Medical Device Systems Engineering Knowledge Repository Report

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2024-04-02

Table of contents

Preface

This is a Quarto report of the Masters Project in Systems Engineering.

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1 Summary

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

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 book that delves into the systems engineering aspects of medical device development.

2.1 Impact

The creation of a comprehensive book 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

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 the FDA a medical device (system) is "any instrument, machine, contrivance, implant, in vitro reagent that's intended to treat, cure, prevent, mitigate, diagnose disease"

Source: Section 201(h) of the Federal Food, Drug, and Cosmetic Act

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


Medtronic
A
B
Medtronic
Medtronic
5:30
6:00
8:00
11:30
READY
READY
READY
READY


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

- Intra-Aortic Balloon Pump
- Medical Information Management System
- Endoilluminator
- 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 commercializeed 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.):


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

- The first process requires that a premarket notification (510(k)) be 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 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.
- The second process requires the submission of a premarket approval (PMA) application to the FDA to demonstrate 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.

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 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 labelling, 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.

3.4 Medical Device Industry Faces Many Challenges

Some important 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.

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

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 throughout the book.

- 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.

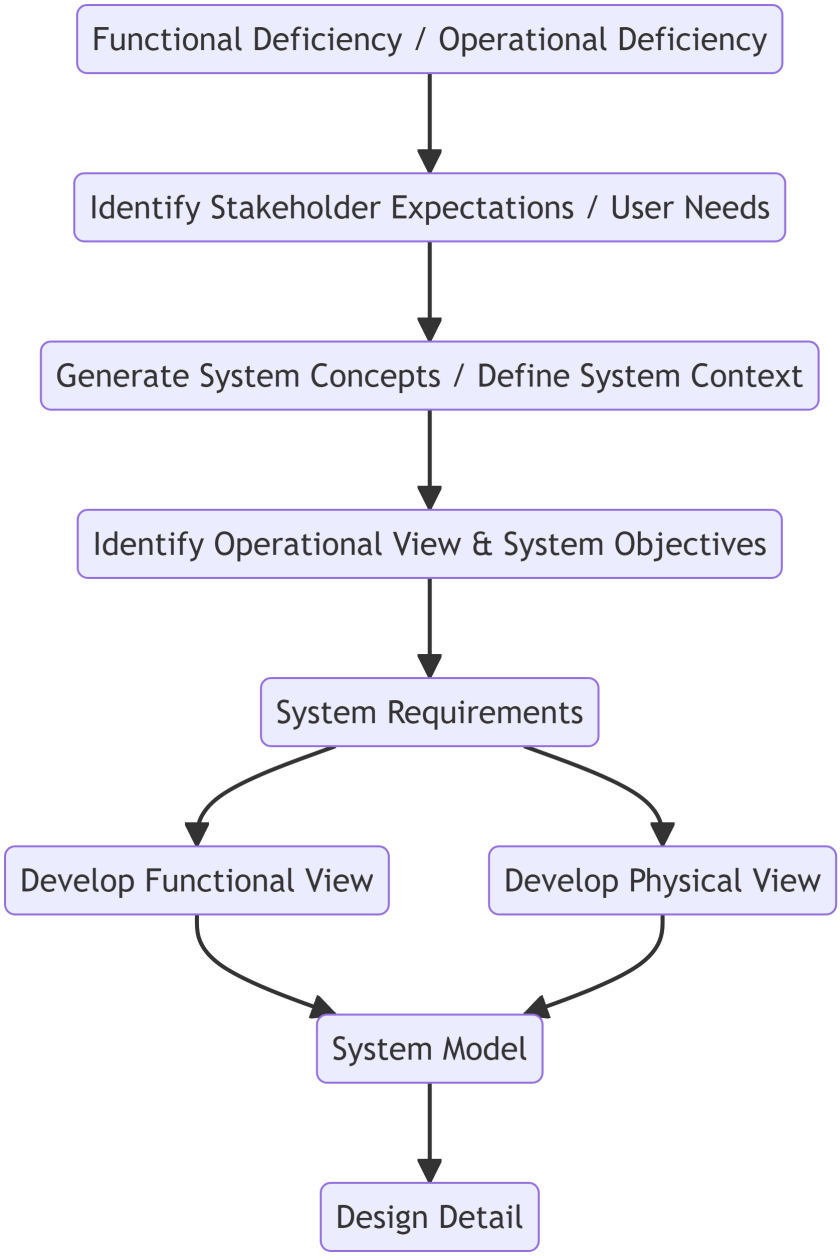


Figure 5.1: System Engineering Strategy

6 Problem

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.

