MULTIDISCIPLINARY DESIGN ANALYSIS AND OPTIMIZATION FRAMEWORK FOR REGULATORY DRIVEN MEDICAL DEVICE DEVELOPMENT

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ABSTRACT

Multidisciplinary design optimization (MDO) is a technique used in the design of systems involving the integration of many disciplines. The architecture and formulation of MDO has an impact on the solution time and optimality of final designs. The process of developing medical devices requires the combination of medical and technical knowledge and abilities. Developing a medical device is done by a complicated collection of Product Development Processes that entail tremendous oversight to ensure conformity to regulatory requirements. Regulatory standards often provide stern "Go / No-Go" policies which may discretize the design variables further increasing the complexity of the optimization problem. This work proposes a novel design approach which utilizes systems engineering practices to undertake complex multidisciplinary design optimization while implementing regulatory guidelines for medical devices. The formulated model is then applied and examined in a case study towards the development of a piezoelectric respiratory sensor. It is observed that the novel framework would extensively improve the design space definition and process driven product development practices.

Keywords: Multi- / Cross- / Trans-disciplinary processes, Optimisation, Biomedical design

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1 INTRODUCTION

Multidisciplinary design optimization (MDO) is a technique used in the design of systems involving the integration of many disciplines. These disciplines are often inextricably linked and cannot be tackled separately. MDO research was first motivated by airplane design (Giunta et al., 1998; Behdinan et al.,2004; Benaouali et al., 2019) , but its applications have spread to various engineering systems. MDO is the use of numerical optimization methods to design the interactions of engineering systems with many disciplines or components. Since inception, several methodologies (architectures) have been created and used to address multidisciplinary design-optimization issues (Martins et al. 2013). When implementing MDO, it is crucial to arrange the discipline-analysis models and optimization tools in tandem with the problem definition in order to produce an optimum design.

In traditional MDO architecture, it is essential to adjust the system to accommodate new configurations, the monolithic architecture of complex design systems often lacks the adaptability to interchange and update a subset of the integrated design modules. A second disadvantage of such a design approach is its scalability. Integration into a single system becomes unfeasible as soon as additional disciplines and impacts are considered throughout the design phase (Ciampa et al., 2020). The architecture and formulation of MDO has an impact not only on the solution time but also on the optimality of final designs. Martins et al. present an in-depth examination of various architectures employed (Martins et al., 2013).

The design of mechatronic devices is a multidisciplinary endeavour undertaken to provide product-related benefits that cannot be attained by undiscipline activities. When many technical disciplines are engaged in the design process, the complexity of the work grows proportionally. Due to the fact that a mechatronic product is comprised of solutions from the fields of mechanics, electronics, and computer software, particular consideration must be given to interdependence within the product and between the design processes. Inattention to dependencies results in integration issues and higher development expenses. (Mørkeberg et al., 2012)

The process of developing medical devices requires the combination of medical and technical knowledge and abilities. The process of developing medical devices necessitates the combination of knowledge and abilities from medicine and engineering. Integration is challenging due to a lack of communication, misaligned objectives, and work-style disparities across those disciplines. Developing a medical device is done by a complicated collection of product development processes that entail tremendous oversight to ensure conformity to regulatory requirements. Several techniques have been developed and implemented to execute multiple PDP phases to ensure that the product meets the customers in its best form. Thus, the method involves an aggressive uptake on the developer's end to ensure the product assuages the multifaceted industry's numerous requirements. The medical device development cycle is mapped in numerous ways and methods whilst accounting for countless FDA directives and New Product development techniques. Ocampo et al. published a systematic analysis of PDPs, demonstrating the extensive regulatory system impact during the production phase (Ocampo et al., 2019)

Ciampa et al. (2020), who are in the process of formalising the agile paradigm, have introduced a shift in emphasis that centres on accelerating the deployment and operation of MDO systems, which can be exploited to accelerate the development of complex products namely in aircraft and aviation industry. Bussemaker et al. (2022) explain the integration of MDO and MBSE expands upon the notions of mapping architecture components and relevant quantities to the central data schema. Several recent studies have improved upon the structure and behaviour of the workflow formally described in the MBSE system model with SysML In this context, Leserf et al. (2015) presented approach for linking MBSE and MDO and demonstrated using an example of an electric coolant pump.

