Medical Device Systems Engineering Knowledge Repository Report

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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 Cognition 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!

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
- 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 Industry Faces Many Challenges

- 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.

3.4 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.

3.5 Role as Medical Device Systems Engineer

Stakeholders that medical device systems engineers work with:

3.5.1 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

3.5.2 External stakeholders

- Patients
- Medicine and Healthcare Professionals

- Insurance Companies
- Governments
- Standards Organizations
- Distributors

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

- 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:

- 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.

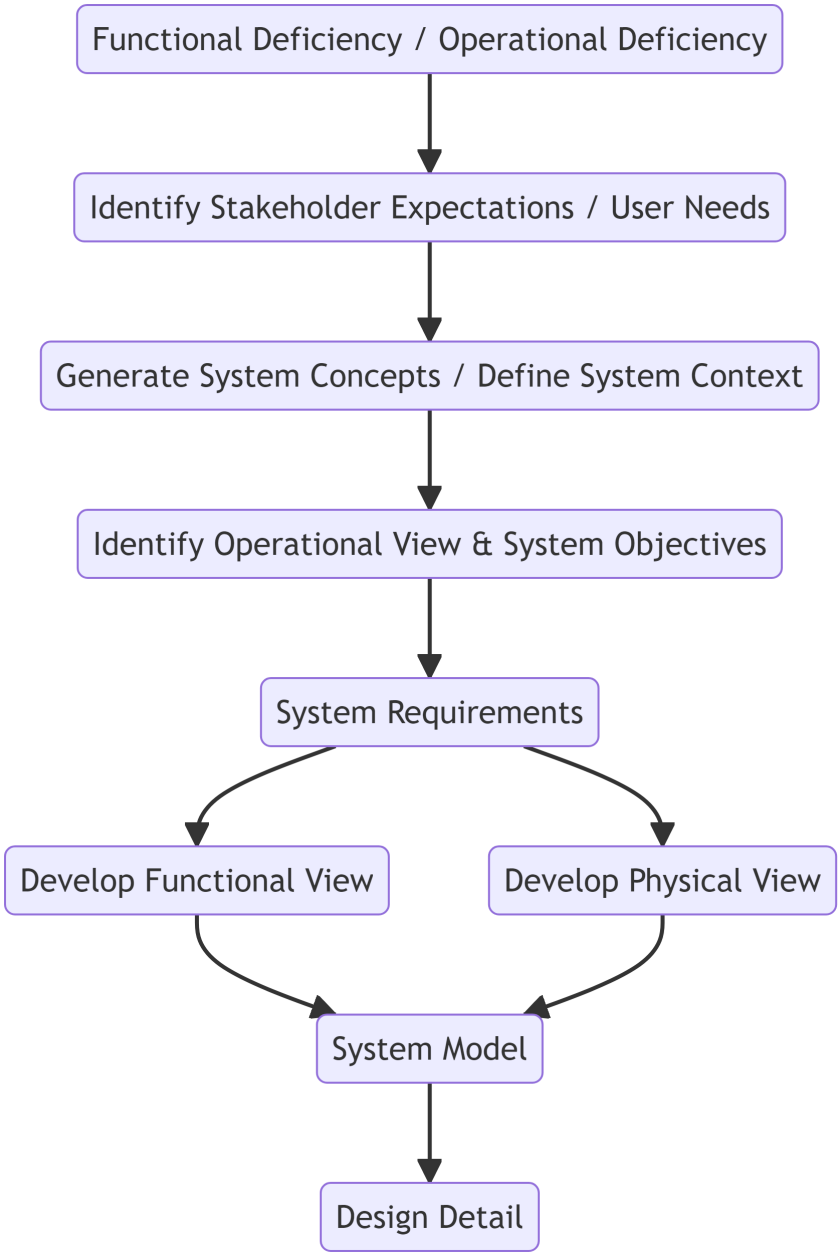


Figure 5.1: System Engineering Strategy

6 Mission Description

This section provides the system mission, and business rationale.

