



Healthcare 
Working Group

5th Annual Systems Engineering in Healthcare Conference

(May 1-2, 2019)

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CONFERENCE AGENDA

May 1st

Time	1-May			
	Ballroom 1	Ballroom 2	Lindbergh	Wright
7:00	Breakfast			
8:00	Introductions			
8:30	Keynote: Gary Strong			
10:00	Break			
10:30	SE Skills and Tools Developing Systems Engineering and Systems Thinking Skills - Chris Unger, Tom Fairlie, Paul Kostek, and Juan Fernandez De Castro	Cyber Security US FDA: Working Toward More Secure Healthcare - Seth Carmody	Healthcare Delivery Human Factors Throughout the Product Design Lifecycle: Best Practices - Jeff Horvath	Agile Methods Using Lean Startup Method (LSM) and Agile for Initial Project Planning (IPP) - Michael Pafford
11:30	Analyzing Your Data for Maximum Insight - Mark Ridgley	Cyber Security Expert Panel - Exploring Risks and Solutions in Medical Device Cyber Security	The Home as a Healthcare Environment: Implications for Medical Device Design and In-Home Care Delivery - Nicole Werner	
12:00	Lunch			
13:00	Saving Cost and Schedule through Early-Phase Systems Engineering - Mark Fiebig	Medical Device Cyber Security - How Does Security Align with Quality? - Steve Abrahamsom	Case Study: Stakeholder Value Model and Compartmental Decisions Matrix - Randy Russell	(Continued) Using Lean Startup Method (LSM) and Agile for Initial Project Planning (IPP)
13:30	Getting Started with Tools and Requirements Management - Paul Kostek		Using qualitative system analysis of healthcare systems and human factors to identify opportunities for medical device design - Samuel Alper	
14:00	Mini-Break			
14:15	Challenges of Scale in Medical Device Development -or- The Care and Feeding of Design Controls, Bryan Simmons, Medela, LLC (Cognition Platinum Sponsor)			
14:45	Risk Management and Resilient Design in an Agile Setting, Joel Hutchinson, Product Manager JAMA Software (Platinum Sponsor)			
15:15	Break			
15:45	Agile Methods The Journey Continues: Scaling Agile Development Processes for Multiple Therapeutic Area Solutions - Eli Snell	Cyber Security Cyber and China - Bill Hagestad, Medtronic	Healthcare Delivery The Evils of Healthcare Fragmentation and SE Solutions at KP - Bo Oppenheim and Michael Kantor	MBSE Performing Trade-Off Analysis within an MBSE Environment - Matthew Hause
16:15	The Agilization of Roche Diabetes Care - Michael Schoemaker			Decision-Driven Product Development - Matthew Hause
16:45		(A Primer on System Threat Modeling - Dan Lyon	Impact of Value Based HealthCare on the Medical Device Industry - Michele Zoromski	SE Skills and Tools Machine Learning, Deep Learning - the Algorithms are the Sizzle, the Systems Engineering is the steak - Steve Zielinski
17:15	Day Adjourns			
17:30	JAMA Reception / Happy Hour			
19:00	Banquet			

CONFERENCE AGENDA

May 2nd

Time	2-May			
	Ballroom 1	Ballroom 2	Lindbergh	Wright
7:00	Breakfast			
8:00	Keynote: Kathy Frisbee			
9:30	Break			
10:00	Agile Methods Using System Engineering Methods in an Agile Development Framework - Kelly Weyrauch	MBSE Dynamic Systems Modeling and Simulation for Medical Device Development - Arvind Ananthan	Healthcare Delivery How Using Simulation in Healthcare Can Reduce Cost & Improve Quality - Chad Jackson	MBSE An Introduction to Model-Based Systems Engineering - Matthew Hause
11:00	Improving the Economics of the Medical Device Value Stream with Scaled Agile - Cindy Vanepps	Transitioning to MBSE for Medical Device Development - Geoffrey Cox	It is broke, how might we fix it? Systems Engineering and ECMO - Drew Pihera	
12:00	Lunch			
13:00	SE Skills and Tools Cultural Considerations for Systems Engineering in Healthcare Organizations - David Walden	MBSE MBSE and LEAN in Health Care: Leveraging Integrated Tools for In Situ Device Development - Chris Meeker	Healthcare Delivery Application of Systems Thinking in Healthcare Quality Improvement - Ajay Jayakumar	(Continued) An Introduction to Model-Based Systems Engineering - Matthew Hause
13:30	Top 10 Ways Engineers Undermine Their Own Success - Sean McCoy	Introducing Arcadia and Capella: deploying MBSE at large using an open source tool - Stephane Lacrampe and Juan Navas	Using Immersive Healthcare Simulation to Transform Practice - Stephanie Swanson	
14:00			The Future of Healthcare Through a Systems Approach - Alan Ravitz	
14:30	Break			
15:00	Unconference			
16:15	Conference Retrospectives			
16:30	Conference Adjourns			



