Medical Device Systems Engineering Knowledge Repository Report

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2024-04-21

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Preface

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This is the report of the Medical Device Systems Engineering (MedSE) Knowledge Repository. The report was written in markdown (a markup language) using the Visual Studio IDE, it was rendered in Quarto to publish html and PDF outputs. This report can be easily re-generated, maintained, transferrable and even upgraded.

1 Summary

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The field of medical device development is rapidly evolving, driven by technological advancements and the increasing complexity of healthcare systems. Ensuring the safety, efficacy, and compliance of these devices is paramount for protecting patient health and well-being. In response to this need, this project proposes the creation of a comprehensive knowledge repository focusing on the systems engineering aspects of medical device development. The objectives of this endeavor include designing a cohesive resource that compiles knowledge and best practices, educating professionals and students in systems engineering about the unique challenges of medical devices, offering practical guidance throughout the device lifecycle, and deepening understanding of regulatory requirements. The proposed methodology entailed developing the book systematically, incorporating industry standards and literature reviews, gathering insights through interviews and surveys, structuring content with clarity and coherence, and validating accuracy through peer review. Leveraging tools like Git and GitHub, this project aims to facilitate collaboration and ensure the relevance of its content. This report encapsulates the systematic approach and comprehensive scope of the project, promising to deliver a valuable resource for those involved in medical device development and systems engineering.

2 Introduction

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The field of medical device development is rapidly evolving, with advancements in technology and the growing complexity of healthcare systems. Ensuring the safety, efficacy, and compliance of medical devices is paramount to protect patient health and well-being. This project proposes the creation of a comprehensive knowledge respository that delves into the systems engineering aspects of medical device development.

2.1 Impact

The creation of a comprehensive knowledge repository on the systems engineering of medical devices is essential to bridge the knowledge gap between engineering and healthcare, ensuring the continued development of safe and effective medical technologies. This project aims to contribute significantly to this important field, benefiting professionals, students, and the broader healthcare industry.

This system will serve as a valuable resource for:

- Systems engineers looking to specialize in medical device development.
- Healthcare professionals and clinicians seeking a deeper understanding of the engineering processes behind medical devices.
- Regulatory experts striving to align systems engineering practices with compliance requirements.

- Students and educators in systems engineering and biomedical engineering programs.

3 Background

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3.1 Systems Engineering in Medical Device Industry

David M. Cronin from a company called Cognition that provides software solutions for requirements management and lifecycle management of medical devices states that for many, the phrase "systems engineering" is typically associated with large aerospace and defense companies; companies making products that are developed over many years, with long lives in the market, extremely high costs, and a relatively low total number of products manufactured. Many of these companies also employ "large," permanent teams of systems engineers, which could be daunting to a small device company. Few device engineers are seen at conferences on systems engineering. Instead, these events include transportation, infrastructure, government, space, and of course aerospace and defense. A casual observer might think that systems engineering is not intended for the medical device industry. This is unfortunate!" (Cronin, n.d.a).

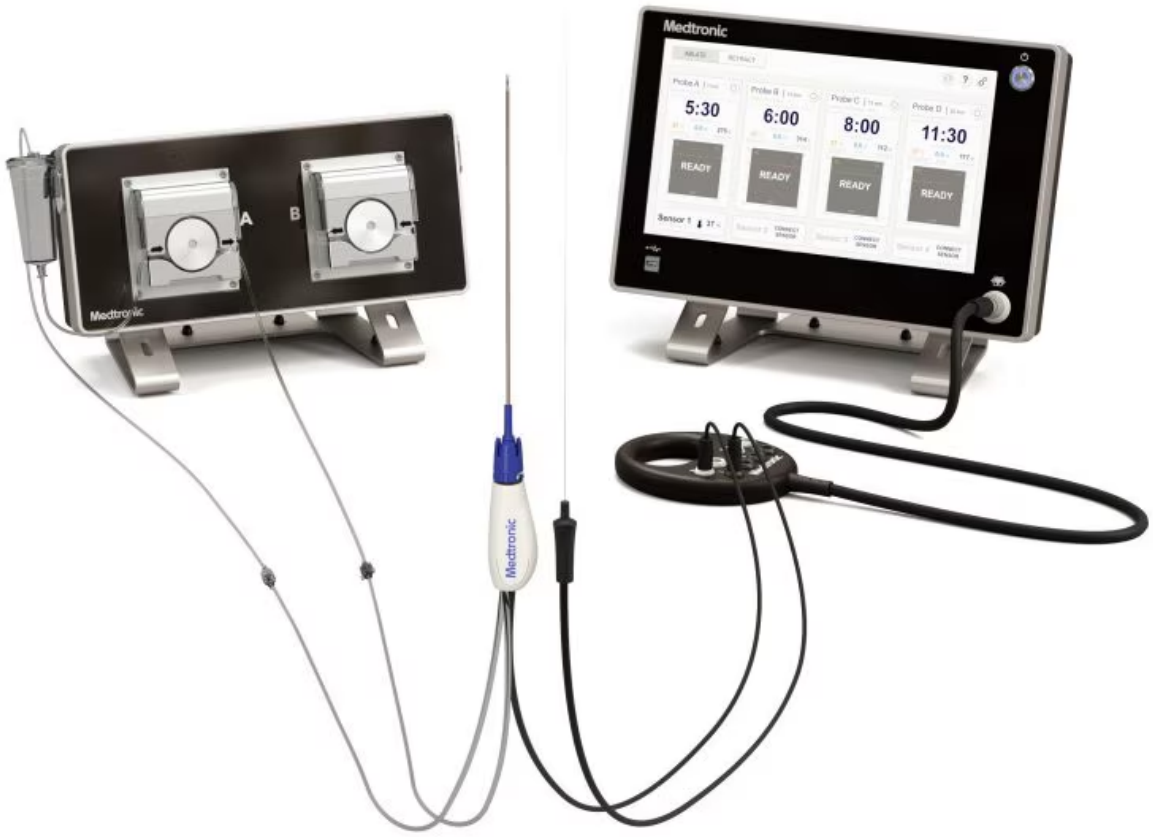
3.2 What is a Medical System?

According to Section 201(h) of the Federal Food, Drug, and Cosmetic Act, a medical device (system) is "any instrument, machine, contrivance, implant, in vitro reagent that's intended to treat, cure, prevent, mitigate, diagnose disease" ("21 USC 321: Definitions; Generally," n.d.a).

3.2.1 Examples of medical systems

The following are examples of medical systems. The list is not exhaustive.

- Spinal Tumor RF Ablation System



- Invasive / Non Invasive Ventilator
- Renal RF Ablation System
- Vascular Compression System
- Intra-Aortic Balloon Pump
- Medical Information Management System
- Endoilluminator


RF 3000™
Time (min:sec)
9:45
Power (W)
35
Impedance (Ω)
220
Active
Electrode
Return
Boston Scientific

- RF Puncture Generator
- Bleed Monitoring System
- Pulsed Field Ablation System
- Nerve Tissue RF Ablation System

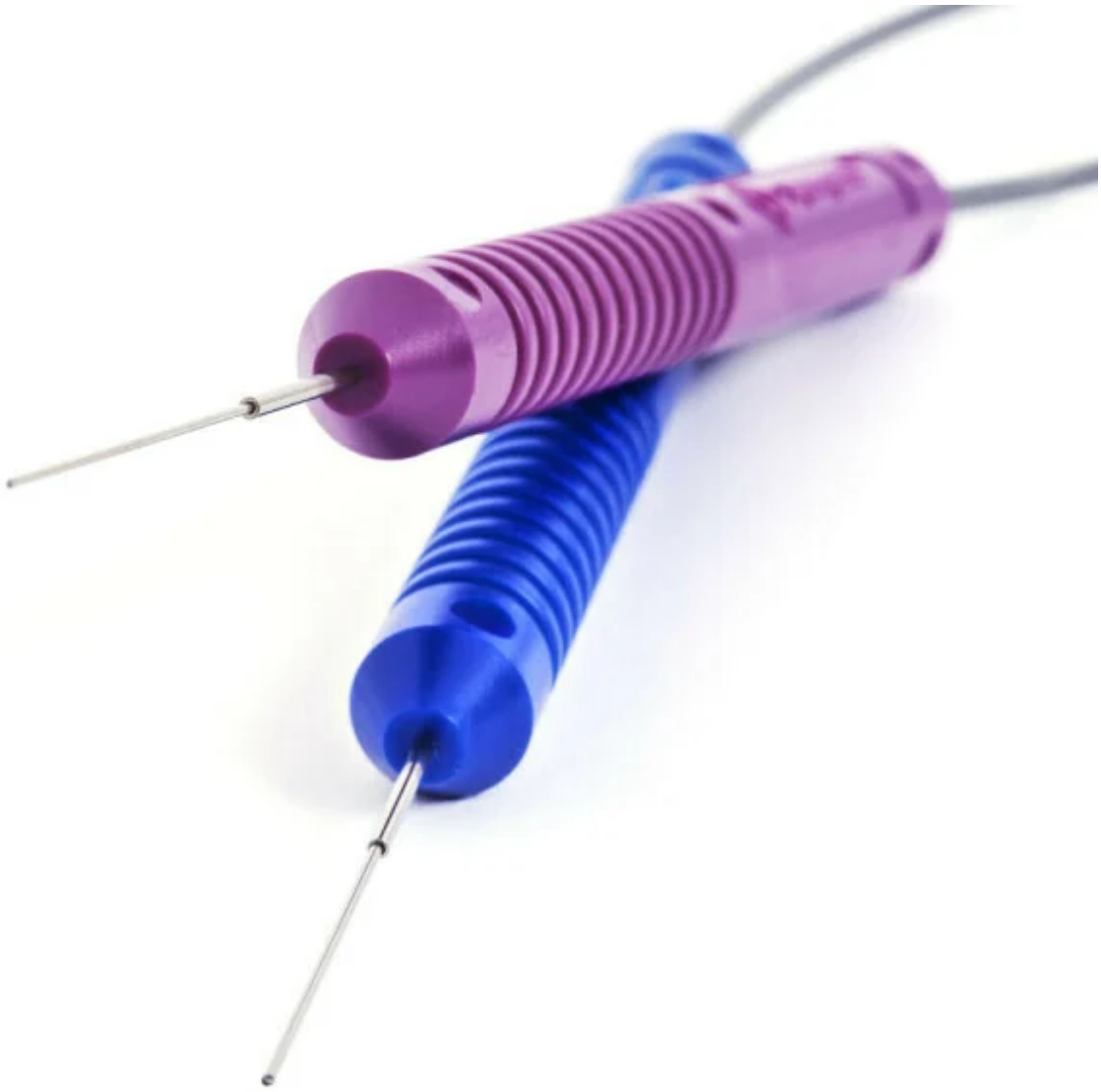
3.3 Medical Device Regulation

The medical devices that are manufactured, marketed and commercialized are subject to regulation by numerous worldwide regulatory bodies, including the FDA and comparable international regulatory agencies. These agencies require manufacturers of medical devices to comply with applicable laws and regulations governing development, testing, manufacturing, labeling, marketing and distribution. Medical devices are also generally subject to varying levels of regulatory control based on risk level of the device.

In the U.S., authorization to distribute a new device can generally be met in one of two ways ("Boston Scientific SEC Filings," n.d.):

3.3.1 Premarket Notification (510(k))

The premarket notification (510(k)) is made to the FDA to demonstrate that the device is as safe and effective as, or substantially equivalent to, a legally marketed device (the "predicate" device). Applicants must submit performance data to establish substantial equivalence. In




PACING CONTROL
Mode
Sync
Async
Cycle Length
500
Channel 1
Disabled
Channel 2
Disabled
PACING
THERAPY CONTROL
End Procedure
VOLTAGE
2.0
FARAWAVE connected
Prepare System
PREPARE
Confirm
CONFIRM
Deliver Energy
DELIVER
Total Deliveries 3

some instances, data from human clinical trials must also be submitted in support of a 510(k) premarket notification. If so, these data must be collected in a manner that conforms to the applicable Investigational Device Exemption (IDE) regulations. The FDA must issue a decision finding substantial equivalence before commercial distribution can occur. Changes to cleared devices that could not significantly affect the safety or effectiveness of the device can generally be made without additional 510(k) premarket notifications; otherwise, a new 510(k) is required.

3.3.2 Premarket Approval (PMA) Application

The submission of a premarket approval (PMA) application to the FDA demonstrates that the device is safe and effective for its intended use. This approval process applies to most Class III devices and generally requires clinical data to support the safety and effectiveness of the device, obtained in adherence with IDE requirements. The FDA will approve the PMA application if it finds that there is a reasonable assurance that the device is safe and effective for its intended purpose and that the proposed manufacturing is in compliance with the Quality System Regulation (QSR). For novel technologies, the FDA may seek input from an advisory panel of medical experts and seek their views on the safety, effectiveness and benefit-risk of the device. The PMA process is generally more detailed, lengthier and more expensive than the 510(k) process.

3.4 European Union (EU)

In the European Union (EU), it is required to comply with the Medical Device Regulation (MDR or EU MDR) which became effective in May 2021, superseding the existing Medical Device and Active Implantable Medical Device Directives. Medical devices which have a valid CE Certificate ("CE Marking," n.d.) to the prior Directives (issued before May 2021) can continue to be sold during the applicable transition period or until the CE Certificate expires, whichever comes first, providing there are no significant changes to the design or intended use. The CE Mark, which is required to sell medical devices in the EU is affixed following a Conformity Assessment and either approval from the appointed independent Notified Body or through self-certification by the manufacturer. The selected pathway to CE marking is based on device risk classification. CE marking indicates conformity to the applicable General Safety and Performance Requirements (GSPRs) for the MDR. The MDR changes multiple aspects of the regulatory framework for CE marking, such as increased clinical evidence requirements, changes to labeling, and new requirements, including Unique Device Identification (UDI), and many new post-market reporting obligations. MDR also modifies and increases the compliance requirements for the medical device industry and will continue to require significant investment over the next few years to transition all products. The CE mark continues to be a prerequisite for successful registration in many other global geographies. In addition, other EU countries continue to impose significant local registration requirements despite the implementation of

MDR, and the United Kingdom has introduced new requirements following its exit from the EU.

It is also required to comply with the regulations of every other country where the product will be commercialized before launch or maintain new products on the market, including regulations that have been introduced in many countries in the Middle East and Southeast Asia that previously did not have medical device regulations, or had minimal regulations. In Japan, it is required to comply with Japan's Ministry of Health, Labor and Welfare (MHLW) regulations. In conjunction with the MHLW, the Pharmaceutical and Medical Device Agency is an independent agency that is responsible for reviewing drug and medical device applications and works with the MHLW to assess new product safety, develop comprehensive regulations, and monitor post-market safety.

The FDA and other worldwide regulatory agencies and competent authorities actively monitor compliance to local laws and regulations through review and inspection of design and manufacturing practices, record-keeping, reporting of adverse events, labeling and promotional practices. The FDA can ban certain medical devices, detain or seize adulterated or misbranded medical devices, order recall or market withdrawal of these devices and require notification of health professionals and others with regard to medical devices that present unreasonable risks of substantial harm to the public health. The FDA may also enjoin and restrain a company for certain violations of the Food, Drug and Cosmetic Act and the Safe Medical Devices Act, pertaining to medical devices, or initiate action for criminal prosecution of such violations. Regulatory agencies and authorities in the countries where business is done can halt production in or distribution within their respective country or otherwise take action in accordance with local laws and regulations.

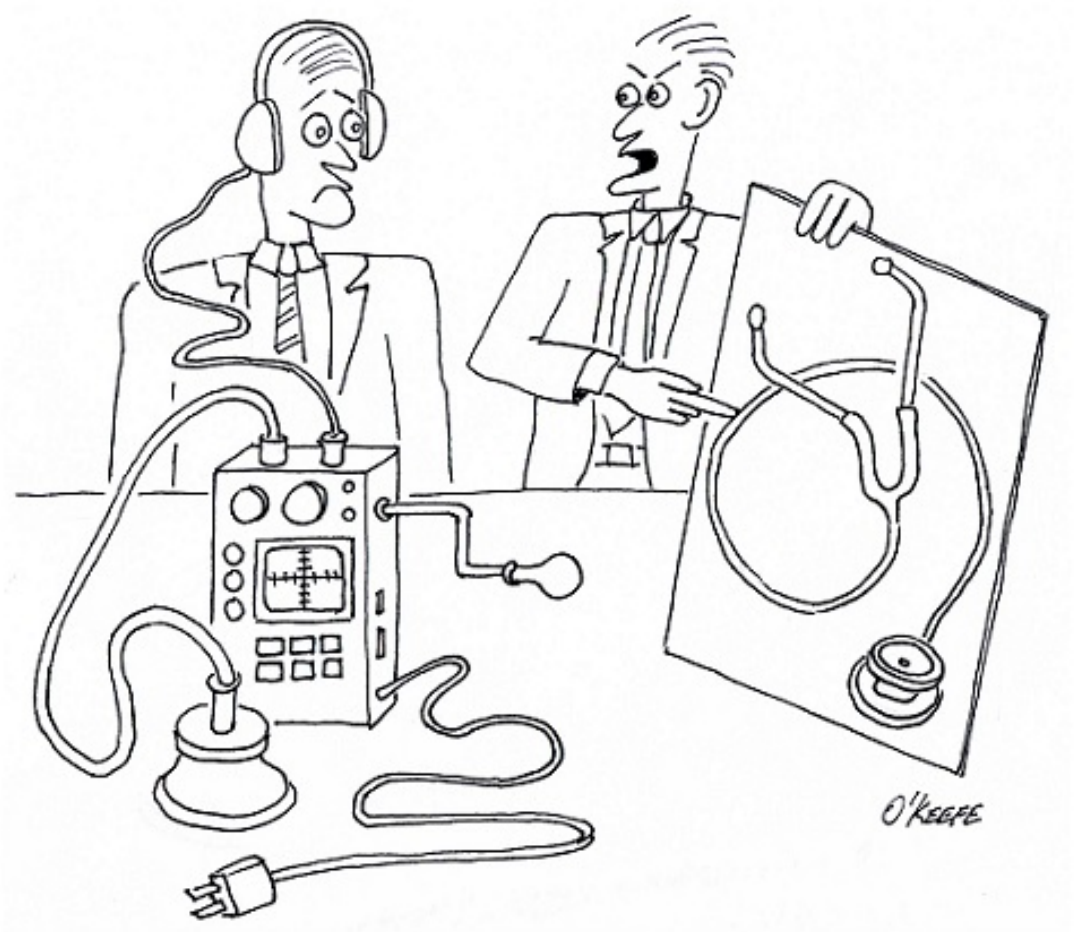
International sales of medical devices manufactured in the U.S. that are not approved by the FDA for use in the U.S., or that are banned or deviate from lawful performance standards, are subject to FDA export requirements. Additionally, exported devices are subject to the regulatory requirements of each country to which the device is exported.

! Important

According to Webinar Applications of Systems Engineering in Healthcare, lead by Chris Unger, Ph.D. ESEP of GE Healthcare and Vincent Balgos of Jama Software, some challenges faced by the medical device industry:

- Constant time pressure launching safe and effective products
  - ~70% of medical products are delivered late.
  - Time to define requirements has increased 29% and unplanned requirements churn has increased 81%.
- Shifting regulatory landscape

  - E.g., Software as a Medical Device (SaMD), Software in a Medical Device (SiMD), Medical Device Regulation (MDR), In Vitro Diagnostic Regulation (IVDR), etc.
  - Cost of adherence and impact on business strategy.
- Quality issues represent significant financial impact
  - Non-routine quality events cost the industry between $2.5 and $5 billion per year on average.
  - On average, one company per year has seen a 10% drop in share price after a single, major quality event.
- Constant increasing complexity, particularly with software
  - Software has become the biggest cause of medical device recalls.
  - E.g., The global artificial intelligence/machine learning medical device market was an estimated $4 billion in 2022 and is anticipated to reach $35.5 billion by 2032.
  - E.g., Remote patient monitoring market was valued at $2.1 billion in 2022 and expected to reach $8.1 by 2030.
  - Increasing risk of cybersecurity concerns.
- Heavy focus on acquisition and geographically distributed development teams
  - E.g., The medical devices sector in Q2 2023 witnessed deals worth $33 billion, a growth of 42% compared to Q1 2023 and 87% compared to Q2 2022.



Interesting design, but this is more of what we had in mind.

3.5 Medical System Product Life Cycle

- Exploratory: Is there viability to solve a clinical need?
- Technology Development: Can we make this technology?
- Product Development: Create the end product.
- Sustaining: Keep a product on the market and enhance the system.

Many life saving devices come with significant risk which must be mitigated through a defined system design process. A seamless integration of the design and development process and the safety risk management process will allow devices to be safety used on humans. The

development process is described in ISO 13485, the international standard for the development of medical devices. ISO 14971 is the international standard for the evaluation of the safety risk of a medical device. Universities and companies hoping to use their devices in clinical trials on patients are required to follow a well-defined process incorporating design and development planning, design input, design output, design review, design verification, and design validation (Wehde 2020).

3.6 Role as Medical Device Systems Engineer

Medical device systems engineers interact with internal and external stakeholders.

3.6.1 Internal stakeholders

- Bioinformatics
- Biotechnology
- Biomedical Engineering
- Chemical Engineering
- Clinical Research
- Control Engineering
- Data Science and Analytics
- Design Quality Assurance
- Electrical Engineering
- Finance
- Industrial Engineering
- Materials Engineering
- Mechanical Engineering
- Project Management
- Regulatory Affairs and Compliance
- Software Engineering
- Computer Science
- Supply Engineering
- Systems Engineering

3.6.2 External stakeholders

- Patients
- Medicine and Healthcare Professionals
- Insurance Companies
- Governments
- Standards Organizations

- Distributors
- Component suppliers

4 Medical Device Systems Engineering

Medical Device Systems Engineering is a multidisciplinary field that encompasses the design, development, and implementation of medical devices. It integrates engineering concepts, medical knowledge, regulatory compliance, and user-centered design principles to ensure the seamless functioning of complex medical systems. This approach bridges the gap between technical innovation and patient-centric care, leading to the creation of advanced devices that address healthcare challenges.

4.1 Components of Medical Device Systems Engineering

According to Nocchi (Nocchi 2023) the following are components that make up medical device systems engineering:

- Requirements Analysis and Definition: Understanding the clinical needs and user requirements is the foundation of any medical device. Engineers collaborate closely with medical professionals to define specifications, ensuring that the device aligns with its intended purpose.
- Design and Development: This phase involves translating requirements into tangible design elements, encompassing hardware, software, and user interfaces. Iterative design processes are common, enabling refinements based on feedback and testing.
- Risk Management: Identifying and mitigating risks is essential to ensure patient safety. Engineers assess potential hazards and develop strategies to minimize or eliminate them throughout the device's lifecycle.
- Verification and Validation: Rigorous testing and validation protocols are crucial to verify that the device meets its intended functionality and is safe for use. This includes laboratory testing, simulations, and clinical trials.
- Regulatory Compliance: Adhering to regulations set by authorities such as the FDA, EMA, or other regional bodies is paramount. Engineers ensure that devices meet these standards and navigate the complex landscape of approvals.
- Human Factors Engineering: Designing devices with user experience in mind is critical for healthcare professionals to effectively operate the technology in real-world settings. Ergonomics and usability are key considerations.
- Interoperability and Integration: Many medical devices are part of larger healthcare systems. Ensuring seamless integration and communication between devices is crucial for data exchange and coordinated care.

4.2 Challenges and Best Practices:

Nocchi (Nocchi 2023) states the following challenges and best practice systems engineers face with medical systems:

- Complexity and Innovation: The integration of diverse technologies, ranging from hardware to software, poses challenges in managing complexity while fostering innovation. Embracing modular design and agile methodologies can streamline the development process.
- Regulatory Compliance: Navigating the regulatory landscape requires a deep understanding of regional requirements. Engaging regulatory experts early in the process and maintaining thorough documentation eases the compliance journey.
- Human-Centered Design: Prioritizing the end user's needs and experience can significantly impact device adoption and success. Regular user testing and feedback loops help refine design elements.
- Risk Management: Identifying and managing risks requires a proactive approach. A thorough understanding of potential hazards, supported by regular risk assessments, is essential.
- Cross-Disciplinary Collaboration: Effective communication among engineers, medical professionals, regulatory experts, and other stakeholders is key. Collaboration fosters a comprehensive understanding of all facets of device development.

4.3 What is different about Medical Technology Industry versus the "Rest of Systems Engineering"?

- Compliance with regulations: Food and Drug Administration (FDA), International Electrotechnical Commission (IEC; French: Commission électrotechnique internationale), International Organization for Standardization (ISO), Health Insurance Portability and Accountability Act (HIPAA), International Classification of Diseases (ICD-10), etc.
- Defects are VERY costly to handle (audit, warning letters, recalls, …)
- Most products are developed in a geographically distributed way
- Rapid technology evolution is impacting development and delivery
  - AI, IoT, product variants, Mobile Medical Apps, complex deployment models, cloud.
- Extreme time to market pressures: 1st to market usually gains 80% share.
- Market Driven versus Contract Driven.
  - Customer of "systems engineering" is internal (marketing, product management).
  - Requirements, dates, budgets are more 'flexible'…success is judged by the market, not by a single customer.

5 Methodology

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The study adopts a Systems Engineering approach, which involves analyzing the entire content management process as a system with interconnected components. This methodology allows for a holistic understanding of the system's requirements, interactions, and potential improvements. The research methodology encompasses:

1. **Requirement Analysis:** Identifying the key requirements for efficient content management, including version control, compatibility with various file formats, and ease of collaboration.
2. **System Modeling:** Utilizing SysML (Systems Modeling Language) to create diagrams such as sequence diagrams, activity diagrams, and state machine diagrams to visualize the content management process and its interactions.
3. **Evaluation:** Assessing existing tools and technologies for content management, including Quatro and its capabilities in rendering content into different formats like HTML and PDF.
4. **Proposal:** Proposing a refined content management methodology tailored to the specific needs of online reference books in medical device systems engineering.

5.1 General methods

The following methodology was used for the Masters Project in Systems Engineering.

- Use Stevens Institute of Technology guidelines and templates for masters project.

