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Toward Next-Generation Medical Devices

A Holistic and Comprehensive SE Framework

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TOWARDS NEXT-GENERATION MEDICAL DEVICES: A HOLISTIC AND COMPREHENSIVE SE FRAMEWORK

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Abstract

The development of medical devices involves a mix of sciences not limited to chemical, electronic, mechanical, polymer, design, and above all adherence to stringent regulations like the MDR, IVDR and FDA. Complex systems like MRI scanners and blood analyzers further complicate matters. Through this paper, we aim to provide in detail the nuances in the product development of medical devices and how systems engineering can enable development of Class 1 and Class 2 medical devices. We also share a unique perspective of what the current product development offers (Design Control Process) and how we can leverage systems engineering practices in symbiosis.

Keywords

Systems Engineering, Medical Devices, Engineering Vee, Vee model, ISO 13485, Design Control Process, class I devices.

Introduction

As we talk about medical devices, we often come across the notion of various classes, and hence it becomes necessary to know what some of them are.

Class 1 medical devices, notated as Class I devices by FDA, are associated with the lowest risk and are therefore subject only to general controls, the lowest level of regulatory controls. Some examples include bandages, disposable gloves, stethoscopes, crutches, dental floss, surgical masks, handheld surgical instruments, imaging instruments, etc.

Class 2 medical devices, notated as Class II devices by FDA, are usually more complicated than class I devices, are associated with the moderate to high risk and are subject to regulatory controls similar to class I medical devices. Some examples include computed tomography (CT) scanners, blood pressure cuffs, syringes, blood transfusion devices, powered wheelchairs, contact lenses, etc.

More often than other industries, medical industry experiences new product developments due to the tailored nature of business. A typical product development takes the form mentioned below

Figure 1. Example of medical device lifecycle

Activities like risk management and usability are also addressed as a part of internal product development. It has been researched on how the development has now shifted to call for a more systematic approach. Gibson et al [1] described how the third edition of IEC 60601-1:2005 introduces a shift from test-based to process-based compliance in medical device development. Key literature also suggests why adoption of systems engineering is imminent. Some key thoughts include integration of safety-risk management and usability engineering throughout the lifecycle, management of interfaces among end users, engineering, regulatory, human factors, and project management; and ensuring compliance with standards through a methodical and cost-effective approach [1].

With global trend towards internet of things (IoT) for healthcare, integration of differently distributed devices that gather, analyze and communicate real-time medical information to open, private or hybrid clouds, making it possible to collect, store and analyze big data streams in several new forms has now become more critical than ever [2].

Design Control often limits the product development capability of product development till Test and Evaluation [3] [4]. The aim of this paper is to promote the adoption of systems engineering as a means of product development to ensure the appropriate addressal of addition of newer technologies to medical devices.

Text Body

A typical medical device development often uses design control method. It aims at ensuring that the manufacturers prove their product is safe and meets user needs. It was initially coined by the Food and Drug Administration (FDA) [5], it is now standard in the ISO 13485; both of which require meticulous documentation, as outlined in 21 CFR Part 820.30, section (j) (design history file), setting the rules for the design control process. A simplified implementation of design control process is shown below listing processes that the manufacturers must go through.

