14	2.00	1.00	3.00	2.1429	0.86444	0.747
Stakeholder Engagement Plan	14	2.00	1.00	3.00	1.8571	0.86444	0.747
Stakeholder Register	14	2.00	1.00	3.00	2.0714	0.82874	0.687
Team Charter	14	2.00	1.00	3.00	1.7143	0.72627	0.527
Test and Evaluation Documents	14	3.00	2.00	5.00	3.2143	1.12171	1.258
Transition of Final Results	14	4.00	1.00	5.00	3.0714	1.68543	2.841
Verified Deliverables	14	4.00	1.00	5.00	3.0714	1.32806	1.764
Work Performance Reports	14	3.00	1.00	4.00	2.4286	1.28388	1.648

Appendix K: Survey Phase II - After Testing Online Beta Tool

Q1 Have you used a maturity assessment model/tool before?

- ○ Yes
- ○ No

Q2 On a scale of 1 to 5, please rate the following about the HFSP-MAT:

	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
Easy to understand	○	○	○	○	○
Useful	○	○	○	○	○
Can help improve our FDA HF validation projects	○	○	○	○	○
Easy to Implement	○	○	○	○	○
Sustainable	○	○	○	○	○

Q8 Do you have further feedback to improve this tool?

- ○ Yes, I have suggestions to improve this tool

○ No, submit my responses

Display This Question:

If Q8 = Yes, I have suggestions to improve this tool

*

Q4
Please enter your feedback below. Then click the next arrow to complete your submission.

_____

_____

_____

_____

_____

End of Block: Default Question Block

Appendix L: Phase 1 – Survey

Phase 1 – Survey "Understanding FDA HF Validation Projects"

Start of Block: 1-Introduction

Q1 **Principal Investigator:** Katia Rojas, MSc. PMP, PhDc

Title of Project: *An Industry Maturity Assessment Tool for FDA Human Factors Validation Projects (Medical Devices and Combination Products)*

You are invited to participate in a study to collect data about FDA human factors (HF) validation projects. We hope to learn about FDA HF validation project management (PM) practices and critical success factors, to develop a maturity assessment tool specific to the field, that can help measure and improve quality. This is an anonymous survey, and no individually identifiable information will be collected about you or your organization. You were selected to participate in this survey because you have the required expertise. If you decide to participate, you will complete an anonymous online survey which will take approximately 14 minutes. You will be able to stop and continue at a later time if you wish (as long as you are on the same device and browser). You will also be able to contact me at any point when filling out the survey. If you have any additional questions or concerns, I will be happy to answer them. I can be reached at kmrojas@binghamton.edu /914-340-40-27

To continue, please select your choice:

- ○ I will participate (1)
- ○ I'm not interested in participating (2)

Skip To: End of Survey If Q1 = I'm not interested in participating

Display This Question:

If Q1 = I will participate

Q2 Thanks for your interest in participating in this study! The following survey will not be measuring your organization's quality regarding FDA HF validation projects. The purpose of this survey is to help study and understand those projects. Therefore, the survey will collect data about current PM practices and success factors, to inform the development of a PM maturity assessment tool for this industry. Please answer truthfully, considering that the information you provide will inform how the intended tool is developed. If you provide unrealistic data, such will be the outcome. If you do not know the exact answer to a question, please provide an educated guess considering your experience. **Incomplete surveys will be deleted.** At the end of the survey, you will see a "thank you" page. Please click next to start the survey.

End of Block: 1-Introduction

Start of Block: Organization

Q3
What is the organization's primary business? (May select more than one)

- [ ] Medical devices (1)
- [ ] Combination products (7)
- [ ] Drug/Pharmaceutical products (2)
- [ ] Biotechnology products (3)
- [ ] ⊗ All of the above (6)
- [ ] Other (please indicate): (4) _____

Q4

Which category best describes the organization with respect to FDA HF projects?

- ○ Supplier/provider of HF services (providing HF services as: consultancy/agency/firm, or a department/unit) (2)
- ○ Procurer of HF services (procuring HF services as: manufacturer/developer, consultancy/firm/regulatory agency services) (1)

Q5 What type of organization?

