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Defining a New Role of System Architect at the Product Strategy Stage of a MedTech Product Development Through the DSM-Based Method

Yaroslav Menshenin[1], Romain Pinquié[1], Pierre Chevrier[1]

[1]Univ. Grenoble Alpes, CNRS, Grenoble INP, G-SCOP

Abstract: Combination Products are medical products comprising two or more regulated components, such as a drug and a device. The drug/device development processes are strictly regulated and are not fully aligned in time. This creates uncertainty for the MedTech companies which have to develop the devices possessing limited knowledge about the final drug formulation to be released by the Pharmaceutical company later in the drug development process. This challenge calls for a holistic systems approach to the Combination Product development process. The paper advocates that systems engineering methods and tools provide appropriate means to support the MedTech product development process. This is achieved through the definition of the role of a system architect and the allocation of his/her responsibilities to the activities using the DSM-based approach. As a case study, the method is applied to the definition of system architect's role in the product strategy stage of drug delivery system development.

Keywords: MedTech, systems engineering, DSM, product development, combination product, drug delivery systems

1 Introduction

Systems engineering principles, methods and tools are used in different challenges humanity is facing. For example, systems engineering contributed to tackling such global challenges as the coronavirus pandemic that started in 2019 and was officially declared as ending in May 2023 (World Health Organization, 2023). Among various efforts to fight the pandemic, the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University created the Coronavirus Resource Center Dashboard utilizing systems science principles (COVID-19, 2023). Systems approach and systems engineering may play a vital role in encoding data and structuring an integrated and holistic approach to healthcare-related challenges (Komashie and Clarkson, 2016).

The COVID pandemic has also pushed decision-makers to reconsider some fundamental approaches which were in place and seemed untouchable for a long time. One of these approaches was a lengthy regulatory approval path for MedTech products. For example, the FDA 510(k) clearance imposed for most medical devices (class 2) took up to six months (FDA 510(k), 2023). During the pandemic, it became clear that such a view does not reflect what society needs. Therefore, FDA issued the so-called Emergency Use Authorizations (EUAs) for Medical Devices such as ventilators and ventilator accessories, personal protective equipment, remote or wearable patient monitoring devices, infusion pumps, blood purification devices, and other medical devices (FDA, 2021). Such a shift – although being influenced by the global pandemic – has demonstrated great potential to speed up regulatory approval procedures for a traditionally very conservative MedTech industry.

As illustrated by the joint INCOSE-OMG Biomedical-Healthcare MBSE Challenge Team (INCOSE-OMG), those premises stimulate the systems engineering community to consider the role of system architect in the MedTech product development process, especially when it comes to such complex products as the Combination Products (introduced in sub-section 2.2). The Combination Product development process is comprised of several processes such as the product strategy definition process, product concept development process, product development process, product qualification process, product launch process, and the end of life of the product. This paper concentrates on the product strategy definition process, which is the earliest phase of product development where innovation plays a significant role and the MedTech design process is dealing with many unknown parameters.

One can ask what is the difference between the system architect's role in those industries where it is traditionally present (e.g. aerospace or automotive) from its role in the MedTech industry. Therefore, what is the novelty of searching for the system architect role in MedTech? The answer to this question is in the nature of the case study considered in current work – Combination Product development (such as autoinjectors) where the MedTech product should fully comply with the interests of Pharmaceutical companies, which in turn develop their product – a drug. Although both industries are operating in the Healthcare domain, the nature of their businesses is quite different. Therefore, the goal of this paper is to define the role of the system architect within the product strategy definition process for the Combination Product development using the DSM-based approach.