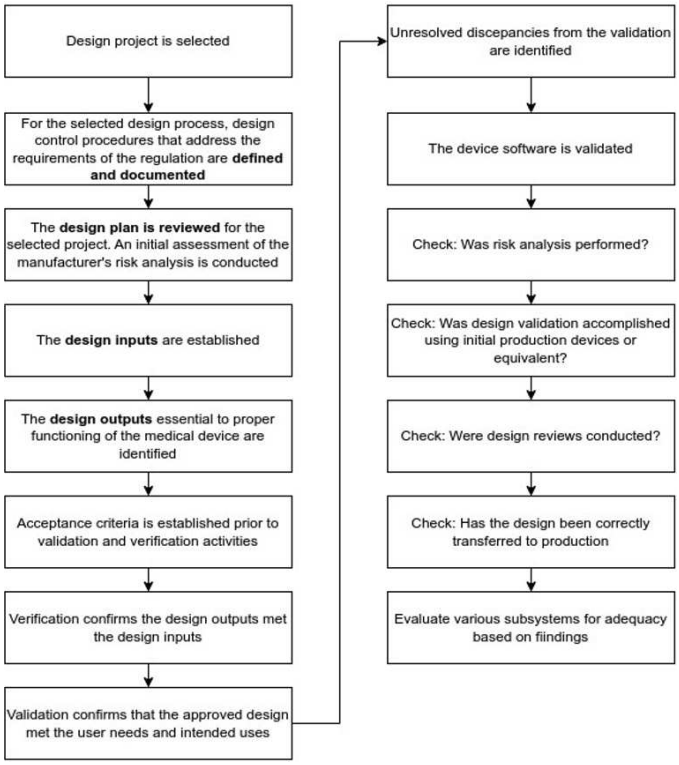

Figure 2. Typical design control process in a medical device: Adapted from Design Controls (2023) [5]

Throughout the product development lifecycle, risk management and quality process are considered, including the traceability between design input, design output and verification and validation. A broader purpose of design control can be assumed to show that the device:

a. Addresses clinical needs (users and patients' requirements).

b. Meets input and requirements (design input).

c. Complies with applicable standards (safety and quality).

d. Achieves performance criteria (effective use).

A manufacturer typically begins the journey with extensive market research and defining the scope. The design control procedures that address the requirements are established and documented, with a

review of the design plan in place. Together, these generate the requirements for the product, such as intended use, performance characteristics, risks, biocompatibility, compatibility with the environment of intended use (including electromagnetic compatibility), human factors, voluntary standards, and sterility, which are recorded as design inputs. With these in place, the design outputs are developed. These are the work products or deliverables of a design stage, such as diagrams, drawings, specifications, and procedures. The outputs from one stage may become inputs to the next stage. The total finished design output consists of the device, its packaging and labeling, and the device master record. The acceptance criteria are defined, and validation and verification are established to ensure that the approved design meets the predetermined user needs and intended uses. The product and project risk analysis is completed during design validation to determine if the design reviews were conducted effectively. The design is then transferred to production using means such as assembly drawings, inspection and test specifications, and manufacturing instructions, etc.

It may sound simple when looked at from the design control point of view, but the medical device lifecycle may consist of numerous other factors that were not discussed above. Refer Figure 3 for various elements that play a major role in a medical device development lifecycle.

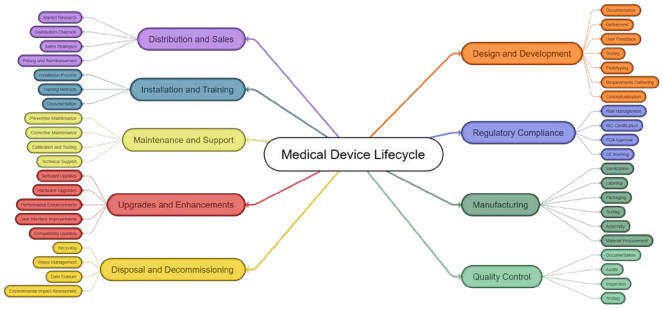

Figure 3. Various elements in a medical device lifecycle

It is evident that the industry demands persistent quality adherence, proactive documentation and planning and a thorough traceability – all of which align seamlessly with the unique strength that systems engineering offers. A shift to process based compliance [1] as described by Gibson et al (2012), describes how well systems engineering can solve the increasing complexity of these devices as they get into the market.

In the restructured approach described in this paper, the design control process is analyzed from a systems engineering perspective and the definition of system lifecycle process in ISO/IEC/IEEE 15288. The similarities are identified along with the gaps from ISO/IEC /IEEE15288, while considering a simple example of an X-ray and its considerations to develop per the systems engineering lifecycle.

The Design control process and the ISO/IEC/IEEE 15288 have a lot in common, as shown in Figure 4. It is evident that various processes of design control are a subset of the systems engineering lifecycle and align under the technical management process, system definition, system realization and system deployment and use.