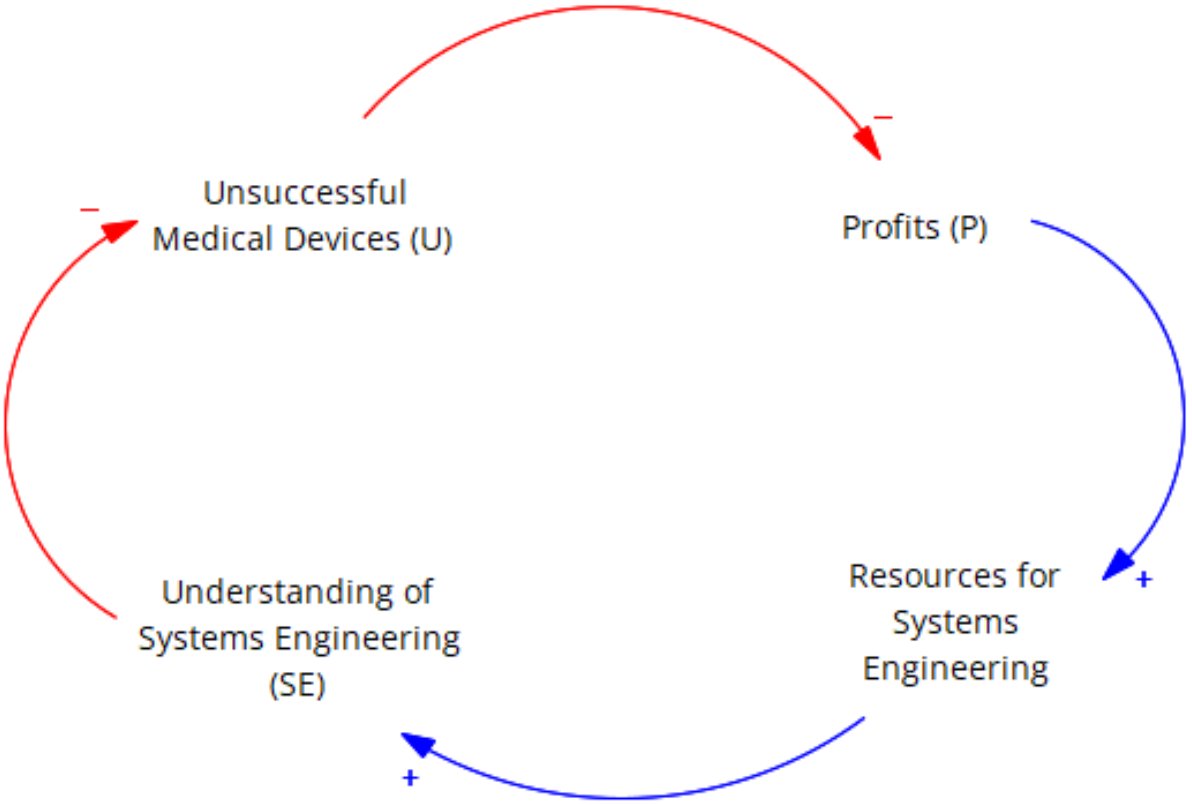


Figure 6.1: Problem modeled as a casual loop

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

This section provides the system mission, and business rationale.

7.1 Mission

8 Sources

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
- 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.