Multiple works illustrate the MDO context with a problem-specific parametric diagram. A constraint satisfaction multicriteria optimization problem is generated and solved in an optimization framework based on this description. This method necessitates that the optimization problem be able to be characterised using parametric diagrams. However, this paper attempts to incorporate non-parametric

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constraints, such as regulatory affairs, into the context of MDO, which may help Biomedical Developers overcome the knowledge limitations of non-technical industry requirements.

Inspired by the author's previous work to create an open-source ventilator assessment framework, it was observed that medical devices are not only driven by their functionality and quality assurance of their subsystems, but are also greatly reliant upon their compliance towards specific design requirements for them to be administered safely (Behdinan et al., 2022). It was noted that any mechatronic product intended to be utilized as a medical device must conform to general standards which dictate several design principles. However, early stages of prototyping do not incorporate such design principles and may require major rework for the changes to be implemented. This is apparent by the number of open-source ventilators in comparison to the ones which were approved for use by the regulatory institutions. Thus, certain general design constraints must be incorporated in the early phases of MDO in order to constraint the design space for exploration.

The verification and validation practices at large firms are usually undertaken by special teams of regulatory compliance specialists who may not necessarily be involved in the development of the design requiring several reviews and information exchange points. To overcome this, this work proposes integrating state-of-the-art methodologies in systems engineering to formalize and define a well constrained design space for improving the agility of the development cycle. It is identified that, to analyze, optimize and manage agile product development, there is a growing need for the development of a smart, user friendly and adaptive information transference methodology for integrating the various system interactions for set-based product design. The formulated model is then applied and examined in a case study towards the development of a piezoelectric respiratory sensor.

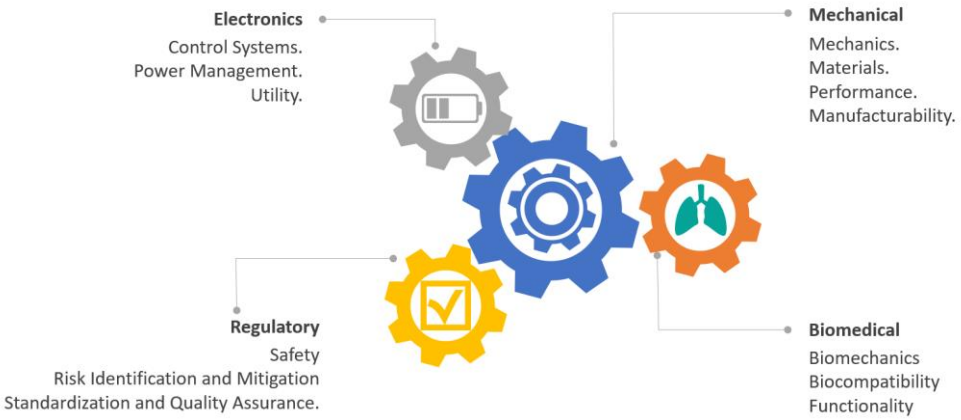

Figure 1: Medical device mechatronic system interactions

2 METHODOLOGY

Studies have shown that engineers continue to spend an excessive amount of time locating information and compiling reports. This tendency has further intensified as the size and complexity of systems have increased, necessitating a huge rise in system needs. Thus, simple solutions like as checklists or ad-hoc methods such as disconnected databases are no longer sufficient for handling requirements (Madni et al., 2018). At present, system modelling efforts are shifting away from a document-centric approach toward a model-driven architecture perspective. The functions provided by this technique enable better management of systems that are becoming more sophisticated and involve a diverse variety of domain-specific settings. In this context, the Model Based System Engineering (MBSE) program is critical in formalizing the procedures, techniques, and tools that serve as support for the field of system engineering. MBSE has gained traction across industries ranging from commercial to aerospace and military. While most understand and embrace the MBSE concepts, effective adoption and implementation within the industry continue to be a difficulty (Estefan et al., 2007). A precise specification of these ideas is one of the primary characteristics that distinguishes an effective model-based system from one that is poorly developed. The evolving MBSE technique provides the technology necessary for designing, analysing, and verifying the structure and behaviour of products

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(Fuchs et al., 2012). Thus, it is feasible to manage large-scale systems effectively throughout all life-cycle stages by integrating the diverse goals and objectives of diverse technical segments.