- Develop the "knowledge repository" as a system: stakeholder needs, concept, architecture, models, requirements, verification/validation.
- Select and utilize systems engineering methods and tools from courses of Stevens School of Systems and Enterprises.
- Select and utilize industry standards such as IEC 15288 and the INCOSE (International Council on Systems Engineering) Systems Engineering Handbook INCOSE (2023).
- Literature Review: Conduct an extensive review of existing literature, research papers, and relevant resources in the field of systems engineering and medical devices.
- Interviews and Surveys: Collect insights and best practices from industry experts, professionals, and academics in both systems engineering and medical device development.
- Content Development: Create well-structured chapters and sections based on the outlined scope, ensuring clarity and coherence.
- Graphics and Illustrations: Include diagrams, flowcharts, and illustrations to enhance understanding and provide practical examples.
- Peer Review: Seek input and feedback from experts in the field to validate the content's accuracy and relevance.
- Use Git and/or GitHub as repository for the master's project artifacts.

5.2 Systems Engineering Methods

5.2.1 System Engineering constraints and considerations

Table 5.1 provides an outline of the system engineering constraints and considerations of the system.

Table 5.1: Systems Engineering Constraints and Considerations

Domain	**Plan**
Strategy	The generation of the system engineering artifacts will follow the roadmap provided in course document SYS-625
Documentation	The system engineering documentation will be generated as Quatro report that is rendered in HTML and PDF.
Units	The system of units used in this document will be the International System of Units (SI) unless otherwise indicated.
Diagrams	System modeling will be made using OMG Systems Modeling Language (OMG SysML).("About the OMG System Modeling Language Specification Version 2.0 Beta. The Object Management Group" 2023)
Tables	All table templates are customized for purposes of this report. There is no work instruction or standard operating procedure that is define the table layouts to use.

Document Navigation	Hyperlinks are embedded in the document to facilitate navigation of information with identifications.

5.2.2 Systems Engineering Model

Figure 5.1 shows the system engineering roadmap used for the Programmable Playground system. The roadmap source of information is course SYS 625.

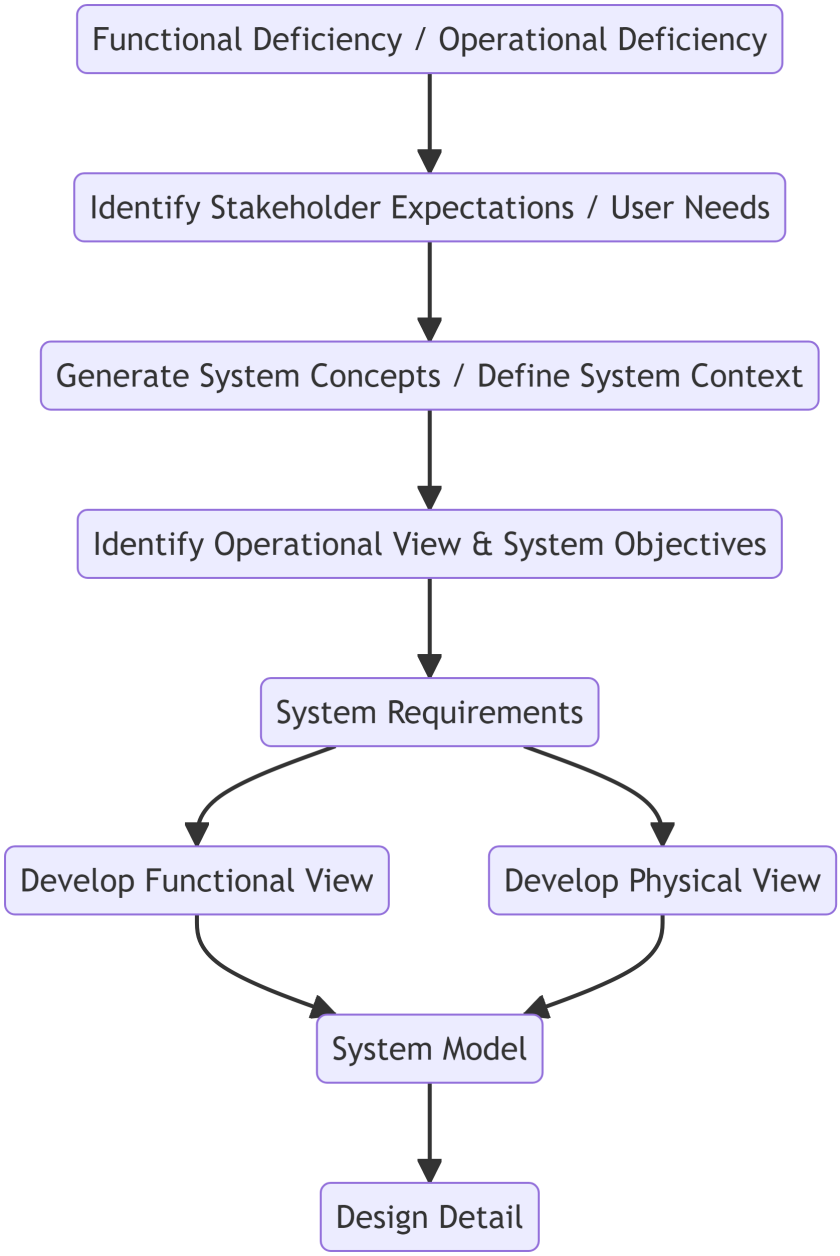

Figure 5.1: System Engineering Strategy

6 Problem

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6.1 Problem Statement

In recent years, the field of medical device systems engineering has gained significant attention due to the increasing complexity of medical devices and the rigorous regulatory requirements they must meet. As a result, there has been a noticeable growth in the number of books and resources dedicated to medical devices . Topics covered in these books may include regulatory compliance, risk management, quality assurance, and design principles tailored to medical devices. But there is very few books on systems engineering for medical devices.

Systems engineering is a broad discipline applied across various industries, including aerospace, automotive, defense, telecommunications, and more. Therefore, there are numerous books available on systems engineering principles, methods, and applications in these fields.

The number of books on systems engineering of medical devices is fewer in comparison to those covering systems engineering in more established industries.

6.1.1 Problem from the perspective of non-systems engineers

Lack of a clear understanding of what is systems engineering of medical devices:

- Colleagues and senior leadership aren't clear…
- If it is 'requirements' (or even models), why does that add value?

- Medical Device Systems Engineering can look like more paperwork (or more modeling work)
- And have a separate function? Why not hire more software and hardware people "who actually deliver things the customer uses"?

6.1.2 Problem from the perspective of systems engineers

Medical Device Systems Engineers don't seem to agree what it is…but everyone seems sure they know and are right.

6.2 Problem modeled as a casual loop

Figure 6.1 is a diagram of a causal loop (Sterman and Sterman 2000) that shows a system where investment in systems engineering yields positive results. The diagram shows that increased profits can lead to more resources for better systems engineering which help reduce unsuccessful medical devices.

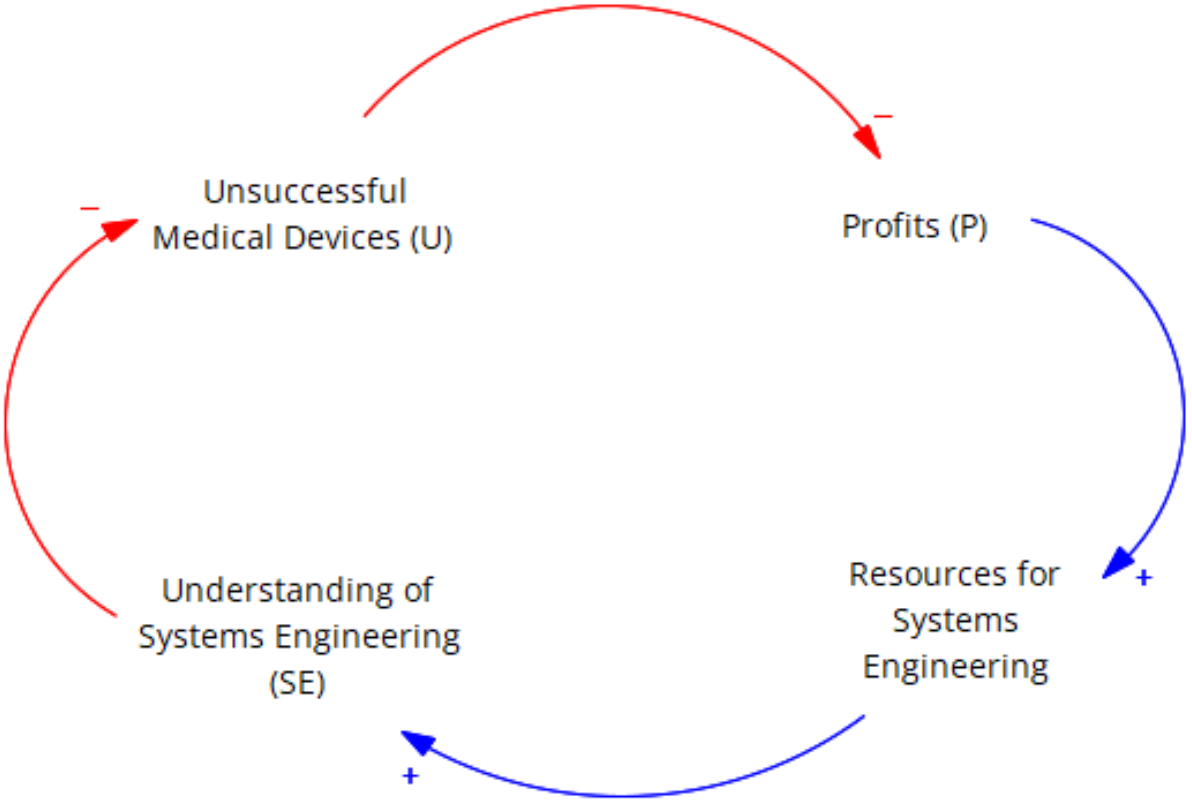

Figure 6.1: Problem modeled as a casual loop

Analysis of the Causal Loop in the Image:

An explanation of the elements that make up the casual loop is given as follows:

- **Unsuccessful Medical Devices (U) –> Decreased Profits (P)** (Negative) - Unsuccessful devices lead to lower sales and profitability.
- **Profits (P) –> Resources for Systems Engineering (SE)** (Positive) - More profits allow for more investment in systems engineering.
- **Understanding of Systems Engineering (SE) –> Decreased Unsuccessful Medical Devices (U)** (Negative) - Better understanding of systems engineering leads to fewer poorly designed devices. If there's a lack of understanding of systems engineering principles among stakeholders in the medical device industry, it can lead to ineffective utilization or implementation of systems engineering methodologies in the development process.
- **Resources for Systems Engineering (SE) –> Improved Understanding of Systems Engineering (SE)** (Positive) - More resources dedicated to systems engineering education improves understanding.

Feedback Loops:

- **Balancing Loop (B):** This loop discourages unsuccessful devices. As unsuccessful devices (U) increase, profits (P) decrease. This decrease in profits (P) leads to fewer resources for systems engineering (SE). Less resources for systems engineering (SE) leads to a poorer understanding of systems engineering (SE), which ultimately leads to more unsuccessful devices (U). This loop creates pressure to improve systems engineering practices to break the cycle of unsuccessful devices.

Key Points:

- The diagram shows a reinforcing cycle (B) that discourages unsuccessful devices. This is because better understanding of systems engineering leads to fewer unsuccessful devices, which increases profits, which allows for more investment in systems engineering, and so on.
- Low adoption of systems engineering results in ineffective medical device development processes. Without proper systems engineering practices, the development processes may lack holistic consideration of all system components, leading to inefficiencies, errors, and delays.
- Ineffective development processes can contribute to increased incidents of device failures. Without robust systems engineering practices, there's a higher likelihood of design flaws, inadequate testing, and safety issues in medical devices, leading to higher failure rates and potential harm to patients.

6.3 Contributing factors

6.3.1 Systems engineering is used more in other fields

Systems engineering is employed more in other fields than the medical device industry. Some of the top fields where systems engineering is used include:

- **Aerospace and Defense:** Systems engineering plays a crucial role in designing and developing complex aircraft, spacecraft, missiles, and defense systems.
- **Automotive Industry:** In the automotive sector, systems engineering is essential for designing vehicles with integrated and optimized systems for safety, performance, and efficiency.
- **Information Technology:** Systems engineering is utilized in IT for designing, implementing, and managing large-scale computer systems, networks, and software applications.
- **Telecommunications:** Systems engineering is vital for designing and optimizing telecommunications networks, including mobile networks, satellite systems, and internet infrastructure.
- **Energy Sector:** Systems engineering is employed in the energy industry for designing and managing complex energy production and distribution systems, including power plants, renewable energy systems, and smart grids.
- **Transportation:** Systems engineering is crucial in designing and optimizing transportation systems, including railways, highways, airports, and public transportation systems.
- **Manufacturing:** Systems engineering is used in manufacturing for designing and optimizing production processes, supply chain management systems, and industrial automation systems.
- **Environmental Engineering:** In environmental engineering, systems engineering is applied to design and manage complex environmental systems, such as water treatment plants, waste management systems, and pollution control systems.
- **Robotics and Automation:** Systems engineering is essential for designing and integrating robotic systems and automation solutions across various industries, including manufacturing, healthcare, and agriculture.

6.3.2 Very few papers on systems engineering of medical devices

There are very few papers on the application of systems engineering to medical devices that are published as articles, and/or presented in conferences.

In the 34th Annual INCOSE International Symposium, of the 83 papers presented none were in the context of medical devices. Of the 48 presentations, only 2 were in the context of medical devices (**is2024?**-).

An article database query was performed using a software called IHS Goldfire ("Goldfire Cognitive Search – Accuris," n.d.) to determine how many peer reviewed articles (including articles within books) discuss systems engineering of a medical device. IHS Goldfire is a software platform developed by IHS Markit that contains tools for knowledge discovery, problem-solving, technology scouting, innovation management, and intellectual property management. Table 6.1 shows the query results per application field. Between 1980 and 2024 there were a total of 3432 articles that discuss systems engineering of a medical device. This is significantly less than the 40732 peer reviewed articles found for systems engineering for military applications.

Table 6.1: Quantity of peer reviewed systems engineering articles per application field since 1980

Application Field	Articles in books	Articles and Journals	Total
Medical Devices	2799	633	3432
Military	14908	25824	40732
Aerospace	12443	19254	31697
Automotive	13082	9433	22515
Software	24587	48953	73540
Telecomunications	15897	10841	26738
Transportation	20139	23044	43183
Manufacturing	21205	28341	49546

6.3.3 Lack of books and literature of systems engineering of medical devices

The are very few books that teach systems engineering in the context of medical device development. Of the few books found are the following:

- "*Robust Systems Engineering for Medical Device Design*" by Mr. Martin A. Coe. Description: This book introduces practical systems engineering methods for the design and development of commercially engineered systems, focused on the design of medical devices. It begins with systems engineering definitions, fundamentals and proceeds by integrating systems engineering activities into the development process to demonstrate a successful system design (Coe 2019).

- "*Healthcare Systems Engineering*" by Paul M. Griffin, et al. Description: Offers comprehensive coverage of the healthcare system, healthcare delivery, and healthcare systems modeling ("Healthcare Systems Engineering | Wiley," n.d.).

7 Mission Description

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This section provides the system mission, and business rationale.

7.1 Mission

8 Sources

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8.1 Source model

Figure 8.1 is a SysML block definition diagram that shows the sources of needs and requirements for designing a MedSE knowledge repository. The blocks in the diagram represent different sources of information that can be used to identify the needs and requirements of the knowledge repository.

The diagram lists valid (legal source element) sources:

- Job descriptions
- Training material
- Literature
- Publications
- Articles
- Standards
- Databases
- Surveys
- Interviews

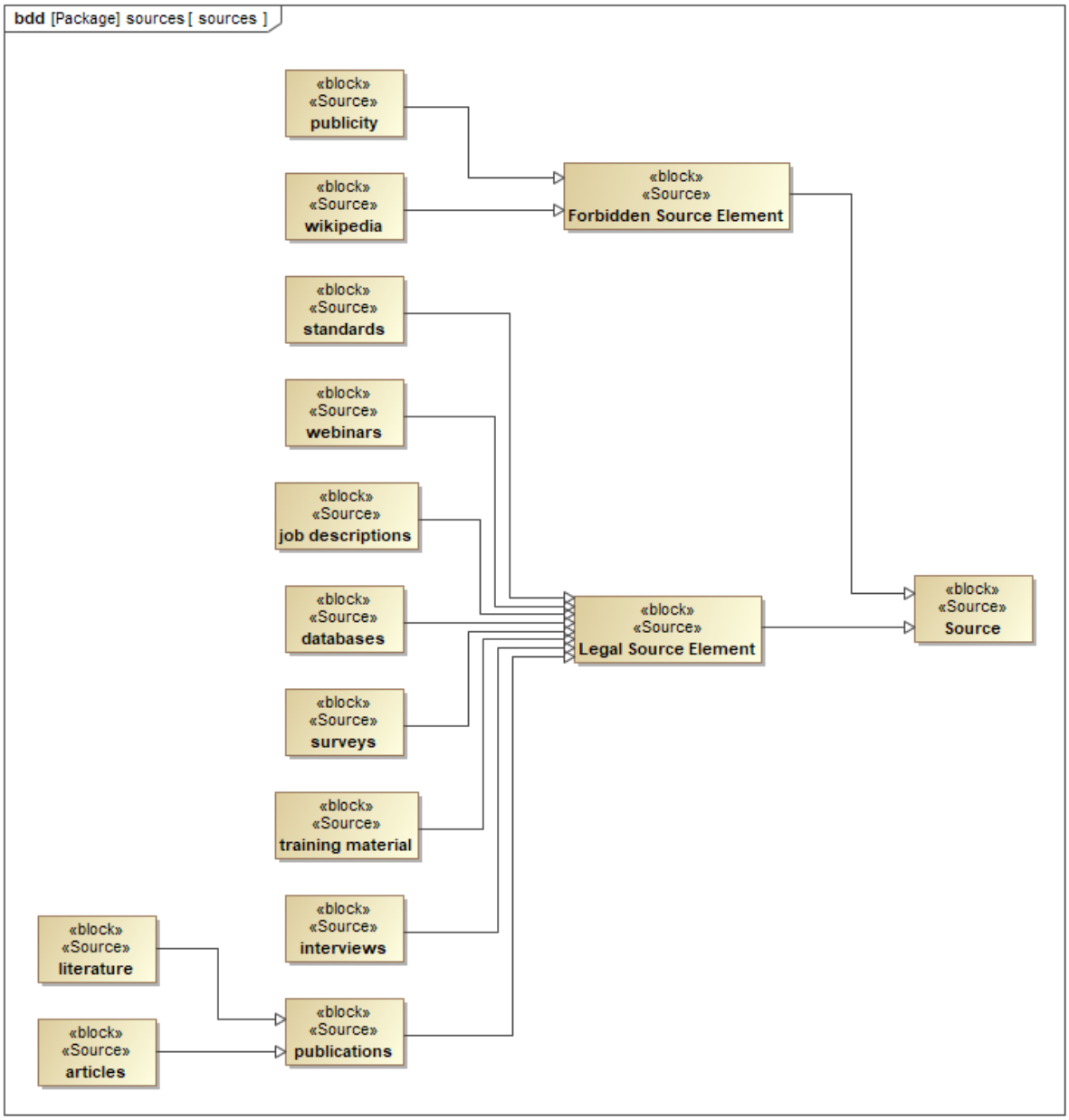

Figure 8.1: The MedSE Knowledge Repository System sources of needs and requirements

- Webinars

The inclusion of "Forbidden Source Element" highlights the importance of critical evaluation when selecting information sources. Reliable and verifiable sources like publications, standards, and legal databases should be prioritized for designing the knowledge repository.

8.2 Articles

Articles that talk about the systems engineering of medical devices can serve as source for the design of the MedSE Knowledge Repository. Some example articles found that can serve as source for the design of the MedSE knowledge repository are:

- Jones, D.J. and Masters, M.T. (2008), 11.1.3 Medical Device Development Process. INCOSE International Symposium, 18: 1215-1230. https://doi.org/10.1002/j.2334-5837.2008.tb00873.x (Jones and Masters 2008)
- Maheshwari, Apoorv. (2015). Application of Systems Engineering to Regulatory Compliance Activities for Medical Devices. (Maheshwari 2015)
- Corns, S. and Gibson, C. (2012), A Model-based Reference Architecture for Medical Device Development. INCOSE International Symposium, 22: 2066-2075. https://doi.org/10.1002/j.2334-5837.2012.tb01457.x (Corns and Gibson 2012)
- "Healthcare Systems Engineering - SEBoK." Accessed: Apr. 18, 2024. Available: https://sebokwiki.org/wiki/Healthcare_Systems_Engineering ("Healthcare Systems Engineering - SEBoK," n.d.)
- Malins, Robert & Stein, Jack & Thukral, Ajay & Waterplas, Christophe. (2015). SysML Activity Models for Applying ISO 14971 Medical Device Risk and Safety Management Across the System Lifecycle. INCOSE International Symposium. 25. 489-507. 10.1002/j.2334-5837.2015.00077.x. (Malins et al. 2015)

8.3 Medical Device Trends

The FDA provides public databases and reports that can provide insight of what are the most common medical devices that are in use and the characteristics of those devices (Health and Radiological 2024c).

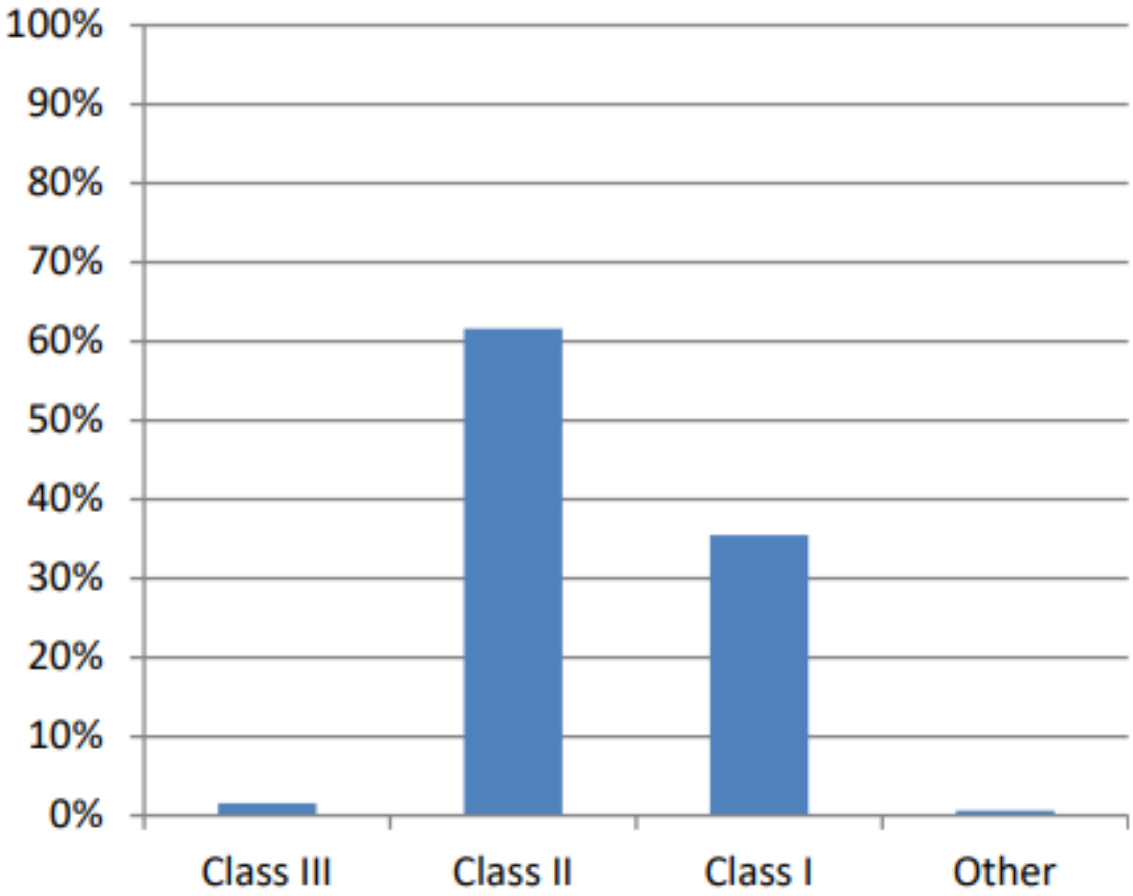

Figure 8.2: Distribution of Medical Devices Registered with the FDA (as of February 1, 2024)

8.3.1 Medical Device Classification

Figure 8.2 shows the distribution in percentage of medical devices registered with the FDA by class, as of February 1, 2024.

Here's a breakdown of the data displayed in the chart:

- Class III makes up the largest portion of registered devices at around 60%.
- Class II is the second most common class of device at around 35%.
- Class I devices and "Other" devices each make up a smaller portion of registered devices.

> **Note**
>
> The FDA regulates medical devices based on the level of risk they pose to patients. Class III devices are considered the highest risk, while Class I devices are considered the lowest risk (Health and Radiological 2023).

8.3.2 Implantable versus non-implantable

Figure 8.3 is a line graph that shows the percentage of implantable and non-implantable medical devices.

The data shows that as of February 1, 2024, implantable medical devices make up a smaller percentage of registered devices than non-implantable devices.

Implantable medical devices are devices that are inserted into the body for a long period of time. Examples of implantable medical devices include pacemakers, artificial hips, and breast implants. Non-implantable medical devices are devices that are used on the body but are not inserted into it. Examples of non-implantable medical devices include stethoscopes, blood pressure cuffs, and bandages.

8.3.3 Medical Specialties

Figure 8.4 shows the distribution of FDA-registered medical devices by medical specialty, based on FDA product codes, as of February 1, 2024.