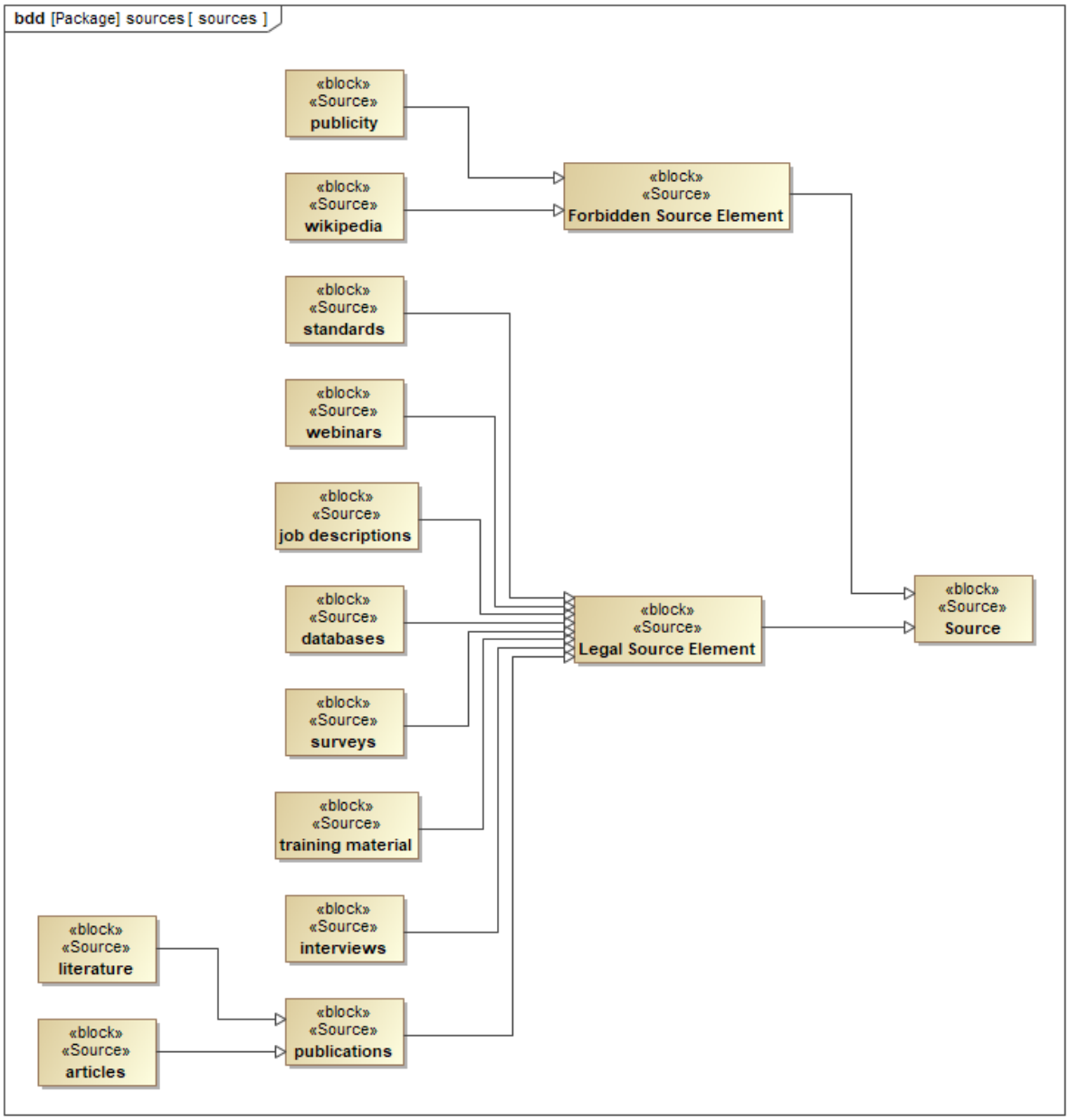


Figure 8.1: The MedSE Knowledge Repository System sources of needs and requirements

8.2 Articles

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)

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 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.

It is important to note that 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).

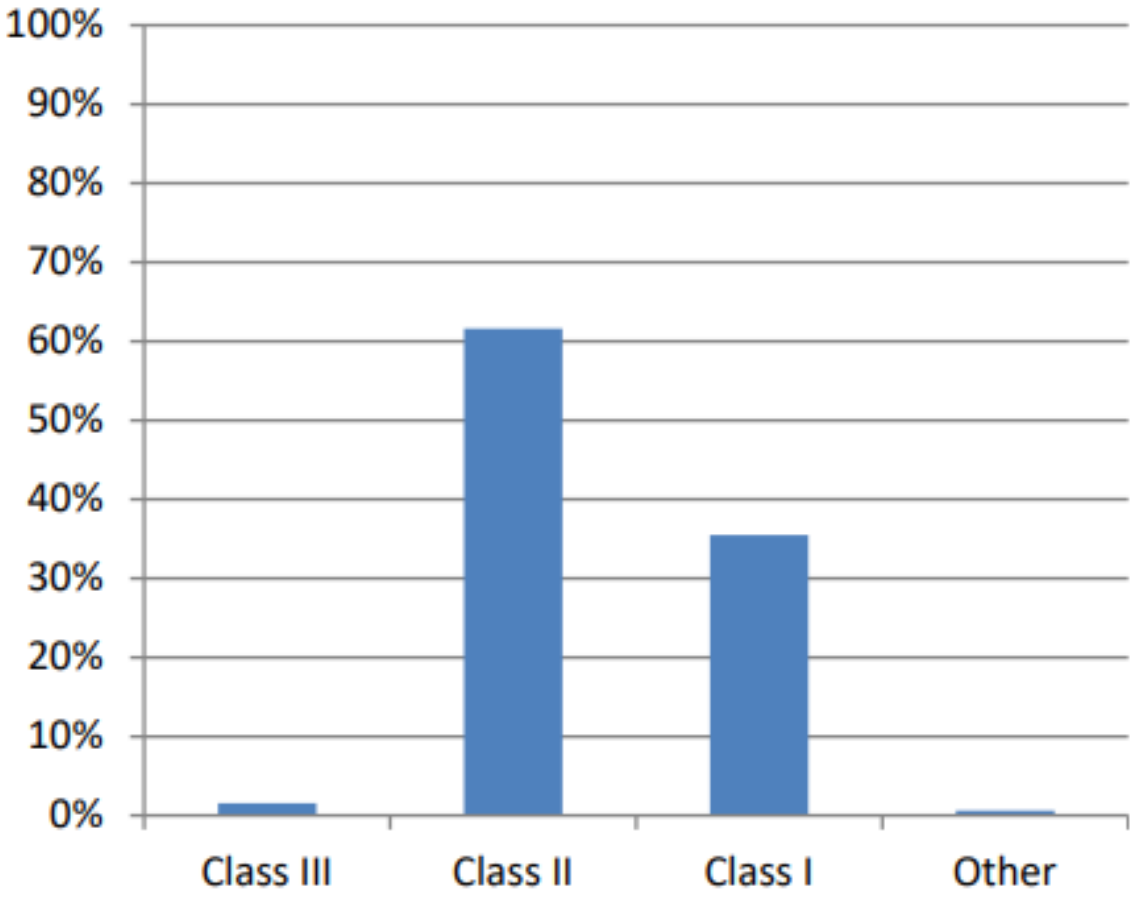


Figure 8.2: Distribution of Medical Devices Registered with the FDA (as of February 1, 2024)