System couplings give a framework for comprehending the interplay between system functions and the system's interaction with its surroundings. A system can have several forms of physical and logical connections. These couplings are not always apparent and might result in emergent behavior that alters the system's couplings (i.e., adding new or changing the response of known couplings). This becomes increasingly apparent with medical devices as new developers struggle with mapping the regulatory requirements for the development of biomedical devices.

In any downstream design process subsequent phases of product design address the design (and, ultimately, optimization) for a given architecture and set of requirements. This includes the selection of design competence (e.g., disciplinary simulations) based on the design stage (e.g., conceptual, preliminary, detailed), the integration into a design process, the deployment of design system (e.g., computational environments), the exploration of the design space, and the selection of the optimal solution (s)

In accordance with the concepts of regulatory design practices as outlined by Ocampo et al. (2019), this paper suggests the incorporation of regulatory-based project requirements into the MDO framework as specific design constraints to define the design space. This enables the incorporation of design principles from the earliest phases of a viable design study, hence enhancing the framework's agility and reducing the number of iterative steps necessary to achieve verification and validation standards for medical device approvals. Using the Vee model for system design and product development and incorporating the MBSE methodology, the suggested model digitizes the information passed across disciplines throughout the creation of a complex mechatronic product. Maintaining a single database for system constraints allows consistent iteration of the design based on discipline criteria and reduces redundancy.

3 REGULATORY DRIVEN MDO FRAMEWORK

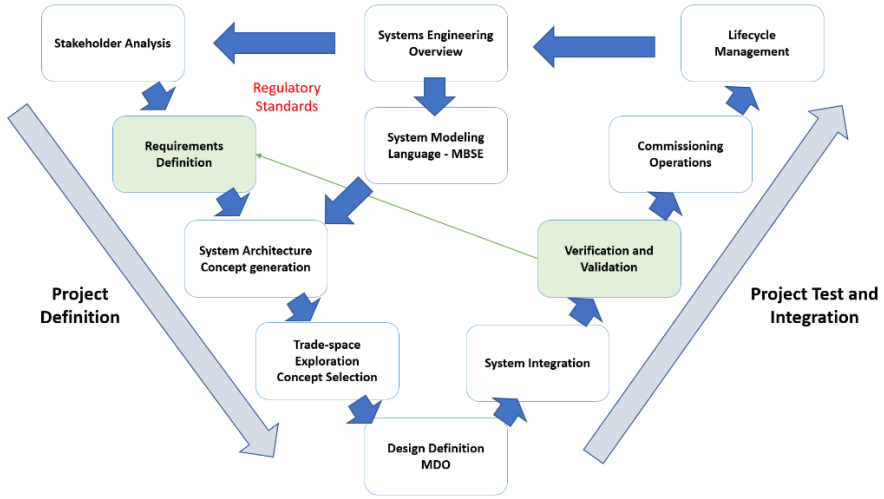

Figure 2: Adopted vee model of systems engineering (Wynn et al. 2018).

In line with the conventional requirements modelling practices of systems engineering, the first stage to commence concept generation for a consumer-driven product is the refinement of stakeholder demands. Nonetheless, we propose the addition of a new parameter for precisely translating the basic criteria for a mechatronic medical device as defined in IEC 60601-1, ISO 13485, and ISO 14971. In addition, these standards should be broadened to include any specific standard applicable to the intended usage of the mechatronic equipment in question. This phase ensures the implementation of high-level technical specification such as the expected factor of safety, general tolerances in assembly, any subjective parameters for user/operator safety and the consideration for risk mitigation practices.

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Furthermore, gaining a clear understanding of these requirements in the early stages gives a clear picture of the expected product development plan to bring the product to market. Utilizing an MBSE framework to store this information enables the firm to prevent rework and can enable the transference of these general constraints to relevant projects seamlessly. The interactions between the various stages of the process leading up to the MDO formulation in accordance to the adopted Vee model is illustrated in Figure 3.