Here's what we can gleaned from the chart:

- **Specialties with the most devices:** The specialties with the highest percentage of registered devices are:
  - Orthopedic

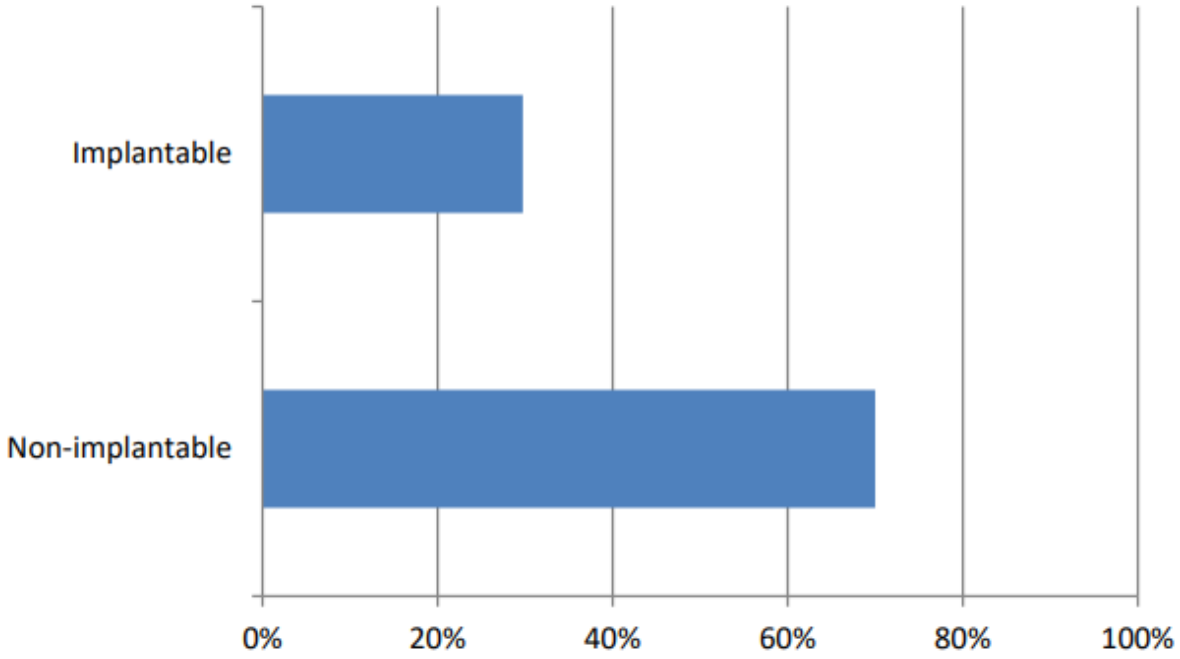

Figure 8.3: Proportion of Implantable vs. Non-Implantable Medical Devices Registered with the FDA (as of February 1, 2024)

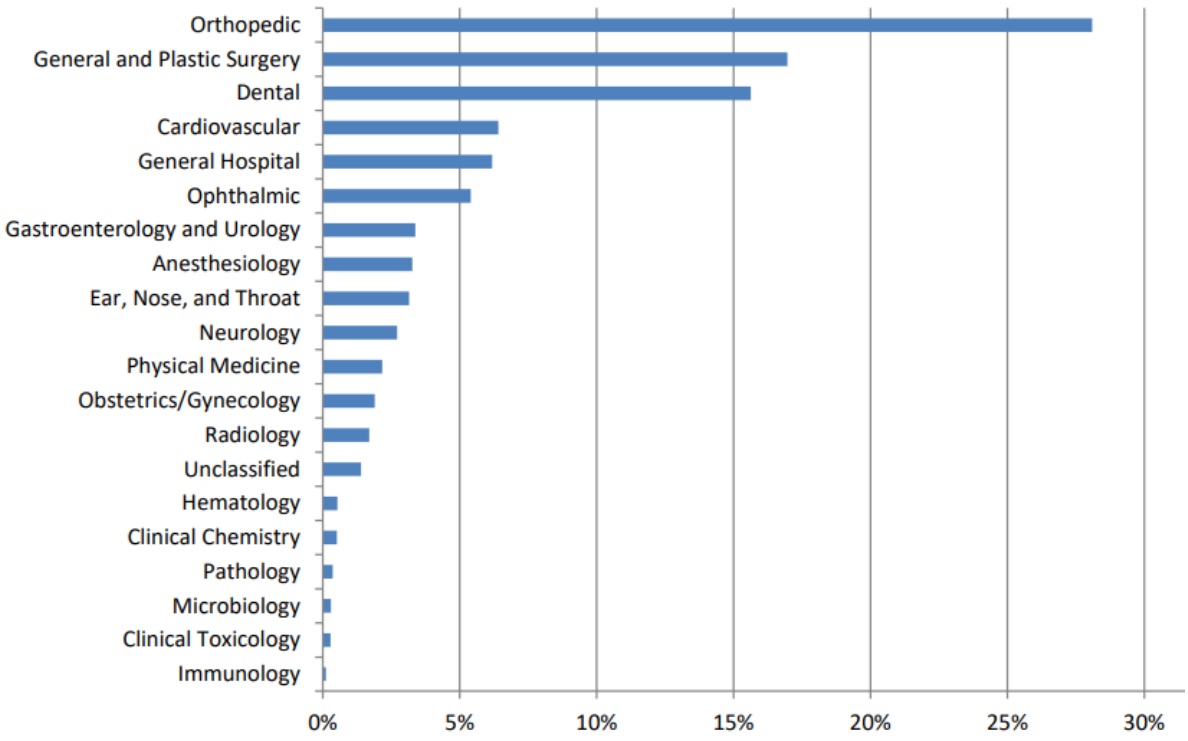

Figure 8.4: Distribution of FDA-Registered Medical Devices by Medical Specialty (as of February 1, 2024)

  - General and Plastic Surgery
  - Cardiovascular
  - General Hospital

- **Specialties with the least devices:** The specialties with the lowest percentage of registered devices are:
  - Clinical Toxicology
  - Immunology
  - Microbiology
  - Clinical Chemistry
  - Hematology

> **Note**
>
> The number of devices registered in a particular specialty doesn't necessarily reflect the number of procedures performed in that specialty. For example, there may be a relatively small number of complex orthopedic devices compared to the number of simple bandages used in wound care, but both would be classified under orthopedic devices.

Some reasons why some specialties might have more devices than others:

- **Surgical specialties:** Surgical specialties tend to have a wider variety of devices because they use devices for a variety of procedures.
- **Chronic conditions:** Specialties that treat chronic conditions may have a wider variety of devices because they may use devices to monitor or treat the condition over time.

8.3.4 FDA Product Code

Figure 8.5 is word cloud that highlights the most frequent terms from FDA Product Codes of registered devices.

Based on the word cloud, the most frequent FDA Product Code Terms for registered medical devices with the FDA as of February 1, 2024:

- **Surgical**
- **Tracheostomy**
- **Cardiovascular**
- **Wireless**

Figure 8.5: Most frequent FDA Product Codes Terms of the registered devices (as of February 1, 2024)

- **Synthetic**
- **Adult**
- **Cervical**
- **Spinal**
- **Electrode**
- **Plastic**

It appears that surgical devices and those used in cardiology are the most common. There is also a high prevalence of terms related to materials like synthetic and plastic, along with terms related to location or application like cervical and tracheostomy.

8.4 Webinars

Webinars that discuss systems engineering in the medical device industry can serve as sources for the needs and requirements of the MedSE knowledge repository. Two examples of webinars that were analyzed to extract source information were the following.

8.4.1 MassMEDIC Sponsored Webinar: Systems Engineering for Medical Device Development by Sunrise Labs, Inc ("MassMEDIC Sponsored Webinar: Systems Engineering for Medical Device Development" 2022).

This webinar discussed how Systems Engineering contributes to success in complex medical device development. It discussed the role of a Systems Engineer and described the Systems Engineering process. From this webinar, the MedSE knowledge repository should incorporate the following key points:

- **Foundational Concepts:**
  - Define Medical Device Systems Engineering and its role in the development lifecycle.
  - Understand the complexities of modern medical devices (electrical, mechanical, software integration).
- **Systems Engineering Process:**
  - Key stages involved in Systems Engineering for medical devices (concept to commercialization).
  - Techniques for requirements definition, management, and traceability.
- **Cross-functional Collaboration:**

  - Effective communication and coordination between various engineering disciplines (electrical, mechanical, software).
  - Integration with other devices and user interfaces.

- **Risk Management:**
  - Identify and mitigating risks associated with medical device development.
  - Design test protocols and mitigation response plans.

- **Regulatory Considerations:**
  - Understand and adhering to design control regulations for medical devices (e.g., ISO 13485).

- **Project Management:**
  - Strategies for staying on budget and schedule in medical device development projects.

- **Case Studies:**
  - Real-world examples showcasing successful application of Systems Engineering in medical device development.

8.4.2 Systems Perspective Engineering : A webinar on Medical Device product development ("Systems Perspective Engineering : A Webinar on Medical Device Product Development" 2020)

This webinar discussed how usability engineering can be integrated into the systems engineering process for medical device development. From this webinar, the MedSE knowledge repository should incorporate the following key points:

- **Usability Engineering Process:**
  - Iterative process applied throughout development.
  - Complements design control and risk management.
  - Follows IEC 62366 and FDA guidance.
  - Involves user research, task analysis, risk analysis, formative evaluations, and summative validation.

- **Systems Engineering Approach (V Model):**
  - Starts with understanding user needs and defining requirements.
  - Breaks down the system into manageable pieces.

  - Focuses on mitigating technical risks early.
  - Integrates different disciplines throughout development.
- **Why Integrate Usability into Systems Engineering?**
  - Usability is a project-level risk that should be mitigated early.
  - Usability engineering tools complement the V model.
  - Early integration reduces design risk and rework later.
- **Who Owns Usability?**
  - Ideally, the systems engineer due to their focus on mitigating risks.
  - Can be someone else with influence to plan and integrate usability activities.
- **Usability Engineering Strategy:**
  - Should be planned early and scaled based on device risk.
  - Defines the types of evaluations and resources needed throughout development.
  - Integrates usability activities throughout all development phases.
- **Recommendations for Reducing Usability Risk:**
  - Consider usability risk mitigation early in system architecture planning.
  - Shift usability evaluation of critical hardware subsystems earlier.
  - Evaluate software user interfaces before coding and implementation.
  - Develop instructions for use and training as subsystems to be iterated on.
  - Strategically sequence development of features based on usability risk.
  - Plan ahead for materials and control of devices for usability studies.

Additionally, the webinar covered:

- Examples of usability engineering tools used throughout the development process.
- How to develop a usability engineering plan.
- How to conduct usability studies at different development phases.

8.5 Courses directed to systems engineers who work in the medical device industry

A company called Technology and Management Training Courses and Seminars (TONEX) provides a course called *“Systems Engineering for Medical Device Development” (“Systems Engineering for Medical Device Development,” n.d.). The 2-day course is designed to equip professionals in the medical device industry with the essential knowledge and skills in systems engineering.

The course has the following learning objectives:

- Understand the fundamentals of systems engineering as applied to medical device development.
- Navigate regulatory requirements and standards specific to the medical device industry.
- Implement risk management strategies to enhance the safety and efficacy of medical devices.
- Apply systems thinking to optimize the integration of diverse components in the development process.
- Design and execute comprehensive verification and validation protocols for medical devices.
- Enhance communication and collaboration among cross-functional teams involved in medical device development.

This course is for professionals and decision-makers involved in various stages of medical device development, including:

- Biomedical Engineers
- Regulatory Affairs Specialists
- Product Managers
- Quality Assurance Professionals
- Systems Engineers
- Project Managers

Course Outline:

Introduction to Systems Engineering in Medical Devices

- Overview of Systems Engineering Principles
- Importance of Systems Thinking in Medical Device Development

- Key Challenges and Opportunities in the Field

Regulatory Landscape for Medical Devices

- Overview of FDA and International Regulatory Agencies
- Current Good Manufacturing Practices (cGMP)
- Ensuring Compliance with ISO Standards

Risk Management in Medical Device Development

- Identifying and Assessing Risks in the Development Process
- Risk Mitigation Strategies and Implementation
- Integration of Risk Management with Regulatory Requirements

Systems Integration and Interdisciplinary Collaboration

- Interconnected Components in Medical Device Systems
- Strategies for Effective Cross-Functional Collaboration
- Role of Systems Engineering in Integration Challenges

Verification and Validation in Medical Device Development

- Designing Comprehensive Verification Protocols
- Conducting Rigorous Validation Testing
- Ensuring Compliance with Regulatory Requirements

Communication and Documentation in the Development Lifecycle

- Effective Communication Strategies for Cross-Functional Teams
- Documentation Best Practices and Regulatory Requirements
- Creating a Culture of Transparency and Accountability in Development Teams

An analysis of the course objectives and outline derived the following MedSE Knowledge Repository needs and requirements.

Needs:

- Gain a deep understanding of how systems engineering principles are applied to the specific context of medical device development.
- Master the Medical Device Development Life Cycle (MDLC) with a focus on the role of systems engineering at each stage.

- Effectively navigate the regulatory landscape governing medical devices (e.g., FDA QSR (Health and Radiological 2024a), ISO 13485).
- Implement robust risk management strategies to ensure the safety and efficacy of medical devices.
- Foster successful integration of diverse components within a complex medical device system.
- Enhance communication and collaboration skills to work effectively with cross-functional teams.
- Stay updated on best practices for verification and validation (V&V) of medical devices.
- Understand how systems engineering needs to adapt to emerging trends in medical device technology.

Requirements:

- **Content:**
  - In-depth coverage of foundational systems engineering principles with a focus on medical device applications.
  - Detailed breakdown of the MDLC with clear explanations of the systems engineering role at each stage.
  - Dedicated chapters on risk management, including relevant techniques and regulatory considerations.
  - Comprehensive discussion of systems integration challenges and best practices in a medical device context.
  - Practical guidance on V&V processes for medical devices, including different testing types and regulatory compliance.
  - Emphasis on communication and documentation best practices for effective cross-functional collaboration.
  - Inclusion of case studies showcasing successful medical device development projects with strong systems engineering involvement.
  - A dedicated chapter on emerging trends in medical device technology and their implications for systems engineering.
  - Appendix with relevant regulatory resources (FDA regulations, ISO standards).
- **Format:**
  - Organized structure with clear headings, subheadings, and bullet points for easy navigation.

  - Use of diagrams, figures, and tables to illustrate concepts.
  - Glossary of key terms specific to systems engineering and medical device development.
  - Index for information retrieval.
  - Availability in both print and digital formats.

- **Usability:**
  - Written at a level appropriate for experienced systems engineers, but with clear explanations for core concepts.
  - Real-world examples and case studies to enhance understanding and practical application.
  - Chapter summaries and review questions to solidify learning.
  - Links to online resources (e.g., regulatory websites, industry best practices documents) for further exploration (optional for digital format).

8.6 Companies that offer systems engineering services for medical device development

8.7 Job Profiles of Systems Engineers of medical device companies

Appendix Medical Device Systems Engineer Job Descriptions contains a sample of eight job descriptions that showcase the variety of roles and responsibilities under the title "Systems Engineer" in the medical device industry. The source of the Job Descriptions was from LinkedIn.

Here's a breakdown of key findings of the eight job descriptions:

Commonalities:

- All positions require a strong understanding of engineering principles and practices.
- Most roles emphasize experience working on complex systems, often involving hardware, software, and electrical components.
- Excellent communication and collaboration skills are crucial for success in this field, as systems engineers frequently interact with various teams (e.g., design, manufacturing, regulatory).
- Ability to manage projects, meet deadlines, and prioritize effectively is essential.

Key Differences:

- **Experience Level:** The roles range from requiring 6+ years of experience (Job Description #4) to 10+ years (Job Descriptions #3, #5, #8).
- **Focus Area:** Responsibilities can be specific to a certain medical device type (e.g., cardiac mapping - Job Description #1, heart failure management - Job Description #6) or broader, encompassing various technologies (Job Description #7).
- **Project Stage:** Some positions focus on the entire development lifecycle (Job Description #5), while others target specific stages like early concept development (Job Description #7) or system verification and validation (Job Description #6).
- **Leadership:** Some roles involve leading and mentoring engineers (Job Descriptions #3, #5, #7, #8), while others focus on individual technical contributions (Job Descriptions #1, #4, #6).

Additional Insights:

- Several positions highlight the importance of adhering to medical device regulations like FDA and ISO standards (Job Descriptions #3, #5, #6, #8).
- Some roles emphasize experience with specific technologies relevant to medical devices, such as Bluetooth or implantable sensors (Job Descriptions #6, #7).

The eight job descriptions for Medical Device Systems Engineers were examined to identify the required qualifications, responsibilities, and skills. The information is presented in several tables for clarity.

8.7.1 Medical Device Systems Engineer Responsibilities (Most Common to Least Common)

Table 8.1 ranks the responsibilities based on how often they appeared in the job descriptions. Participating in cross-functional teams, managing projects, and developing system requirements are the most common. Less frequent responsibilities include conducting training and managing intellectual property.

Table 8.1: Medical Device Systems Engineer Responsibilities (Most Common to Least Common)

Responsibility	# of Job Descriptions
Participate in cross-functional teams	8
Manage projects	7
Develop system requirements	7
Communicate effectively with various teams	7
Lead design reviews	6

Responsibility	# of Job Descriptions
Perform risk analysis	6
System verification and validation	6
Develop design documentation	5
Troubleshoot and solve technical problems	5
Translate user needs into technical specifications	4
Manage external vendors	3
Create and maintain technical documentation	3
Conduct training	2
Partner with research and development teams	2
Identify unmet user needs	1
Lead brainstorming sessions	1
Manage intellectual property	1

8.7.2 Medical Device Systems Engineer - Systems Engineering Skills (Most Common to Least Common)

Table 8.2 focuses on skills specific to systems engineering. Complex systems thinking, system requirements development, and system design and architecture are the most common. Test plan development and execution, and trade-off analysis are less frequently mentioned.

Table 8.2: Medical Device Systems Engineer - Systems Engineering Skills (Most Common to Least Common)

Skill	# of Job Descriptions
Complex systems thinking	7
System requirements development	7
System design and architecture	6
Risk analysis and management	6
System verification and validation	6
Interface management (between subsystems)	3
Systems modeling and simulation	2
Test plan development and execution	2
Trade-off analysis (considering various factors)	1
Systems integration and deployment	1

8.7.3 Medical Device Systems Engineer - Medical Device Skills (Most Common to Least Common)

Table 8.3 highlights medical device specific skills. General medical device experience and knowledge of regulatory affairs (FDA, ISO) are common requirements. Experience with specific technologies or domains are less frequent.

Table 8.3: Medical Device Systems Engineer - Medical Device Skills (Most Common to Least Common)

Skill	**# of Job Descriptions**
Medical device experience (general)	4
Regulatory affairs knowledge (e.g., FDA, ISO standards)	4
Experience with specific medical device technologies (e.g., implantable sensors)	2
Experience in a specific medical device domain (e.g., Renal Care)	1

8.7.4 Medical Device Systems Soft Skills (Most Common to Least Common)

Table 8.4 categorizes soft skills required for the role, with communication, collaboration, and problem-solving being the most sought-after. Public speaking and teaching/mentoring are the least common skills mentioned.

Table 8.4: Soft Skills (Most Common to Least Common)

Skill	**# of Job Descriptions**
Communication (written and oral)	8
Collaboration	8
Problem-solving	7
Analytical skills	6
Attention to detail	5
Technical expertise (engineering principles)	5
Project management	6
Leadership	4
Regulatory knowledge (FDA, ISO)	4
Creativity	2
Public speaking	1
Teaching/Mentoring	1

8.7.5 Medical Device Systems Engineer Qualifications (Most Common to Least Common)

Table 8.5 ranks the qualifications listed in the job descriptions by frequency. A Bachelor's degree in Engineering and strong communication skills are the most common requirements, while an advanced degree (Ph.D. or Post-Graduate) and experience in a specific medical device domain are the least common.

Table 8.5: Medical Device Systems Engineer Qualifications (Most Common to Least Common)

Qualification	# of Job Descriptions
Bachelor's degree in Engineering or related field	8
Strong communication skills	8
Ability to work effectively in a team	7
Experience with complex systems	7
Project management skills	6
Master's degree in Engineering or related field (or equivalent experience)	4
Medical device experience	4
Regulatory affairs knowledge (e.g., FDA, ISO standards)	4
Experience with specific medical device technologies (e.g., implantable sensors)	2
Leadership experience	2
Advanced degree (Ph.D. or Post-Graduate)	1
Experience in a specific medical device domain (e.g., Renal Care)	1

8.7.6 Medical Device Systems Engineer - Preferred Qualifications (Most Common to Least Common)

Table 8.6 summarizes qualifications that are desirable but not always mandatory. A Master's degree, leadership experience, and expertise in specific medical device technologies are preferred by some employers.

Table 8.6: Medical Device Systems Engineer - Preferred Qualifications (Most Common to Least Common)

Qualification	# of Job Descriptions
Master's degree in Engineering or related field (or equivalent experience)	4
Leadership experience	2

Qualification	# of Job Descriptions
Experience with specific medical device technologies (e.g., implantable sensors)	2
Advanced degree (Ph.D. or Post-Graduate)	1
Experience in a specific medical device domain (e.g., Renal Care)	1
Proficiency in generating system/subsystem specifications	1
Familiarity with advanced needs and requirements definition methods	1

The following sources for the MedSE Knowledge Repository was obtained from the analysis of the eight job descriptions:

Foundational Engineering Knowledge:

- **Solid grounding in engineering fundamentals:** This includes mechanics, electronics, thermodynamics, and materials science.
- **In-depth coverage of a specific engineering discipline:** Mechanical, electrical, or biomedical engineering would be most relevant.

Systems Engineering Skills:

- **Systems engineering mindset:** Understandi complex systems, their interactions, and life cycle.
- **System requirements development:** Capture user needs, translate them into technical specifications, and perform requirements analysis.
- **System design and architecture:** Design and modeling the overall system and its subsystems.
- **Risk analysis and management:** Identify potential risks throughout the development lifecycle and implement mitigation strategies.
- **Systems verification and validation:** Ensure the system meets requirements and performs as intended.
- **Project management:** Planning, scheduling, budgeting, and managing resources for successful project completion.

Medical Device Specific Knowledge:

- **Medical device regulatory landscape:** Focus on key regulations like FDA 510(k) and ISO 13485.
- **Common medical device technologies:** Sensors, actuators, microprocessors, communication protocols.

- **Biocompatibility principles:** Selection of materials that are safe for human interaction within the body.
- **Ethical considerations in medical device design:** Ensuring patient safety, privacy, and data security.
- **Emerging trends in medical device technology:** Artificial intelligence, machine learning, and telehealth.
- **Career paths for medical device systems engineers:** Explore various specializations and leadership opportunities.
- Case studies of successful medical device development projects.
- Real-world examples and exercises to reinforce learning and practical application.
- Guidance on professional development resources and certifications relevant to the field.

8.8 Survey

This section dives into the insights gleaned from a survey conducted in April 2024. The survey targeted systems engineers working in the field of medical device development. The survey received responses from a diverse group of professionals from leading companies including Boston Scientific, the FDA, Nudge BG, BIOTRONIK, and others. The primary objective of this survey was to identify the knowledge and resources that are most valuable to medical device systems engineers in their daily work.

The analysis of the survey responses was aimed to inform the development of the MedSE knowledge repository.

The following section will present a detailed analysis of the survey findings.

For reference, the template used for the survey questions is included in Appendix Survey of this report. This will allow readers to gain a deeper understanding of the specific questions asked and the context surrounding the survey responses.

9 Survey Results

> **Caution**
>
> The report published on this website is a draft and subject to frequent updates. Please be aware that the content may change over time as revisions are made. Thank you for your understanding.

> **Tip**
>
> If you have questions, comments, or feedback, please contact Esteban Solorzano.
> esteban.solorzano@gmail.com

This section contains the survey results for a total of 22 respondents.

9.1 Question 1: Please identify the primary challenges you have encountered in the systems engineering process for medical devices. Select all that apply from the following options:

Figure 9.1 is a bar graph of question 1 results.

The biggest challenge according to question 1 results is **Systems Integration** with 13 respondents. Following closely behind are **Interdisciplinary Collaboration** and **Safety and Efficacy** at 11 and 14 respondents respectively.

Other challenges faced by systems engineers working on medical devices include:

- **Cybersecurity** (9 respondents)
- **Usability and Human Factors** (7 respondents)
- **Regulatory Compliance** (9 respondents)
- **Cost Constraints** (3 respondents)
- **Global Market Access** (1 respondent)
- **Emerging Technologies** (2 respondents)

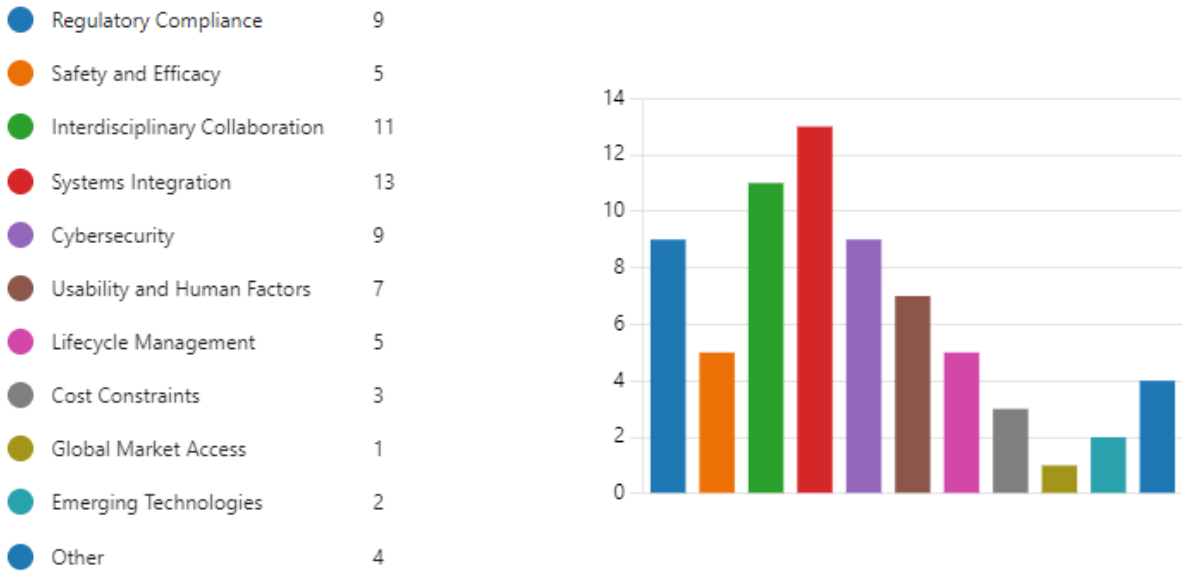

Figure 9.1: Question 1 results

- **Other** (4 respondents)

9.2 Question 2: What tools do you find indispensable in your daily tasks as a systems engineer? Please select all that apply from the following options:

Figure 9.2 is a bar graph of question 2 results.

Based on question 2 results, the most indispensable tools for systems engineers working on medical devices are **Requirement management software** and **Documentation tools**, with 18 and 15 respondents selecting them respectively.