6.1 Mission

7 Goals and Objectives

Section 7.1 provides the list of active, passive and sponsor stakeholders of the programmable playground system. Section 7.2 provides the list of stakeholder expectations that are classified as either capability or characteristic. Section 7.3 extracts which stakeholder expectations are considered sacred. Section 7.4 provides the system objectives. Section 7.5 explains the concept of operations of the system.

7.1 Stakeholders

Table 7.1: Stakeholders

ID	Stakeholder	Description	Type [active, passive, sponsor]

7.2 Stakeholders expectations

Stakeholder expectations were elicited from the stakeholders and documented in Table 7.3. 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 7.2: Stakeholders expectations

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

7.3 Sacred expectations

Table 7.3 shows the stakeholder expectations determines as “sacred”.

Table 7.3: Sacred stakeholder expectations

Stakeholder expectation ID	Expectation Title	Expectation Description

7.4 Objectives

Table 7.4 provides the list of the system objectives.

Table 7.4: 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.

7.5 Concept of Operations

This section defines the system context for the 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 7.1 shows the Medical Device System context.

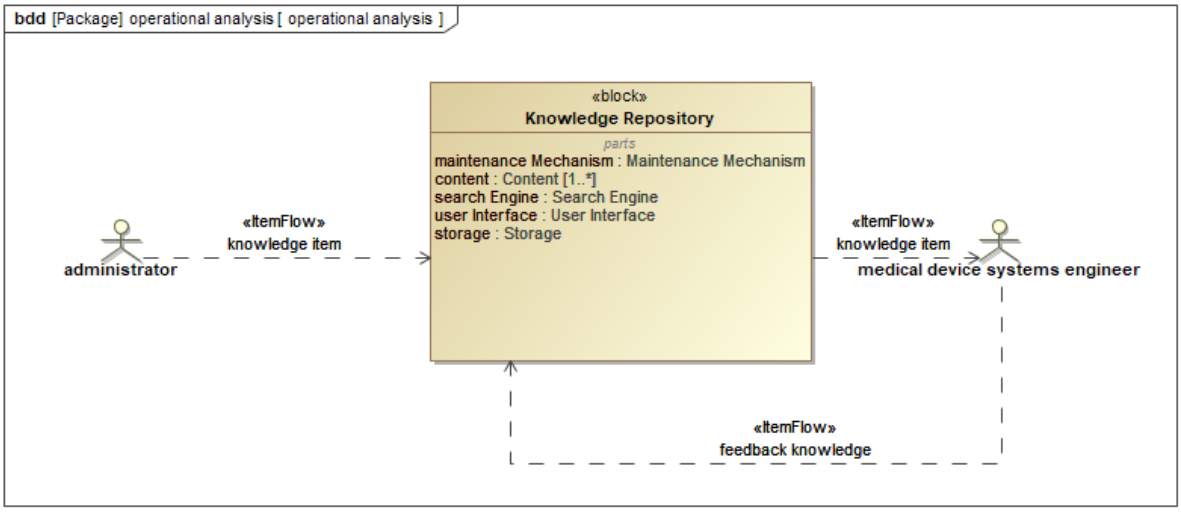


Figure 7.1: Medical Device System Context Diagram

8 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.).

8.0.1 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.

8.0.2 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.

8.1 System Use Cases

This section analyzes the knowledge repository system use cases and modeled with a SysML use case diagram. Figure 8.1 depicts a central block representing the knowledge repository itself, surrounded by actors and their associated use cases.