- ○ Manufacturer/developer (1)
- ○ Agency/consultancy firm (2)
- ○ Other: (4) _____

Q6 Business location:

▼ Afghanistan (1) ... Zimbabwe (195)

Q7 Organization's years in business:

- ○ < 1 (1)
- ○ 2-3 (8)
- ○ 4-6 (3)
- ○ 7-10 (4)
- ○ 11-16 (5)
- ○ 17-20 (6)
- ○ > 21 (7)

Q8 Number of employees?

- ○ 1-5 (1)
- ○ 5-10 (9)
- ○ 11-50 (2)
- ○ 51- 200 (3)
- ○ 201-1000 (4)
- ○ 1001- 5000 (5)
- ○ 5001- 20,000 (6)

○ 21,000- 40,000 (7)

○ > 41,000 (8)

Q9 In geographic terms (sponsor's location) how are most of your FDA HF projects classified?

○ Mostly local (USA) (1)

○ Mostly international (3)

○ Both local and international (2)

Q10 Please select only the **most** common products for FDA HF submissions in this organization:

☐ Combo (New Drug) (1)

☐ Combo (Bio-similar) (2)

☐ Combo (Generics) (3)

☐ Combo (Interchangeability) (4)

☐ Medical device (predicates) (5)

☐ Medical device (high risk) (6)

☐ Medical device (De Novo) (7)

☐ ⊗ All equally common (9)

End of Block: Organization

Start of Block: 4-FDA HF Validation Projects

Q11 Quality Systems (QS) in the development of medical devices/combination products are mandated by the FDA. This research also proposes that the application of project management (PM) methods can serve as the QS for FDA HF validation projects. In that sense, this section will collect information about the organization's project management practices.

Q12 In reference to FDA HF projects, is there a quality system implemented in your organization?

- ○ Yes (1)
- ○ No (2)
- ○ I don't know (4)

Display This Question:

If Q12 = Yes

Q13 Please briefly specify what kind of QS?

_____

Display This Question:

If Q12 = No

Q14 Since you selected there is not a specific QS in your organization, are there plans to implement one?

- ○ No (1)
- ○ Yes (2)
- ○ I don't know (3)

Display This Question:

If Q14 = Yes

Q15 Please briefly indicate what kind of QS you plan to implement in the future:

_____

Q16 Project managers typically plan, budget, monitor, and report on a project using a PM methodology/tool. Please enter the name of the PM methodology/tool used in your organization to manage FDA HF projects.

- ○ Name of PM methodology/tool: (9)

_____

- ○ We don't use a PM methodology/tool (10)
- ○ I don't know (11)

Q17 Please select what personnel is normally responsible for **leading** the PM tasks related to HF projects for FDA submissions, in your organization?

- ○ Product Engineers (10)
- ○ Product designers (9)
- ○ Senior management (3)
- ○ Project managers (1)
- ○ Human factors personnel (2)
- ○ Product managers (8)
- ○ Other (please specify): (4)

_____

Q18 How many project managers are in this organization (dedicated to managing HF projects for FDA submissions)?

- ○ 0 (17)
- ○ 1 (18)
- ○ 2-3 (19)
- ○ 4-5 (20)
- ○ 6-7 (21)
- ○ > 8 (23)

Q19 Considering the indicated personnel responsible for PM tasks in your organization: how many FDA HF projects are managed by one person at any one time?

- ○ 1 (14)
- ○ 2-3 (16)
- ○ 4-6 (17)
- ○ 7-10 (18)
- ○ > 11 (19)

Q20 PM tasks include (among others): scoping, planning, scheduling, budgeting, managing resources and assigning tasks to a team, ensuring stakeholder engagement, communication, and client satisfaction; documentation, monitoring and reporting progress. In that sense, how many hours per week per each FDA HF project in your organization, are exclusively PM activities/tasks?

- ○ < 5 (1)
- ○ 5-10 (6)

- ○ 11-20 (2)
- ○ 21-40 (3)
- ○ 40-80 (4)
- ○ > 81 (5)

Q21 Yearly, what is the average number of FDA HF validation projects completed in this organization?

	< 5											> 100	Not Applicable
	4	10	17	23	30	36	43	49	56	62	69	75	82	88	95	101	
FDA HF projects yearly ()																	

Q22 A project's baseline is defined as the original scope, cost, and schedule. At completion of FDA HF validation projects, in your organization, what is **normally** the case regarding the project's original desired **SCHEDULE** (baseline)?

