Building the Future of Healthcare: The Systems Engineer at Boston Scientific

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R&D

All Divisions

Systems Engineering CoP

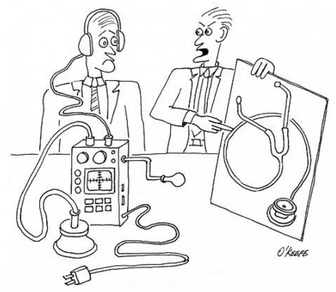
Problem Statement: How Can We Cultivate Seamless Collaboration and Shared Expertise Among Boston Scientific's Systems Engineers?

Key Learning or Achievement:

- Implemented the Systems Engineering Community of Practice
- Boston Scientific and Stevens collaborating in the development of the first book on Medical Device Systems Engineering for the industry and academia.

The Unsung Hero of Medical Device Innovation

- **Medical Device MacGyver:** Solves complex problems across engineering disciplines (hardware, software, electrical) to create cutting-edge medical devices.
- **Safety Sherriff:** Ensures devices meet strict regulations for patient safety – think real-world superhero!
- **Doctor Whisperer:** Translates doctor and patient needs into technical solutions, making sure the tech serves healthcare heroes.

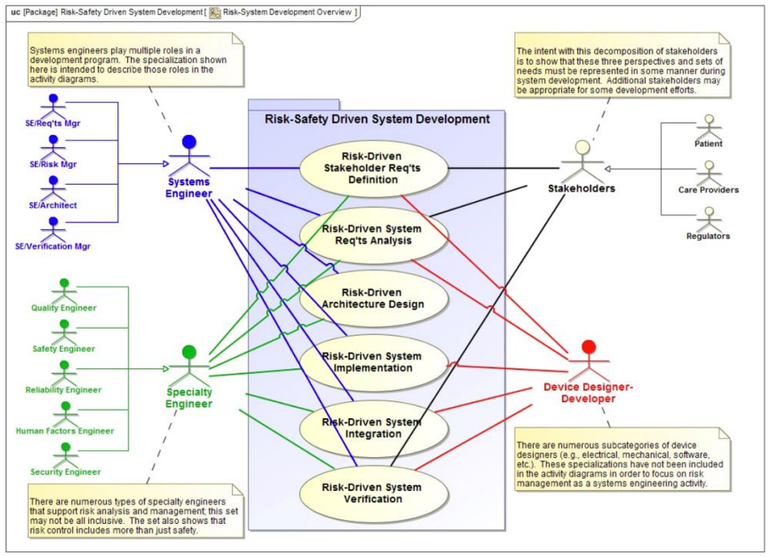


Interesting design, but this is more of what we had in mind.

Systems Engineering *is a* ***transdisciplinary*** *and* ***integrative*** *approach to enable the successful realization, use, and retirement of* ***engineered systems****, using* ***systems principles and concepts,*** *and scientific, technological, and management methods.*

How Systems Engineers Make a Difference

- **Safety & Efficacy:** Ensure devices meet regulatory requirements for patient safety and effectiveness.
- **Project Efficiency:** Streamline development processes, minimizing risks and delays.
- **Innovation:** Contribute to the creation of cutting-edge medical technologies.



Mapping of 21 CFR820.30 to ISO/IEC/IEEE 15288 and the INCOSE SE Handbook

21CFR820.30	ISO/IEC/IEEE 15288:2015	INCOSE *SE Handbook*
Design and development planning	6.3.1 Project Planning Process	5.1 Project Planning Process
Design input.	6.4.2 Stakeholder needs and requirements definition process 6.4.3 Systems requirements definition process	4.2 Stakeholder needs and requirements definition process 4.3 Systems requirements definition process
Design output	6.4.5 Design definition process 6.4.7 Implementation process	4.5 Design definition process 4.7 Implementation process
Design review	6.3.2 Project Assessment and Control process	5.2 Project Assessment and Control process
Design verification	6.4.9 Verification Process	4.9 Verification Process
Design validation	6.4.11 Validation Process	4.11 Validation Process
Design transfer	6.4.10 Transition Process	4.10 Transition Process
Design changes	6.3.5 Configuration Management Process 6.4.13 Maintenance Process	5.5 Configuration Management Process 4.13 Maintenance Process
Design history file	6.2.6 Knowledge Management Process	5.6 Information Management Process

Empowering Your Systems Engineering Journey

Resources for professional growth:

- **Internal**:
  - SharePoint site for internal resources, documents, and templates.
  - 92579657, Global KSD Systems Engineering Role
- **External**:
  - MIT Open Courseware Systems Engineering Certification.
  - INCOSE: International Council on Systems Engineering certification programs
  - **Textbook**: "Medical Device Systems Engineering" under development at Stevens Institute of Technology.
  - **Masters Programs:**

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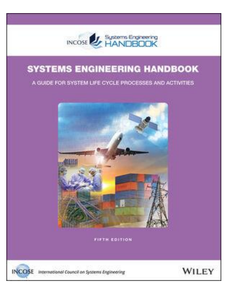
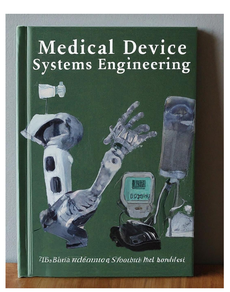
CoP SharePoint





Book Development Report