A Comprehensive Systems Engineering Approach to Medical Device Development: From Concept to Commercialization

by

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A PROJECT

Submitted to the Faculty of the Stevens Institute of Technology

in partial fulfillment of the requirements for the degree of

MASTER OF engineering – School of Systems and Enterprises

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# 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.

# Project Stakeholders

Table 1 provides the list of the project stakeholders.

Table 1 Project Stakeholders

| **Stakeholder ID** | **Contact** | **Institution** | **Proposed Role** | **Contact Email** |
| --- | --- | --- | --- | --- |
| STK0001 | Dr. Dinesh Verma  A close-up of a person smiling  Description automatically generated | Stevens Institute of Technology, SERC | Project Advisor | [dverma@stevens.edu](mailto:dverma@stevens.edu) |
| STK0002 | Dr. Alparslan Emrah Bayrak | Stevens Institute of Technology | Academic Advisor | [ebayrak@stevens.edu](mailto:ebayrak@stevens.edu) |
| STK0003 | Esteban M. Solórzano | Stevens Institute of Technology, Boston Scientific, INCOSE | Candidate | [Esteban.SolorzanoZeledon@bsci.com](mailto:Esteban.SolorzanoZeledon@bsci.com) |
| STK0004 | Adam Reinhardt | Boston Scientific | Supervisor, independent reviewer | [Adam.Reinhardt@bsci.com](mailto:Adam.Reinhardt@bsci.com) |
| STK0005 | Bijan Elahi  A person in a suit and tie  Description automatically generated | Medtronic | Medtronic Technical Fellow, corporate advisor, independent reviewer  Safety risk management | [bijan.elahi@medtronic.com](mailto:bijan.elahi@medtronic.com) |
| STK0006 | Sandy Weininger  A person in a suit and tie  Description automatically generated | FDA, AAMI | Medical Device Regulatory Agency advisor, independent reviewer | [Sandy.Weininger@fda.hhs.gov](mailto:Sandy.Weininger@fda.hhs.gov) |
| STK0007 | Colin Mellars  A person with a beard and glasses  Description automatically generated | Roche | Director Systems Development and Integration, contributor | [colin.mellars@gmail.com](mailto:colin.mellars@gmail.com) |
| STK0008 | Howard Simms  A person smiling for a picture  Description automatically generated | Boston Scientific, retired | Medical Device Industry advisor, independent reviewer | [systems2718@gmail.com](mailto:systems2718@gmail.com) |

# Project Objectives

Table 2 provides the list of the main objectives of this project.

Table 2. Project Objectives

|  |  |
| --- | --- |
| **Objective ID** | **Description** |
| OBJ0001 | Compile and synthesize knowledge and best practices related to systems engineering in medical device development. |
| OBJ0002 | Provide a comprehensive resource that educates professionals and students in the field of systems engineering about the unique challenges and considerations specific to medical devices. |
| OBJ0003 | Offer practical guidance and tools for applying systems engineering principles throughout the entire lifecycle of medical device development. |
| OBJ0004 | Foster a deeper understanding of the regulatory requirements and standards governing medical devices and how they intersect with systems engineering processes. |

# Scope

The book will cover the following key areas:

* Introduction to Medical Devices: An overview of the medical device industry, its regulatory landscape, and the importance of systems engineering in ensuring device safety and effectiveness.
* Systems Engineering Fundamentals: Explaining the core concepts and methodologies of systems engineering, including requirements analysis, design, verification, and validation.
* Medical Device Lifecycle: A detailed examination of each phase of the medical device lifecycle, from concept development and design through manufacturing, testing, and post-market surveillance.
* Regulatory Compliance: A comprehensive review of the regulatory requirements and standards governing medical devices, such as ISO 13485 [1] and FDA regulations, and how to align systems engineering processes with these requirements.
* Risk Management: The integration of systems engineering into risk management.
* Interdisciplinary Collaboration: Discussing the importance of cross-functional collaboration among engineers, clinicians, regulatory experts, and other stakeholders in the medical device development process.
* Case Studies: Real-world case studies illustrating successful applications of systems engineering principles in medical device projects.

# Methodology

* Follow Stevens guidelines and templates for masters project [2], [3], [4], [5].
* Develop the book 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 [6] and the INCOSE Systems Engineering Handbook [7].
* 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 GitHub as repository for the master’s project artifacts.

# Deliverables

The final deliverable of this project will be a comprehensive book on the systems engineering of medical devices, complete with:

* Well-researched and structured chapters.
* Illustrations and diagrams to enhance understanding.
* Practical tools, templates, and checklists for applying systems engineering principles in medical device development.
* Case studies and examples.
* Comprehensive references and citations.

# Expected 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 book 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.

# Timeline

The project is expected to be completed within one semester.

# Budget

A budget estimate will be prepared in the planning phase, including expenses related to research, content development, graphics, and peer review.

# References

[1] 14:00-17:00, “ISO 13485:2016,” *ISO*, Jun. 02, 2021. https://www.iso.org/standard/59752.html (accessed Sep. 19, 2023).

[2] “FORMATTING AND SUBMISSION GUIDELINES FOR MASTER’S AND Ph.D. STUDENTS.” Accessed: Sep. 19, 2023. [Online]. Available: https://assets.ctfassets.net/mviowpldu823/3TB8wQTkQC8oVgMHZU7jjA/ce1505d08915c608059e6ba6843facec/scwlibrary\_gradthesisdissertationsubmission-edit.pdf

[3] “Master’s Thesis Defense Logistics.” https://my.stevens.edu/provost/grad-academics-and-student-success/content/masters-thesis-defense-logistics (accessed Sep. 19, 2023).

[4] R. Espinel, “Research Guides: Formatting & Submission Guidelines for Senior Theses, Master’s Theses, and Dissertations.” https://library.stevens.edu/c.php?g=1308692&p=9618575 (accessed Sep. 19, 2023).

[5] “Sample Pages,” *Stevens Institute of Technology*. https://www.stevens.edu/sample-pages (accessed Sep. 19, 2023).

[6] 14:00-17:00, “ISO/IEC/IEEE 15288:2023,” *ISO*. https://www.iso.org/standard/81702.html (accessed Sep. 19, 2023).

[7] INCOSE, *INCOSE Systems Engineering Handbook: A Guide for System Life Cycle Processes and Activities*, 4 edition. Hoboken, New Jersey: Wiley, 2015.

# Appendix

## ID tag definitions

Table 3. Identification tags definitions

|  |  |
| --- | --- |
| **ID tag** | **Definition** |
| STKXXXX | Stakeholder |
| OBJXXXX | Objective |

## Acronyms

Table 4. Acronyms definitions

|  |  |
| --- | --- |
| **Acronym** | **Description** |
| INCOSE | International Council on Systems Engineering |
| FDA | United States Food and Drug Administration |
| AAMI | Association for the Advancement of Medical Instrumentation |
| SERC | Systems Engineering Research Center |
| FMEA | Failure Mode and Effects Analysis |
| IEC 13485 | Medical devices — Quality management systems — Requirements for regulatory purposes |
| IEC 15288 | Systems and software engineering — System life cycle processes |