The rest of this manuscript is structured as follows. Section 2 is a literature review, covering systems engineering in the MedTech industry landscape (sub-section 2.1), Combination Product introduction (sub-section 2.2), and briefly discussing the DSM's form of utility for the system architect role definition in MedTech (sub-section 2.3). The method is proposed in Section 3. Section 4 rationalizes the systems perspective on Combination Product development challenges (sub-section

4.1) and explains the product strategy definition process (sub-section 4.2). Section 4 also presents a case study – a drug delivery system such as autoinjector, which is an example of the Combination Product. Section 5 allocates the system architect role in the MedTech Combination Product development context based on the DSM/DMM approach. Section 6 concludes the paper with the discussion and conclusion.

2 Literature Review

Systems Engineering has been used in the MedTech and healthcare sectors in the past. However, its utility for the challenges related to the Combination Product development has been explored in a limited way. In this section, the systems engineering for the MedTech industry landscape is discussed (sub-section 2.1), and the challenges of the Combination Product development are outlined (sub-section 2.2). Sub-section 2.3 discusses the DSM as a systems engineering-based tool to define the role of a system architect.

2.1 Systems Engineering in the MedTech industry landscape

A lack of a holistic systems design approach has been observed in the relevant healthcare design literature (Komashie and Clarkson, 2016). Such a holistic approach would include the health artefacts elicitation (Pannunzio *et al.*, 2019) and their interconnections definition. The traditional medical device development was focused on linear device development, however, "... due to the many challenges and complexities associated with medical device design and development, a smooth development path rarely occurs", which calls for a more iterative design process (Shluzas *et al.*, 2009; Glazkova *et al.*, 2022).

Systems engineering methods have been applied in MedTech industry in the past. Among such efforts are the SysML application to develop the system architecture for the drug delivery system (Corns and Gibson, 2012); and to safety and risk management of the MedTech devices (Malins *et al.*, 2015). An example of software development for MedTech through Simulink has been presented by Hoadley (2010). The model-based representation for a wide variety of applications in the healthcare domain has been demonstrated in the work of Zwemer and Intercax (2016). However, to the best of the authors' knowledge systems engineering has not been applied to the challenges related to the MedTech Combination Product development.

2.2 Combination Products

Formally, the Combination Product is defined as "a product comprised of two or more regulated components, i.e., drug/device […] that are physically, chemically, or otherwise combined or mixed and produced as a single entity" (FDA, 2018). This definition sheds light on the complexity associated with Combination Product development: it is developed by a few industries (such as the MedTech industry and Pharmaceutical industry) with their design processes. The compliance implies that the new product development processes for the drug and the device should be aligned. However, both industries work in parallel and some of the critically important data might not be available for the MedTech company until the moment when the Pharmaceutical company formulates the final version of the drug and when Pharma needs an injector to start the clinical trials (see the detailed representation of it in Figure 1). Therefore, the MedTech company operates under a significant level of uncertainty which should be managed to be able to adapt the device to the Pharmaceutical company's requirements (Menshenin *et al.*, 2023). This should be done quickly in order not to miss a competitive advantage.

An additional layer of complexity comes from the fact that all those new product development processes must comply with a strict regulatory landscape. Therefore, one can expect a clear need to have a role or a function which could capture a Combination Product as a whole and could establish the required interfaces between different industries (for example, the MedTech and Pharmaceutical ones) and the functions within them.

In the B2B context, the MedTech product is sold to the Pharmaceutical company, which is a primary customer of the MedTech industry. Yet, the MedTech company should develop the MedTech product as part of the Combination Product taking into account the need to make it user-friendly and easy to use for the final user – be it a patient himself/herself, or the healthcare professional. Value co-creation has been studied in the B2B context revealing a very challenging landscape due to a complex environment (Hein *et al.*, 2019). Cycle management was introduced as the "manufacturing planning to cope with the challenges for the innovation process" (Koch et al., 2014; Schönmann *et al.*, 2017) focusing on various aspects of concurrently run planning approaches and manufacturing execution.