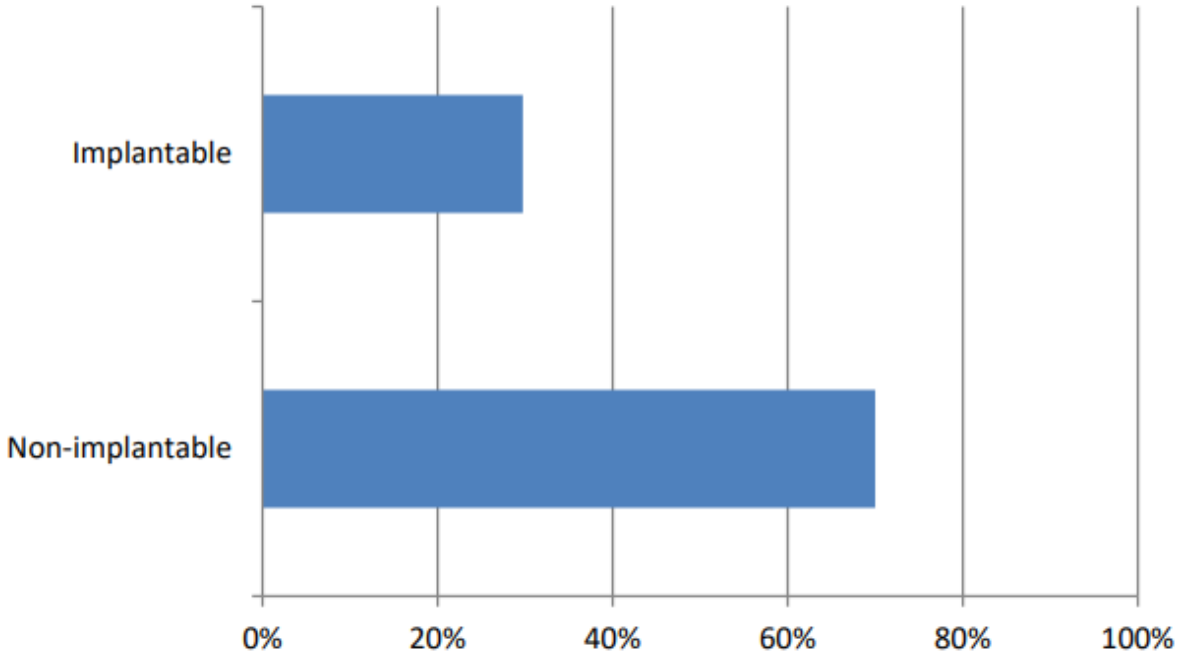


Figure 8.3: Proportion of Implantable vs. Non-Implantable Medical Devices Registered with the FDA (as of February 1, 2024)

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.

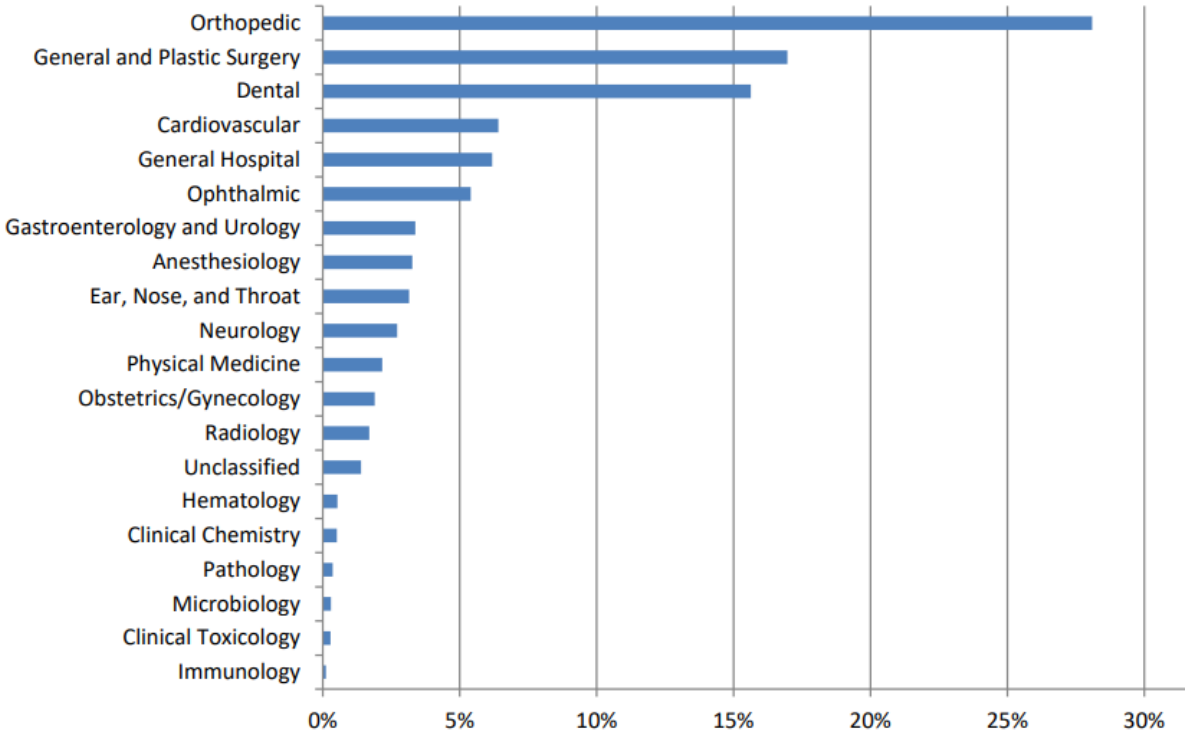


Figure 8.4: Distribution of FDA-Registered Medical Devices by Medical Specialty (as of February 1, 2024)

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
  - 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

It's important to note that 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**

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

- **Tracheostomy**
- **Cardiovascular**
- **Wireless**
- **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, by discussing the role of a Systems Engineer and describing 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 Survey