In addition, the elements not defined in the design control process, but essential to the medical device development that varies from manufacturer to manufacturer, can be standardized using the systems lifecycle process such as organization project enabling process could be used for quality and knowledge management of medical devices; extended technical management processes could be used for project planning, configuration management and quality assurance; the technical process with system architecture and definition reducing the reliance on medical and clinical experts to take quicker decision within the organization and to stay on top of the game with standardized regulatory architectures; system deployment and use to plan the product disposal and so on.

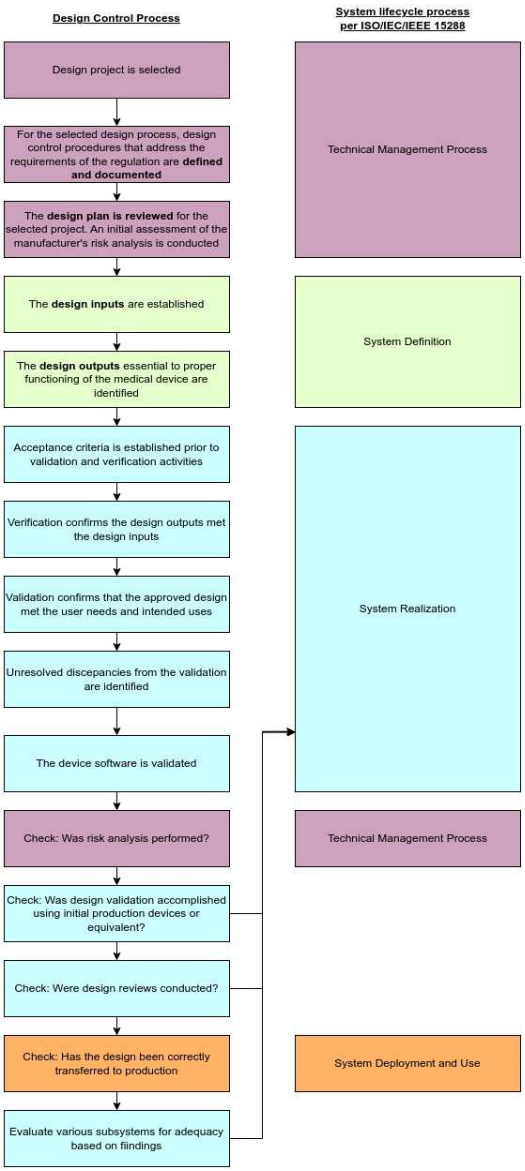

Figure 4. Processes from ISO/IEC/IEEE 15288 mapped to Design control process

A simplified systems Vee model is established to employ the example of an X-ray in product development is considered and the below implementation of Vee model is incorporated to it. Moderate tailoring was done to ensure some product development aspects are considered like real-life product development by various manufacturers. Shown in Figure 5, a slightly tailored vee model that can be used for class I and class II medical devices. It is to be understood that this model reflects those aspects of cybersecurity, risks, regulatory needs, and the introduction of new technology explicitly at the beginning of product development. It is also important to notice that this model hands over functional specifications and requirements to design and the architecture is used only to define the higher order system. This is a representative relationship model for the standard systems engineering development [6], however, currently it is a temporal model for the medical device product development. Legends are introduced to define roles and responsibilities at each stage of product development. The bottom of this model represents few elements of like risk, configuration, etc. that need to be considered by independent departments who enable product and project specific managements (legend shall not be referred for these).

Within this tailored framework for the medical industry, four major stages of product development have been considered, each involving multiple stakeholders using x-ray machines as an example to demonstrate the application of this framework.