- ○ Far behind the schedule baseline (114)
- ○ Moderately behind the schedule baseline (115)
- ○ Exactly as the schedule baseline (117)
- ○ Moderately ahead of the schedule baseline (119)
- ○ Far ahead of the schedule baseline (120)

Q23 At completion of FDA validation projects, what is normally the case regarding the original desired BUDGET (baseline)?

- ○ Far above the budget baseline (136)

- ○ Moderately above the budget baseline (137)
- ○ Exactly as the budget baseline (139)
- ○ Moderately under the budget baseline (141)
- ○ Far under the budget baseline (142)

Q24 At completion of FDA validation projects, what is normally the case regarding the original desired SCOPE (extent of work)?

- ○ Much more than the scope baseline (41)
- ○ Moderately more than the scope baseline (42)
- ○ About the same as the scope baseline (44)
- ○ Moderately less than the scope baseline (46)
- ○ Much less than the scope baseline (47)

Q25 Regardless of why: how often are formative studies implemented for FDA HF validation projects in your organization? (Please remember your answer to this question when answering the next three questions).

- ○ Always (23)
- ○ Most of the time (24)
- ○ About half the time (25)
- ○ Sometimes (26)
- ○ Never (27)

Q26 Consider all HF activities/tasks for an FDA HF validation project in your organization. In terms of project BUDGET, please select **up to** what amount would you classify FDA HF validation projects to be either "small" or "medium," and **above** what amount would you consider it to be "large"? ($000's).

< $100,000 > 1.5 million

10 155 300 445 590 735 879 1024 1169 1314 1459 1604

Small ()	
Medium ()	
Large ()	

Q27 Consider all HF activities/tasks for an FDA HF validation submission in your organization. In terms of **project SCHEDULE** (duration in months), please select **up to** how many months would you classify FDA HF validation projects to be either "short-term" or "medium-term," and **above** what duration would you consider it to be "long-term"?

< 1 month > 48 months

1 3 5 7 9 11 13 15 17 19 21 23 26 28 30 32 34 36 38 40 42 44 46 48 50

Short-term ()	
Medium-term ()	
Long-term ()	

Q28 Considering your previous answer: how frequent are the following projects in your organization? Please rank in order of frequency (1 = most frequent):

- _____ Short-term FDA HF Projects (1)
- _____ Medium-term FDA HF Projects (2)
- _____ Long-term FDA HF Projects (3)

Q29 Do HF validations for FDA submission normally involve communication with the FDA in your organization?

○ We only communicate with the FDA if there is a problem during the submission (3)

○ Yes, throughout the different phases of the project (initiation to clearance) (1)

○ No, we specifically deliver the HF report (no interaction with the FDA) (2)

Display This Question:

If Q29 = We only communicate with the FDA if there is a problem during the submission

*

Q30 You indicated you communicate with the FDA only if there is any problem during the HF validation submission. When that is the case, what are the top issues/problems?

_____

Q31 Once the HF report has been delivered by your organization, how often has the FDA rejected or found deficiencies?

○ Never (1)

○ Sometimes (2)

○ About half the time (3)

○ Most of the time (4)

○ Always (5)

Display This Question:

If Q31 = Sometimes

Or Q31 = About half the time

Or Q31 = Most of the time

Or Q31 = Always

Q32 What are the top reasons the FDA has rejected or found deficiencies in your organization's HF validation submissions?

_____

Q33 How successful do you know this organization is, in helping achieve FDA clearance (vs. competitors)?

- Much more successful (42)
- Moderately more successful (43)
- About the same as competitors (45)
- Moderately less successful (47)
- Much less successful (48)
- No way to know it (49)

Q34 What do you consider are your best practices that lead to your level of success?

_____

Q35 What have been the top challenges/frustrations faced during HF validation projects for FDA submissions?

_____

Display This Question:

If Q4 = Procurer of HF services (procuring HF services as: manufacturer/developer, consultancy/firm/regulatory agency services)

Q36 What are key factors considered in this organization in the selection of an external provider of FDA HF services?

_____

Display This Question:

If Q4 = Supplier/provider of HF services (providing HF services as: consultancy/agency/firm, or a department/unit)

Q37 What have been the key factors in your organization to work smoothly with clients/procurers of FDA HF services (internal or external clients)?

_____

Q38 What is your level in this organization?