2.3 DSM and system architect role definition in MedTech

The Design Structure Matrix (DSM) approach proved its utility in various ways. One area of utility is the DSM application to different industrial cases, showing its universal utility among various topics (Eppinger and Browning, 2012), such as aerospace (Xiong *et al.*, 2015), petroleum (Golkar *et al.*, 2009), automotive (Gaertner *et al.*, 2015). Another area of utility is the extension of the method itself towards the cross-domain Domain Mapping Matrix (DMM) approach (Danilovic and Browning, 2007; Danilovic and Browning, 2004) and the Multiple-Domain Matrix (MDM) (Maurer, 2007; Lindemann *et al.*, 2008). In this work, the DMM is used to map the MedTech functions to the activities present in the product strategy definition process. DMM is formally defined as a "matrix-based approach, used to map between two different project domains" (Danilovic and Browning, 2007).

This paper primarily uses the DMM approach to demonstrate how the different functions of the MedTech R&D team are mapped to different activities of the product strategy definition process (Section 5), which makes it similar to the RACI (Responsible-Accountable-Consulted-Informed) matrix (Smith *et al.*, 2005). However, the focus of the current work is on the elucidation of the system architect's role, therefore, only binary representation has been used to define where he/she plays a significant role from a holistic perspective on the Combination Product.

3 Method

The first step in the definition of the system architect role in the MedTech Combination Product development process is to analyze the AS-IS situation in MedTech company. This implies the elicitation of the core activities as they are present in the company's product strategy definition process. AS-IS definition includes the allocation of the inputs provided by different functions (divisions/departments) within MedTech industry. The second step is to create a DSM/DMM matrix, which lists the activities and inputs in rows, and the corresponding function (divisions/departments) in columns. The purpose of performing this step is to allocate roles to activities/inputs. The third step is to analyze the DMM to identify the potential system architect's role during the product strategy definition process in the MedTech organization. The same method applies to the product concept definition process, product development process, etc. In the current work, the focus is made on the product strategy definition process only.

4 Eliciting a System Architect role in MedTech Combination Product development

4.1 Systems perspective on Combination Product development challenges

From the MedTech company perspective, the development of the "device constituent part of the Combination Product" (indicated as a "Drug delivery system (DDS)" in Figure 1) encounters a few challenges. By nature, Combination Product development is a B2B market where the MedTech industry sells the MedTech product to the Pharma industry which develops a drug in parallel to the device development. Therefore, the primary responsibility of the MedTech company is to develop a DDS (Figure 1), which includes the device itself, DDS packaging, the DDS instructions for use (IFU), and the syringe (the syringe may not be part of the MedTech product in some scenarios). In turn, the primary responsibility of the Pharmaceutical company is to develop the Combination Product, including its IFU, drug, packaging, and adding the DDS developed by MedTech. Depending on the use case, the system map also includes a vial and vial adapter, as illustrated in the example of Figure 1.

However, the Combination Product development process is not sequential. In the B2B segment, it would seem logical for the MedTech company to start the DDS product development process after receiving the drug formulation/specification. However, it does not happen this way in practice due to a highly competitive market. The drug development process and the device development process (both regulated by the FDA) are highly regulated having their sub-processes and deliverables. Those processes are described in Figure 1 under the "Device" and "Drug" blocks – for the device development process, and for the drug development process, respectively. Due to the market pressure and competitive landscape, MedTech should start the MedTech DDS development process before it is provided by Pharma with all requirements and drug-related parameters (e.g., viscosity and volume). Therefore, MedTech is operating in a highly uncertain environment, developing the device mature enough to be presented to Pharma when required, but still maintaining flexibility, especially the design margin (Eckert *et al.*, 2019; Eckert *et al.*, 2020), to adapt the product design to the Pharma needs and requirements.

Besides the challenge associated with the unknown drug-related parameters, there is uncertainty related to the primary container allocation and its type. In an illustrative example in Figure 1, it is a part of the DDS (the syringe) therefore being under the MedTech industry's responsibility. However, in some scenarios, it can also be under Pharma's responsibility, which would relocate that block one layer upper in Figure 1. For example, the type of the primary container would play an important role and allocation in system map – be this the empty syringe or the prefilled syringe.