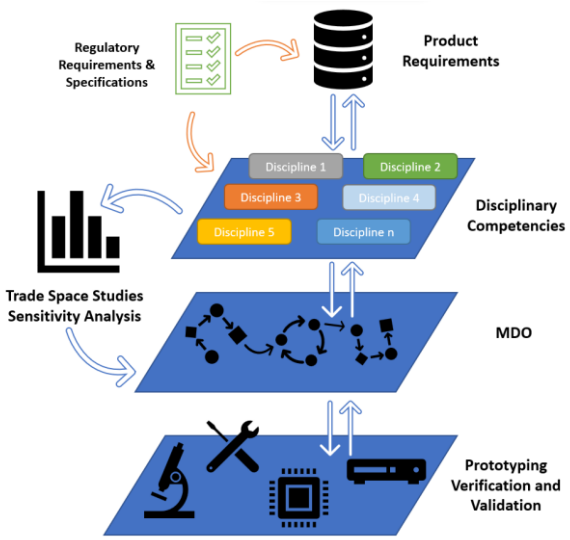

Figure 3: Role of regulatory standards in formulation of MDO and concept selection.

The process of data extraction in smaller design teams can be challenging based on the vast libraries of regulatory indications which may dictate further design refinements. Traditionally such practices are passed down to specialized regulatory agencies which specialize in making medical devices audit ready, making the process increasingly subjective based on the individualized approach of such agencies. However, in larger firms, more often than not, there are specialized regulatory and quality assurance teams which provide testing and verification reviews at various design milestone for reiteration. The fundamental utilization of this framework is to accelerate these review processes to shorten the reiteration loop at the precipice of design conceptualization. Using an MBSE methodology or a centralized database of design requirements as indicated in Figure 3 we intend to enable all stakeholders within the organization to contribute towards the design requirements. For example, the quality assurance and regulatory practitioners may create design requirements for the intended product such that discipline-wide changes can be easily implemented. This would also allow designers to be more cognizant of such constraints from the outset, resulting in fewer design revisions. This process is currently conducted using traditional experience-based knowledge, making the organization's ability to speed product development highly dependent on its personnel capabilities. Using the suggested methodology, however, it is anticipated that multidisciplinary teams will be able to see further in the design lifecycle, particularly in larger organisations where the team has narrowly defined objectives and little knowledge of the bigger picture.

3.1 Framework application: respiratory sensor

A sensor is a device that, when influenced by a physical quantity, such as pressure, heat, humidity, movement, and force, generates an output signal that can be readily obtained and examined. In contrast to an analogue sensor, which generates an electrical signal, a smart sensor outputs a digital number that directly reflects an estimate of the input amount. A smart sensor incorporates, inside the same physical device, the sensing component, the acquisition stage, the processing and transmission blocks. In this study we shall focus on the sensing component. (Massaroni et al., 2019)

The respiratory system is responsible for the process of breathing, which consists of inhalation and exhalation. During inhalation, human beings take in oxygen-rich air, which causes expansion of the lungs, and a downward movement of the diaphragm. Exhalation in humans involves the release of carbon dioxide, the contraction of the lungs, and the movement of the diaphragm upward and back to

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its original position. The expansion and contraction of the chest and abdomen are caused by shifts in the volume of the lungs and the movements that correspond to those shifts in the diaphragm. The act of breathing, which encompasses the complete process from intake to expiration, is also referred to as the respiration cycle, and the term "respiratory rate" refers to the total number of cycles of respiration that occur in one minute. The range of the typical respiratory rate for individuals who are healthy is anywhere from 12 to 20 breaths per minute. If a person's respiration rate is more than 27 breaths per minute, it implies that they are in critical condition (Hill et al., 2020). A respiratory sensor enables one to track the respiratory rate of the user to ascertain any anomalies during the act of breathing during various activities. (Nicolo et al., 2020)

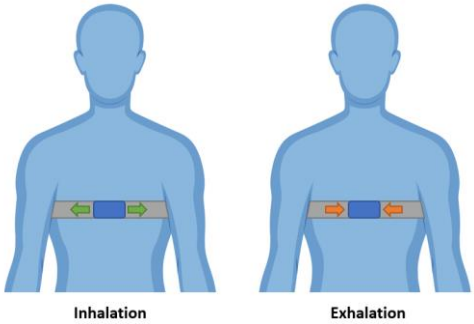

Figure 4: Respiratory sensor working principle.