8.6 Training program outlines

9 Stakeholders

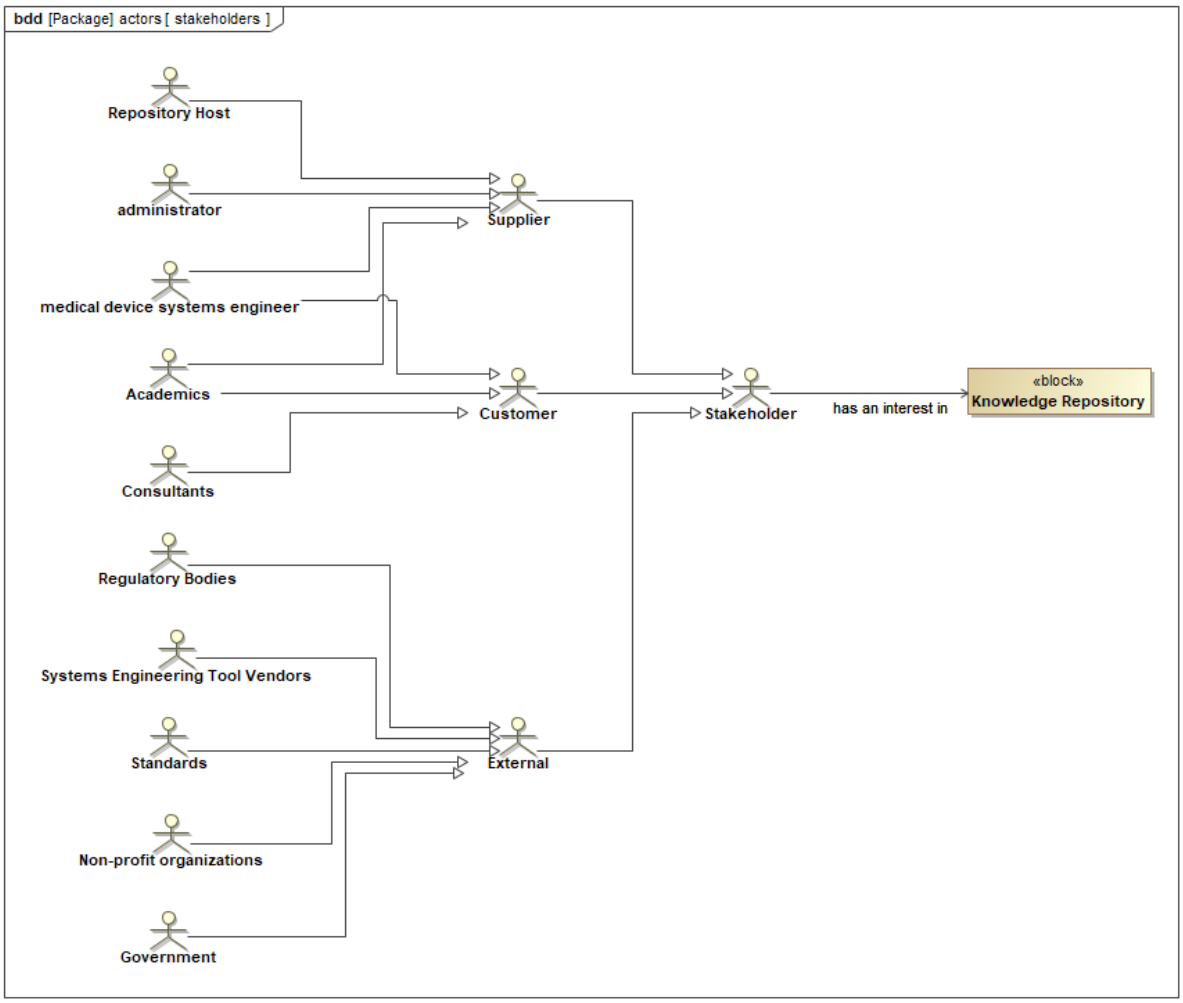


Figure 9.1: MedSE Knowledge Repository Stakeholders View

Figure 9.1 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.
- **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.

10 Goals and Objectives

Section 10.1 provides the list of active, passive and sponsor stakeholders of the programmable playground system. Section 10.2 provides the list of stakeholder expectations that are classified as either capability or characteristic. Section 10.3 extracts which stakeholder expectations are considered sacred. Section 10.4 provides the system objectives. Section 10.5 explains the concept of operations of the system.

10.1 Stakeholders

Table 10.1: Stakeholders

ID	Stakeholder	Description	Type [active, passive, sponsor]

10.2 Stakeholders expectations

Stakeholder expectations were elicited from the stakeholders and documented in Table 10.3. 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 10.2: Stakeholders expectations

ID	Expectation Title	Expectation Description	Expectation type [capability, characteristic]	Stakeholder ID

10.3 Sacred expectations

Table 10.3 shows the stakeholder expectations determines as “sacred”.

Table 10.3: Sacred stakeholder expectations

Stakeholder expectation ID	Expectation Title	Expectation Description

10.4 Objectives

Table 10.4 provides the list of the system objectives.

Table 10.4: Objectives

ID	Objective
OBJ001	Design a system that will compile and synthesize knowledge and best practices related to systems engineering in medical device development.
OBJ002	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.
OBJ003	Offer practical guidance and tools for applying systems engineering principles throughout the entire lifecycle of medical device development.
OBJ004	Foster a deeper understanding of the regulatory requirements and standards governing medical devices and how they intersect with systems engineering processes.

10.5 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 10.1 shows the Medical Device System context.