Taking into account the above-mentioned challenges, it is especially important to build a Combination Product system map, the example of which is shown in Figure 1. The allocation of specific blocks may vary depending on the business case scenario, however, it is important to have this map from the systems engineering standpoint and to communicate it across all stakeholders and product designers to be aware of responsibilities and interfaces between different parts of the MedTech design process. Capturing the candidate system maps also helps to assess the impacts of a preferred design choice down to (sub-)systems and sub-systems requirements, architectures, detailed designs, and V&V plans before conducting changes easily and rapidly.

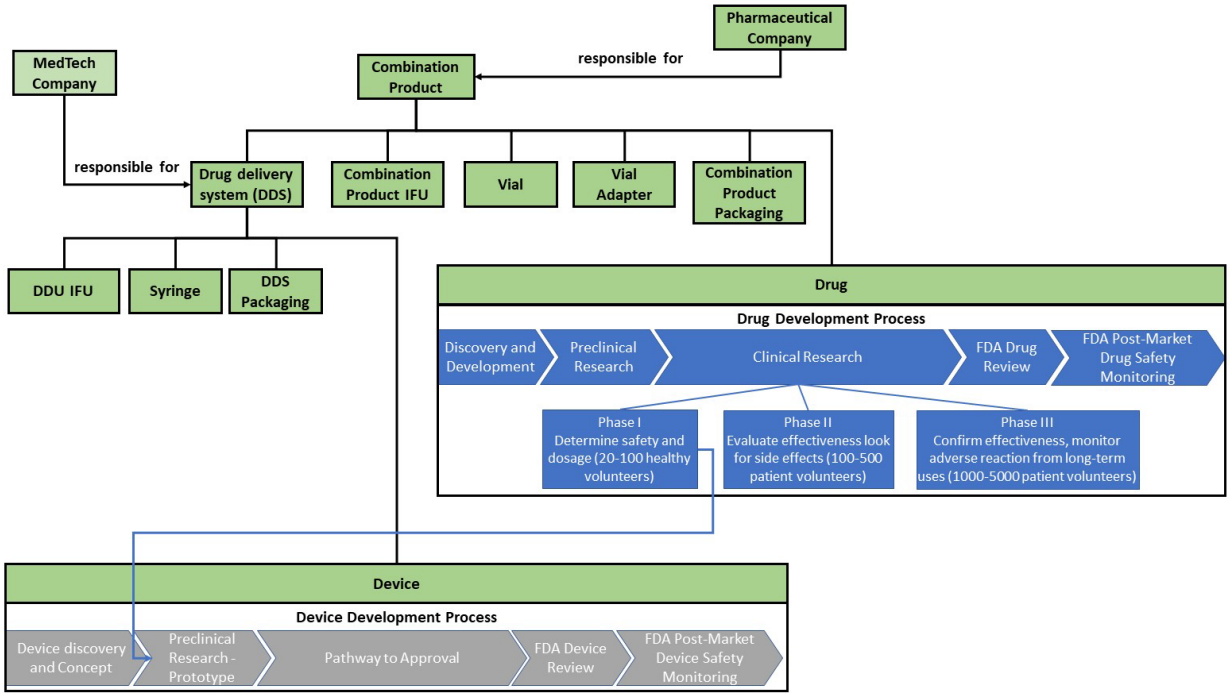

Figure 1. Example of a Combination Product system map

4.2 Product Strategy definition process

One of the first and core processes of MedTech's new product development is the product strategy definition process. This phase is critically important, as many inputs formulated at this stage are shaping the constraints for the design and are later flown into the later stages of the design. From the MedTech perspective operating in a B2B segment, the needs and intended use (inputs 1 and 2, respectively, in Figure 2) can only be assumed, as the final drug formulation and business case scenario is not known at this point. Therefore, uncertainty is embedded in the product strategy definition. The activity "A1 - problem identification" (Figure 2) forms the basis for the activity "A2.1 - Product lifecycle definition", for which the inputs are product lifecycle analysis (input 3) and product lifecycle mapping (input 4). This activity is important in the product strategy definition, as depending on the lifecycle phase the stakeholders (inputs 5 and 6) are different (activity "A2.2 - Stakeholders definition"). The need for the definition of various stakeholders leads to an iterative loop from the definition of stakeholders to the definition of the product lifecycle. The market analysis and competition analysis are the inputs (7 and 8, respectively) to the "A3.1 - Industry landscape assessment" activity. This