**Keynote: So You Wanna Be a Rock 'n Roll Star;
Maximizing Your Impact as a System Engineer**

Gary Strong - CT and PET Engineering GM at General Electric, Retired

Time: Wednesday May 01, 2019, 08:30 AM

Room: Ballroom

System Engineers play a critical leadership role in the development of new products, bringing clarity and direction to ambiguity and chaos. To be a "Rock Star" Systems Engineer, you must develop your "leadership brand" in addition to learning the "tools of the systems engineering trade." In this presentation the author will share some leadership ideas and experiences that he hopes will help you be a "Rock Star" on your next project.

Gary Strong joined Goodyear Aerospace in 1984, where he led a small team in the development of a prototype cutting-edge cruise missile guidance system (algorithms, software and hardware). The team completed successful flight tests of the system in late 1988. Gary then joined GE Healthcare in 1989 as a CT System Design Engineer. He held many roles growing in responsibility, including Image Quality Systems Engineer, Project Leader of the CT Image Reconstruction team, Lead System Designer for LightSpeed QX/i (the world's first multi-slice CT) and Program Manager for several new products including LightSpeed Ultra (GE's first Cardiac CT system) and LightSpeed VCT (64-Slice CT). Gary then led the CT Engineer team's regulatory compliance efforts for 2 years, and finally led the product concept definition for Revolution CT (GE's current Super-Premium CT offering). In 2010, Gary joined GE Global Research as a Technology Leader for CT, X-Ray and Functional Imaging where he led a group of 50 Engineers and Scientists. In 2013 Gary returned to GE Healthcare as the Chief Engineer for the Detection and Guidance Solutions Business (X-ray, Interventional and Mammo products). In 2015 Gary was named Engineering General Manager for CT and PET, and led a team of over 200 engineers. Throughout his 28 year GE career, Gary played a key role in driving innovative technology into products, and in setting a culture of engineering excellence.



Keynote: The Digital Transformation of Healthcare

Kathleen L. Frisbee - Ph.D., MPH, Executive Director, Connected Health, Office of Connected Care, Veterans Health Administration (VHA), U.S. Department of Veterans Affairs (VA)

Time: Thursday May 02, 2019, 08:00 AM

Room: Ballroom

Digital technologies are rapidly transforming the way health care is delivered. There is a growing recognition that traditional health care delivery determines only a small fraction of health, and a system's virtual health strategy must address more than delivering access to care. It needs to account for the other factors that impact health - socioeconomic factors, physical environment, health behaviors, health care. The alignment of health information technologies produces a consistent experience for users, and increasing engagement means that now health depends on more than just appointments with a provider. To avoid disruption, and reduce barriers to care, old models must be updated to accommodate digital health trends and technologies, while also being prepared for what's next. The emergence of digital health has changed the way patients engage and will continue to for the foreseeable future. Digital health technologies allow for better self-management, capturing of patient-generated data, remote monitoring and communications with a specialist. Users today expect innovative options for receiving care and more convenience. Providing tools that foster user's participation in their health care, improves care coordination between health teams and users, and brings healthcare to patients when and where they need it, makes it easy for the patient to easily get the care they need and improve their quality of life.

Dr. Kathleen L. Frisbee is the Executive Director of Connected Health, under the Office of Connected Care in the Veterans Health Administration within the U.S. Department of Veterans Affairs. Dr. Frisbee is part of a leadership team charged with the effort to improve services to Veterans, their families and Caregivers by increasing access, fostering continuity and promoting patient empowerment through electronic health technologies. Dr. Frisbee has worked for the Department of Veterans Affairs for more than 25 years. Prior to her current role, she served as the Director of Web and Mobile Solutions, where she led several mobile health initiatives including Veteran and clinician mobile applications focused on supporting VHA delivery of patient-centered care. Dr. Frisbee has also served as the Special Advisor to the Chief Consultant for Patient Care Services and the Associate Deputy Under Secretary for Quality and Safety. During her tenure at VA, Dr. Frisbee has worked as the Deputy Director of the VHA Support Service Center where she developed an information management system used widely throughout the VA. She also held posts at the Austin Outpatient Clinic and the Northeast Regional Office, where she provided various levels of technical support to the offices. Dr. Frisbee received her Bachelor of Science in Pharmacy from Albany College of Pharmacy, earned a Master of Public Health from the University of Alabama at Birmingham and completed her Ph.D. degree in Engineering Management at George Washington University.