- ○ Sr. Management (3)
- ○ Management (11)
- ○ Coordinator (10)
- ○ Associate/Team member (9)
- ○ Consultant (12)
- ○ Other (please specify): (5)

_____

Q39 As an individual (not the organization), how many FDA HF related projects have you completed?

< 1 > 100

0 10 20 30 40 51 61 71 81 91 101

Completed FDA HF projects ()	

Q40 What is your level of education?

- ○ Less than high school (1)
- ○ High school (8)
- ○ Undergraduate (3)
- ○ Master's (2)
- ○ Doctoral (9)

Q41 Please indicate your main academic/expertise area. Example: human factors research, product design, engineering, project management, marketing, etc.

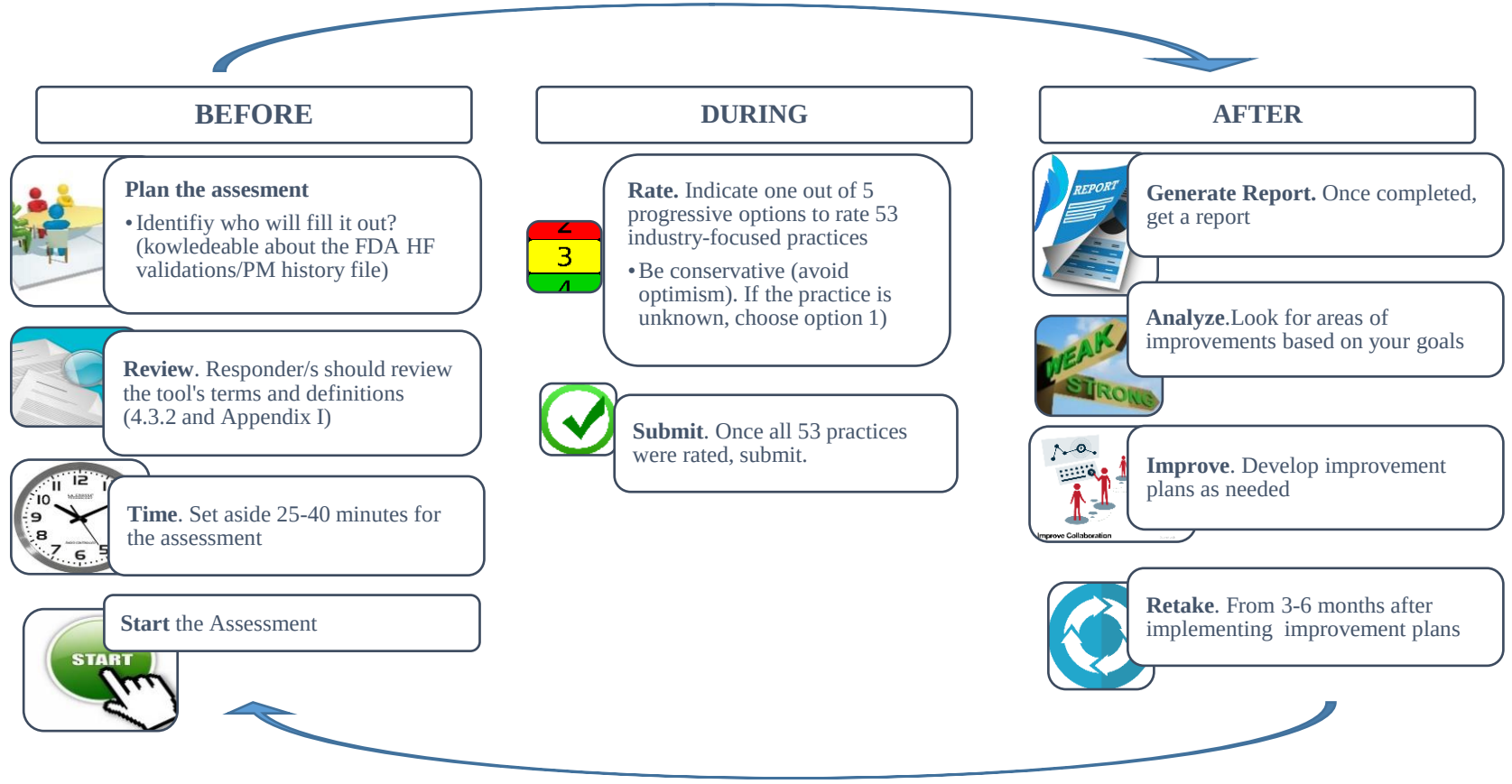
_____

Q42 If there is anything you would like to share, please feel free to comment below, and then click next to finalize the survey.