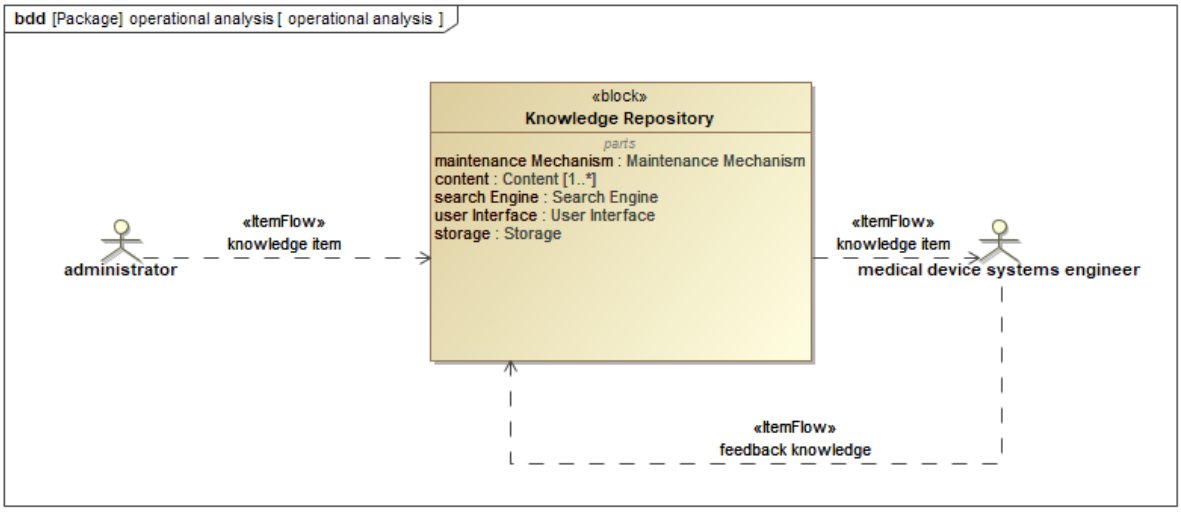


Figure 10.1: Medical Device System Context Diagram

11 Operational Analysis

> "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).

11.0.1 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.

11.0.2 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.

11.1 System Use Cases

This section analyzes the knowledge repository system use cases and modeled with a SysML use case diagram. Figure 11.1 depicts a central block representing the knowledge repository itself, surrounded by actors and their associated use cases.

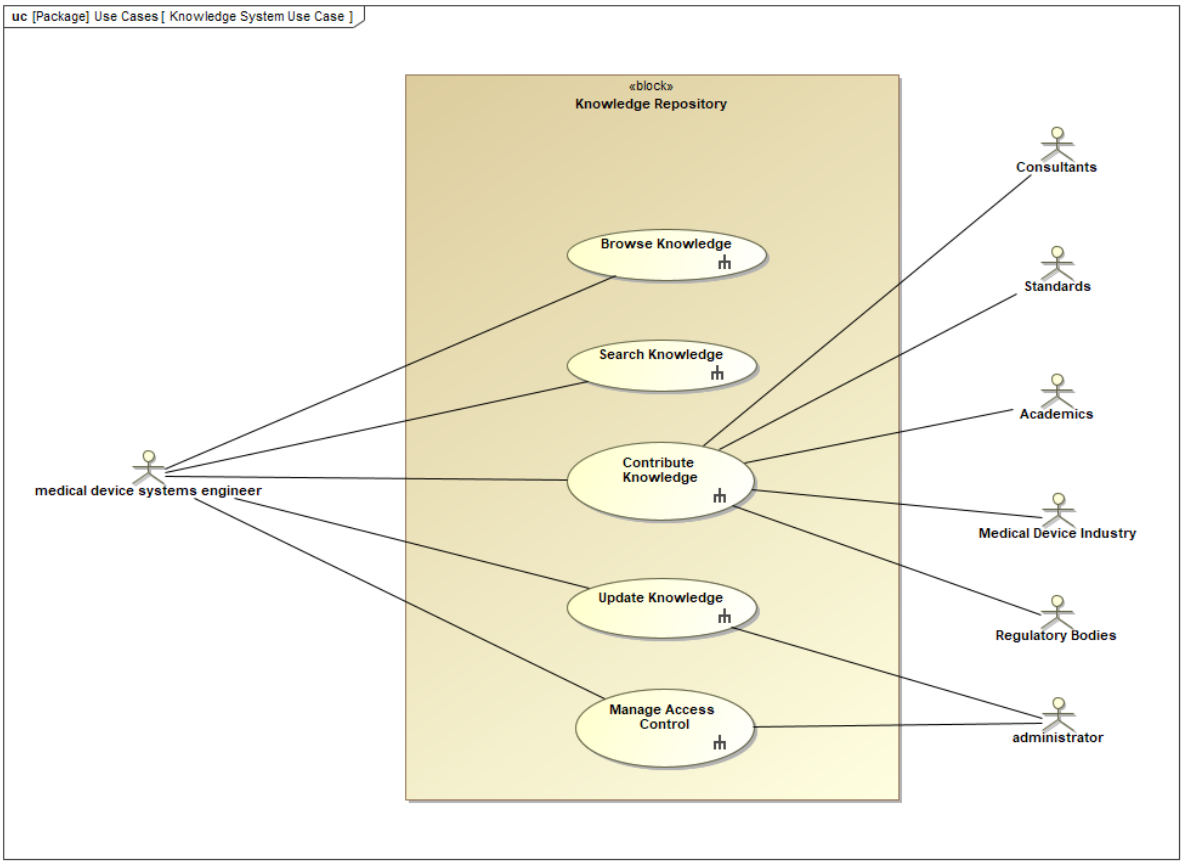


Figure 11.1: System Use Cases

11.1.1 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:** This use case allows actors to explore the knowledge repository freely, potentially leading to serendipitous discovery of relevant information.
- **Search Knowledge:** This use case facilitates targeted knowledge retrieval through a search mechanism within the repository.
- **Contribute Knowledge:** This use case empowers qualified actors, such as engineers and consultants, to enrich the repository by adding new knowledge.
- **Update 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.

