INCOSE Healthcare Working Group

NEW

10th Annual Systems Engineering in Healthcare Conference

April 29-May 1, Minneapolis, MN

The "Fundamentals" Track

Each year, the Systems Engineering in Healthcare Conference delivers exciting content reflecting the state-of-the-practice and state-of-the-art in systems engineering. This year we are introducing a Fundamentals Track targeted for participants who are:

- *New to systems engineering and building their foundation*
- *New to INCOSE and wanting to understand its terminology and framing for SE*
- *Experienced practitioners looking for a refresher on the fundamentals*

The Fundamentals Track is particularly focused on key systems engineering concepts tailored to MedTech targeting participants in their first five years in systems engineering. This track will consist of a full-day Fundamentals tutorial on April 29th, followed by focused talks during the main conference.

What will you learn?

The full-day tutorial will consist of four 90-minute classes and exercises focused on Stakeholder Management, Systems Architecting, Managing Systems Risk (Safety), and Writing Systems Requirements. About half the time will be spent in lectures, and half the time the students will work on an example as a team to practice what they are learning. We will supply supporting reference documents for those who want to learn more, as well as example solutions.

101 Stakeholder Management

How to select and prioritize your stakeholders
How to effectively interview stakeholders to gather needs
Managing user needs vs. other stakeholder needs
Developing a stakeholder management plan (including communication)

102 System Architecture

Recognize the purpose of architecture
Understand the value and uses of architectural views (e.g., logical, physical)
Recognize and avoid bias in architectural analyses and decisions
Understand the definition of an interface and how to manage them
Recognize the value of iterative cycles in architecture

103 System Risk Management

Understand safety, technical, and program risk and how to manage them
Understand p-Diagrams, and their value; when and how to use them
Awareness of the many common risk analyses used for medical systems
How to update a System Safety Hazard Analysis.
How to disposition discovered risks.

104 Requirements Management

Understand requirements quality and completeness checks
Awareness of EARS format
How to decompose user needs, functional architecture, and risk controls into systems requirements
Ability to include Product Quality Characteristics

*Registration for the full-day tutorial is $250 and is independent of the main conference on April 30th and May 1st.

Register now!

Conference Website

INCOSE Healthcare Working Group

Instructors

The instructors are a team of experienced MedTech Systems Engineering practitioners who have a combined 200 years of experience in systems engineering, over 100 of which are in Medical Technology Systems Engineering.

Dave Walden

Dave Walden is an Expert Systems Engineering Professional (ESEP) with over 45 years of practical experience and proven results in Systems Engineering. He has broad experience in technical leadership and corporate-level process improvement and has systems engineering consulting and instruction expertise in several domains including: agriculture & construction; automotive; biomedical & healthcare; building controls & automation; consumer goods; defense & aerospace; government departments & agencies; professional services; and universities. He was the Editor-in-Chief of the International Council on Systems Engineering Systems Engineering Handbook.

Joseph Green

Joseph Green is a Distinguished Engineer and Technical Fellow at Medtronic based in Mounds View, MN, USA. As the Chief Systems Engineer for CRM Patient Care Systems (PCS) and software he focuses on concept engineering, architecture, and risk burndown for early phase programs involving PCS platforms and products. His passion for coaching and mentoring led him to embrace the role of evangelist in driving organizational adoption of Model-Based Systems Engineering (MBSE) and Digital Engineering (DE) at CRM, Medtronic, and across the medical device industry. Joseph serves as the Medtronic representative on the Corporate Advisory Board of INCOSE.

John Vantuno

He is a self-described “Design Integrator” who has been involved in all product lifecycle phases, cradle to grave. John spent his first 10 years in the aerospace industry as a Systems Engineer at Lockheed-Martin. Seventeen years ago he transitioned to the medical device industry, working as a Systems Engineer on tumor ablation and electrosurgical generators at Covidien/Medtronic and connected drug delivery devices at Eli Lilly. John was involved in Medtronic’s annual Systems Engineering Symposiums from their inception in 2016 until 2019 when he was the chairman. At Eli Lilly, John has been championing process improvements to accommodate the company’s recent foray into system of systems (SoS) and product line engineering (PLE) product development. John Vantuno is an INCOSE Expert Systems Engineering Professional (ESEP) and holds 6 patents.

Mike Celentano

Mike Celentano has been influencing the Medical Devices sector since 1987. He has broad product development experience including but not limited to systems engineering, program management, advanced research, multi-disciplinary engineering management, prototyping, risk management, enterprise architecture, stakeholder management, system of systems, product line engineering, and directing technology portfolios. He has worked for Technicon, Miles, Bayer, Seradyn, UMM, Roche, Lilly and System Optimization Specialists, S.O.S. LLC.

Chris Unger

Chris Unger is the retired Chief Systems Engineer for GE Healthcare and the founder of Practical SE, LLC. He was responsible for the definition and improvement of systems engineering process globally. He is a member of the Chicagoland chapter of INCOSE, the co-leader of the INCOSE Healthcare WG, and the co-founder of the “Systems Engineering in Healthcare” conference. Chris has worked as a systems engineer in the defense and medical fields for 40 years. Chris is a certified Master Black Belt with fifteen issued patents and two patents applied for. He is an INCOSE certified Experienced Systems Engineering Professional. He graduated with a B.S. in Mathematics and B.S. in Philosophy from M.I.T. and a Ph.D. in Physics from Boston University. Chris is the principal at PracticalSE, LLC a systems engineering consulting company.