Following these two are:

- **Data analysis and visualization tools** (11 respondents)
- **Collaboration tools** (13 respondents)

These findings suggest that a significant portion of a systems engineer's time is spent on managing requirements, documenting processes, collaborating with team members, and analyzing data.

Here's a deeper look into some of the other tools selected by the respondents:

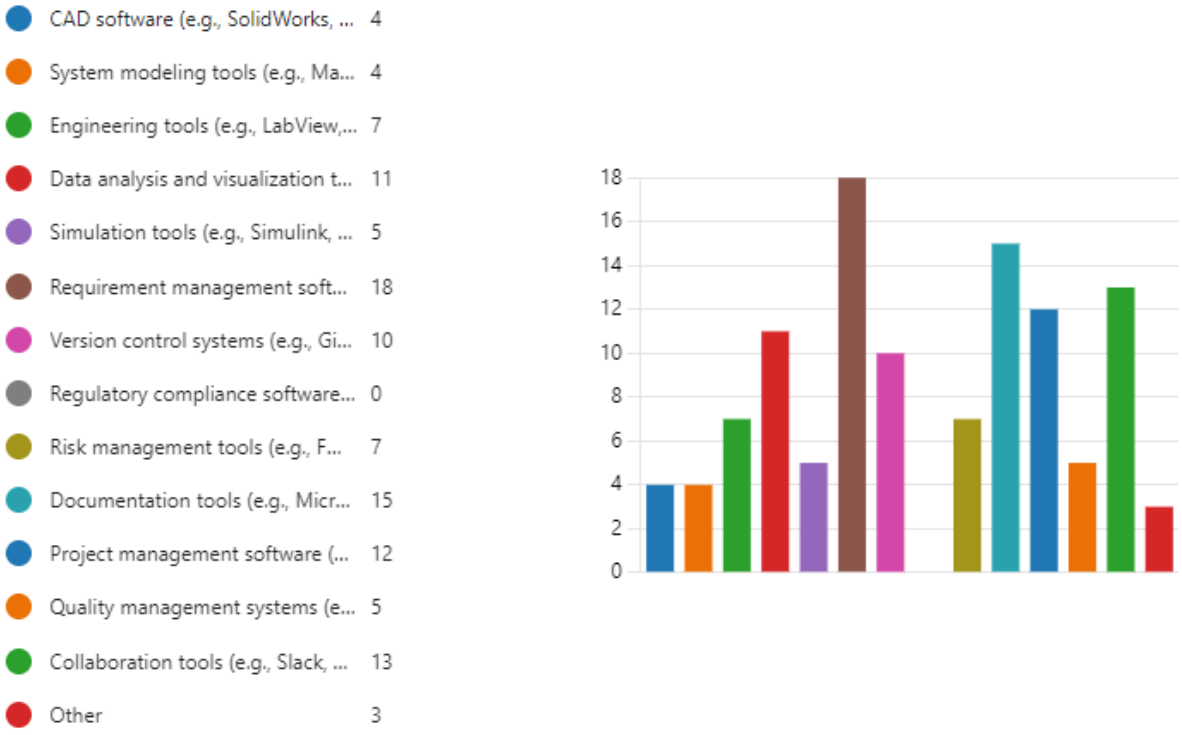

Figure 9.2: Question 2 results

- **Engineering tools** (e.g., LabView) (7 respondents)
- **Risk management tools** (e.g., FMEA) (7 respondents)
- **Simulation tools** (e.g., Simulink) (16 respondents)
- **Version control systems** (e.g., Git) (10 respondents)
- **Project management software** (12 respondents)
- **Quality management systems** (5 respondents)

9.3 Question 3: Could you please elaborate on why you find the selected tools valuable in your day-to-day work as a systems engineer? Feel free to provide specific examples or experiences that illustrate their importance.

Figure 9.3 is a word cloud of question 3 results.

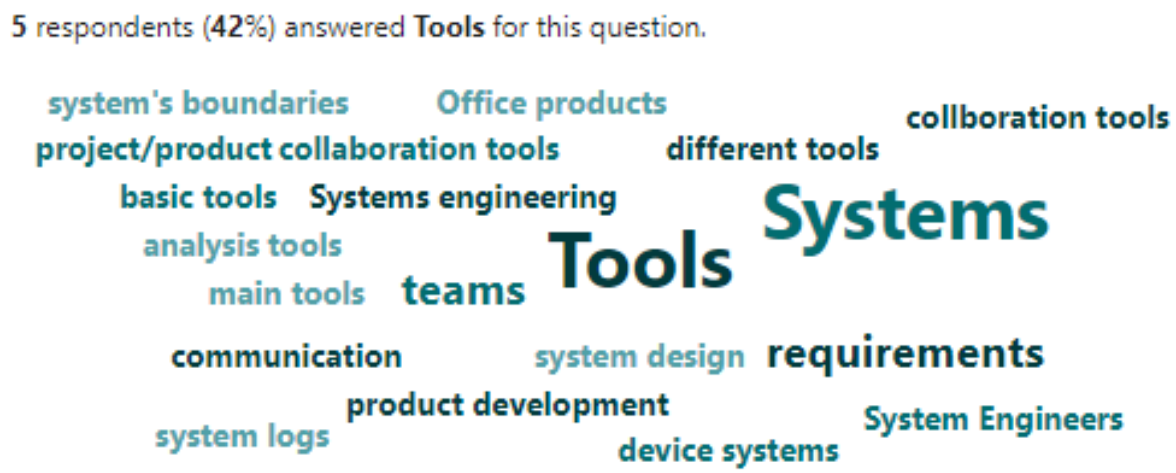

Figure 9.3: Question 3 results

The analysis of the results of this follow-up question reveals several key themes regarding why systems engineers find specific tools valuable:

1. Structure and Documentation:

- Requirement management and documentation tools provide a framework to record decisions and trace how activities meet requirements. This ensures traceability and simplifies demonstrating compliance with regulations. (Example: “Cockpit is used to navigate, trace and clearly understand our requirements and source/rationale”)

2. **Collaboration and Communication:**

   - Collaboration tools are essential for communication within the team and across disciplines. They facilitate information dissemination and decision making throughout the development process. (Example: "Collaboration and communication is key for Systems engineering. Tools that help facilitate communication and the system's boundaries are critical.")

3. **Information Management:**

   - Data analysis and visualization tools, version control systems, and quality management systems help gather information, keep it up-to-date, and create a clear picture of the project's status. (Example: "It's the only way to create a complete picture of product design requirements, risks, and tests.")

4. **Specific Needs of Medical Device Development:**

   - Some engineers highlighted the importance of tools tailored to medical device development, such as FMEA for risk management. (Example: "As a Design Assurance Engineer, I focus on communication/collaboration tools, project management software (JIRA), and requirements management (JAMA).")

5. **Balancing Functionality with Efficiency:**

   - While some emphasized the importance of powerful tools like Matlab, others stressed that tools should not become a hindrance and should prioritize getting the job done efficiently. (Example: "Overall, they help in getting the job done without being a hinderance.")

> **Note**
>
> - The responses suggest a preference for familiar and widely used tools like Microsoft Office suite alongside more specialized engineering tools.
> - There's a recognition that the "best" tools depend on the specific role and project within medical device systems engineering.

9.4 Question 4: Which methodologies do you consider most beneficial in your daily tasks as a systems engineer working with medical devices? Please select all that apply from the following options:

Figure 9.4 is a bar graph shows the results of a survey question asking systems engineers working on medical devices which methodologies they find most beneficial in their daily tasks.

Figure 9.4: Question 4 results

Here's a breakdown of the findings:

- **Model-Based Approaches (e.g., MBSE, SysML)** is the most popular methodology, with 12 respondents selecting it.
- **Engineering Practices (e.g., Requirements Engineering, Design Reviews)** follows closely behind at 15 respondents.
- **Quality and Compliance (e.g., FMEA, HACCP)** is another well-regarded methodology, with 16 respondents finding it beneficial.

These results suggest that systems engineers working on medical devices heavily rely on methodologies that provide structure and guidance throughout the development process. This is likely due to the rigorous requirements for safety and regulatory compliance in the medical device industry.

Here's a closer look at some of the other methodologies selected by the respondents:

- **Risk Management (e.g., ISO 14971)** (14 respondents)
- **Verification and Validation Processes** (12 respondents)
- **Change Control Processes** (10 respondents)
- **Configuration Management** (8 respondents)
- **Agile Methods (e.g., Agile, Kanban)** (6 respondents)
- **Human Factors and Usability (e.g., HFMEA)** (4 respondents)
- **Lean and Continuous Improvement** (6 respondents)
- **Cross-disciplinary Collaboration** (12 respondents)
- **Innovative Design Approaches (e.g., TRIZ)** (5 respondents)

9.5 Question 5: Could you please provide insights into why you find the selected methodologies valuable in your day-to-day work as a systems engineer for medical devices? Describe the outcomes or benefits you've experienced by employing these methodologies. Additionally, if applicable, mention any alternative methodologies that were considered but not chosen, and the rationale behind your selection.

Figure 9.5 is word cloud of question 5 results.

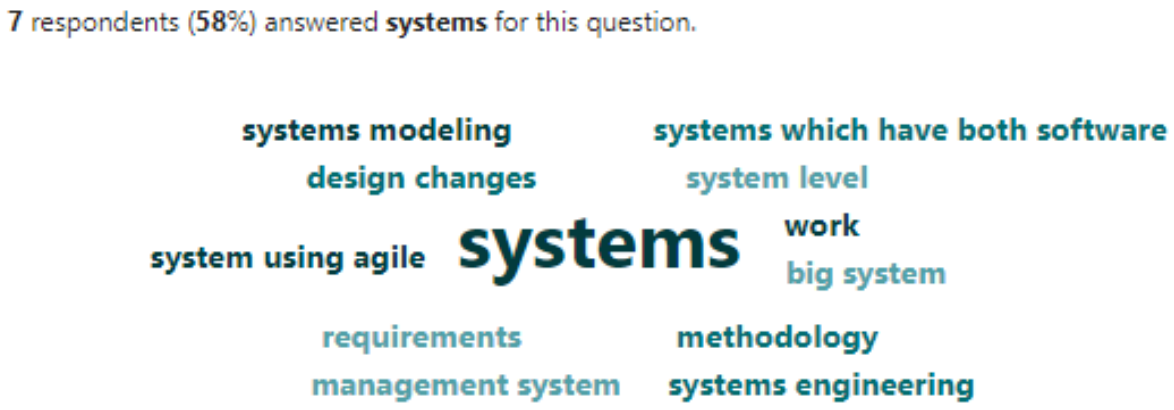

Figure 9.5: Question 5 results

The follow-up survey question provided valuable insights into why specific methodologies are beneficial for systems engineers working on medical devices. Here's a breakdown of the key themes:

1. **Emphasis on Requirements and System Definition:**

   - The system engineers highlighted the importance of methodologies like **requirements engineering** and **model-based approaches (MBSE)**. These methodologies ensure a clear understanding of what the system needs to do and how it will function, leading to fewer rework loops and more efficient development. (Example: "Don't know, what are my choices? have to get the requirements correct and properly scoped… Model-based approaches allow better insight into how the system might behave…")

2. **Communication and Collaboration:**

   - The critical role of **cross-disciplinary collaboration** was emphasized. Methodologies that facilitate communication across teams (e.g., engineering, design, user experience) are essential for developing a cohesive medical device. (Example: "Cross-disciplinary collaboration is at the heart of what I do - nothing sticks if there isn't full understanding and agreement…")

3. **Risk Management and Safety:**

   - **Quality and compliance methodologies** (e.g., FMEA, HACCP (Nutrition and Applied 2024a)) were considered valuable for managing risks and ensuring the device meets regulatory requirements. (Example: "These are either required or the most efficient approaches to getting work completed. Procedures and systems drive these tools more than others…")

4. **Specific Needs of Medical Devices:**

- Some system engineers pointed out that some methodologies, like Human Factors and Usability are particularly important for medical devices due to the focus on user safety and interaction. (Example: "Human Factors and Usability - reports on things like formative studies are important to have in documenting requirement rationale.")

5. **Balancing Efficiency and Innovation:**

- While **engineering practices** and established methodologies are crucial, some mentioned the potential benefits of **agile methods** for flexibility and adapting to changing requirements. (Example: "Agile methods are highly effective in helping to focus on the highest value first, preventing scope creep and supporting a 'fail fast' mindset.")

6. **Regulatory Considerations:**

- A few responses suggested that regulatory requirements should not solely dictate the chosen methodologies. However, a well-defined systems engineering approach can facilitate regulatory compliance. (Example: "Again, many of processes listed did not strike me as medical device specific. I also think regulatory should not drive systems engineering but good systems engineering should deliver what you need to get the product approved in many cases.")

9.6 Question 6: Which job roles do you primarily engage with in your daily activities?

Figure 9.6 is a bar graph depicting the results of a survey question asking systems engineers working on medical devices which job roles they interact with most in their daily activities.

Here's a breakdown of the findings, based on the number of respondents who selected each category:

- **System Engineers** (20 respondents) are the most frequently mentioned collaborators, likely due to their crucial role in bringing the designed system to life.
- **Project Managers** (13 respondents) closely follow, highlighting the importance of cross-functional collaboration on medical device projects.

Following these two roles are:

- **Software Engineers** (15 respondents)
- **Quality Assurance/Quality Control (QA/QC) Engineers** (14 respondents)
- **Regulatory Affairs Specialists** (9 respondents)

Biomedical Engineers	7
Systems Engineers	20
Mechanical Engineers	10
Electrical Engineers	14
Quality Assurance/Quality Contr...	14
Regulatory Affairs Specialists	9
Product Development Engineers	9
Manufacturing Engineers	2
Clinical Engineers	2
Software Engineers	15
Project Managers	13
Research and Development Scie...	8
Design Engineers	9
Process Engineers	0
Field Service Engineers	4
Technical Support Engineers	5
Validation Engineers	2
Risk Management Specialists	7
Compliance Engineers	4
Supply Chain/Logistics Engineers	2
Marketing/Sales	6
Other	2

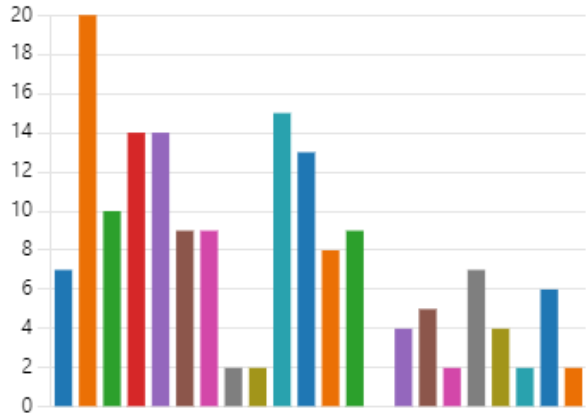

Figure 9.6: Question 6 results

These responses demonstrate the interdisciplinary nature of systems engineering in the medical device field. Effective communication and collaboration among these various roles are essential for the successful development of medical devices.

Here's a look at some of the less frequent interactions, but still important for systems engineers:

- **Design Engineers** (9 respondents)
- **Field Service Engineers** (4 respondents)
- **Technical Support Engineers** (5 respondents)
- **Validation Engineers** (2 respondents)
- **Risk Management Specialists** (7 respondents)
- **Compliance Engineers** (4 respondents)
- **Supply Chain/Logistics Engineers** (2 respondents)
- **Marketing/Sales** (6 respondents)

9.7 Question 7: Please indicate which job roles, in your opinion, possess a good understanding of the deliverables and artifacts produced by systems engineers?

Figure 9.7 is a word cloud of question 7 results.

The overlap between the two most frequently mentioned job roles in both surveys is interesting. Here's a breakdown of the findings:

- **Project Managers** (13 respondents in the previous survey and 8 respondents in the follow-up question) continue to be identified as a key role that understands the deliverables and artifacts produced by systems engineers. This highlights the importance of their role in overseeing the entire project lifecycle and ensuring systems engineers' work aligns with project goals.

Here are some other insights from the follow-up question:

- **Quality Assurance/Quality Control (QA/QC) Engineers** (14 respondents in the previous survey and 9 respondents in the follow-up question) are likely involved in the verification and validation processes of medical devices, making them familiar with the systems engineering deliverables needed to ensure quality.

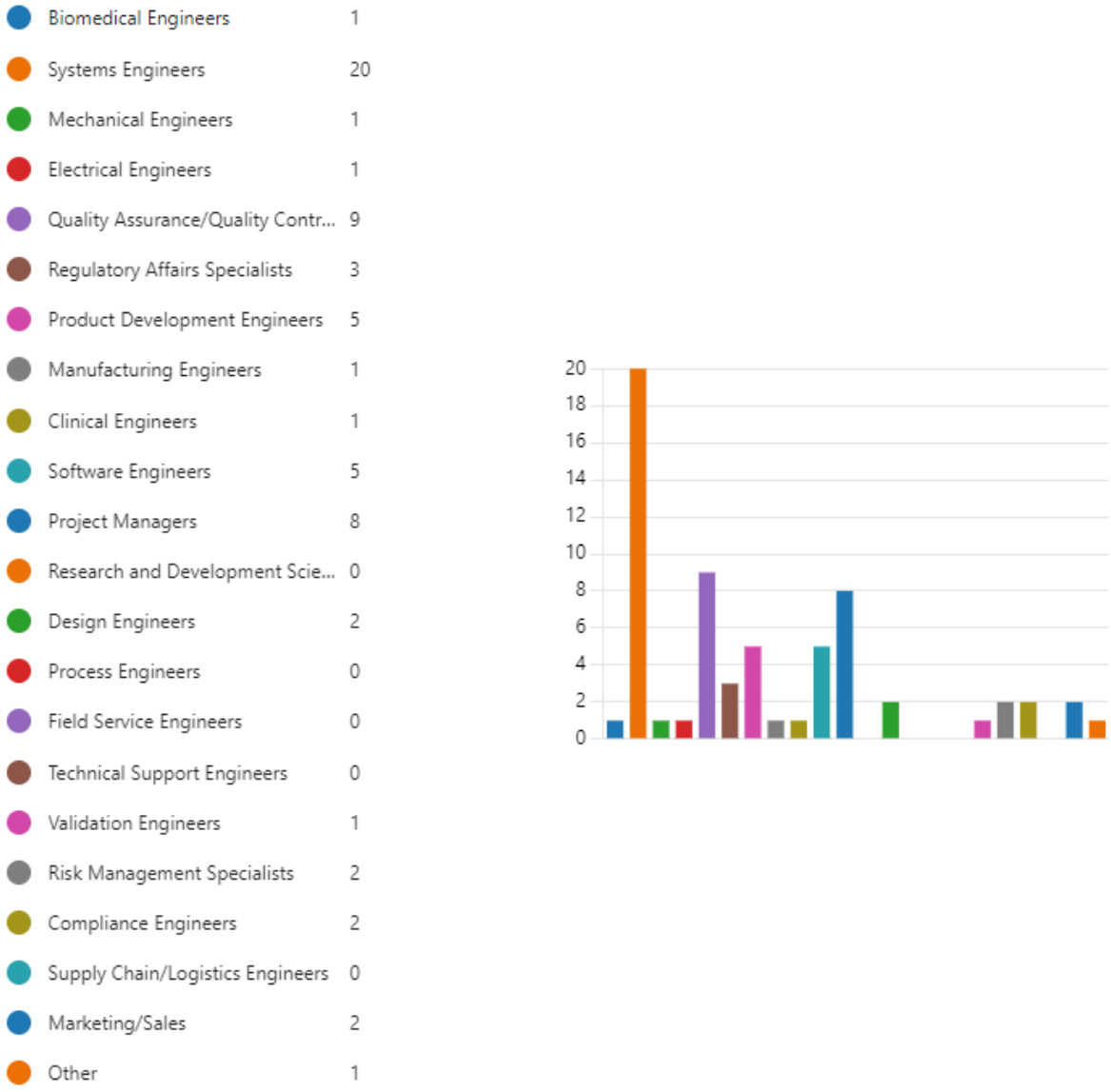

Figure 9.7: Question 7 results

- **Regulatory Affairs Specialists** (9 respondents in the previous survey and 3 respondents in the follow-up question) understand the regulatory requirements that systems engineers consider throughout the design process.

The follow-up question also highlights some roles that may benefit from a stronger understanding of systems engineering deliverables:

- **Software Engineers** (15 respondents in the previous survey and 5 respondents in the follow-up question) collaborate frequently with systems engineers, but their understanding of deliverables might be limited depending on their area of focus within the software development process.
- **Electrical and Mechanical Engineers** (24 respondents in the previous survey and 2 respondents in the follow-up question) could benefit from a clear understanding of the system-level design considerations provided by systems engineers.

Overall, the survey results suggest that while some roles naturally have a better understanding of systems engineers' deliverables due to close collaboration (e.g., project managers, QA/QC engineers), there's an opportunity to improve communication and knowledge sharing across disciplines (e.g., software engineers, design engineers). This can enhance overall collaboration and ensure everyone involved has a clear understanding of how their work contributes to the medical device development process.

9.8 Question 8: Could you share examples of books, articles, or papers that have resonated with you as a systems engineer working with medical devices? Please provide one or more titles and, if possible, briefly explain how they impacted your work or perspective. Your insights will help us better understand valuable resources in this field.

Figure 9.8 is a word cloud of question 8 results.

The following is a breakdown of the mentioned resources and how they resonated with the respondents:

Books:

- **Design for Six Sigma by Creveling, Slutsky, and Antis (ISBN 0-13-009223-1):** This book focuses on a methodology for process improvement, which can be valuable for optimizing medical device development (Creveling, Slutsky, and Jr. Antis 2002). (One respondent mentioned it but no details on impact were provided)

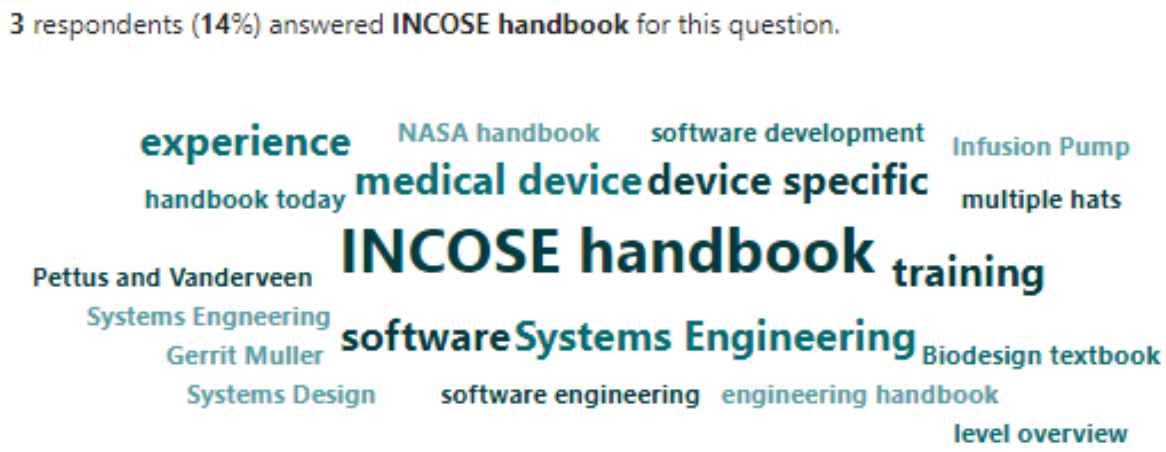

Figure 9.8: Question 8 results

- **Human error: models and management by James Reason:** This book explores human factors and error management, a crucial aspect of medical device safety (Reason 1990). (One respondent mentioned it but no details on impact were provided)
- **Anything by Nancy Leveson or Gerrit Muller:** These authors are known for their work on safety-critical systems, highly relevant to medical devices. (One respondent mentioned these authors but no specific titles were mentioned)
- **The Five Dysfunctions of a Team by Patrick Lencioni:** This book, though not specific to medical devices, addresses team collaboration and communication, essential skills for systems engineers (Lencioni 2002). (One respondent highlighted its impact on their understanding of cross-functional collaboration)
- **Systems Engineering, Principles and Practice:** This book provides a general overview of the field, useful for understanding core systems engineering concepts even if not specific to medical devices (Kossiakoff et al. 2020). (One respondent mentioned it as a high-level overview)

Articles and Papers:

- **"Worth the Effort? Closed Loop Infusion Pump Integration" by Pettus and Vanderveen (AAMI 2013):** This article likely focuses on a specific case study of medical device integration, potentially offering practical insights (Pettus and Vanderveen 2013). (One respondent mentioned it but no details on impact were provided)

Training Materials:

- **Architecture and Systems Engineering Online Program from MIT**: This training focused on modeling, a crucial skill for systems engineers (Technology, n.d.). (One respondent highlighted its value)
- **INCOSE Systems Engineering Handbook:** This widely recognized resource provides a comprehensive guide to systems engineering practices (*INCOSE Systems Engineering Handbook* 2023). (Multiple respondents mentioned it as a main guide or reference)
- **Stanford Biodesign textbook:** This resource likely focuses on biomedical device design and development processes ("Biodesign | Biomedical Engineering," n.d.). (One respondent mentioned it but no details on impact were provided)
- **Webinars from Intertek on 60601 standards:** These webinars address medical device safety standards (IEC 60601), essential knowledge for systems engineers. (One respondent mentioned them as a valuable resource)
- **Company Training Materials (Boston Scientific):** Some respondents learned from their employers' training programs, highlighting the importance of company-specific processes and knowledge sharing.

Overall Insights:

- There is no single "go-to" resource, but a combination of books, articles, training materials, and on-the-job experience appears to be most beneficial.
- **Systems Engineering** fundamentals are considered crucial, with resources like the INCOSE Systems Engineering Handbook being highly regarded.
- **Medical Device Specific Knowledge:** Resources that address specific challenges and considerations of medical device development are also valuable (e.g., standards, case studies).
- **Soft Skills:** Resources on collaboration, communication, and team dynamics can be beneficial for systems engineers working in a cross-functional environment.

9.9 Question 9: In your opinion, what regulations or standards should be covered in a comprehensive medical device systems engineering book? Please provide your suggestions below.

Figure 9.9 is a word cloud of question 9 results.

The survey question provide information for what regulations and standards should be covered in the MedSE knowledge repository. Here's a breakdown of the suggestions:

Essential Standards:

5 respondents (23%) answered ISO for this question.