11.1.2 Browse Knowledge Use Case

11.1.3 Search Knowledge Use Case

11.1.4 Contribute Knowledge Use Case

11.1.5 Update Knowledge Use Case

11.1.6 Manage Access Control Use Case

11.1.7 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.

11.2 Operational Scenarios

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

11.2.1 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 11.2 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:

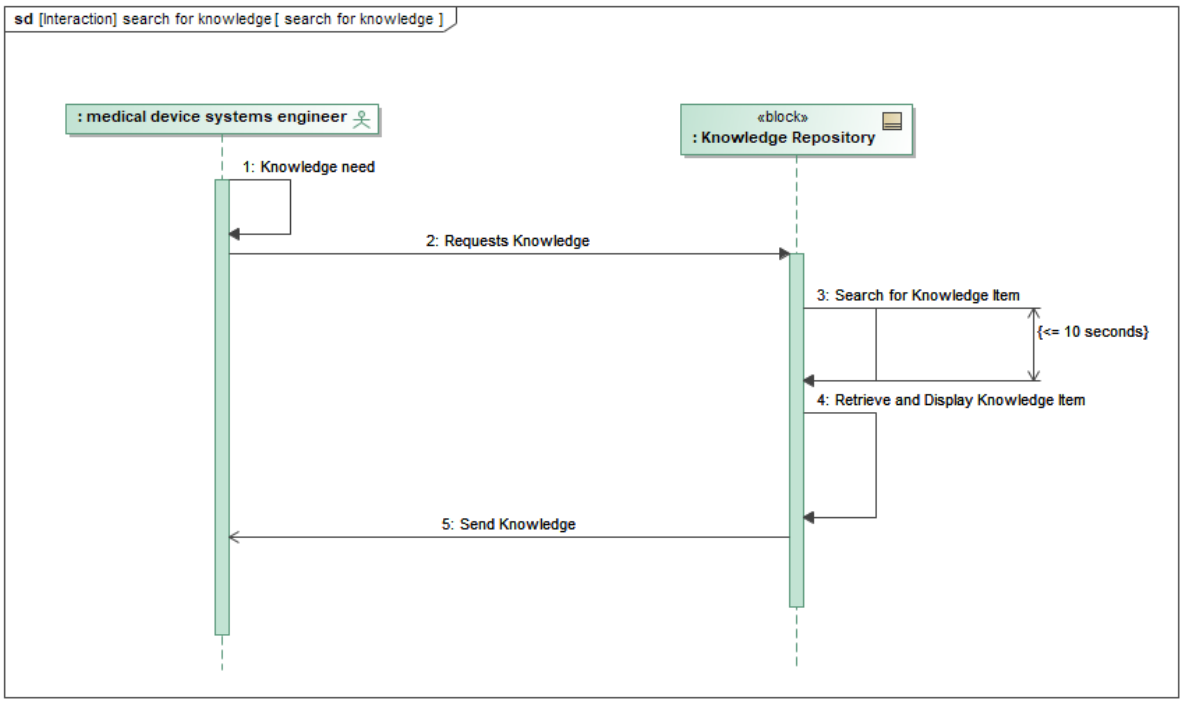


Figure 11.2: System Main Function Sequence Diagram

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

11.2.2 Browse Knowledge Operational Scenario

11.2.3 Search Knowledge Operational Scenario

11.2.4 Contribute Knowledge Operational Scenario

11.2.5 Update Knowledge Operational Scenario

Figure 11.3 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.