TALK ABSTRACTS

USING LEAN STARTUP METHOD (LSM) AND AGILE FOR INITIAL PROJECT PLANNING (IPP)

Author: Michael Pafford, INCOSE

Theme: Agile Methods

Time: Wednesday May 01, 2019, 10:30 AM

Room: Wright

An interactive Tutorial sharing a hybrid approach to Initial Project Planning (IPP) that uses best practices from the Lean Startup Method (LSM) and Agile Systems and Software Engineering, as well as Agile Project Management. This hybrid IPP approach was used during three IPP workshops for an ongoing Model-Based Systems Engineering (MBSE) project to develop a "Resilient Hospital Reference Model (RHRM)". The RHRM MBSE project will deliver a Reference Architecture that any hospital can use as part of a Decision Support Tool Suite to plan for continuing hospital critical operations during an extended power outage. The three RHRM MBSE IPP workshops, held at the Johns Hopkins University Applied Physics Laboratory (JHU/APL) between April and September 2018, brought together engineers, managers, and other decision makers from INCOSE, IEEE, FBI/InfraGard, and the Medical Profession. The project was given an award for "Collaboration in 2018" at the INCOSE International Workshop 2019. This Tutorial will review all the LSM and Agile steps used in the three IPP workshops that has helped the RHRM MBSE project, and will help any other system solution development project, "Get It Right, Right From the Start".

US FDA: WORKING TOWARD MORE SECURE HEALTHCARE

Author: Seth Carmody, US FDA

Theme: Cyber Security

Time: Wednesday May 01, 2019, 10:30 AM

Room: Ballroom 2

Over the last several years FDA has been working with the healthcare industry to improve the level of security in patient care. The need for effective cybersecurity to ensure medical device functionality and safety has become more important with the increasing use of wireless, Internet- and network- connected devices, portable media, and the frequent electronic exchange of medical device-related health information. In addition, cybersecurity threats to the healthcare sector have become more frequent, more severe, and more clinically impactful. Cybersecurity incidents have rendered medical devices and hospital networks inoperable, disrupting the delivery of patient care across healthcare facilities in the US and globally. To accelerate progress of security in healthcare FDA has collaborated with industry to produce guidance documents on addressing security both "pre-market" and "post-market" introduction. FDA is in the process of updating its Pre-Market guidance and is currently reviewing comments from industry as it prepares this revised guidance. The FDA approach emphasizes three key principles: Resilience, Trustworthiness, and Transparency. Resilience refers to designing devices to sustain functionality and ability to provide safe patient care in an ever increasing threat environment. Trustworthiness is a concept that encompasses ensuring that devices provide known and appropriate security features and support commitment to establish a level of trust with users of devices. Transparency is integral to risk management by allowing users of devices to understand and manage risks. Transparency is an important element of establishing trust. This discussion will explore FDA's approach toward working with industry to improve security within healthcare, and how this is reflected in the upcoming revision to their Pre-Market guidance document.

HUMAN FACTORS TESTING OF MEDICAL DEVICES: BEST PRACTICES & LESSONS LEARNED

Author: Jeff Horvath, Balanced Experience

Theme: Healthcare Delivery

Time: Wednesday May 01, 2019, 10:30 AM

Room: Lindbergh

In the health and medical domain, human factors is fundamentally about reducing the risk of harming a patient. Over the past few years, there has been a significant increase in regulatory oversight about proper human factors validation for manufacturers of medical devices and treatments. In this talk, we'll use a case study to walk through the human factors testing process. We'll talk about the FDA regulatory process and some of the unwritten rules of the game. In the case study that we'll explore, we'll talk about how what it looks like when things go well and what it looks like when they don't.