Figure 9.9: Question 9 results

- **ISO 13485:2016 - Medical devices - Quality management systems - Requirements for regulatory purposes:** This standard outlines the quality management system requirements for medical device manufacturers. (Multiple respondents mentioned it)
- **IEC 60601 series - Medical electrical equipment:** This series of standards sets forth safety requirements for various aspects of medical electrical equipment. (Multiple respondents mentioned it, with some highlighting specific parts like IEC 60601-1)
- **ISO 14971:2019 - Medical devices - Application of risk management to medical devices:** This standard outlines a risk management process for medical devices. (Multiple respondents mentioned it)

Additional Considerations:

- **ISO 9001:2015 - Quality management systems - Requirements:** While ISO 9001 is a general quality management standard, it can be a foundational principle for medical device quality systems. (One respondent mentioned it)
- **ISO 10993 series - Biological evaluation of medical devices:** This series addresses the biocompatibility (interaction with living tissue) of medical devices. (One respondent mentioned it)
- **Other Standards:** A few respondents mentioned specific standards like ISO 15288 (Systems and software engineering — System life cycle processes) or IEC 62304 (Medical Device Software - Software Life Cycle Processes) that may be relevant depending on the specific medical device being developed.

Structure and Application:

- Several respondents emphasized the importance of presenting the regulations and standards in a hierarchical manner, starting with foundational concepts and then progressing to more specific details.
- One respondent highlighted the need for the MedSE knowledge repository to explain how these regulations apply within the context of ISO 13485, the core quality management system standard for medical devices.

Beyond Just Standards:

- A few respondents suggested including systems engineering fundamentals and common themes that apply across various regulations and standards.
- One respondent emphasized the need for a scalable systems engineering process tailored to medical devices, which could be useful for training purposes.

Overall, the survey results suggest that a comprehensive medical device systems engineering book should cover the following:

- Core regulations and standards, including ISO 13485, IEC 60601 series, and ISO 14971.
- Additional standards may be relevant depending on the specific device being developed.
- The MedSE knowledge repository should explain how these regulations and standards are applied within the medical device development process.
- Foundational systems engineering principles should be integrated throughout the MedSE knowledge repository.
- The presentation of information should be structured and hierarchical, allowing readers to find information based on their level of understanding.

9.10 Question 10: What learning formats do you find most accessible and beneficial? Please select all that apply from the following options:

Figure 9.10 is a bar graph of question 10 results.

The survey question results show the following preferences for learning formats among systems engineers working on medical devices:

- **E-books (8 respondents)** and **Webinars (6 respondents)** are the most popular options, likely due to their flexibility and accessibility. They allow engineers to learn at their own pace and convenience.

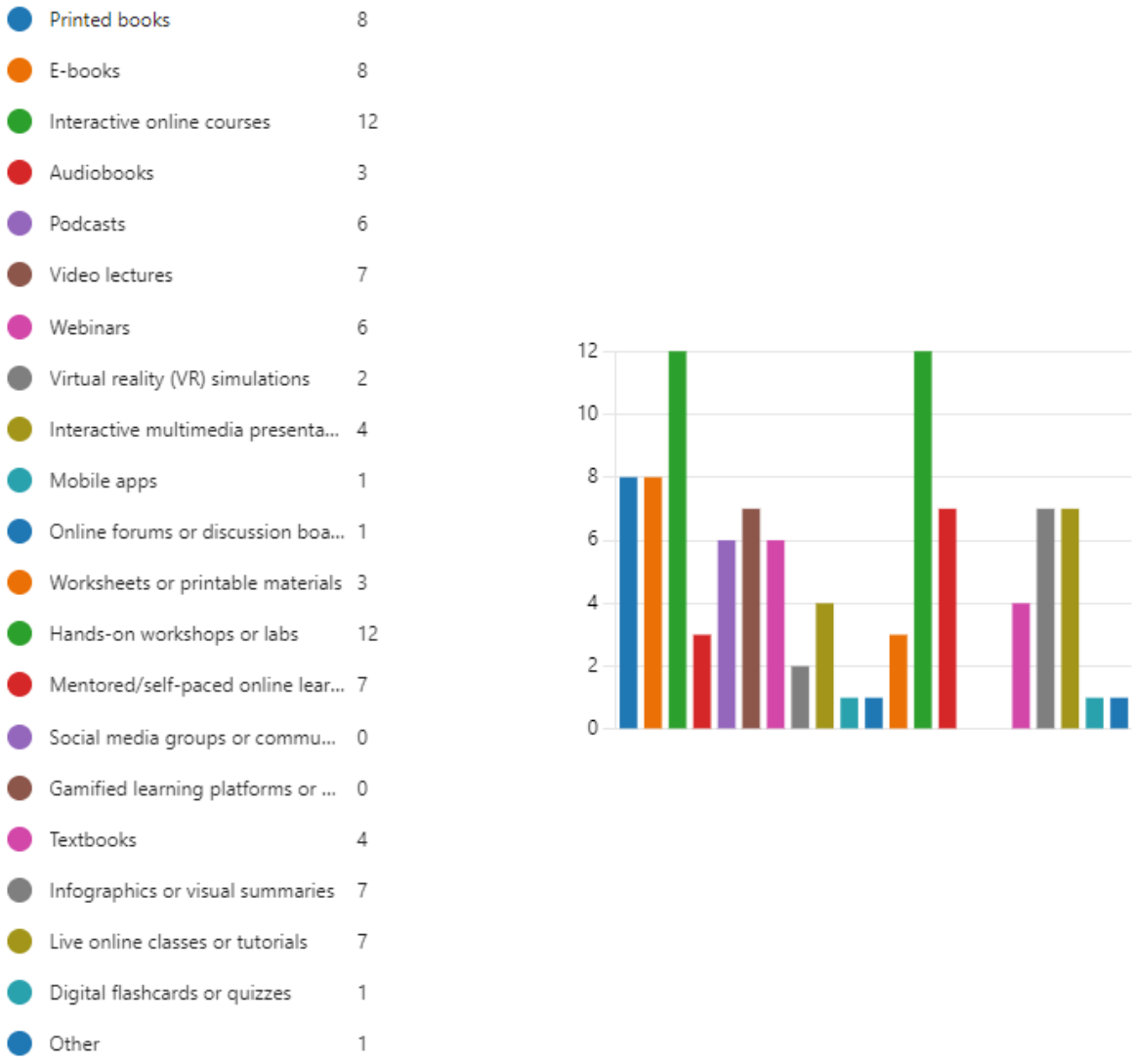

Figure 9.10: Question 10 results

- **Interactive online courses (12 respondents)** are also relatively popular, providing a more structured learning experience with opportunities for interactivity.
- **Printed books (8 respondents)** remain a valuable resource, offering in-depth information and a reference point for future needs.

Here's a look at some of the less frequent selections:

- **Audiobooks (3 respondents)** and **Podcasts (6 respondents)** can be helpful for consuming information while multitasking or commuting.
- **Video lectures (7 respondents)** can be informative, but may require dedicated viewing time.
- **Mobile apps (1 respondent)** may be useful for on-the-go learning but may lack depth on complex topics.
- **Online forums or discussion boards (1 respondent)** and **Social media groups or communities (0 respondents)** can be helpful for staying updated on the latest trends and connecting with other professionals, but may not be the most structured way to acquire in-depth knowledge.
- **Hands-on workshops or labs (12 respondents)** were selected by a significant number of respondents, highlighting the importance of practical learning for systems engineers.
- **Mentored/self-paced online learning (7 respondents)** can provide personalized guidance and flexibility.

> **Note**
>
> Respondents could select all that apply, so many engineers likely utilize a combination of these formats to maximize their learning and stay up-to-date in medical device systems engineering.

10 Stakeholders

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Figure 10.1 depicts a SysML block definition diagram (bdd) centered on a block named "Knowledge Repository" which represents the MedSE knowledge repository. The diagram showcases various stakeholders that have an interest in this repository.

There are three categories of stakeholders (Sterman and Sterman 2000), which are as follows:

- **Customer**, which represents the set of roles that will benefit from the medical device systems engineering knowledge repository system.
- **External**, which represents the set of roles that have an interest in the system that will limit or restrict the system in some way.
- **Supplier**, which represents the set of roles that are interested in developing and delivering the system.

Here's a breakdown of the stakeholder that have interest in the "Knowledge Repository" block:

- **Government:** This block signifies government entities with an interest in the knowledge repository. This could include regulatory bodies that oversee the medical device industry.
- **Non-profit organizations:** This block represents non-profit organizations that may have a stake in the knowledge repository. This could include organizations such as AAMI (Association for the Advancement of Medical Instrumentation) that focus on patient safety or medical device innovation.

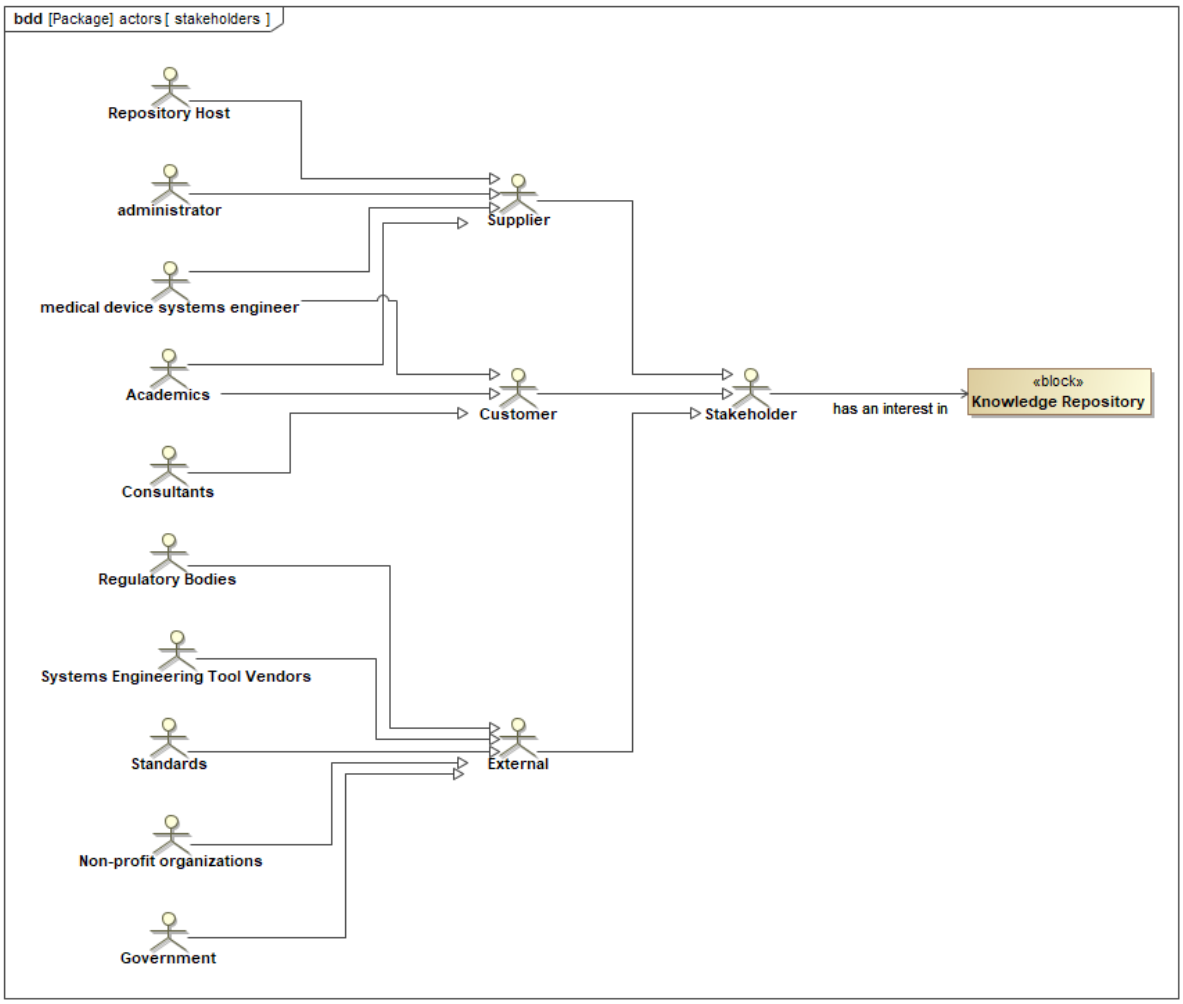

Figure 10.1: MedSE Knowledge Repository Stakeholders View

- **Standards organizations:** This block signifies standards organizations that set requirements for medical devices. These standards organizations would likely have an interest in ensuring that the knowledge repository includes information on relevant standards.
- **Systems Engineering Tool Vendors:** This block represents vendors that develop systems engineering tools. These vendors may have an interest in the knowledge repository as a way to improve the capabilities of their tools.
- **Regulatory Bodies:** This block signifies regulatory bodies that govern the medical device industry. These regulatory bodies would likely have an interest in ensuring that the knowledge repository includes information on relevant regulations.
- **Consultants:** This block represents consultants who provide services to the medical device industry. These consultants may have an interest in the knowledge repository as a way to stay up-to-date on the latest developments in medical device systems engineering.
- **Medical Device Systems Engineers:** This block signifies medical device systems engineers who design and develop medical devices. These engineers would likely be the primary users of the knowledge repository.
- **Academics:** This block represents academic institutions that conduct research in medical device systems engineering. These institutions may have an interest in the knowledge repository as a way to share their research findings.
- **Repository Host:** This block signifies the organization or entity that hosts the knowledge repository. This could be a government agency, a non-profit organization, or a commercial entity.
- **Administrator:** This block signifies the person or team responsible for administering the knowledge repository. This could include tasks such as adding new content, maintaining the repository software, and ensuring security.

Overall, the SysML block definition diagram provides a useful high-level overview of the stakeholders who have an interest in the medical device systems engineering knowledge repository. This information is helpful for understanding the needs of these stakeholders and for planning the development and maintenance of the knowledge repository.

11 Goals and Objectives

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Section 11.1 provides the list of active, passive and sponsor stakeholders of the programmable playground system. Section 11.2 provides the list of stakeholder expectations that are classified as either capability or characteristic. Section 11.3 extracts which stakeholder expectations are considered sacred. Section 11.4 provides the system objectives. Section 11.5 explains the concept of operations of the system.

11.1 Stakeholders

Table 11.1: Stakeholders

ID	Stakeholder	Description	Type [active, passive, sponsor]

11.2 Stakeholders expectations

Stakeholder expectations were elicited from the stakeholders and documented in Table 11.3. The stakeholders were interviewed and/or surveyed to record their expectations. Not all

stakeholders were addressed directly, this was case of the medical device regulatory bodies. Published medical device regulations were consulted to determine what are the expectations of the Regulatory Bodies.

Table 11.2: Stakeholders expectations

ID	Expectation Title	Expectation Description	Source Stakeholder	Validation Method
STK1	STK1 Knowledge Access	Access to comprehensive and up-to-date knowledge related to medical device systems engineering.	Medical Device Systems Engineers	Demonstration
STK2	STK2 Regulatory Information	Access to regulatory standards, guidelines, and documentation relevant to medical device systems engineering.	Regulatory Compliance Officers	Demonstration
STK3	STK3 Quality Management	Information on quality management systems, validation, verification, and testing methodologies for medical devices.	Quality Assurance Professionals	Demonstration
STK4	STK4 Research and Innovation	Access to research papers, patents, and emerging technologies in medical device systems engineering.	Research and Development Teams	Demonstration
STK5	STK5 Clinical Requirements	Knowledge of clinical requirements, usability considerations, and human factors engineering in medical device design.	Clinical Specialists	Demonstration
STK6	STK6 Market Insights	Insights into market trends, customer needs, and competitive analysis for medical devices.	Product Managers	Demonstration

STK7	STK7 Safe and Effective Devices	Safe and effective medical devices that meet their clinical needs and preferences.	End Users (Healthcare Professionals and Patients)	Analysis
STK8	STK8 Repository Management	Oversight and management of the knowledge repository, including resource allocation and performance monitoring.	Administrators and Decision Makers	Demonstration
STK9	STK9 Content Type	Variety of content type such as articles, videos, interactive content.	Medical Device Systems Engineers	Inspection

11.3 Sacred expectations

Table 11.3 shows the stakeholder expectations determines as "sacred".

Table 11.3: Sacred stakeholder expectations

Stakeholder expectation ID	Expectation Title	Expectation Description

11.4 Objectives

Table 11.4 provides the list of the system objectives.

Table 11.4: Objectives

ID	Objective
OBJ0001	Design a system that will compile and synthesize knowledge and best practices related to systems engineering in medical device development.

ID	Objective
OBJ0002	Provide a comprehensive resource that educates professionals and students in the field of systems engineering about the unique challenges and considerations specific to medical devices.
OBJ0003	Offer practical guidance and tools for applying systems engineering principles throughout the entire lifecycle of medical device development.
OBJ0004	Foster a deeper understanding of the regulatory requirements and standards governing medical devices and how they intersect with systems engineering processes.

11.5 Concept of Operations

This section defines the system context for the MedSE knowledge repository. The analysis employs a SysML block definition diagram.

A context diagram is a diagram that defines the boundary between the system, or part of a system, and its environment, showing the entities that interact with it. ("System Context Diagram" 2019)

The context diagram shows the system's inputs and outputs and sets a baseline for developing the internal architecture (Larson et al. 2009). Context is what surrounds the system. It contains entities that are "just on the outside of the system" but are relevant to it (Crawley, Cameron, and Selva 2015).

Figure 11.1 shows the Medical Device System context.

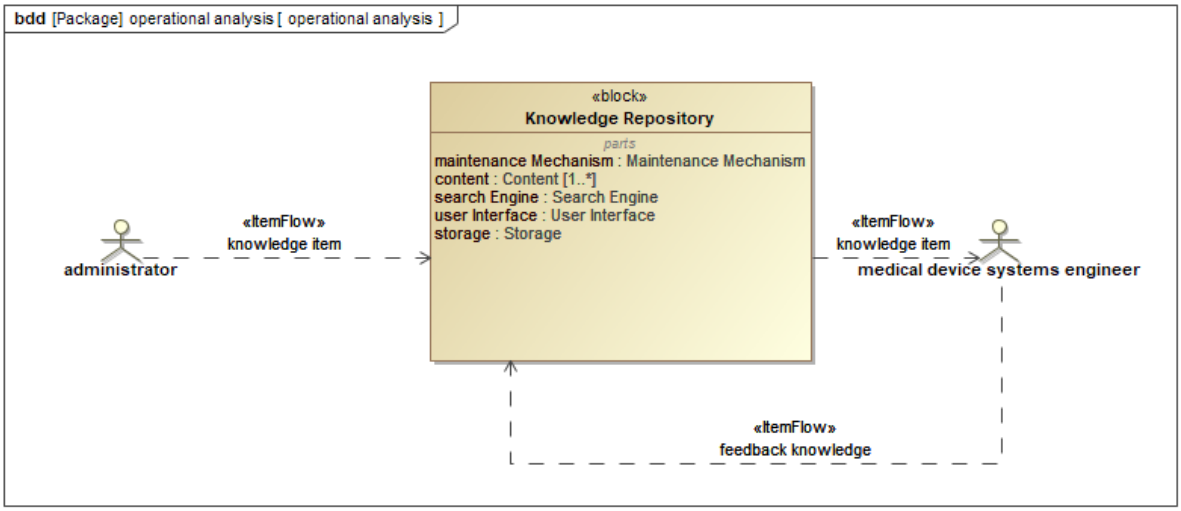

Figure 11.1: Medical Device System Context Diagram

12 Operational Analysis

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"What the system users must achieve".

The Operational Analysis perspective analyses the issue of operational users (actors), by identifying stakeholders that have to interact with the system, their goals, activities, constraints and the interaction conditions between them. This perspective allows to model the required high-level operational capabilities and perform an operational needs analysis without even defining the system-of-interest, in fact the system may not even mentioned in this section (Cronin, n.d.b).

12.0.1 Knowledge Repository

The core element of the system is the **Knowledge Repository** block. This block represents a database or information storage system that houses the medical device systems engineering knowledge base. The knowledge base is comprised of multiple **Content** elements, indicated by the notation "[1..*]". This multiplicity signifies that the repository must contain at least one content element, and the number of content elements can be limitless. The content would likely encompasses details about regulatory, risk management, requirements management, and other relevant medical device systems engineering information.

The knowledge repository also includes a **Search Engine** component. This component plays a critical role in facilitating efficient retrieval of information from the content base. Users can leverage the search engine to locate specific knowledge items based on their needs.

The knowledge repository possesses two key properties:

- **Maintenance Mechanism:** This property acknowledges the importance of maintaining the accuracy and completeness of the knowledge base over time. The specific mechanisms for maintenance are not explicitly shown in the diagram but could involve processes for adding, updating, and removing content.
- **Storage:** This property refers to the physical infrastructure responsible for storing the knowledge repository. While the specific technology is not depicted, it likely involves a database server, physical medium or cloud-based storage solution.

Interaction and Data Flow

The diagram depicts two key data flows associated with the knowledge repository:

- **User Interface:** This bidirectional flow signifies the interaction between users and the knowledge repository. Users can provide input, such as search queries, through the user interface. The system, in turn, can deliver output, such as search results or retrieved information, through the same channel.
- **Knowledge Item:** This flow represents the movement of knowledge items between the knowledge repository and potentially other parts of the system or external actors. Knowledge items could be retrieved from the repository by authorized users or potentially transferred to other system components for further processing.

12.0.2 Actors and System Stakeholders

The diagram identifies two primary actors that interact with the system:

- **Administrator:** This actor plays a crucial role in managing the knowledge repository. Their responsibilities likely include adding, updating, and deleting content within the repository. Additionally, the administrator is responsible for managing access control, ensuring that only authorized users can access and modify the knowledge base.
- **Medical Device Systems Engineer** and **Consultant:** These actors represent the primary consumers of information within the knowledge repository. They can leverage the search engine functionality to locate relevant knowledge items pertinent to their work in medical device development or consultation.

The SysML block definition diagram portrays a knowledge repository for medical device systems engineering. The repository stores and manages essential information related to medical device systems engineering. Authorized users, such as systems engineers and consultants, can access and search the repository using a search engine. An administrator maintains the knowledge base and ensures its integrity through appropriate maintenance mechanisms. This system architecture facilitates knowledge sharing and access within the medical service domain. Further analysis could explore the internal structure of the knowledge repository, including the specific data model used to represent medical service information, to gain a deeper understanding of the system's knowledge representation and retrieval capabilities.

12.1 System Use Cases

This section analyzes the knowledge repository system use cases and modeled with a SysML use case diagram. Figure 12.1 depicts a central block representing the knowledge repository itself, surrounded by actors and their associated use cases.

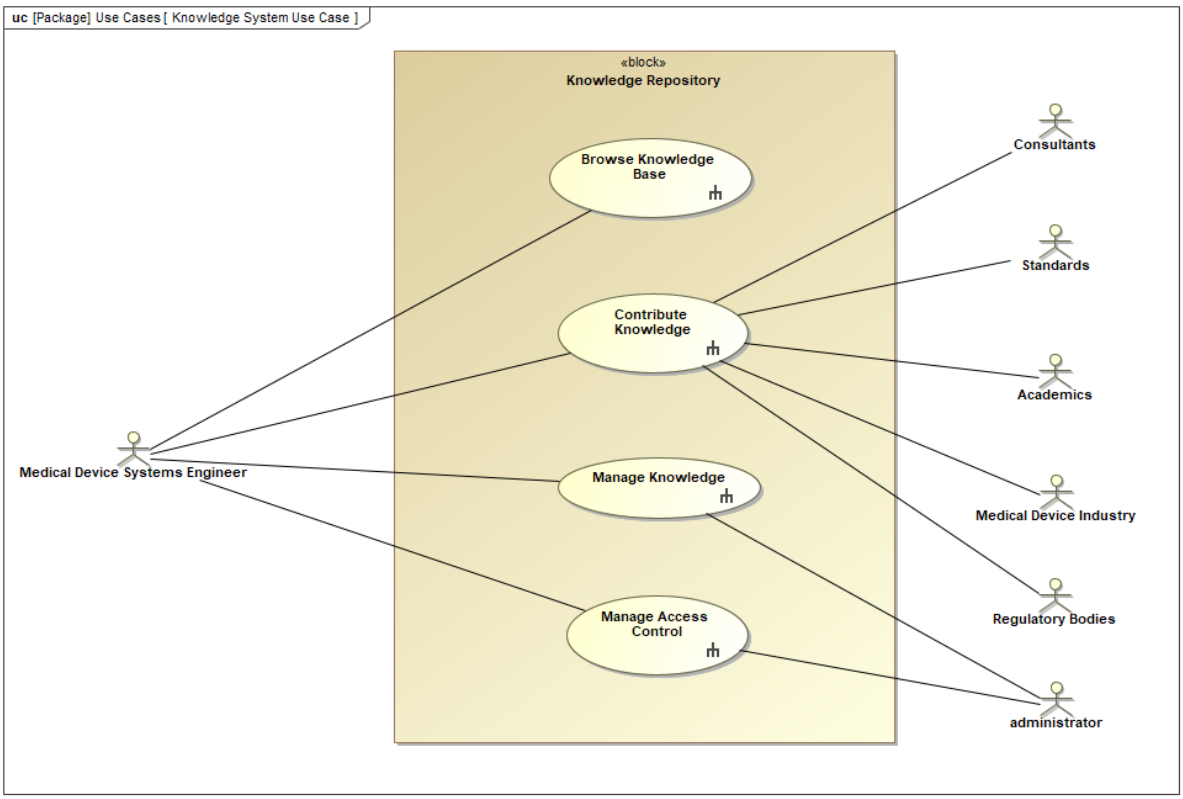

Figure 12.1: System Use Cases

12.1.1 Actors and their Roles

- **Medical Device Systems Engineer:** This primary actor interacts with the system for browsing, searching, contributing, and updating knowledge relevant to medical device engineering.
- **Consultants:** Similar to systems engineers, consultants utilize the system for various knowledge management tasks.
- **Standards Bodies:** This actor leverages the repository to access and potentially contribute knowledge related to medical device standards.
- **Academics:** This actor participates by searching for and potentially contributing knowledge that furthers the academic understanding of medical devices.

- **Regulatory Bodies:** Regulatory bodies interact with the system to access relevant knowledge for their oversight functions within the medical device industry.
- **Administrator:** This privileged actor plays a crucial role in managing access control, determining what information different actor types can view and update within the repository.