activity can be performed in parallel with "A3.2 - Business model definition" with its related inputs on business model analysis (input 9) and go-to-market assessment (input 10). The purpose of all those 5 activities with 10 inputs is to quickly iterate the Preliminary Target Product Profile (TPP) to be able to have at least a draft version of it.

The Preliminary TPP is flown into the next activity "A4 - Technical approaches to address needs", alongside such inputs as claims (input 11), targeted population (input 12), and targeted geographies (input 13). The purpose of this activity is to assess potential technical means to meet the assumed needs. The activity "A5 - Generation of concept solutions" has such inputs as Human Factor study (input 14), regulatory constraints (input 15), and concept generation (input 16). The activity "A6 - Technical readiness of concept solutions assessment" is conducted with the inputs of DFM (input 17), DFA (input 18), and IP assessment (input 19). The activity "A7 - Risk assessment and mitigation plan" is cross-functional, meaning that the risk assessment (input 20) is provided by each function of the MedTech company. Since the product strategy definition process is the earliest process within the new MedTech product development, "Activity 8 - High-level work activities, milestones and resources needs for the next phase" is aiming to outline the work activities for the next processes (such as product concept development process, product development process, etc.) This activity also has a cross-functional nature with the inputs with the list of activities (input 21) provided by different functions. The ultimate goal of the product strategy definition process is to formulate the draft TPP, as it is indicated in Figure 2.

The challenge of the product strategy definition process is that at this first stage, the data is provided not only by R&D, but also by multiple functions and roles in the MedTech company, which makes it hard to have a comprehensive, holistic, and traceable view of the product. This calls for the role of a system architect to support data acquisition, preservation, and transfer – potentially, through the model-based approach.