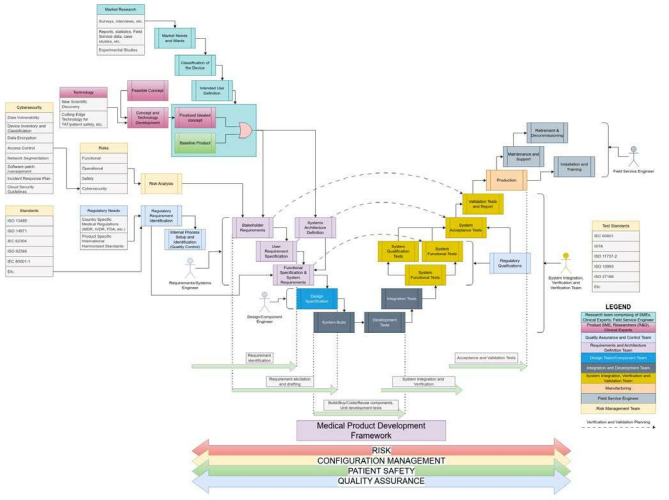

Figure 5. Medical product development framework

Phase-I: Defining the Intended use and deriving a product concept

Comprehensive market research is done, identifying key stakeholders (as their insights and perspectives will shape the development). At this stage, the goal is to gain a deep understanding of the market dynamics, regulatory landscape, recent technological advancements, and most importantly, the needs of the end-users. For an x-ray machine, this means exploring perspectives from radiologists, healthcare providers, and even patients who undergo x-ray procedures. Additionally, understanding potential

challenges in the development and adoption of x-ray devices is critical.

Market research can take various approaches, and key stakeholders may include regulatory bodies for compliance, medical professionals for usability, and technological experts who influence innovation. By delving into these perspectives, we lay the foundation for a robust product concept for the X-ray machine. List of a few stakeholders and the rationale for choosing them has been listed below in Table-1.

Serial	Stakeholders	Intentions (Rationale)
1	Medical Professionals	• Radiologists and technologists. • Healthcare administrators.
2	Manufacturers and Suppliers	• Companies involved in manufacturing x-ray devices. • Suppliers of components and materials used in x-ray device.
3	Regulatory Authorities	• FDA (Food and Drug Administration) or relevant regulatory bodies in different countries. • Compliance officers.
4	Healthcare Institutions	• Hospitals, Imaging centers, Diagnostic laboratories.
5	Patients	• Individuals who undergo x-ray procedures. • Patient advocacy groups.
6	Research and Development Teams	• Engineers and scientists involved in x-ray technology development. • Academic institutions conduct research in medical imaging.
7	Government Agencies	• Health departments. • Agencies involved in healthcare policy and regulation.
8	Technology Experts	• Experts in imaging technology. • Professionals with knowledge of emerging technologies in medical imaging.
9	Investors and Financial Analysts	• Financial analysts tracking the medical device industry.
10	Competitors	• Other companies in the x-ray machine market. • Market leaders and emerging players.
11	Trade Associations and Industry Groups	• Organizations representing the medical imaging industry. • Trade associations related to healthcare technology.

Table 1. List of stakeholders for x-ray system development

With this in place and the data gathered from these stakeholders noted, geography and demography identified, the next step involves translation of insights from this market research into clearly defined intended use, the intention of which is to contain definition of the x-ray in various medical applications, targeted patient populations, clinical strengths, and diagnostic focus. This step ensures alignment with user needs, regulatory requirements, and the findings from market study. The intended use document shall guide the subsequent development steps along with the market needs and wants and product concept definition. A few other entities are defined in the process, some of which are:

User requirements: Considering the human aspect, the needs of healthcare professionals, usability, and outlining user training requirements are elicited.

Regulatory compliance: Adherence to applicable regulatory standards, emphasizing safety and performance standards that govern the x-ray machine in targeted countries of production.

Technology considerations: Specifying the imaging technology and any innovative features on the product.

Risk management: Risk Management Plan is devised, identifying potential failure modes and strategies for mitigation.

At this stage, the classification of the x-ray machine is determined, considering the risk associated with it. A summarized Phase-I framework based on systems engineering development shall look like what is shown in Figure 6. The output of this stage is intended to be a baseline product, in case of a brownfield project, or a finalized ideated concept, in case of a greenfield project.

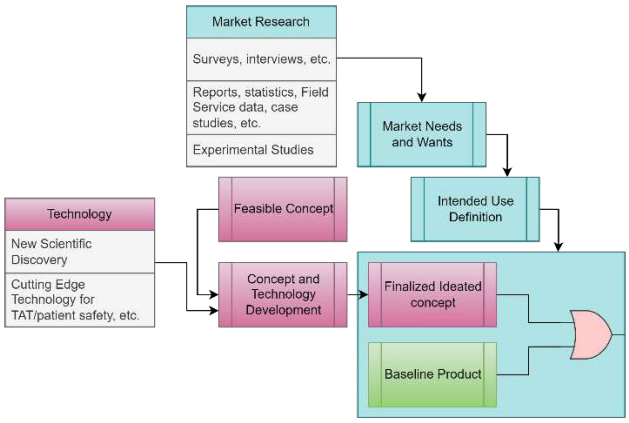

Figure 6. Phase-I framework

Further categorization of different events during phase-I can be seen in Figure 7 and Figure 8, where the relevant stakeholders and artefacts generated at that stage are shown.