_____

End of Block: 4-FDA HF Validation Projects

Appendix M: Implementation Blueprint



What to expect? Before, During and After the Assessment

The assessment can be completed either manually or online. For the manual option, the matrices provided in Appendix B to Appendix H can be used. However, if you choose this option, make sure to review the scoring approach in section 4.3.5. The troubles of doing the assessment manually can be avoided by using the online option: www.hfsp-mat.online, which will generate a report automatically. Whichever the approach, the above blueprint applies (substitute automatic generation of the report by manual generation).

Not a survey. Please keep in mind this is not a survey or a questionnaire. You will not be asked for any identifiable information about you or your organization, and there will not be elaborated questions. It will be more helpful if you see the assessment as a "self-audit". The idea is to identify the current state of your organization's PM practices with focus on your HF validation projects that seek FDA approval. You are checking which ones of the industry-focused practices exist in your organization and how developed they are. From a process development point of view, you will need to identify where each practice is in your organization by selecting one out of the five options provided. Basically, from 1 to 5, the meaning is: (1) not documented, (2) documented, (3) standardized, (4) measured, (5) optimized. Those options will be the same for each practice throughout the assessment.

Before the Assessment

Plan. Get ready before starting the assessment. It is important to **identify who** in your organization can provide informed answers about your FDA HF validation projects.

Ideally, it will be those with a project management role or closely involved in planning, executing and delivering FDA HF validations. Nonetheless, it could involve several individuals providing inputs to complete the assessment as a team, while being led by a senior manager who can submit the assessment. It is important that the person completing the assessment is knowledgeable about the organizations PM practices relevant to FDA HF validations.

Review terms & definitions. While supporting information is available all throughout the site and descriptions will be shown during the assessment, for optimal experience, the definition for each one of the presented practices should be reviewed prior to the assessment (4.3.2 and Appendix I). Also, you are free to consult terms and definitions. The tool is based on established standards both in PM and HFE so if you want to dig a little more, much information is readily available online with a simple search.

Set time aside. Completing the assessment could take between 25 to 40 minutes, depending on how much time you need for deliberation before choosing your answers. The more careful you are about selecting your answer, the more accurate your report will be, and the better your improvement plans.

During the Assessment

Rate. In a scale of 1 to 5 (see details about the levels in section 4.3.5) you will indicate the state (in your organization) of 53 PM industry-specific practices, identified as critical factors for success in FDA HF validation projects. These 53 practices will be presented as follows:

- Practices from 1 to 15 are exclusively about the key practices in the *HFE Dimension* based on the FDA HF guidance and IEC-62366-1.
- Practices from 16 to 53 belong to the *PM Dimension* and are based on the *PMBOK*®, carefully tailored to support the HFE Dimension.

For each one of the practices you will be able to choose from five possible options. Basically, from 1 to 5, the meaning is: (1) not documented, (2) documented, (3) standardized, (4) measured, (5) optimized. The options provided are the same throughout for all the practices (each one indicates the criteria for a given level). In that sense, the answers are progressive, which means for instance, that you **should not select** the answer number 3, if 1 and 2 are not being met in your organization. *Choose o*nly the option that best represents your organization's *current state regarding FDA HF validation projects.*

Be conservative. Please, mind the limitations of self-assessments and make the best use of this tool by avoiding answering based on optimism. That is, avoid deciding that a certain practice exist in your organization if you are not even sure about it. If unsure, you will get a more accurate result by being **conservative** in your options (e.g.: If the practice does not exist in your organization or you think it does not apply, select option 1, "not documented"). Otherwise, the resulting report will not help you in the development of the necessary improvements for your current reality. Do not trick yourself!

After the Assessment

Analyze the report. Wait a few seconds after submitting your assessment, and you will be redirected to your report. This report describes your current maturity level as well as some logical steps to get to the next level.

Improve. The report and graphs can help you understand your areas of improvement in order to develop a plan to reach a desired state.

Reassess. Implement the improvement plans according to your strategic goals (see 4.4.5 about ideal PM maturity). Then retake the assessment in about 3 to 6 months.

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