Use Cases and System Functionality:

- **Browse Knowledge Base:** This use case allows actors to explore the knowledge repository freely, potentially leading to serendipitous discovery of relevant information.
- **Contribute Knowledge:** This use case empowers qualified actors, such as engineers and consultants, to enrich the repository by adding new knowledge.
- **Manage Knowledge:** This use case enables actors to maintain the accuracy and relevance of the repository by allowing them to update existing information.
- **Manage Access Control (Administrator):** This restricted use case allows administrators to define and enforce access permissions, ensuring the integrity and security of the knowledge base.

12.1.2 Browse Knowledge Use Case

12.1.2.1 Medical Device Systems Engineer Perspective

Figure 12.2 is a diagram of the use case Browse Knowledge Base from the perspective of the Medical Device Systems Engineer. This use case signifies the core function where the Medical Device Systems Engineer (MDSE) can navigate and explore the MDSE knowledge repository.

The system allows for optional extensions to this functionality through:

- Search Knowledge Base: This allows the MDSE to look for specific information within the repository using keywords.
- Filter Knowledge Base: This enables the MDSE to filter the knowledge base based on pre-defined categories (e.g., standards, design principles, risk management)to narrow down the search results.

12.1.3 Contribute Knowledge Use Case

12.1.4 Manage Knowledge Use Case

Figure 12.3 is a SysML use case diagram that focuses on the responsibilities of the Knowledge Repository Administrator. The primary use case, “Manage Knowledge Base Content,” is de-

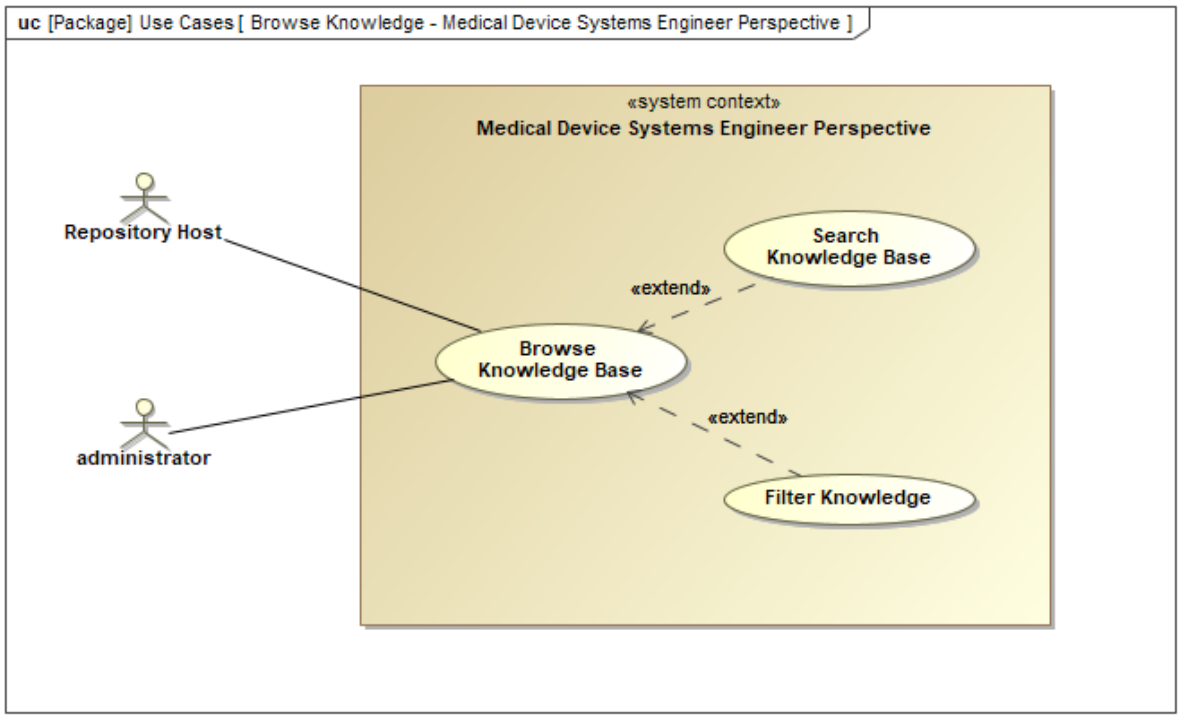

Figure 12.2: Browse Knowledge Use Case from the perspective of the Medical Device Systems Engineer

composed into its constituent functions: adding, editing, and deleting entries. This highlights the Administrator's role in maintaining the knowledge base.

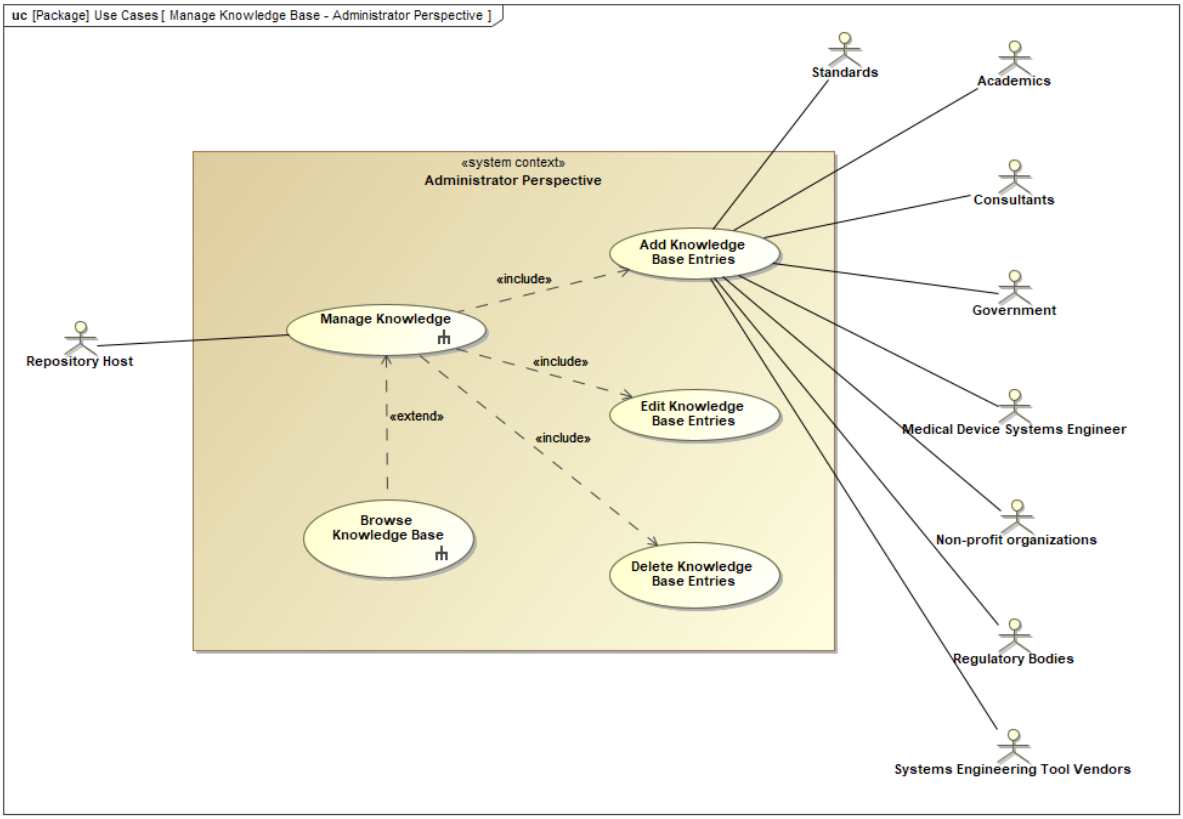

Figure 12.3: Manage Knowledge Base Content Use Case from the perspective of the Administrator

The SysML use case diagram depicts the core functionalities of the Knowledge Repository Administrator. The primary use case, "Manage Knowledge Base Content," represents the Administrator's responsibility for maintaining the knowledge base. The breakdown of this use case into its constituent parts (Add, Edit, Delete) provides clarity on the specific actions the Administrator can perform.

Here's a further breakdown of the functionalities:

- **Add Knowledge Base Entries:** This allows the Administrator to incorporate new information, articles, or resources into the knowledge base.
- **Edit Knowledge Base Entries:** This empowers the Administrator to update existing content within the knowledge base to ensure accuracy and reflect changes.

- **Delete Knowledge Base Entries:** This grants the Administrator the ability to remove outdated or irrelevant information from the knowledge base.

The optional "Browse Knowledge Base" use case acknowledges that the Administrator might need to browse the repository for reference.

12.1.5 Manage Access Control Use Case

12.1.6 Collaboration and Knowledge Sharing

The presence of diverse actors and their associated use cases highlights the collaborative nature of the knowledge repository system. The system fosters knowledge sharing within the medical device industry, allowing engineers, consultants, and regulatory bodies to access and contribute valuable information. Academics and standards bodies can also benefit by leveraging the repository for research and standard development purposes.

The SysML use case diagram demonstrates a well-defined knowledge repository system designed to facilitate knowledge sharing and management within the medical device industry. The diverse set of actors and their associated use cases emphasize the system's potential to serve a wide range of stakeholders. Future analysis could explore the system's internal structure, including its knowledge representation and retrieval mechanisms, to provide a more comprehensive understanding of its functionality.

12.2 Operational Scenarios

The operational scenarios are created to demonstrate the use cases can be satisfied (validation).

12.2.1 Main System Operational Scenario

This section analyzes a SysML sequence diagram representing the interaction between a medical device systems engineer and a knowledge repository system. Figure 12.4 depicts the knowledge retrieval process crucial for informed systems engineering within the medical device development domain.

Actors and Interactions:

The sequence diagram focuses on two primary actors:

- **Medical Device Systems Engineer:** This actor represents the user of the system, an engineer seeking knowledge pertinent to medical device design or development.

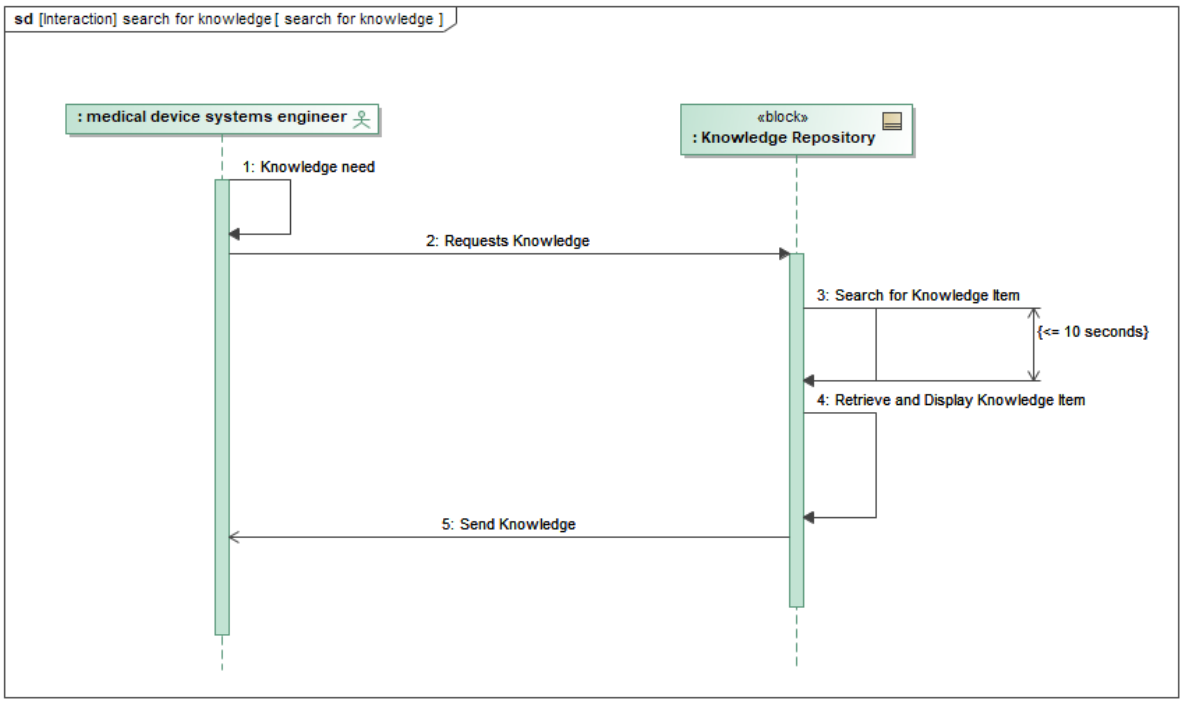

Figure 12.4: System Main Function Sequence Diagram

- **Knowledge Repository:** This block represents the system component housing the relevant knowledge base for medical devices.

The interaction commences with the activation of the **Medical Device Systems Engineer**. This signifies the engineer encountering a **knowledge need**, prompting them to initiate a search within the knowledge repository. The engineer transmits a request to the knowledge repository, likely specifying the desired knowledge domain or specific keywords related to their need.

Knowledge Retrieval Process:

Upon receiving the request, the knowledge repository executes a **Search for Knowledge Item** operation. This operation signifies the system's internal process of identifying relevant knowledge within its storage. The diagram incorporates a time constraint, indicating that the search should be completed within 10 seconds or less. This emphasizes the system's prioritization of search efficiency, ensuring timely knowledge retrieval for the engineer.

Following a successful search, the knowledge repository retrieves the identified knowledge item. This retrieved item could encompass various formats such as technical references, design guidelines, or regulatory guidelines relevant to medical devices. Finally, the knowledge repository transmits the retrieved knowledge item back to the engineer, enabling them to analyze the information and utilize it to address their specific knowledge need.

Significance for Medical Device Development:

This SysML sequence diagram offers a simplified yet insightful representation of a critical interaction within the medical device development process. Efficient access to relevant knowledge empowers engineers to make informed decisions concerning design, development, and regulatory compliance. The time constraint on the search operation underscores the importance of a well-structured and indexed knowledge repository, facilitating rapid retrieval of necessary information.

Further Considerations:

While this diagram provides a foundational understanding of the knowledge search process, further exploration could involve:

- Investigating alternative interaction scenarios, such as browsing by category or utilizing advanced search functionalities.
- Analyzing potential error conditions during the search process and the system's response mechanisms.
- Considering the knowledge repository's internal structure and indexing methods for efficient retrieval.

By delving deeper into these aspects, a more comprehensive understanding of the knowledge retrieval system and its impact on informed decision-making within the medical device development domain can be achieved.

12.2.2 Browse Knowledge Operational Scenarios

12.2.2.1 Browse Knowledge Base (Actor: Medical Device Systems Engineer)

Figure 12.5 depicts the interaction between a Medical Device Systems Engineer (MDSE) and a Knowledge Repository system during the browsing of knowledge base entries.

The message sequence is the following: 1. MDSE Activates System: The MDSE initiates the interaction by activating the Knowledge Repository system, likely by launching the application or visiting a website. 2. System Provides Browse Options: The Knowledge Repository system responds by presenting the MDSE with browse options. These options might include browsing by category, topic, or keyword search. 3. MDSE Selects Browse Option: The MDSE selects a desired browse option. In this specific diagram, the option chosen is to browse by category. 4. System Sends Category List: The Knowledge Repository system sends a list of available categories to the MDSE. 5. MDSE Selects Category: The MDSE selects a category of interest from the list provided by the system. 6. System Sends Knowledge Base Entries: The Knowledge Repository system retrieves knowledge base entries matching the selected category and sends them to the MDSE. 7. MDSE Reviews Entries: The MDSE reviews the list of knowledge base entries provided by the system. This might involve reading titles, descriptions, or summaries

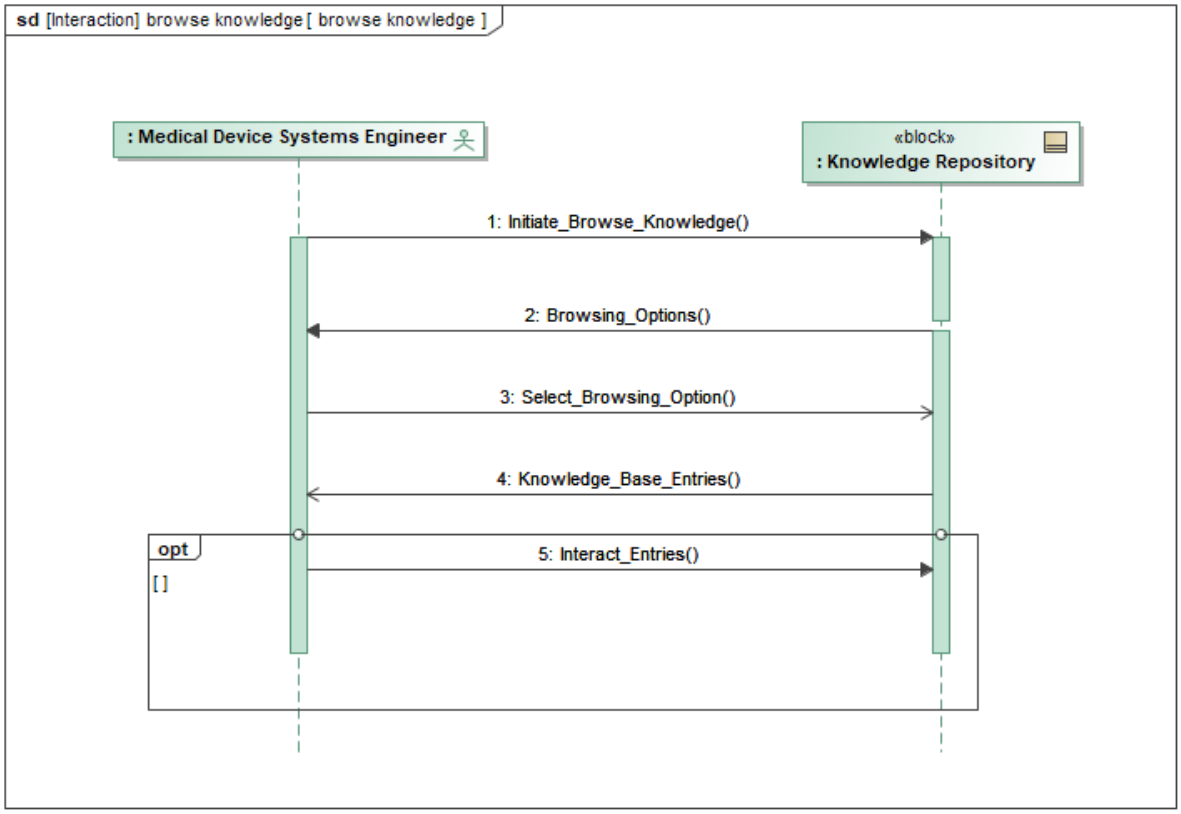

Figure 12.5: SysML Sequence Diagram: Browse Knowledge Base (MDSE)

to determine if the entries are relevant to the MDSE's needs. 8. (Optional) MDSE Selects Entry: If an entry is of particular interest, the MDSE might select it for further exploration (e.g., clicking on an article title to view its details).

The diagram highlights the key interactions:

- The system offers various browse options, allowing the MDSE to navigate the knowledge base efficiently based on their needs.
- Filtering by category provides a structured approach to exploring the knowledge base.
- The ability to review entry details empowers the MDSE to assess the relevance of each entry before potentially diving deeper.

12.2.2.2 Search Knowledge Base (Actor: Medical Device Systems Engineer)

Figure 12.6 is a SysML sequence diagram that illustrates the interaction when the MDSE utilizes the optional "Search Knowledge Base" functionality.

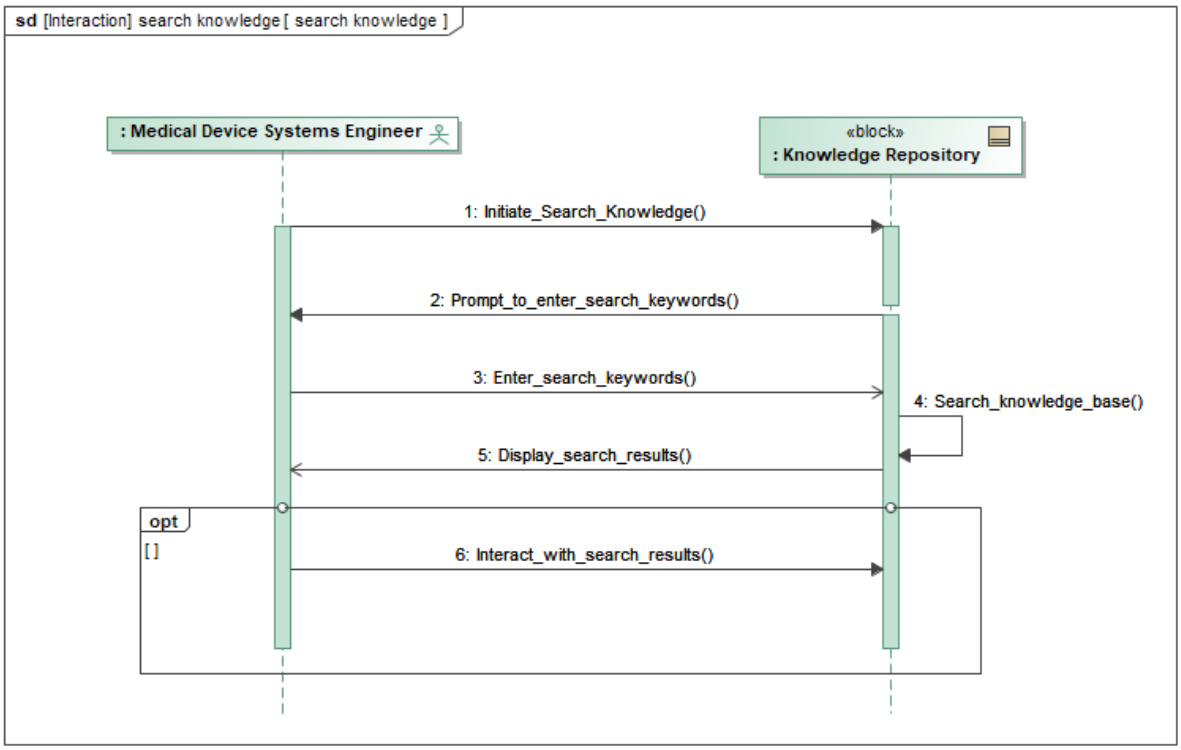

Figure 12.6: Knowledge Repository Search Functionality - SysML Sequence Diagram

The MDSE activates the system and initiates the "Search Knowledge Base" use case. The Knowledge Base System prompts the MDSE to enter search keywords, after which the MDSE

enters the keywords. The system then searches the knowledge base based on the entered keywords and displays the search results to the MDSE. Optionally, the MDSE can interact with the displayed search results.

Here's a breakdown of the interaction:

1. The diagram starts with the engineer initiating the search for knowledge (`Initiate_Search_Knowledge()`).
2. The system prompts the engineer to enter search keywords (`Prompt_to_enter_search_keywords()`).
3. The engineer enters the search keywords (`Enter_search_keywords()`)
4. The system utilizes the entered keywords to search the knowledge base (`Search_knowledge_base()`)
5. Once the search is complete, the system displays the search results (`Display_search_results()`)
6. Optionally, the engineer can interact with the search results (`Interact_with_search_results()`) which likely involves further refining the search or selecting specific results for detailed viewing.

12.2.2.3 Filter Knowledge Base by Category (Actor: Medical Device Systems Engineer)

Figure 12.7 is a SysML sequence diagram that captures the step-by-step interaction between the MDSE and the Knowledge Base System during the process of filtering knowledge base entries by category. It begins with the MDSE activating the system and initiating the filtering use case. The Knowledge Base System then presents a list of available categories, allowing the MDSE to make a selection. Upon selecting a category, the system retrieves and displays the corresponding knowledge base entries. Finally, the MDSE has the option to interact with the displayed entries as needed.

Messages:

1. **MDSE activates the system and initiates the "Filter Knowledge Base by Category" use case**:
   - The MDSE triggers the filtering process by activating the system, indicating the intent to filter the knowledge base entries based on a specific category.
2. **Knowledge Base System presents a list of available categories to the MDSE**:
   - Upon activation, the Knowledge Base System responds by presenting a list of available categories to the MDSE.
   - This message indicates the system's readiness to receive input from the MDSE regarding the desired category for filtering.
3. **MDSE selects a category from the list**:

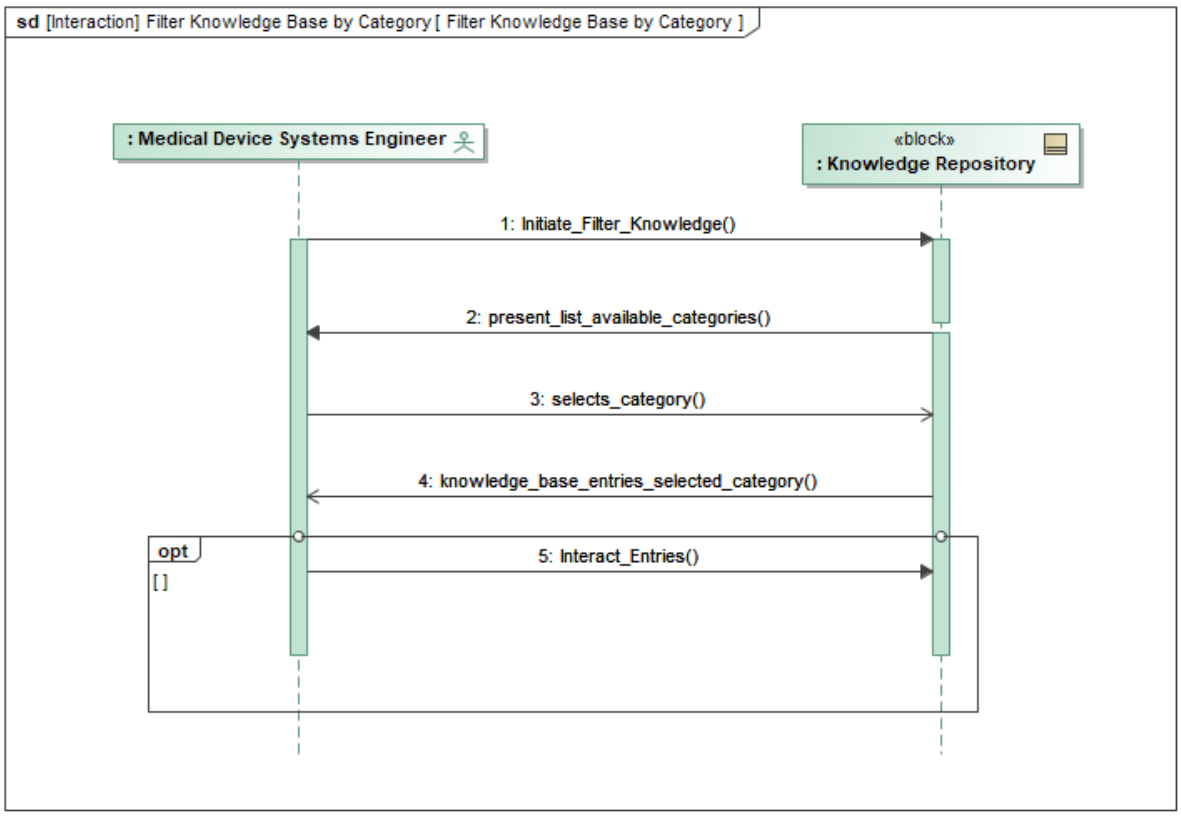

Figure 12.7: Sequence Diagram: Filter Knowledge Base by Category (Actor: Medical Device Systems Engineer)

- The MDSE selects a category from the presented list, specifying the criteria for filtering the knowledge base entries.
- This interaction allows the MDSE to narrow down the search scope to retrieve relevant information.