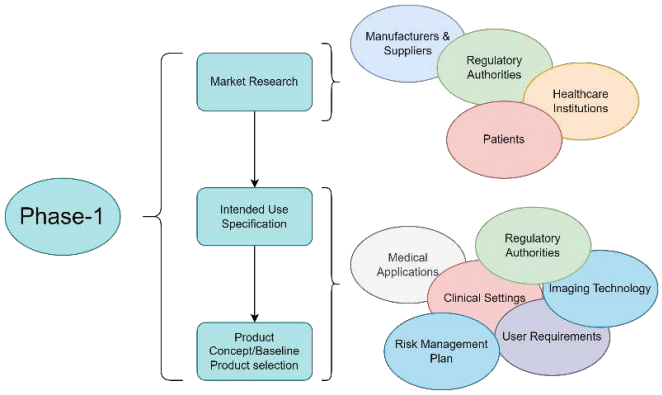

Figure 7. Stakeholders for phase-I

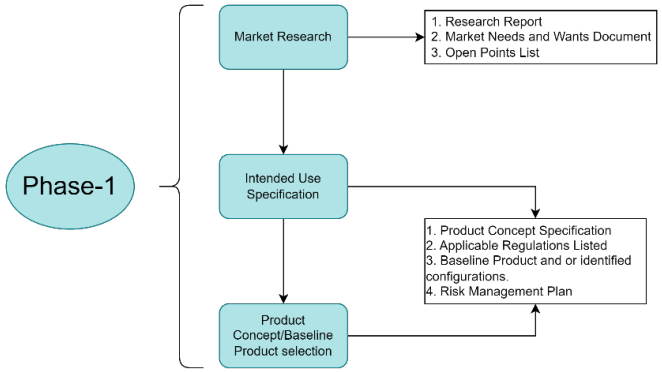

Figure 8. Artefacts generated at phase-I

Phase-II: Defining the Requirements

Building upon the intended use, product concept and other elements derived during phase-I, the logical next step in a systems engineering environment is to elicit the stakeholder requirements progressing through the functional-logical-physical system architecture after relevant sub-systems have been identified.

As an example, the x-ray system is broken into a few critical subsystems namely:

- ***X-ray source system***: Logical components related to the generation of x-rays, including the x-ray tube and associated control mechanisms.
- ***Detector system***: Components/elements responsible for capturing and processing X-ray images, such as detectors and image acquisition systems.
- ***Control system***: The central control mechanisms, performing the operation of x-ray machine and coordination with/among other subsystems.
- ***Image processing system***: Processing and enhancement of x-ray images, including algorithms and software/digital components (if any).
- ***Mechanical support and positioning system***: Physical framework and mechanisms supporting the X-ray machine to ensure effective operation and patient safety

The aim to define subsystems at a high level is to establish a modular foundation for the x-ray system and subsequently be able to establish requirements definition and architectural design. Figure 9 represents the x-ray system and the subsystems we identified during phase-II.

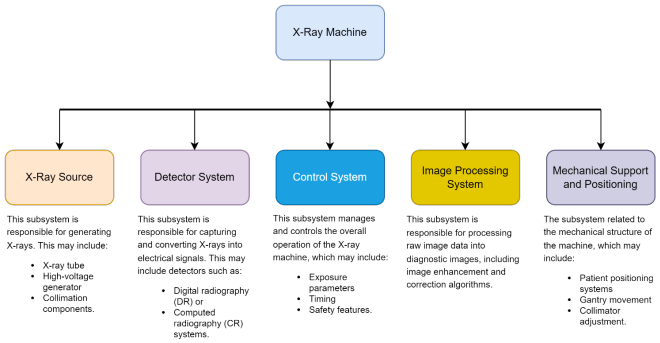

Figure 9. Example of decomposition of x-ray system into subsystems

The stakeholder needs, market demands, targeted geography and demography were gathered during Phase-I, which then were elicited into stakeholder requirements, system requirements, subsystem requirements and system architectures. Medical device development, however, considers regulations to be of paramount importance. As a result, we have noted down a few of them not limited to x-ray development in Table 2 below. These regulations cover quality management systems, risk management, software life cycle processes, usability engineering, sterilization, packaging, clinical investigation, biological evaluation, and in vitro diagnostic devices, etc.