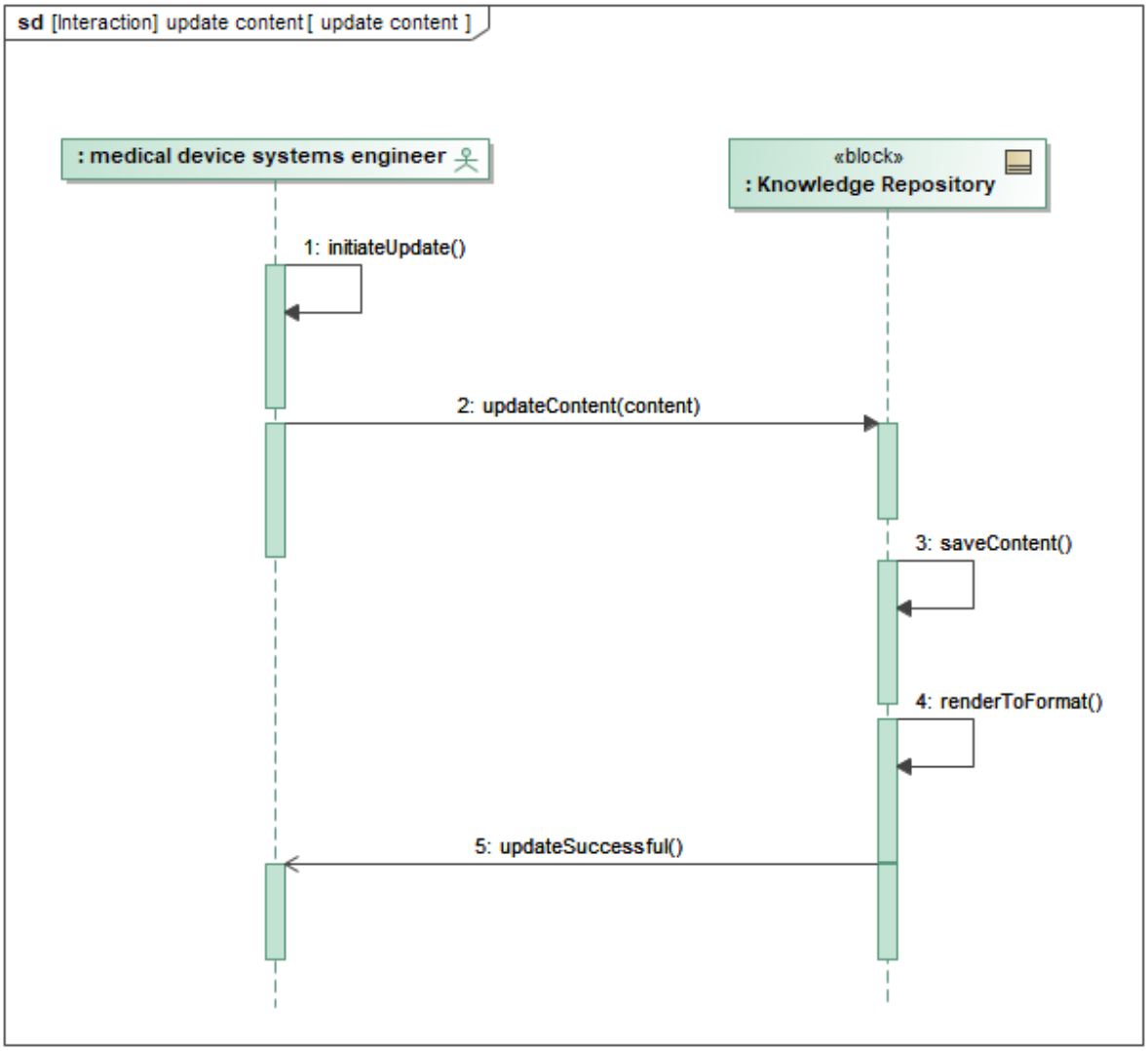


Figure 11.3: Update Content Sequence Diagram

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.
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.

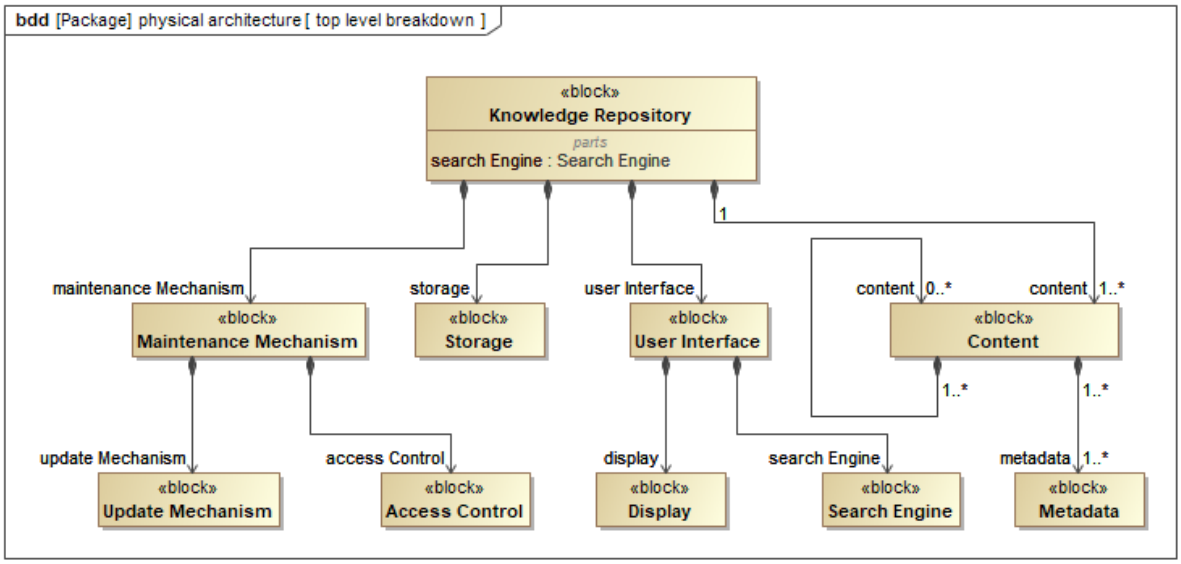
11.2.6 Manage Access Control Operational Scenario

12 Physical Architecture

"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.

12.1 Top Level System Breakdown



The image is a SysML block definition diagram (BDD) for a physical architecture. It shows the breakdown of a system into its parts at a high level. Here's a breakdown of the components:

- **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.
  - **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:** This block refers to the data that is presented by the user interface and displayed.
- **Metadata:** This block provides data about other blocks in the system.

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 Conclusions

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 Survey Knowledge Needs

The following survey was used to collect knowledge needs from systems engineers. 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

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
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 Definitions

Table C.1: Definitions

Term	Definition
AAMI	Association for the Advancement of Medical Instrumentation
CFR	Code of Federal Regulations
EU MDR	European Union Medical Device Regulation
FDA	Food and Drug Administration
INCOSE	International Council on Systems Engineering
ISO	International Organization for Standardization
Medical device	Section 201(h) of the FD&C Act (21 USC 321(h)) 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
SysML	Systems Modeling Language

D Risks

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.