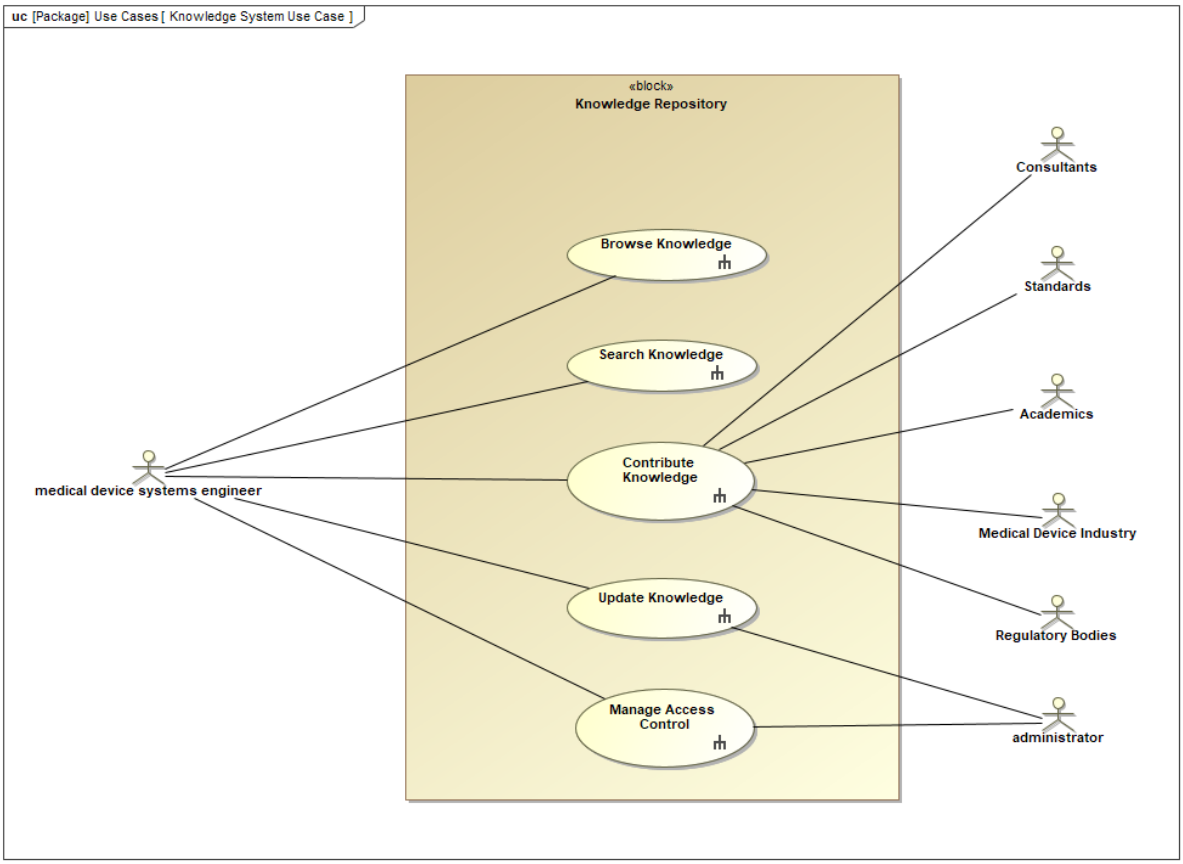


Figure 8.1: System Use Cases

8.1.1 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.

8.1.2 Browse Knowledge Use Case

8.1.3 Search Knowledge Use Case

8.1.4 Contribute Knowledge Use Case

8.1.5 Update Knowledge Use Case

8.1.6 Manage Access Control Use Case

8.1.7 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.

8.2 Operational Scenarios

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

8.2.1 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 8.2 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:

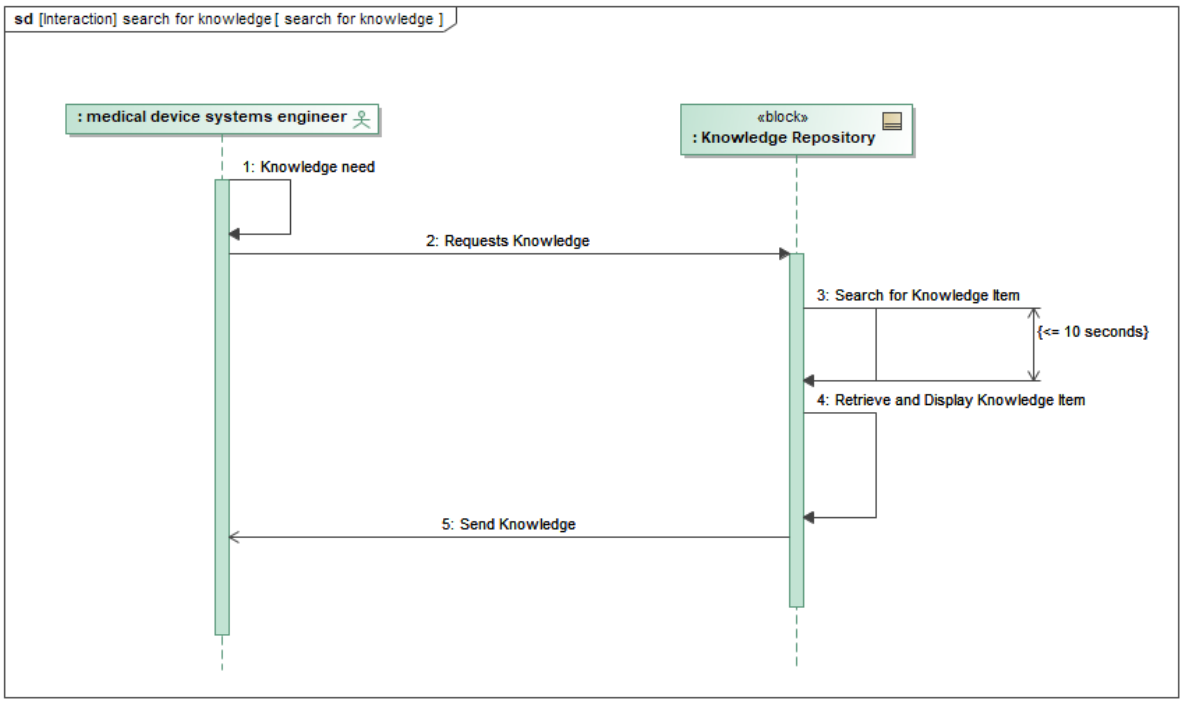


Figure 8.2: System Main Function Sequence Diagram

- **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.

8.2.2 Browse Knowledge Operational Scenario

8.2.3 Search Knowledge Operational Scenario

8.2.4 Contribute Knowledge Operational Scenario

8.2.5 Update Knowledge Operational Scenario

Figure 8.3 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.

Here's a breakdown of the interaction sequence:

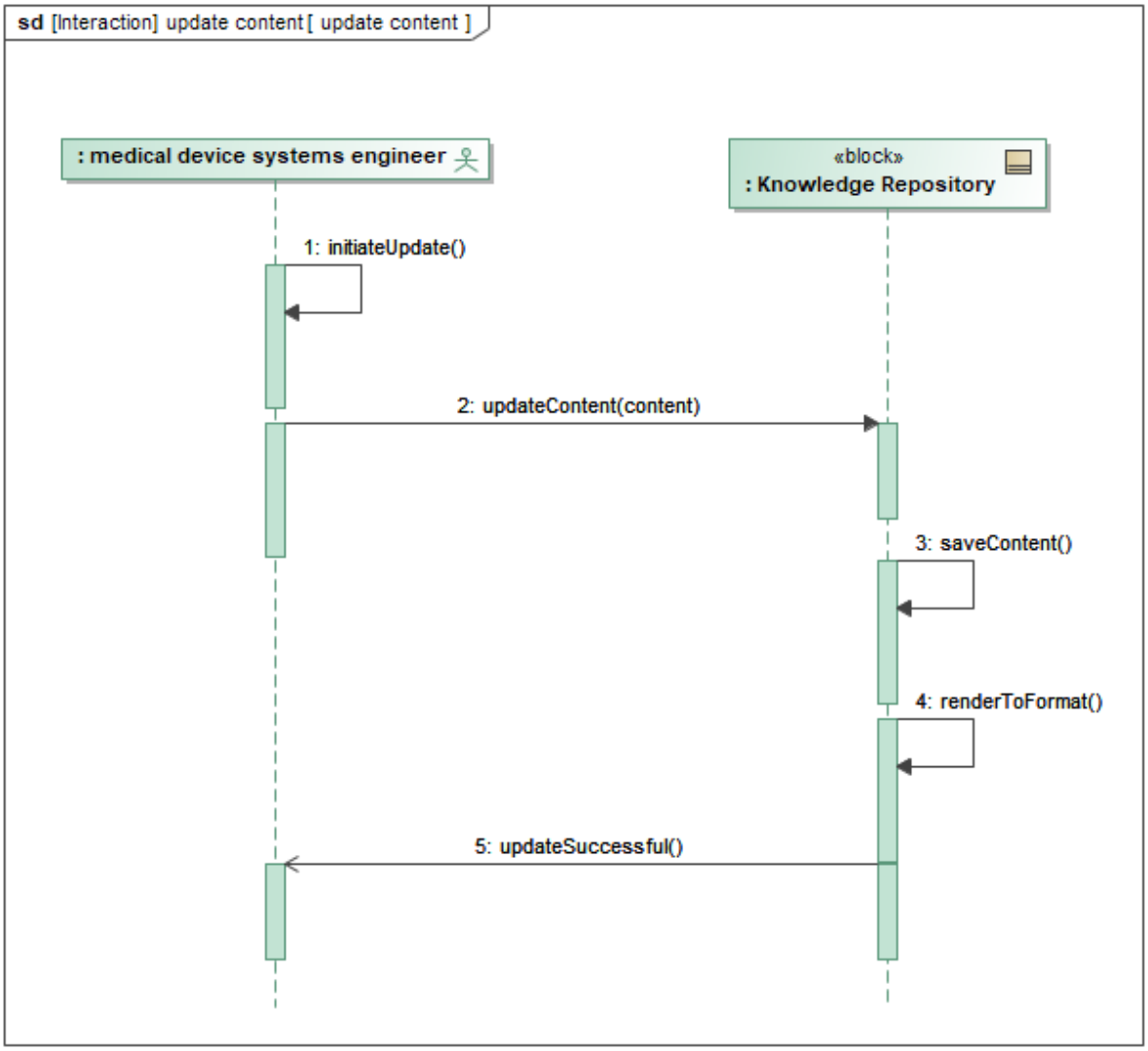


Figure 8.3: Update Content Sequence Diagram

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.

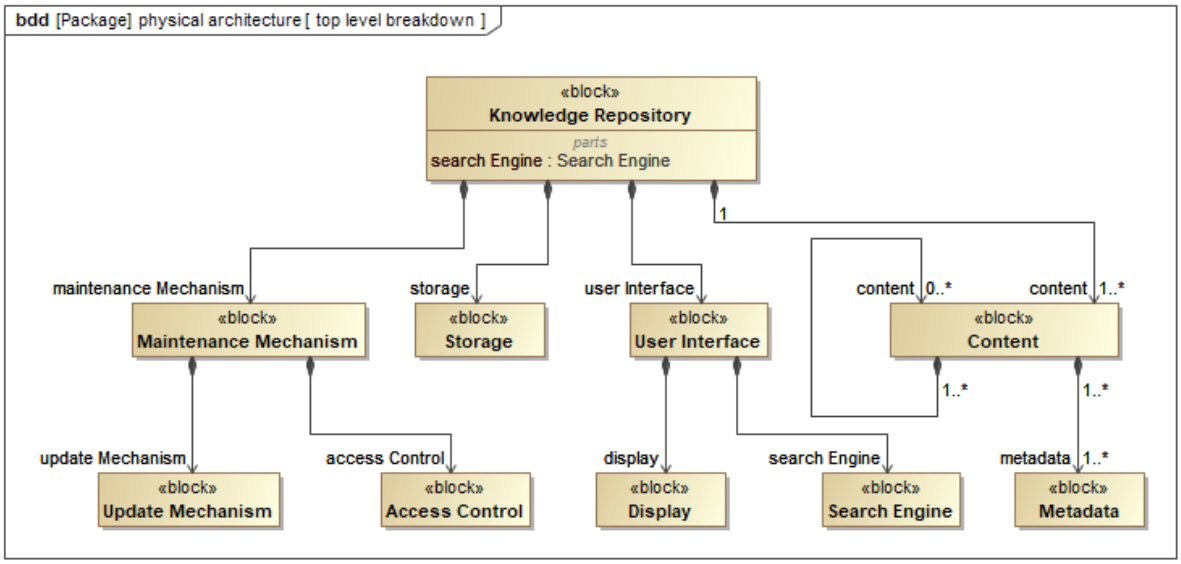
8.2.6 Manage Access Control Operational Scenario

9 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.

9.1 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.

10 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