Standard	Title
ISO 13485	Medical devices — Quality management systems — Requirements for regulatory purposes
ISO 15223-1	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
ISO 16142-1	Medical devices — Recognized essential principles of safety and performance of medical devices — Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards
ISO 14155	Clinical investigation of medical devices for human subjects — Good clinical practice
ISO 80001-1	Safety, effectiveness and security in the implementation and use for connected medical devices or connected health software — Part 1: Application of risk management
ISO 11137-1	Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
ISO 15189	Medical laboratories — Requirements for quality and competence
ISO 14971	Medical devices — Application of risk management to medical devices
ISO 12052	Health informatics — Digital imaging and communication in medicine (DICOM) including workflow and data management
ISO 13482	Robots and robotic devices — Safety requirements for personal care robots
ISO 17664-2	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices
ISO/IEEE 11073-10101	Health informatics — Device interoperability — Part 10101: Point-of-care medical device communication — Nomenclature
ISTA	International Safe Transit Association Standards
ISO 45001	Occupational Health and Safety Standard

Table 2. Examples of some standards applicable in the medical device manufacturing

While not every standard listed may be applicable to every manufacturer, this compilation serves as a valuable guide during regulatory assessment. Manufacturers often try to comply with various other standards such as FDA, ANVISA, Canadian regulations, and more. It is common for organizations to sell their products globally, and though specific regulations may vary, there is often a significant overlap in the requirements across regions. For instance, certain sections in the regulatory requirements, such as ISO 13485:2016 and 21 CFR 820, share similarities. Usually, manufacturers have a regulatory team to deal with the derivation of the regulatory requirements.

With these in place, the stakeholder requirements or needs document and the system Architecture serve as primary sources for developing the system requirements definition document. In the medical industry, grasping the applicability of these requirements is crucial, considering the di-verse stakeholders like clinical experts, healthcare professionals, doctors and patients. These stakeholders directly influence requirements which may affect the decision on device states and subsystems, HMI, statistical data for long and short-term maintenance, etc. These act as design constraints and specifications and are considered in the system design definition document.

It can be noticed how systems engineering fits perfectly to the landscape of the medical device development while establishing processes until now. It is similarly important to identify acceptance criteria (verification and validation methods) for each requirement. This will later contribute to the planning, generation, and execution of the verification and validation activities.

As the focus shifts to the subsystem level, the requirements become specific. Domain expertise kicks in and the definitions become precise. This may involve detailing requirements for each of the identified subsystems from Figure 9 and enabling teams to further be able to take decisions on component level requirements, while considering the make/buy/code/reuse aspects.

It is understood that this stage is iterative in both design control and systems engineering approach, especially for the system requirements writing, analysis and definition since a lot of internal stakeholders are involved. It usually iterates until the intended problem is accurately defined. Manufacturers can leverage system architecture while the requirements drafts are issued and a few requirements mature, and as a result perform analysis that can help identify gaps and verify system functionality through logical sequence of events.

Phase III: Design and Integration

The development has transitioned to the lower section of the Vee representation of Figure 5. Design, integration, verification activities are planned and executed for individual units as well as lower-level subsystems developing towards a fully integrated system.

Integration efforts often go beyond unit designs and include hardware-software integrations, communication system integrations, etc. It is also important

to note that interfaces identified during architecture are detailed out with the exact specification of the exchange elements, risks, etc. enabling various interface documents to be generated and signed off between subsystems ensuring robust compatibility and internal boundaries.