Health Canada has classed a respiratory sensor for personal health monitoring as a Class I medical device due to its minimal risk to the user. Due to the danger associated with the failure of the proposed product, a comparable device used in the use case of driving a critical care equipment, such as a ventilator, may be classed as a Class II Medical device. This study does not examine the details of the device required to fulfil various regulatory criteria for a respiratory sensor, but explores the influence of regulatory requirements on the design of a novel piezoelectric respiratory sensor that is currently under development. Some of the relevant standards and their scope pertaining to their design, functionality and testing are outlined in Table 1.

Table 1: Standards applicable to design of a piezoelectric respiratory sensor.

Standard	**Scope**
IEC 6238	IEC 62368 pertains to devices designed to transmit and receive electricity through communication cables or ports. It outlines certain standards for circuits intended to deliver DC power from a power sourcing equipment (PSE) to a powered device (PD)
IEC 60601-1-11	This international standard is about the basic safety and essential performance of medical electrical equipment and medical electrical systems for use in the home healthcare environment.
IEC 60601-1	This international standard applies to the basic safety and essential performance of medical electrical equipment and medical electrical systems
IEC 62830-6	This document is for energy-harvesting devices that can be used as power sources for wearable devices and wireless sensors used in healthcare monitoring, consumer electronics, general industries, the military, and space applications.
ISO 10993	This document can be used to evaluate the biological effects of all kinds of medical devices, including those that are active and those that aren't, as well as those that can be implanted and those that can't. This document also gives guidelines for assessing biological hazards caused by: (i) risks, such as changes to the medical device over time, as part of the overall biological safety assessment; (ii) breakage of a medical device or medical device component that exposes body tissue to new or novel materials.

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ISO 62304	This standard applies to the development and maintenance of medical device software when the software is itself a medical device or when the software is an embedded or integral part of the final medical device.
ISO 13485	This standard outlines the requirements for a quality management system that can be used by an organisation that is involved in one or more stages of a medical device's life cycle, such as design and development, production, storage and distribution, installation, service, final decommissioning and disposal, and design and development or provision of related activities (e.g. technical support).
ISO 14971	This document gives terms, principles, and a process for risk management of medical devices, like software as a medical device and in vitro diagnostic medical devices. The process outlined in this document is meant to help makers of medical devices find the risks and hazards associated with their products, estimate and evaluate those risks, control those risks, and keep an eye on how well the controls are working.

In alignment with the standards outlined in Table 1, we map the design constraints derived from each standard towards the disciplines involved in the functioning of the respiratory sensor. As illustrated in Figure 5, we observe that the design constraints refine the design requirements from early stages of conceptualization. For example, unlike most commercial products, a medical product must be functional overcoming "single fault" conditions. A single fault condition of a medical device is defined as a *condition in which a single means for reducing a risk is defective or a single abnormal condition is present*. This condition enforces higher reliability and risk management strategies which must be employed towards the tolerances, component placement and protection as well as several other design conditions. Furthermore, standards also provide stringent systems constraints which pertain towards the safety of the device towards the user, operator and the environment. Such constraints result in drastic design changes when carried out in the later stages of iterations and can prove to be time consuming. Traditionally, the device is reviewed in usable form in the verification and validation phase by special auditors and regulatory practitioners. In this work, we propose transference of knowledge between these classes of specialized personnel and the design team. While mapping these requirements in the early stages, such constraints ensure that the generated concepts and design exploration occurs within the feasible design space while also expanding the design space considering the holistic design lifecycle. While utilizing this approach one may spend a considerable amount of effort in the system modelling phase however, once modelled, the exploration of feasible design is faster due to automated design exploration.

Conventional MDO procedures involve the management of the product's technical and sub-technical requirements to determine the ideal operational output. With a larger firm and a more complicated product, however, integrating discipline expertise for a synergistic product becomes impossible. For instance, the commercially accessible product's design decisions may not be able to incorporate all stakeholder requirements into the decision-making process. If so, there would be multiple iterative design studies and analyses that attempt to manage expectations and trade-offs in smaller phases, therefore extending the project's development time. In this case study, we employ regulatory practises as the key issue for medical devices and the multidisciplinary optimization procedure. According to the numerous MDO architectures illustrated by Martins et al. (2013), the majority of decisions are objective and can only be examined through the operational model's limitations. It is up to the optimization job to iteratively traverse these programmed limitations in order to arrive at an optimal solution. During optimization, we forget the subjective and difficult-to-program objectives that a product must satisfy, which are entirely dependent on the organization's competency before or after the optimization task itself. In this proposed framework we try to address this issue by proposing a holistic framework formalizing both operational and the more "non-technical" stakeholder's role in product development which may be communicated to designers to integrate in the design at early stages of development. For example, the device may require a specific process of sterilization for reuse which may require it to be disassembled, this issue may be further realized during the verification and quality assurance phase, however, MBSE captures such requirements from early stages for designers to be mindful of such a scenario.