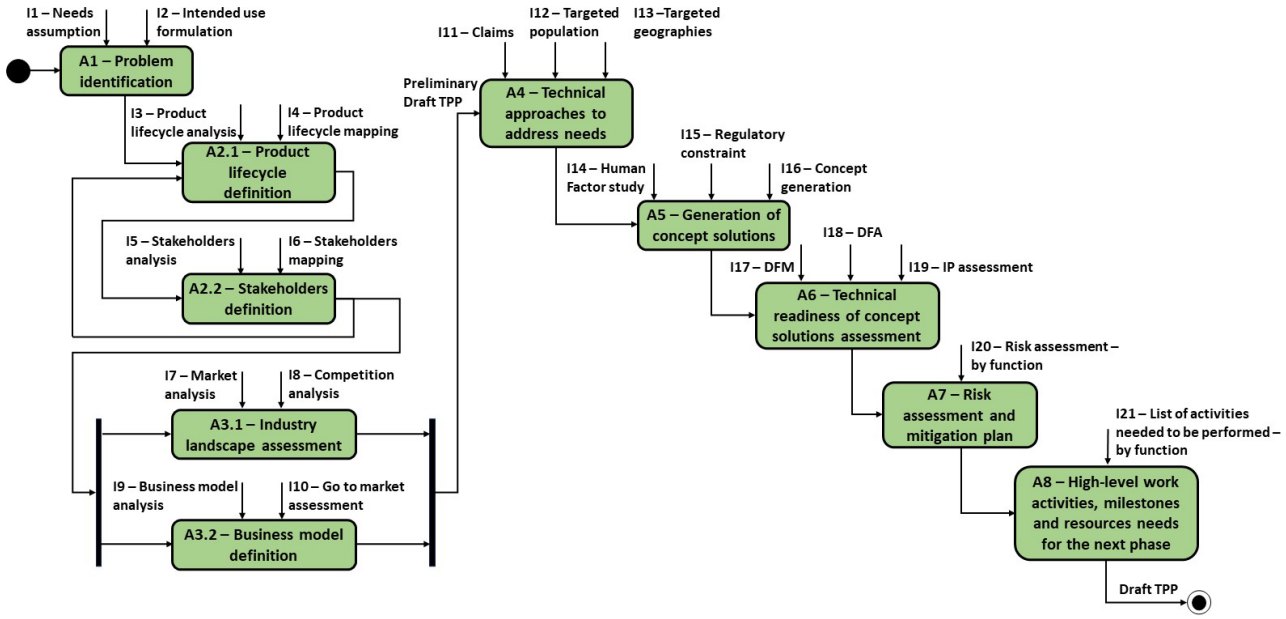

Figure 2. Product strategy definition process in the MedTech industry.

5 DSM/DMM for allocation of roles to activities in Combination Product development context

Following the method described in Section 3, the second step is to create a DSM/DMM matrix, which lists the activities and inputs within the product strategy definition process in rows, and the corresponding function (divisions/departments) in columns. This data from Figure 2 has been transferred to the DMM shown in Figure 3. The participation of the specific function in the specific input is marked by "V". Figure 3 maps the activities/inputs as they are present in the product strategy definition process to the MedTech industry functions using the DMM approach. For example, one can see that the R&D and Marketing functions are providing the assumed needs (input 1) within the problem identification activity (A1). The intended use formulation (input 2) is delivered by Marketing and Medical Affairs teams. Some of the inputs are cross-functional, meaning that all functions participate in them – for example, the risk assessment (input 20). Overall, based on the description of activities in Figure 2, 10 activities and 21 inputs have been identified. From the MedTech company perspective, 7 core functions have been elicited – R&D, Marketing, Medical Affairs, Regulatory Affairs, Legal/IP, Quality, and Operations.

Figure 3 contains the core activities and inputs where the role of a system architect can be identified and seen. In particular, those inputs include the needs assumption (input 1), product lifecycle analysis (input 3) and product lifecycle mapping (input 4), stakeholders analysis (input 5) and stakeholders mapping (input 6), as well as the concept generation (input 16). From the R&D perspective, the system architect's role is to integrate the data from the risk assessment (input 20) and to summarize the list of activities for the next process (input 21). It is important to mention that a unique perspective of the allocation of a system architect for the Combination Product development is that he/she does not necessarily owns all those activities/inputs listed in Figure 3. The role of a system architect is to integrate a holistic picture of the Combination Product through the systems engineering principles, methods and tools, such as DSM and Model-Based Systems Engineering (MBSE), to name a few. The role of system architect is to encode the data in an MBSE environment – for instance, CatiaMagic software is one of the potential candidates to store the data from Figure 1 and Figure 2.

Although the MBSE approach offers several advantages (Henderson and Salado, 2021), studies (Akundi *et al.*, 2022) point out the lack of acceptance of conceptual modeling visual notations by notational non-experts (e.g., marketing, quality, operations or medical affairs) for whom the effort to learn a new modeling language, method and software is a barrier. Thus, in addition to the coordination of functions and the integration of inputs, the system architect role plays a key role in the capture of data in an MBSE approach as he/she masters the MBSE implementation in the MedTech company to define the product lifecycle and to iteratively assign the stakeholders to those lifecycles to generate potential concepts and to finally contribute to the TPP draft.