Another key focus at this phase is identification of suppliers and initiation of the interactions (mostly at the detail design phase) and usually ends before the integration activities start. Tailoring the system build, development tests and integration tests for x-ray systems, the following activities have been identified:

Stage	Activities	Example
System build	a. Assembling physical components, including the x-ray tube, detectors, and supporting structures. b. Integrating hardware elements to form a system architecture. c. Implementing software functionalities based on the designed algorithms. d. Ensuring the alignment of physical and software components with the overall system requirements.	In the x-ray machine development, this stage involves physically building the machine by assembling the subsystems such as the x-ray tube, integrating sensors for the detector system, and implementing the necessary control software
Development tests	a. Conducting tests on individual subsystems such as the x-ray source, detector system, and control mechanisms. b. Verifying the performance and functionality of each component against its specified requirements. c. Identifying and addressing any issues or discrepancies in the behavior of individual subsystems. d. Ensuring that each unit meets quality and performance standards before integration.	For the x-ray machine, development tests might include validating the accuracy of the detector system in capturing images, assessing the emission capabilities of the x-ray source, and ensuring the responsiveness of the control system
Integration tests	a. Verifying the interaction between different subsystems within the X-ray machine. b. Testing communication protocols and interfaces between hardware and software components. c. Assessing the overall system functionality and performance under integrated conditions. d. Identifying and resolving issues related to the integration of hardware and software elements.	Integration tests for the X-ray machine would involve validating that the X-ray source effectively communicates with the detector system, ensuring the control system operates in sync with the imaging subsystem, and verifying the overall system's functionality

Table 3. Various system development stages of phase-III and associated activities

Phase-IV: Verification and Validation

Following the integration of subsystems, this phase focuses on system verification and validation. It aims to confirm that the x-ray does not only meet the identified requirements but also qualifies for a few more aspects of a medical device listed below:

a. ***Addressing clinical needs***: Ensuring the x-ray machine caters to the requirements of clinical needs, including the perspectives of users, patients, and clinical trials.
b. ***Complying with inputs and requirements***: Validating that the x-ray machine aligns with the design inputs, ensuring a transition from initial requirements to final design outputs.
c. ***Adhering to applicable standards***: Compliance with safety and quality standards, as well as harmonized standards such as FDA, ISTA, and ISO.
d. ***Qualifying for performance criteria***: Demonstrating that the x-ray machine meets specified performance criteria, ensuring its effective use in medical applications.

Once phase-IV concludes and the x-ray machine is production-ready (design is transferred), the transfer documentation is generated. This documentation is shared with relevant authorities for validation and serves as a guide for manufacturing, service, and maintenance of the product.

This transition marks the end of internal product development, handing over the activities to production. However, it is essential to consider additional parameters during implementation in the production phase. Key factors include packaging, labeling (such as CE and ESD markings), and transportation considerations.

Conclusion

As medical devices progress through their lifecycles, from concept to production and customer delivery, the application of systems engineering emerges as a well-suited approach existing symbiotically with design control process. Employing a holistic and interdisciplinary methodology (as mentioned in the abstract about how different disciplines intertwine with a great complexity to give rise to a medical device), systems engineering significantly enhances

the development, design, and implementation of a diverse range of medical devices.

This conclusion draws insights from the example of the x-ray machine, a complex and intricate medical device, to illustrate the impact of systems engineering. The systematic approach inherent in systems engineering plays a decisive role in orchestrating the seamless integration of components within medical devices, addressing not only technical intricacies but also aspects such as regulatory compliance, user needs, and safety requirements. Systems engineering methodologies, represented through the x-ray machine, seem to address the inherent complexity of medical device development, offering a structured approach.

With these elements in place and experience with product development, the use of systems engineering in the development of medical devices offers several advantages over the design controls methodology outlined by the U.S. Food and Drug Administration (FDA). I have noted down some key points of distinction below in Table 4:

	Systems Engineering	Design Controls
Holistic Approach	Emphasizes a holistic and interdisciplinary approach, considering not only individual components but also their interactions within the entire system. This helps in addressing complexities and interdependencies early in the design process.	Focuses on individual design elements and specifications, potentially overlooking the broader system-level considerations. It may not inherently provide a comprehensive understanding of how different elements interact.
Risk Management	Integrates risk management throughout the entire development process, identifying and addressing potential risks early on. It allows for a proactive approach to risk mitigation by considering the entire system.	While Design Controls include risk management as one of its components, it may not inherently provide a systematic and integrated approach to identify and manage risks across the entire system.
Interdisciplinary Collaboration	Encourages collaboration among diverse teams, including engineers, clinicians, regulatory experts, and end-users. This interdisciplinary approach ensures a more comprehensive understanding of user needs and regulatory requirements.	Primarily focuses on design aspects and may not explicitly promote interdisciplinary collaboration, potentially leading to gaps in understanding user needs and regulatory considerations.
Flexibility and Adaptability	Provides a flexible framework that can adapt to changes in technology, user requirements, and regulatory standards. It accommodates evolving needs and allows for the incorporation of emerging technologies.	Can sometimes be perceived as rigid, potentially making it challenging to adapt to rapid changes in technology or regulatory requirements.
Emphasis on System Optimization	Aims at optimizing the entire system's performance, considering both technical and non-technical factors. This focus on optimization contributes to the development of more efficient and user-friendly medical devices.	Primarily concentrates on meeting individual design specifications, and there may be less emphasis on optimizing the overall system performance.

Table 4. Advantages of systems engineering approach over design control

Recommendation

The organized nature of systems engineering serves as a guiding force throughout the journey of medical devices. By understanding and establishing a disciplined methodology for the interactions within these devices, systems engineering becomes a linchpin for advancing healthcare outcomes. Its impact facilitates robust and efficient development processes, empowering medical device manufacturers to deliver innovative solutions that meet and exceed the highest standards of quality, safety, and performance. The successful progression of medical devices through their lifecycles, as demonstrated through the simplified example of various stages of an x-ray machine, serves as evidence of the influence of systems engineering within the realm of medical device innovation and product development.

Systems engineering can facilitate engineers to identify potential challenges early in the development process. This proactive approach minimizes risks, reduces errors, and enhances the overall reliability and efficiency of medical devices. Moreover, the methodical nature of systems engineering allows for communication and collaboration among multidisciplinary teams, including engineers, clinical experts, regulatory experts, and end-users. This collaborative effort ensures that medical devices are not only technologically advanced but also user-friendly, meeting the diverse needs of both healthcare professionals and patients.

While design controls are crucial for regulatory compliance and ensuring the safety and effectiveness of medical devices, integrating systems engineering principles can enhance the overall development process by offering a more comprehensive and adaptive approach. Ideally, a combination of both methodologies would be beneficial, with systems engineering providing a broader perspective and comprehensive product management on the entire system.

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Biography

Prabhudutta Dash

is a Systems Engineering practitioner with 14+ years in aerospace and MedTech, specializing in MBSE and requirements management. He has led complex programs in defense and commercial aviation, ensuring compliance with global standards like ARP4754A and DO-160. Skilled in architecture modeling and digital transformation, he advocates MBSE adoption across industries. Prabhudutta holds a postgraduate degree in Business Analytics and Lean Six Sigma Black Belt Certification.

Stueti Gupta

Stueti Gupta is the Co-Founder and Director at BlueKei Solutions. Stueti has 17+ years of experience in both industry and academia. With formal systems engineering methods and principles she wants to empower decision makers to establish the digital fabric of engineering data from conceptualization to use and maintenance of the product and through its entire lifecycle. She received her dual degree from BITS Pilani in M.Sc. Physics and B.E. Mechanical. She has completed two masters in mechanical design engineering, one from BITS Pilani and second from Cornell University, USA. To strengthen her interest in systems engineering, Stueti received formal training in Systems Design and Management from Massachusetts Institute of Technology, Cambridge. Stueti is purpose driven systems engineer, technology leader and STEM advocate. Stueti is an active volunteer and associated with various not-for-profit communities like INCOSE, Bureau of Indian Standards, Society of Women Engineers (SWE), Lean2Lead, Mentor at Mentor Together. She is the founder of SWE in Pune and received Distinguished New Engineer Award in 2016 and Local Most Engaged Advocate Award in 2020 from SWE. She is very active in the International Council on Systems Engineering (INCOSE) and was past President of India Chapter and currently in the Board of Directors as Secretary.