4. **Knowledge Base System retrieves and displays knowledge base entries belonging to the selected category**:
   - Upon receiving the selected category from the MDSE, the Knowledge Base System retrieves and displays the knowledge base entries that correspond to the specified category.
   - This message signifies the system's action of processing the MDSE's request and presenting the filtered results accordingly.
5. **MDSE (Optional): MDSE can interact with the displayed entries**:
   - Optionally, the MDSE can interact with the displayed knowledge base entries to further analyze, review, or utilize the information.
   - This interaction provides flexibility to the MDSE in exploring the filtered results based on their specific requirements or preferences.

12.2.3 Contribute Knowledge Operational Scenario

12.2.4 Manage Knowledge Operational Scenario

12.2.4.1 Update Content

Figure 12.8 is a sequence diagram demonstrates a simplified content update process within the knowledge repository system. It highlights the interaction between the engineer and the knowledge repository, but doesn't show details like content format validation or error handling.

The image depicts a SysML sequence diagram for updating content in the knowledge repository system. The diagram showcases the interaction between a medical device systems engineer and the knowledge repository.

Here's a breakdown of the interaction sequence:

1. The `medical device systems engineer` initiates the update process by calling the `initiateUpdate()` function.
2. The `knowledge repository` receives the `initiateUpdate()` call and responds with the `updateContent(content)` function, prompting the engineer to provide the new content.
3. The engineer provides the content through the `updateContent(content)` function call.

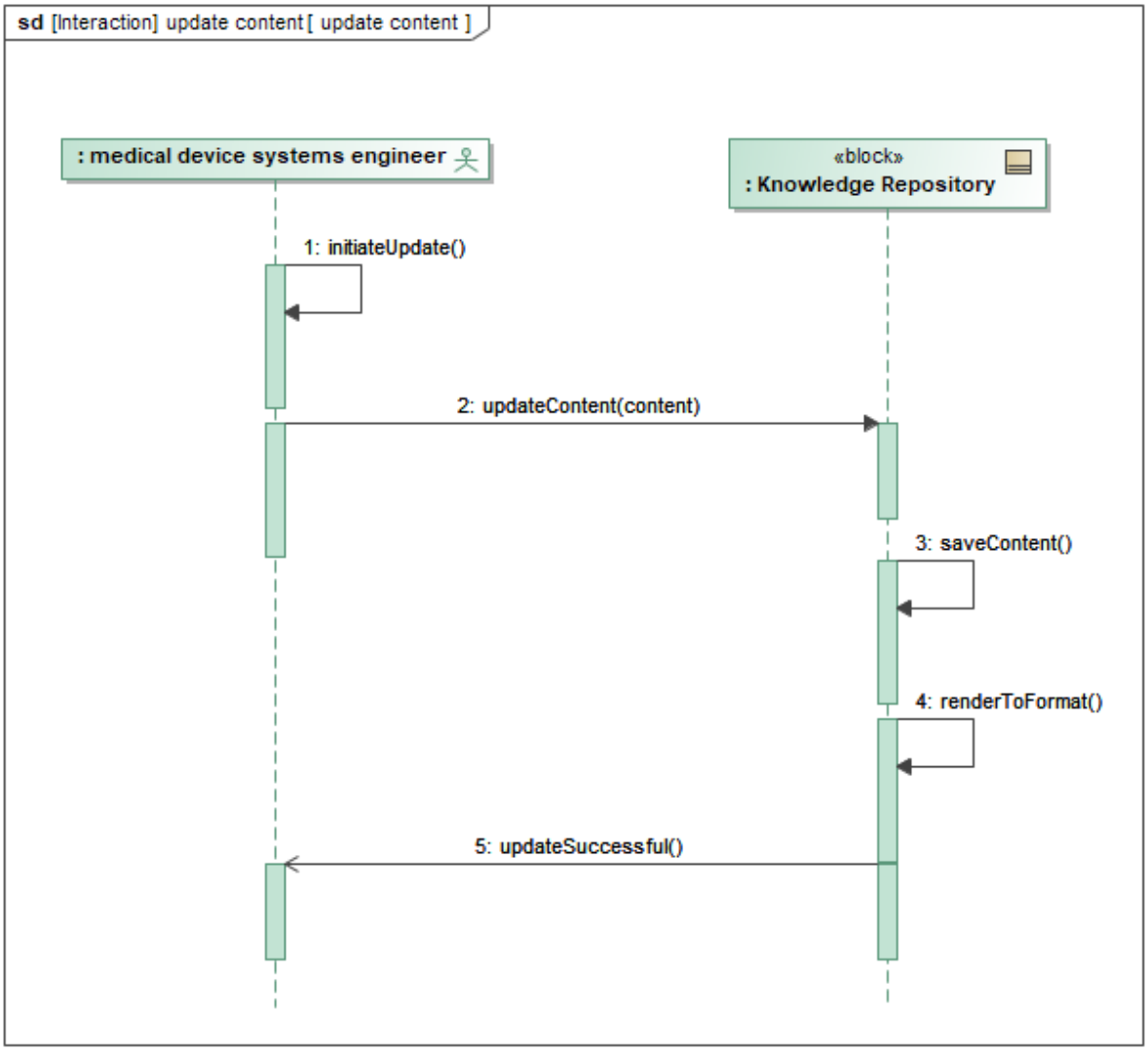

Figure 12.8: Update Content Sequence Diagram

4. The `knowledge repository` then performs the `saveContent()` function to store the updated content.
5. After successful update, the `knowledge repository` sends a confirmation message through the `updateSuccessful()` function.

12.2.5 Manage Access Control Operational Scenario

13 Physical Architecture

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"How the system will be built".

The Physical Analysis perspective defines the finalized architecture of the system, as it should be completed and integrated. It adds the functions required by the implementation and technical choices, and reveals the behavioral components that perform these functions. These behavioral components are then implemented using host implementation components that offer them the necessary material resource.

13.1 Top Level System Breakdown

Figure 13.1 is a SysML block definition diagram (BDD) for a physical architecture. It shows the breakdown of a system into it assemblies at a high level.

Here's a breakdown of the assemblies:

- **Knowledge Repository:** This block stores knowledge, the data that the system operates on.
- **Search Engine:** This block finds information within the knowledge repository. It takes a search query as input and provides results.
- **Maintenance Mechanism:** This block is responsible for maintaining the system. It includes an update mechanism and access control.

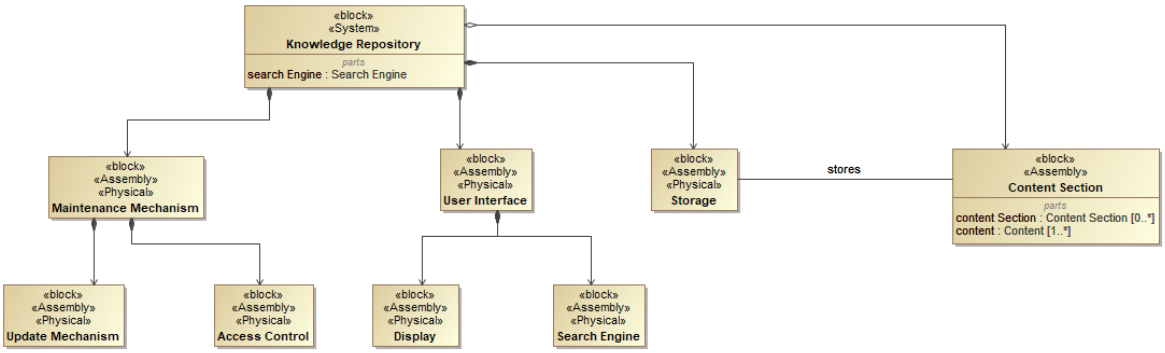

Figure 13.1: Top Level Physical Architecture

  - **Update Mechanism:** This block updates the knowledge repository.
  - **Access Control:** This block controls access to the system, by authenticating users.

- **Storage:** This block stores data, the knowledge repository or other system data.
- **User Interface:** This block allows users to interact with the system. It provides content to the user and can receive content from the user.
- **Display:** This block presents information to the user.
- **Content Section:** This block refers to the data that is presented by the user interface and displayed.

The diagram also shows the relationships between these blocks. For example, the search engine has a part relationship with the knowledge repository. This means that the search engine is a component of the knowledge repository. The user interface also has a content relationship with the content block. This means that the user interface displays content.

13.2 MedSE Knowledge Repository Content and Metadata Structure

Figure 13.2 is SysML block definition diagram depicts the content structure of the MedSE knowledge repository. It represents the various content types and their interrelationships.

13.2.1 Content Breakdown:

The diagram is segregated into two primary sections:

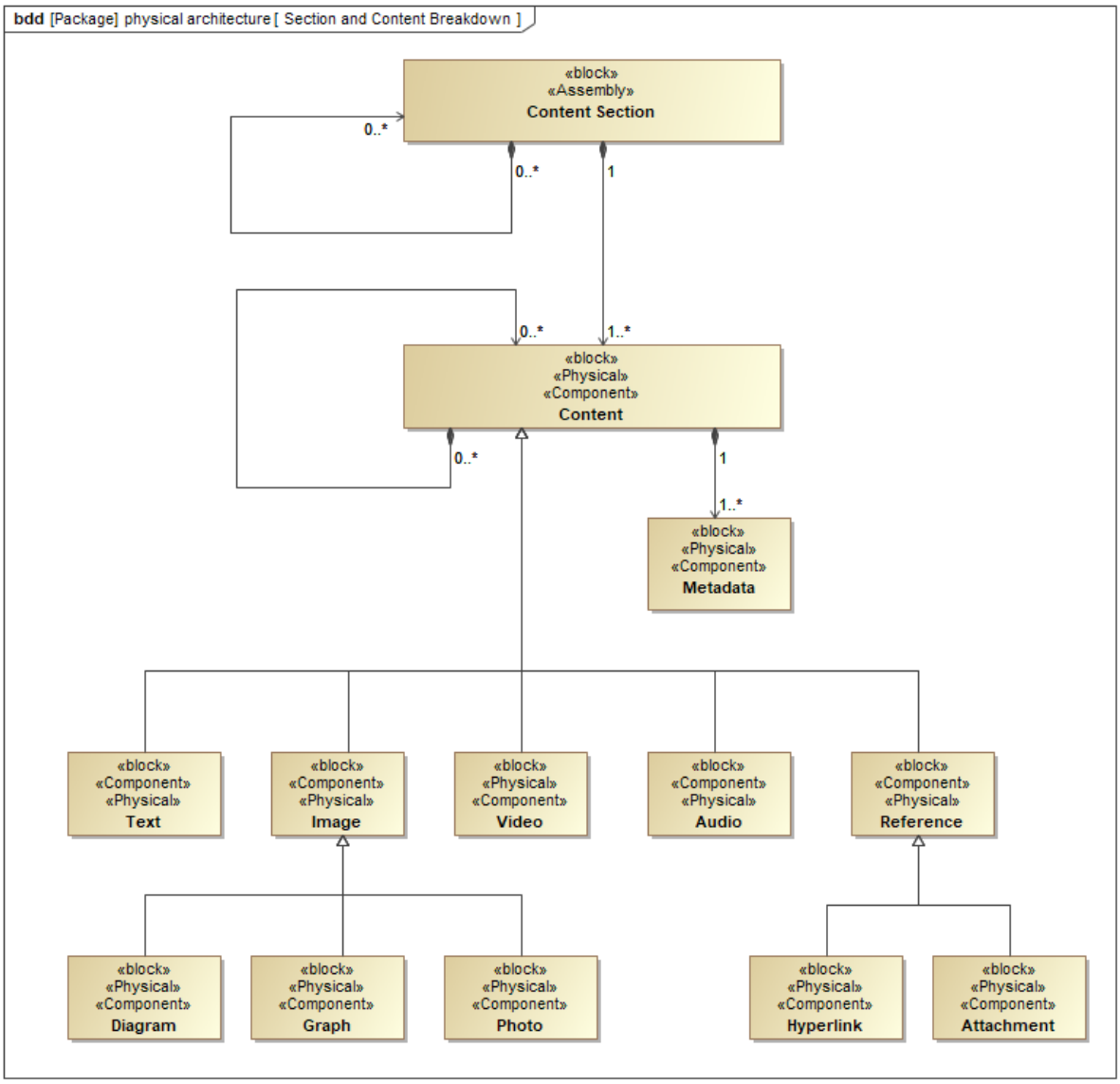

Figure 13.2: Content Physical Architecture

1. **Content Section:** This section serves as the heart of the repository, encapsulating the actual knowledge pertaining to medical device systems engineering. It encompasses a diverse range of content formats to cater to various learning styles and information needs. Here's a breakdown of the content block types:

    - **Text:** This block represents core textual content, including articles, research papers, technical specifications, design documents, and user manuals.
    - **Image:** This block encompasses visual content such as diagrams, schematics, flowcharts, anatomical illustrations, and photographs of medical devices.
    - **Video:** This block signifies instructional videos, animations, demonstrations of medical device functionalities, and surgical procedures.
    - **Audio:** This block represents audio content, such as lectures, presentations, and interviews with medical device experts.
    - **Reference:** This block allows referencing other knowledge elements within the repository, fostering a network of interconnected information.
    - **Diagram:** This block specifically addresses technical diagrams beyond general schematics, potentially including block diagrams, system architecture diagrams, and system behavior diagrams.
    - **Graph:** This block incorporates visualizations of data related to medical devices, such as performance charts, reliability graphs, and risk assessment histograms.
    - **Photo:** This block focuses on high-resolution photographs of medical devices, their components, or specific functionalities.
    - **Attachment:** This block caters to non-standard content formats, including external documents (e.g., spreadsheets, simulation results), software code snippets, and design files.
    - **Hyperlink:** This block facilitates linking to external resources relevant to the medical device domain, such as online databases, regulatory guidelines, and manufacturer websites.

2. **Metadata:** This section complements the Content Section by providing additional information about the content pieces. It serves as a crucial indexing mechanism for efficient knowledge retrieval.

13.2.2 Relationship Representation:

The arrows connecting the blocks depict the relationships between different content types. These relationships are typically directed with cardinalities specifying the number of instances involved. Here's an interpretation of some key relationships:

- **Content Section** can have **zero or more** instances of each specific content type (Text, Image, Video, etc.). This flexibility accommodates diverse knowledge representation within the repository.
- A specific content type block (e.g., Text) can only belong to **one Content Section**. This ensures proper organization and avoids content duplication.
- **Reference** block establishes connections between content elements, enabling users to navigate the knowledge base and discover related information.

14 System Requirements

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Table 14.1 is the MedSE Knowledge Repository System Requirements. The requirements were modeled as a SysML requirements table and exported as an HTML file that was embedded to this report.

Table 14.1: System Requirements

15 Conclusions

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The following are the conclusions of the project:

- Explain the importance of a systematic and comprehensive approach to medical device development, particularly emphasizing the integration of systems engineering principles.
- Highlight the evolving landscape of healthcare technology, the critical need to prioritize safety, efficacy, and compliance in device development, and the unique challenges posed by medical devices within this context.
- Explain the proposed project's objectives, methodology, and collaborative approach, recognizing the value of creating a cohesive resource that synthesizes knowledge, educates stakeholders, provides practical guidance, and fosters deeper understanding of regulatory requirements.
- Ephasize the significance of addressing these considerations holistically to ensure the successful development and deployment of safe and effective medical devices.

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A Medical Device Systems Engineering Survey Template

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The following survey template was used to elicitate knowledge needs from systems engineers who work with medical devices. The survey was deployed as a Microsoft Form at the following link: https://forms.office.com/r/UKeWtta0gv

1. Please identify the primary challenges you have encountered in the systems engineering process for medical devices. Select all that apply from the following options:

☐ Regulatory Compliance
☐ Safety and Efficacy
☐ Interdisciplinary Collaboration
☐ Systems Integration
☐ Cybersecurity
☐ Usability and Human Factors
☐ Lifecycle Management
☐ Cost Constraints
☐ Global Market Access
☐ Emerging Technologies
☐ Other:

2. What tools do you find indispensable in your daily tasks as a systems engineer? Please select all that apply from the following options:

☐ CAD software (e.g., SolidWorks, Altium, Autodesk Inventor, CATIA)

☐ System modeling tools (e.g., MagicDraw, Capella, Enterprise Architect, Hardware Description Languages)
☐ Engineering tools (e.g., LabView, compilers, IDEs, debuggers, test automation software, instrumentation software)
☐ Data analysis and visualization tools (e.g., Minitab, MatLab, R, Python, Tableau)
☐ Simulation tools (e.g., Simulink, ANSYS, COMSOL, SPICE)
☐ Requirement management software (e.g., Cockpit, IBM DOORS, Jama)
☐ Version control systems (e.g., Git, AccuRev, SVN)
☐ Regulatory compliance software (e.g., MasterControl, Greenlight Guru)
☐ Risk management tools (e.g., FMEA software)
☐ Documentation tools (e.g., Microsoft Office, OneNote, Markdown, Wiki, Html)
☐ Project management software (e.g., Jira, Microsoft Project)
☐ Quality management systems (e.g., ISO 13485-compliant software)
☐ Collaboration tools (e.g., Slack, Microsoft Teams, SharePoint)
☐ Other:

3. Could you please elaborate on why you find the selected tools valuable in your day-to-day work as a systems engineer? Feel free to provide specific examples or experiences that illustrate their importance.

4. Which methodologies do you consider most beneficial in your daily tasks as a systems engineer working with medical devices? Please select all that apply from the following options:

☐ Agile Methods (e.g., Agile, Kanban)
☐ Traditional Development Models (e.g., V-Model, Waterfall, Spiral Model)
☐ Model-Based Approaches (e.g., Model-Based Systems Engineering, Prototyping)
☐ Quality and Compliance (e.g., Design for Six Sigma, ISO 13485, IEC 62304)
☐ Risk Management (e.g., ISO 14971, FMEA)
☐ Verification and Validation Processes
☐ Change Control Processes
☐ Configuration Management
☐ Lean and Continuous Improvement (e.g., Continuous Integration/Continuous Deployment, Value Stream Mapping)
☐ Human Factors and Usability (e.g., Human Factors Engineering, IEC 62366, Usability Engineering)
☐ Regulatory Compliance (Regulatory Compliance Frameworks: FDA, CE Mark; Design Control, System Safety Engineering: IEC 60601 series)
☐ Engineering Practices (e.g., Requirements Management, Reliability Engineering)
☐ Cross-disciplinary Collaboration
☐ Innovative Design Approaches (e.g., Design Thinking Methods, Theory Inventive Problem Solving)
☐ Other:

5. Could you please provide insights into why you find the selected methodologies valuable in your day-to-day work as a systems engineer for medical devices? Describe the outcomes or benefits you've experienced by employing these methodologies. Additionally, if applicable, mention any alternative methodologies that were considered but not chosen, and the rationale behind your selection.

6. Which job roles do you primarily engage with in your daily activities?

☐ Validation Engineers
☐ Supply Chain/Logistics Engineers
☐ Research and Development Scientists
☐ Systems Engineers
☐ Compliance Engineers
☐ Regulatory Affairs Specialists
☐ Project Managers
☐ Technical Support Engineers
☐ Electrical Engineers
☐ Process Engineers
☐ Design Engineers
☐ Mechanical Engineers
☐ Biomedical Engineers
☐ Clinical Engineers
☐ Product Development Engineers
☐ Quality Assurance/Quality Control Specialists
☐ Software Engineers
☐ Risk Management Specialists
☐ Marketing/Sales
☐ Field Service Engineers
☐ Manufacturing Engineers
☐ Other:

7. Please indicate which job roles, in your opinion, possess a good understanding of the deliverables and artifacts produced by systems engineers? Software Engineers

☐ Validation Engineers
☐ Electrical Engineers
☐ Biomedical Engineers
☐ Marketing/Sales
☐ Compliance Engineers
☐ Process Engineers
☐ Regulatory Affairs Specialists
☐ Field Service Engineers
☐ Design Engineers
☐ Quality Assurance/Quality Control Specialists

☐ Supply Chain/Logistics Engineers
☐ Product Development Engineers
☐ Project Managers
☐ Clinical Engineers
☐ Risk Management Specialists
☐ Technical Support Engineers
☐ Systems Engineers
☐ Research and Development Scientists
☐ Mechanical Engineers
☐ Manufacturing Engineers
☐ Other:

8. Could you share examples of books, articles, or papers that have resonated with you as a systems engineer working with medical devices? Please provide one or more titles and, if possible, briefly explain how they impacted your work or perspective. Your insights will help us better understand valuable resources in this field.

9. In your opinion, what regulations or standards should be covered in a comprehensive medical device systems engineering book? Please provide your suggestions below.

10. What learning formats do you find most accessible and beneficial? Please select all that apply from the following options:

☐ Printed books
☐ E-books
☐ Interactive online courses
☐ Audiobooks
☐ Podcasts
☐ Video lectures
☐ Webinars
☐ Virtual reality (VR) simulations
☐ Interactive multimedia presentations
☐ Mobile apps
☐ Online forums or discussion boards
☐ Worksheets or printable materials
☐ Hands-on workshops or labs
☐ Mentored/self-paced online learning platforms
☐ Social media groups or communities for learning
☐ Gamified learning platforms or apps
☐ Textbooks
☐ Infographics or visual summaries
☐ Live online classes or tutorials
☐ Digital flashcards or quizzes
☐ Other:

11. Would you be open to further contact if there were follow-up questions?

☐ Yes
☐ No

12. Email

B Standards

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Table B.1 shows a list of examples of standards and regulations relevant to medical device systems engineering.

Table B.1: Reference Standards and Regulations

Reference	**Title**
21 CFR 820	CFR - Code of Federal Regulations Title 21
21 USC 321	Chapter 9-Federal Food, Drug, and Cosmetic Act Subchapter II-Definition
EN 45502-1	Implants for surgery – Active Implantable Medical Devices – Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
ISO 9001:2015	Quality management systems - Requirements
ISO 10993-1:2018	Biological evaluation of medical devices, Part 1: Evaluation and testing within a risk management process
IEC 13485	Medical devices — Quality management systems — Requirements for regulatory purposes
ISO 14971	Application of Risk Management to Medical Devices
IEC 15288	Systems and software engineering — System life cycle processes
IEC 60068-2-82	Environmental Testing – Part 2-82: Tests – Test Tx: Whisker Test Methods for Electronic and Electric Components
IEC 60601-1	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
IEC/TR 60601-4-2	Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
IEC 60812:2018	Failure modes and effects analysis (FMEA and FMECA)
IEC 61025	Fault Tree Analysis
IEC 62304	Medical Device Software - Software Life Cycle Processes
IEC 62353	Medical electrical equipment – Recurrent test and test after repair of medical electrical equipment
IEC 62366-1	Medical devices – Part 1: Application of usability engineering to medical devices
IEC DTR 60601-4-2	Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
ISO 14971	Medical devices - Application of risk management to medical devices
JEDEC/IPC JP002	Current Tin Whisker Theory and Mitigations Practices Guideline
2011/65/EU	Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment
2016/679	Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)

C Terminology

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Table C.1: Definitions

Term	Definition
AAMI	Association for the Advancement of Medical Instrumentation
CE Certificate	An acronym for the French “Conformite Europeenne” (“CE Marking,” n.d.)
CFR	Code of Federal Regulations
EU MDR	European Union Medical Device Regulation
FDA	Food and Drug Administration
FMEA	Failure Modes and Effects Analysis
GSPR	General Safety and Performance Requirements
HACCP	Hazard Analysis Critical Control Point (Nutrition and Applied 2024b)
INCOSE	International Council on Systems Engineering
ISO	International Organization for Standardization
IVD	In Vitro Diagnostic
MDLC	Medical Device Development Life Cycle
MDSE	Medical Device Systems Engineer

Term	Definition
Medical device	Section 201(h) of the FD&C Act ("21 USC 321: Definitions; Generally," n.d.b) provides that the term "device" means: an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is– (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.
MedSE	Medical Device Systems Engineering
PMDA	Pharmaceuticals and Medical Devices Agency
QA/QC	Quality Assurance/Quality Control
QMS	Quality Management System
QSR	Quality System Regulations (Health and Radiological 2024b)
STEM	Science, Technology, Engineering, and Math
SysML	Systems Modeling Language
TRIZ	Russian acronym for "Theory of Inventive Problem Solving" ("TRIZ" 2024)
UDI	Unique Device Identification
V&V	Verification and Validation

D Risks

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The following risks have been identified for medical device companies that can be mitigated with medical device systems engineering:

- Labor shortages such as qualified systems engineers for medical device industry cost of direct labor,
- The impact of disruptions in the supply of the materials and components used in manufacturing our products or the sterilization of our products,
- The performance of, and physician and patient confidence in medical products and technologies,
- The impact and outcome of ongoing and future clinical trials and market studies,
- Variations in clinical results, reliability or product performance,
- Ability to acquire or develop, launch and supply new or next-generation products and technologies worldwide and in line with commercialization strategies in a timely and successful manner,
- Ability to attract and retain talent, including key personnel associated with acquisitions,
- The impact of enhanced requirements to obtain and maintain regulatory approval in the U.S. and around the world, including EU MDR and the associated timing and cost of product approval,

Regulatory Compliance, Litigation and Data Protection

- Risks associated with our regulatory compliance and quality systems and activities in the U.S., the EU and around the world, including meeting regulatory standards applicable to manufacturing and quality processes,
- The effect of global legal, regulatory or market responses to climate change and sustainability matters, including increased compliance burdens and costs to meet regulatory obligations,
- Ability to minimize or avoid future field actions or FDA warning letters relating to our products and processes and the ongoing inherent risk of potential physician advisories related to our or our competitors' products,
- Ability to secure information systems that support business operations and protect data integrity and products from a cyber-attack or other breach that may have a material adverse effect on our business, reputation or results of operations

Innovation and Certain Growth Initiatives

- The timing, size and nature of strategic growth initiatives and market opportunities, including with respect to internal research and development platforms and externally available research and development platforms and technologies and the ultimate cost and success of those initiatives and opportunities,
- Ability to identify and prioritize our internal research and development project portfolio and our external investment portfolio on profitable net sales growth opportunities as well as to maintain the estimated timing and costs of such projects and expected revenue levels for the resulting products and technologies,
- Ability to develop, manufacture and market new products and technologies successfully and in a timely manner and the ability of competitors and other third parties to develop products or technologies that render products or technologies noncompetitive or obsolete,
- Ability to execute appropriate decisions to discontinue, write-down or reduce the funding of any research and development projects, including projects from in-process research and development from acquisitions, in growth adjacencies or otherwise,
- Dependence on acquisitions, alliances or investments to introduce new products or technologies and to enter new or adjacent growth markets and ability to fund them or to fund contingent payments with respect to those acquisitions, alliances and investments.