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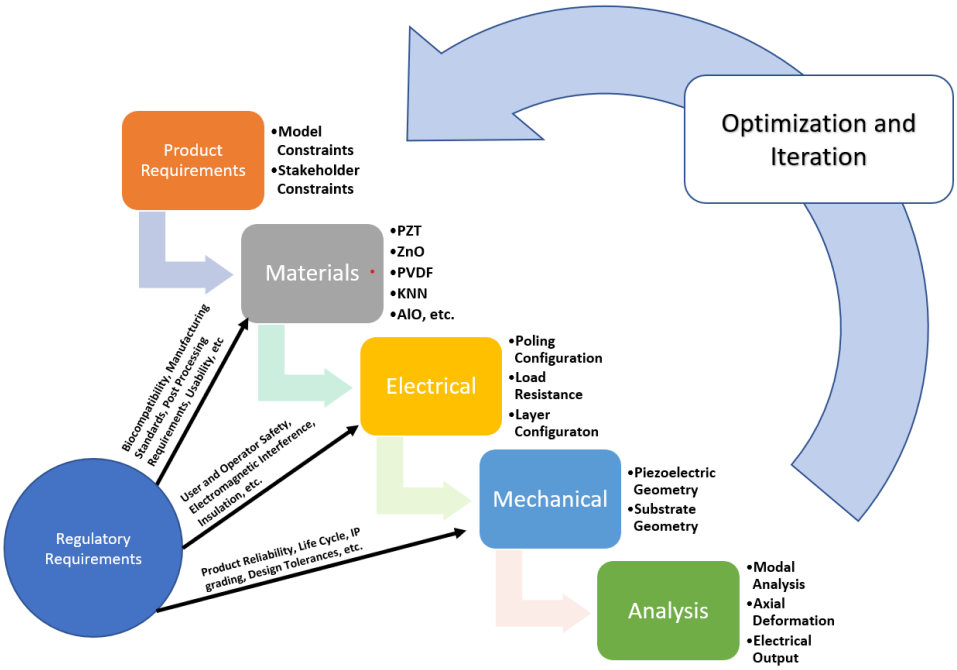

Figure 5: MDO (IDF) interactions for respiratory sensor with regulatory constraints.

4 CONCLUSION

MBSE has now become a formalised approach towards defining and modelling a system while implementing them into the design process. However, the methodology has yet to be fully utilised towards MDO undertakings. Most MDO formulations require one to carefully consider the nature of variables being discrete or continuous. Regulatory standards often provide stern “Go / No-Go” policies which may discretize the design variables further increasing the complexity of the optimization problem. However, this is a trade-off between quality compared to efficiency of the process. Furthermore, due to the various rigorous testing requirements such as single fault conditions require one to implement advanced modelling approaches such as reliability-based design optimization and possibility-based design optimization. (Behdinan et al., 2011). Although these implementations may not necessarily have to be adopted to save development time, but including these constraints in the global database may enable developers to consciously avoid pitfalls. This also enables developers employ risk mitigation strategies in the early phases of design considering the various aspects of the design lifecycle while accelerating the later stages of verification and validation practices and process design. The ideology of the proposed framework is in alignment with several design and development processes as highlighted by Ocampo et al. (2019). While building on the concepts of the medical device development and understanding the influence regulatory affairs we integrate subjective and functional parameters to model the design space for optimization. Using the MBSE approach we also enable users to automate the design history file and risk management file which must be provided for regulatory approvals from initial stages of product definition and requirements modelling. This ongoing research shall enable developers to accelerate and efficiently track the progress of complex mechatronic devices such as Medical Devices.

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