					MedTech industry function (division/department)						
					R&D	Marketing	Medical Affairs	Regulatory Affairs	Legal/ IP	Quality	Operations
Product Strategy definition process	A1	Problem identification	I1	Needs assumption	V	V					
			I2	Intended use formulation		V	V				
	A2.1	Product lifecycle definition	I3	Product lifecycle analysis	V	V					
			I4	Product lifecycle mapping	V	V					
	A2.2	Stakeholders definition	I5	Stakeholders analysis	V	V					
			I6	Stakeholders mapping	V						
	A3.1	Industry landscape assessment	I7	Market analysis		V					
			I8	Competition analysis	V	V					
	A3.2	Business model definition	I9	Business model analysis		V					
			I10	Go to market assessment		V					
	A4	Technical approaches to address needs	I11	Claims	V						
			I12	Targeted population	V						
			I13	Targeted geographies	V						
	A5	Generation of concept solutions	I14	Human Factor study			V				
			I15	Regulatory constraints				V			
			I16	Concept generation	V						
	A6	Technical readiness of concept solutions assessment	I17	DFM	V						
			I18	DFA	V						
			I19	IP assessment					V		
	A7	Risk assessment and mitigation plan	I20	Risk assessment	V	V	V	V	V	V	V
	A8	High-level work activities	I21	List of activities (next process)	V	V	V	V	V	V	V

Figure 3. Allocation of MedTech industry function (division/department) to the product strategy definition process activities/inputs.

6 Discussion and Conclusion

This paper discusses the challenges associated with the product strategy definition process for the development of a new Combination Product and proposes a systems approach to tackle those challenges. Due to the different industries involved in the design of a Combination Product, the holistic approach to the product and the surrounding context is inevitable to encode core design data and communicate it appropriately among all stakeholders. This is the area where systems engineering can provide powerful means to achieve those goals, and the system architect in MedTech R&D could serve an important role in mediating those activities. In this work, the AS-IS situation in the MedTech company was first analyzed to capture the core activities as they are present in the company's product strategy definition process. During the second step, the DSM/DMM matrix has been created to list the activities and inputs and map them to the corresponding functions (divisions/departments) in the MedTech company. In the third step, the DMM has been analyzed to identify the system architect's presence in the product strategy definition process as it is defined in the MedTech organization.

In the current work, the following core functions of the system architect in the MedTech new product development process were identified. The first of them is to integrate the core data from the cross-functional activities into the product strategy definition process. Among those data are the problem identification, product lifecycle definition, stakeholders definition, as well as the generation of concept solutions. The system architect should also communicate with all other functions within the MedTech organization to integrate the data from the risk assessment (input 20) and to summarize the list of activities for the next process (input 21) for the R&D view. The second function of the system architect is to develop a systems engineering-based view on the MedTech Combination Product, engaging the MBSE solutions. This function is not limited by only the model-based representations but also includes the implementation of the systems engineering principles tailored to the MedTech context, terminology, and practice. The third role of a system architect is to facilitate the system architecture analysis – for example, through the DSM-based methods.

A wider study is required as a direction for future work. Such a study would include design interviews with MedTech Combination Product designers – not only from the R&D function but from external functions, such as marketing, medical affairs, regulatory affairs, business development, legal, quality, operations and manufacturing. These interviews should be aligned with the ones to be conducted in the Pharmaceutical company. The ultimate goal would be to develop the Combination Product development process, fully aligned with the regulatory constraints imposed by such organizations as the FDA. Another goal would be to identify the nature of dependencies between MedTech and Pharma products.

Another direction of future work is to widen research beyond the MedTech industry. The DMM presented in Figure 3 could be used in the Healthcare industry at large. This would include the possibility to outline the role of system architect in Pharmaceutical companies, for example. Besides that, the approach could be considered as a universal one which may be adapted to any other organization even beyond Healthcare and MedTech. The system architect's role could be defined based on the specifics of concrete organization or industry, yet the steps and approach presented in the current work would allow to establish those core activities and inputs.

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Contact: Yaroslav Menshenin, Univ. Grenoble Alpes, CNRS, Grenoble INP, G-SCOP, 46 Av. Félix Viallet, 38031 Grenoble, France, +33 7 66 899 507, yaroslav.menshenin@grenoble-inp.fr