E Medical Device Systems Engineer Job Descriptions

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E.1 Job Description #1

You'll have the chance to be a critical contributor on our Electrophysiology Systems Engineering team focused on delivering the future in Advanced Mapping technologies. This role will involve a range of responsibilities including but not limited to collaborating and leading teams in the development and analysis of system performance and system integration for our next generation products. In this role you will be a key member of a product development team to bring systems from concept to launch.

E.1.1 Responsibilities

- Contribute to the technical and business strategy at the core team level for major system-level programs.
- Utilize multidisciplinary engineering knowledge and experience to design, develop, and troubleshoot new products specific for cardiac mapping and ablation.
- Provide system engineering leadership and take ownership for overall project success for new products from concept phase through launch.
- Work with Product Marketing, Clinical Engineering, and Key Opinion Leaders to develop design input requirements from user and business needs.

- Communicate to Sr. Management including technical presentations, status updates, and program reviews.
- Lead project-level system architecture and system behavior definition activities utilizing use case modeling and other appropriate tools.
- Lead cross-functional working groups to solve complex problems, mitigate risks, and develop strategies to overcome challenges.
- Plan, manage, and report on overall systems integration activities including root cause analysis and solution generation.
- Provide input into the technology and product roadmaps.
- Be a strong team player and lead cross-functional teams to resolve issues and meet budget and schedule requirements.
- Create a positive, collaborative culture amongst the technical teams while working to solve challenging engineering problems.
- Mentor junior engineers.
- Ensure compliance with procedural and documentation requirements, FDA, ISO and other regulatory bodies.

E.1.2 Required Qualifications:

- Bachelor's degree in Electrical Engineering, Biomedical Engineering, or related field with 10+ years of experience in developing highly complex electrical hardware, software, and signal-processing based systems.
- Demonstrated ability to leverage and/or engage others to accomplish project goals.
- Demonstrated ability to solve complex engineering problems and mentor other engineers.
- Strong verbal and written communications with ability to effectively communicate at multiple levels in the organization.
- Ability to work within a team and as an individual contributor in a fast-paced, changing environment.
- Ability to multitask, prioritize and meet deadlines in timely manner.
- Strong organizational skills, as well as attention to detail.

E.1.3 Preferred Qualifications

- Masters degree in Engineering and/or Science (could substitute for 2 years of engineering experience).
- 3+ years of experience as a Systems Engineer.
- Medical device experience, specifically supporting cardiac mapping and/or ablation systems
- Experience working in a broader enterprise/cross-division business unit model.
- Detailed understanding of 60601 and other related electrical hardware regulations.
- Experience in managing one or more direct reports.

E.2 Job Description #2

As part of the Engineering Organization, the Reliability Architect is primarily responsible for supporting the ongoing execution by helping establish Service Level Objectives of the different Engineering teams to achieve the business Reliability goals, You will refine performance targets, provide the strategic vision and reliability roadmap, lead design improvements, generate observability metrics targeting business and technical audiences, and enforce reliability best practices. You will maintain the Surgery DFR process and drive the quality of the different business releases. This role is instrumental in ensuring that our products perform as specified and do not fail in the install Base. A high level of quality is expected from our products.

E.2.1 Responsibilities

- Identify process and infrastructure gaps to increase operational reliability.
- Responds to production Install Base incidents and determine how we can prevent them in the future.
- Partner with other Engineering team leads to bring best practices and enforce the DFR process.
- Train the organization on the Surgery DFR process.
- Triage testing data to work with the Software and Hardware teams to address issues. Ensure reliability growth to fulfill the reliability goals of the final product.
- Facilitate Technical discussions during the Development phase to address the resolution of issues.
- Participate in the review of Hardware test plans definition and Technical Reviews to promote good reliability practices.
- Build and support Automated Testing Infrastructure.
- Develop an adequate System level understanding of all the Surgery platforms and products.
- Supports the monitoring of software performance over the development of the products.
- Partner with other SREs to have a common strategy to implement the DFR process in the different programs.
- Create team mechanism(s) to follow up on the activities of the other SREs to look for reliability progress, potential needs, or issues.
- Define the adequate SLOs of the Software and Hardware Teams.
- Develops Technical papers to define the necessary statistical methodologies to implement the DFR process.
- Define a common strategy for the System level reliability technical reviews and ensure the proper flow down to the other Engineering reviews.
- Work with the Functional Engineering Managers to define the resources and timelines required to execute the defined SLOs.
- Participate with the GE HealthCare Reliability Central Team, defining and promoting good reliability practices.

- Provides necessary information to Upper Management to make decisions around quality during the development and conclusion of the programs.
- Work with global Surgery reliability leads to the exchange of data or work in initiatives.
- Develops new automated testing strategies customized by the program; this will include the ability to adapt the infrastructure to new statistical approaches.
- Triage Install Base information such as service replacements to identify the opportunities for improvements. Additionally Supports the Service team in the understanding of Install Base issues.
- Participate with the Complaint Handling Unit team in triaging information to understand the baseline of the new products and the level of effectiveness of the active projections.

E.2.2 Required Qualifications

- Bachelor's degree in Systems Engineering, Reliability or Science in STEM degree.
- Minimum 6 years of experience in product development or research development environment.
- Experience in data and trending analysis.
- Experience in reliability statistical methodologies.

E.2.3 Preferred Qualifications:

- Master's degree is a plus.
- Experience in Medical or other Regulated Industries.
- Reliability Certification.
- Demonstrated Strong problem-solving skills.
- Demonstrated ability to set and meet tight deadlines and function well under pressure.
- Ability to work in a dynamic and fast-paced environment.

E.3 Job Description #3

The Principal Systems Engineer provides technical leadership, direction, and expertise in the design and development of instruments, software, or automation used in clinical laboratories to perform diagnostic tests. The Principal Systems Engineer works with project leads and teams to ensure that user, customer, and business needs are correctly translated into system and component level architectures, then selects technologies and designs module and system functions to create design specifications that can be implemented in a robust and verifiable manner. This role may also be responsible for supervision or mentoring of engineers.

E.3.1 Responsibilities

- Create and determine hardware and software architectures and workflows at system and component levels.
- Define and detail component functions, interfaces, signal, data, and information flows.
- Actively engage with key stakeholders to comprehend the spectrum of available technology options and collaborate on their integration and application to products.
- Evaluate and select technologies needed to meet design goals.
- Communicate pros and cons of technology and design options and reasons for selection.
- Champion introduction, learning, and implementation of new technologies.
- Conduct creative analyses and high-level decision making.
- Communicate and document designs and lead design and technical reviews.
- Collaborate with cross-functional teams responsible for the design and development of clinical diagnostic products to meet product design goals while maintaining compliance with the quality system requirements.
- Lead system development decisions affecting product development issues.
- Lead the process to identify problems, investigate alternatives, and collaborate on the ideation and confirmation of potential solutions.
- Serve as the technical lead on preparing reports and analysis and interpretation of data and results as related to system/software/hardware development and improvement.
- Actively participate with research and technology efforts to ensure alignment with strategic priorities.
- Prepare reports and analysis of results related to product performance improvements.
- Report status of assigned projects through the preparation of detailed reports and documentation that summarize progress and performance results.
- Interpret results of experiments and trials and recommend alternative approaches.
- Create, review, and approve design history file documentation.
- Present information and updates at project or departmental meetings.
- Work within established project timeframes.
- Manage external vendors to meet part and assembly design specifications.
- Apply excellent attention to detail and meticulous record keeping.
- Apply excellent analytical, problem solving, organizational, and decision-making skills.
- Ability to work collaboratively with scientists, engineers, and software programmers.
- Uphold company mission and values through accountability, innovation, integrity, quality, and teamwork.
- Support and comply with the company's Quality Management System policies and procedures.
- Maintain regular and reliable attendance.
- Ability to act with an inclusion mindset and model these behaviors for the organization.
- Ability to work nights and/or weekends, as needed.
- Provides technical leadership, guidance, training, and mentoring.
- Ability to work on a mobile device, tablet, or in front of a computer screen and/or

perform typing for approximately 90% of a typical working day.
- Ability to comply with any applicable personal protective equipment requirements.
- Ability to travel 5% of working time away from work location, may include overnight/weekend travel.
- Ability and means to travel between Exact Sciences locations.

E.3.2 Required Qualifications

- Ph.D. in Engineering or field as outlined in the essential duties; or Master's Degree in Engineering or field as outlined in the essential duties and 4 years of experience in lieu of a Ph.D.; or
- Bachelor's Degree in Engineering or field as outlined in the essential duties and 8 years of experience in lieu of a Ph.D.
- 10+ years of experience working in a biotech/IVD/medical device related setting.
- Demonstrated ability to work in a senior role with a well-established IVD or medical device company.
- Demonstrated ability to work with CFR 21 part 820 and ISO 13485 compliance for software and instrumentation development.
- Demonstrated ability to contribute to the development of successful medical device products.
- Demonstrated ability to work with assembly, integration, troubleshooting, and testing custom equipment and instrumentation.
- Advanced knowledge of engineering software tools used in a specific engineering discipline.
- Demonstrated ability to perform the Essential Duties of the position with or without accommodation.

E.4 Job Description #4

In this position the Systems Engineer will be the primary technical lead and decision maker for a variety of medical device projects from the early concept phase to design, realization, test, and production. This is a dynamic role that adapts to the needs of clients, the user, and technical challenges as projects progress.

The ideal candidate for this role will thrive on solving challenging problems, have the ability to strategize a creative path forward, and communicate technical information effectively to several audiences. An individual with strong experience with cross-functional, technical team leadership in an Engineering arena with an emphasis on creating, documenting, and communicating system architecture and requirements while actively driving the technical direction of a product team. This individual should be well-versed in translating client needs into technical

descriptions that can be built and verified, and possess the ability to then distill the technical implementation into real-world implications to the business, clients, and the users. The ideal candidate would be willing to lean in and strategically guide the customer towards a well-balanced product within a business context.

E.4.1 Responsibilities

- Organize the technical approach, architecture, requirements, and the technical team to communicate and execute product development strategies to the client and across our internal teams to realize well designed medical products that positively impact patient outcomes.
- Create work proposals for new clients detailing technical approach, scope and work estimates.
- Assess client project inputs to generate requirements, system architecture and design documentation.
- Conducts analysis, review, and/or evaluation of design alternatives across various technologies and multiple disciplines.
- Assigned to substantial tasks on major projects of high complexity (assignments may be broad in nature and require creativity and ingenuity).
- Works to influence organizational direction while leading other engineers while leading a multidisciplinary, integrated team.

E.4.2 Required Qualifications

- Bachelor's or Master's degree in Software, Electrical, Biomedical or Mechanical Engineering.
- 6+ years of experience in developing electronic-based devices or complex electromechanical systems.
- Experienced with requirements writing and multidisciplinary, technical team leadership
- Proficient at quickly solving high-complexity system-level problems.
- Experience in interpreting and applying technical regulatory requirements.
- Strong interpersonal, communication (both written and oral) & analytical skills coupled with excellent interpersonal skills with multiple disciplines & clients.
- Strong emphasis on the ability to work independently, while also functioning as a team player.

E.5 Job Description #5

The Principal System Engineer position is a key technical leadership role at BMT and will integrate inputs and outputs to support the definition and development of complex software

systems involving software services and multiple electro-mechanical medical device products. As design owner of a product solution, you are responsible for ensuring that your solution is built in accordance with customer, business, and regulatory requirements. This is done by effectively translating product requirements to design outputs, managing technical risks of the product, and following the technology roadmap. This position typically overlaps many technical and human-centered disciplines, including industrial engineering, functional engineering, human factors, marketing, regulatory affairs, quality assurance, and project management; a strong candidate will demonstrate a keen ability to facilitate cross-functional collaboration. The engineer is a key leader in development and management of support activities such as technical planning, systems integration, verification and validation, cost and risk, life-cycle management, and effectiveness for total systems.

E.5.1 Responsibilities

- Ensure the logical and systematic translation of user and project needs into a comprehensive set of system and sub-system requirements in collaboration with the technical design leaders.
- Take technical ownership of the product throughout its lifecycle and provide effective technical leadership to the product and engineering teams.
- Resolve technical challenges by providing technical guidance to the product and engineering team through rigorous trade-off analysis to create robust and effective solutions.
- Facilitate cross-functional technical decision-making and optimize the balance between technical and schedule risk with the cost targets of the product lifecycle needs.
- Lead the integration of systems and devices, ensuring that the product meets the user and system requirements.
- Demonstrate the traceability of requirements through Validation and Verification.
- Lead the risk, hazard, and timeline analysis in to quantitatively evaluate design concepts & solutions
- Plan, coordinate, and manage system and cross-system design activities and interface directly with the product leadership team on project issues and status.
- Integrate sound design principles and standards into your programs including Design for Reliability, Manufacturing, and Service.
- Identify user groups, environments, use scenarios and critical tasks for task analysis, instructions, guides, user training and system verification
- Engage with the test teams to ensure plans for verification and validation activities are successful.
- Mentor other members of the organization on hospital connectivity and interoperability.
- Initiate and lead activities such as Failure Modes and Effects Analysis (FMEA) that identify design issues and lead the team in developing mitigations to address these issues.
- Help the team members in developing high-quality documentation for all phases of product development, including design specifications, verification test plans, project schedules, and change orders associated with medical devices.

- Partner with the functional technical leaders (Architects/Principals) to develop significant and impactful Intellectual Property to fuel the growth of the business.
- Perform work in adherence to the Quality Management System (QMS), including development and maintenance of documentation.
- Develops products that meet requirements regulated by FDA, EU regulatory body, Pharmaceuticals and Medical Devices Agency (PMDA) and other governing bodies as defined by product management.
- Commit to fostering and driving an environment and work output based on continuous improvement.

E.5.2 Required Qualifications

- Bachelors' degree in Engineering, or other scientific discipline, preferably computer, software, or control engineering.
- 10+ years of engineering experience.
- 3-5 years new product development and exposure to systems engineering roles.
- 2+ years of working with development of software products.
- Demonstrated experience with Enterprise Architecture and Systems Engineering.
- Technical Risk Management & Mitigation for Cloud-hosted solutions in Medical Device "connected" domain.
- Knowledge of network concepts and use, including firewalls, VLANs, routing, VPNs, etc.
- Experience with hospital system connectivity, including PACS, HIS/RIS, EMR.
- Experience interfacing with Hospital IT customers, Radiologists, and imaging technicians.
- Experience with network authentication solutions.
- Demonstrated experience with risk management and systems engineering processes.
- Demonstrated ability to clearly and accurately translate needs and requirements.
- Ability to grow productive, trusting, and open relationships with a wide variety of constituencies.
- Excellent communication, influencing skills and ability to gain buy-in for initiatives.
- High degree of organizational skills and high attention to detail.
- Ability to handle multiple tasks and prioritize effectively.
- Ability to work both independently and as part of a team.
- Ability to develop protocols, conduct system tests and write reports.
- Strong initiative and passion about new technologies with high energy.

E.5.3 Preferred Qualifications

- Graduate degree in Engineering (Software or Systems) or another scientific discipline.
- 5+ years of research and development experience.
- Familiarity with Medical Device Interoperability.

- Experience with IHE profiles relating to IT infrastructure and device communication.
- Experience with Active Directory integration.
- Understanding of IT system virtualization techniques.
- Experience with Hybrid & Cloud Services, Cloud-hosted Data & Deployments.
- Experience with hybrid cloud deployments.
- Experience working with physicians and customers in a medical device product development role.
- Experience with product concept development, customer interaction, systems engineering, verification of engineering requirements, and validation of customer needs/design requirements.
- Experience with risk management and systems engineering processes.
- Ability to translate needs and requirements clearly and accurately.
- Awareness and working knowledge of system-level constraints in all disciplines, including mechanical, electrical, human factors and software.
- Voice-of-customer experience and fluency with clinical radiology terminology.

E.6 Job Description #6

We are recruiting a Senior Systems Engineer to join our team where we are focused on helping people with heart failure manage their health and ultimately change and save lives. The engineer will be primarily working on the CardioMEMS HF portfolio, which remotely monitors changes in pulmonary artery (PA) pressure, an early indicator of the onset of worsening heart failure, to aid physicians in preventing worsening heart failure, lower heart failure mortality rates, and improve quality of life for our heart failure patients. The role is responsible for executing product development and systems engineering tasks for a wide range of CardioMEMS products including implantable sensors, external reader systems used by clinicians and patients, mobile application software, and cloud-based web applications. This person will participate and lead tasks in development of new programs and next generation products, including system design and architecture, requirements definition and management, design documentation, and system testing, verification, and validation.

E.6.1 Responsibilities

- Plans, develops, and executes system verification based on established system requirements.
- Drives review and optimization of project-wide and cross-project verification efforts to ensure adequate coverage, minimize duplication, and increase transparency and understanding of system - verification versus sub-system verification versus other types of testing.
- Contributes to and supports gathering, analyzing, and reviewing system level and subsystem requirements.

- Clearly documents test procedures and related material. Effectively documents test results, prepares test reports.
- Participates in broad cross-functional reviews of work output. Presents at design reviews, documents and resolves associated issues.
- Participates in risk management activities.
- Identifies tools, fixturing, and other resources necessary for system verification. Contributes to development, documentation, and validation of tools and fixtures.
- Applies industry best practices and applicable regulations to work area.
- Gathers information, frames problems, provides status and progress, and adjusts/measures success within scope of responsibility to improve development efforts. Applies skills to planning product - development and testing work; capturing requirements, designing solutions, defining behaviors, investigating issues, evaluating trade-offs, and validating output under direction of another engineer for complex projects and independently for smaller projects.
- Participates and supports implementation, development, enhancements, and modifications to existing and new products.
- Debugs, troubleshoots, and isolates problems, as well as offers strategic solutions, analysis, and advice regarding identified issues. Conducts root-cause analysis of failures and product issues.
- Develops and applies an expert understanding of designated systems as well as serves as a subject matter expert for the development team regarding behaviors, implementation, customer needs, clinical applications, and system and sub-system verification methodologies.
- Communicates effectively with cross-functional teams and project management. Keeps leadership informed of progress and issues.
- Support all Company initiatives as identified by management and in support of Quality Management Systems (QMS), and other regulatory requirements.
- Complies with U.S. Food and Drug Administration (FDA) regulations, other regulatory requirements, Company policies, operating procedures, processes, and task assignments.

E.6.2 Required Qualifications

- Bachler's Degree in Engineering (Mechanical, Computer, Electrical, or Software), Computer Science, or related discipline.
- 7+ years of in a similar position, including systems engineering and integration experience (integrating all system components, electrical, mechanical, software), system architecture, requirement/user need gathering, end-to-end (ideation to commercialization) technical product development experience, and/or system-level verification.

E.6.3 Preferred Qualifications

- Advanced degree in Engineering (Mechanical, Computer, Electrical, or Software), Computer Science, or related discipline.
- Experience and expertise with systems consisting of hardware, software, mobile app, and cloud components.
- Experience and expertise with systems with RF, electromagnetics, ASICs, Bluetooth, and NFC technologies.
- Class III implantable medical device experience, specifically supporting heart failure and/or cardiovascular systems and experience with biologic sensors (flow, pressure, EKG, etc).
- Strong knowledge of a development process consistent with ISO, FDA design control standards or requirements, and risk management practices.
- Demonstrated ability to effectively integrate information from varied disciplines including Clinical Medicine, Engineering, Marketing and Regulatory Affairs.
- Ability to work within a team and as an individual contributor and leader in a fast-paced, changing environment.

E.7 Job Description #7

As a Senior Principal Systems Engineer on our Exploratory and Innovation team you join a talented and diverse group of engineers and scientists in the identification and early-stage development of new novel approaches to the treatment of kidney disease.

E.7.1 Responsibilities

- Partner with our commercial and medical teams to identify and prioritize user needs, lead development of concepts to address those needs as well as the testing and analysis to demonstrate feasibility of the most concepts.
- Directly contribute to the identification of unmet user needs and new approaches to addressing user needs through direct interaction with our customers and patients.
- Lead Brainstorming sessions and ideation workshops to generate new ideas and concepts for innovative products, technologies, and solutions.
- Work within the R&D organization to define and implement innovation strategies, multi-generational product plans, and technology roadmaps to enable successful delivery of innovation to the marketplace.
- Bring rigorous critical thinking to ensure that key “killer” questions are addressed early in exploratory through best-in-class application of modeling, analysis, and empirical methods.

- Foster collaboration and partnerships with internal teams, external research organizations, academia, startups, and industry partners to accelerate innovation and leverage complementary expertise and resources.
- Identify and protect intellectual property through patent filings and strategic partnerships to create and safeguard innovation.

E.7.2 Required Qualifications

- Graduate or Post-Graduate in Biomedical, Chemical, Mechanical, Electrical Engineering or related discipline. An advanced technical degree preferred.
- Experience should include 8-10 years of relevant technical experience, including 5 years of leadership experience. Prior experience in the Renal Care domain is a plus.
- Must possess a strong knowledge of engineering disciplines and solid knowledge of related disciplines, Electro/Mechanical, Systems, Fluid Mechanics, Sensing, Algorithm Development, etc.
- A demonstrated track record in electromechanical system development and commercialization, preferably medical devices.
- Recognized team player with proven facilitative leadership skills in a cross-functional global team environment. Proven performance in a matrix environment with ability to influence and align stakeholders.
- Experience in leading small to medium cross functional teams with diverse backgrounds including engineering, clinical, sciences, and commercial.
- Strong technical and problem-solving skills. Proven ability to make sound decisions, think critically and break down complex problems through application of first engineering principles.
- Solid interpersonal skills. Ability to interact externally and internally to support business and innovation strategy.
- Solid communication, presentation, and interpersonal skills, with the ability to influence and engage stakeholders at all levels.
- Creative thinking, curiosity, and passions for exploring new ideas and pushing the boundaries of innovation.

E.8 Job Description #8

This position is responsible for maintaining and enhancing the technical excellence of research and development work, including new product development, product sustaining, and manufacturing support. The primary role of the Principal Systems Engineer is to act as Technical Leader on development programs, leading all aspects of the technical execution of projects, assuming responsibility for technical project deliverables and working with Program Managers to assure successful project outcomes. The Principal System Engineer will also work with the engineering management team to ensure appropriate technological expertise.

Principal Systems Engineers will provide input to Program Managers and direction to other technical personnel and will assume appropriate level of responsibility for technical work to facilitate the development or manufacturing of world class products or assemblies.

E.8.1 Responsibilities

- Understand and communicate best practices of Systems Engineering.
- Experience with combined hardware, software system architecture. Ability to determine appropriate system architecture and include necessary safety mitigations.
- Provide expertise across functional groups to define product implementations and solve problems with the ability to clearly communicate key product risk/benefit trade-offs. Provide support across multiple projects and teams to define system implementation strategies.
- Develop testable product and interface requirements that include support for necessary features and performance, and include considerations for human factors, product safety testing, regulatory submissions, product packaging, environmental conditions, manufacturing and service. Support the development of requirement templates for use across projects. Use of JAMA for requirements management a plus.
- Frequent use and application of medical device technical standards, including but not limited to IEC 60601 family of standards, IEC 62304, and FDA guidance's. Monitor the regulatory environment to be able to communicate updates.
- Develop and review risk analysis' including and specifically design failure modes and effects analysis (FMEAs), and hazard analysis compliant with ISO 14971. Support the development and training of risk analysis methods.
- Conducts analysis, review, and/or evaluation of design alternatives across various technologies and disciplines. Develop strategies for assisting multiple projects.
- Support and direct system integration activities. Direct and develop plans to solve integration issues.
- Support testing activities including design verification. Direct and provide options for issue resolution.
- Prepares and reviews design documentation and manufacturing documentation. Lead design reviews. Assist with review and development of documentation templates, particularly for compliance with standards.
- Support medical device builds including prototypes, animal and human use devices, and production equivalent verification builds.
- Support design and manufacturing transfer into production. Assist with improving transfer processes.
- Familiarity with the product development process including the use of established procedures. Assist and review product development process updates.
- Ability to work and direct internal technical teams while coordinating with external customer teams. Must be able to communicate tradeoffs between risks, benefits, and

performance while considering impact on budgets and schedules. Must be able to provide budget estimates for ongoing projects.
- Provides mentorship and direction to less-experienced engineers.
- Provides marketing and sales support by communicating with potential clients including articulating the technical and development process. Provide task and development estimates in support of projects proposals.
- Propose and develop process improvement initiatives.
- Work with Engineering Managers to identify and obtain necessary technical expertise, training and resources to support a diverse range of new product development and support efforts.
- Participate in medical device industry events and organizations to maintain awareness of developments and best-in-class practices in the industry.

E.8.2 Qualifications

- Master's degree in an engineering, technical or scientific discipline or equivalent experience.
- 10+ years experience in developing software and/or electronic-based medical devices.
- In depth knowledge of FDA QSR's, ISO13485, and IEC601 for medical devices.
- Experience in interpreting and applying technical regulatory requirements to medical devices.
- Strong mentoring skills.
- Strong interpersonal, communication (both written and oral) & analytical skills.
- Excellent interpersonal skills with multiple disciplines & clients.
- Ability to work independently, but also function as a team player.