DEVELOPING SYSTEMS ENGINEERING AND SYSTEMS THINKING SKILLS

Authors: Chris Unger (GE Healthcare), Tom Fairlie (Medtronic), Paul Kostek (Base 2 Solutions) and Juan Fernandez De Castro (Beckman Coulter)

Theme: SE Skills and Tools

Time: Wednesday May 01, 2019, 10:30 AM

Room: Ballroom 1

Effective systems engineering individuals and teams combine SE skill expertise, influencing and leadership skills, and critical thinking skills. What is the right balance of technical and leadership skills, and what is the best way to develop each? What is the right balance of technical breadth and depth? Developing good systems engineers takes patience, but there are simple tools which can help. Finally, we talk about approaches to developing the systems engineering organization as a whole.

CYBER SECURITY EXPERT PANEL - EXPLORING RISKS AND SOLUTIONS IN MEDICAL DEVICE CYBER SECURITY

Authors: Seth Carmody (US FDA), Jeffrey Brown (GE Healthcare), Bill Hagestad II (Medtronic), and Steven Abrahamson (GE Healthcare)

Theme: Cyber Security

Time: Wednesday May 01, 2019, 11:30 AM

Room: Ballroom 2

Cyber security in medical devices is a primary concern of medical device manufacturers, health delivery organizations, and regulators. A variety of adverse effects can result from cyber security incidents, including patient safety risk, loss of patient data confidentiality, and loss of device availability. Threats can originate with trusted insiders, cyber criminals, and nation states. How do we establish a priority for cyber security within the healthcare ecosystem? How do we plan for long-term resilience? How has our perspective on risk changed over the last few years and how do we see it changing in the future? These questions do not have simple answers. This session will provide an opportunity to explore the challenges and opportunities within healthcare cyber security with a panel of experts with varying perspectives and experiences. Participants will be encouraged to join in the discussion and offer their own insights to these and other questions.



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THE HOME AS A HEALTHCARE ENVIRONMENT: IMPLICATIONS FOR MEDICAL DEVICE DESIGN AND IN-HOME CARE DELIVERY

Author: Nicole Werner, University of Wisconsin-Madison

Theme: Healthcare Delivery

Time: Wednesday May 01, 2019, 11:30 AM

Room: Lindbergh

Caring for medically complex patients in the home necessarily transforms the home environment. Assessing the home environment is critical because it contributes to individuals' well-being and function and affects the care that families are able to provide, both positively and negatively. Bringing medical devices into the home alters the environment from one associated with safety and comfort to one resembling the healthcare environment, which can include impersonal relations and sickness. For example, the technical aspects of managing medical devices (e.g., feeding tubes and pumps, ventilators, nebulizer machines, etc.) requires operating the machinery, maintaining sterility, and troubleshooting technical problems. Although the direct influence of the home environment itself on the health of medically complex patients and their families is poorly described, emerging research from related populations suggests the impact is considerable. A series of studies will be presented aimed to explore the physical environment of the home using a sociotechnical system framework, and how the physical environment shapes and is shaped by medical devices, health information technologies, and professional and non profession healthcare providers.

ANALYZING YOUR DATA FOR MAXIMUM INSIGHT WITH DIADEM

Author: Mark Ridgley, Radius Technologies, LLC

Theme: SE Skills and Tools

Time: Wednesday May 01, 2019, 11:30 AM

Room: Ballroom 1

We can create and collect complex data at tremendous rates, but unless we can manage and analyze that data, it's useless. In this presentation, Mark introduces you to data management and analysis software, discusses the importance of data management and analysis and introduces you to National Instruments DIADEM – a tool that enables you to quickly import, inspect and analyze your data so you can transform that data into valuable insights. This presentation also features a brief demonstration of DIADEM's capabilities to illustrate how DIADEM can be applied to a broad range of industries and application areas. Don't miss it!

MEDICAL DEVICE CYBER SECURITY - HOW DOES SECURITY ALIGN WITH QUALITY?

Author: Steven Abrahamson, GE Healthcare

Theme: Cyber Security

Time: Wednesday May 01, 2019, 01:00 PM

Room: Ballroom 2

Healthcare cybersecurity is now recognized as critical to our ability to improve the quality of healthcare and access to healthcare. Failure to effectively manage this risk can have significant adverse effect on safety of patient care, privacy of patient data, and the availability of medical devices to provide care. In May 2017 the initiation of the cyberattack known as "WannaCry" was a wake-up call to those who had been ignoring the problem. Given this level of impact, what is the relationship between Security and Quality? Is Security a set of requirements that can be addressed fully within the Quality System? How is it aligned with Quality System Regulations (e.g. US FDA 21CFR Part 820)? This session will discuss these relevant topics and how thinking on these has evolved over the last 5 years. This session will also address various perspectives on the meaning of "quality" and how an MDM can consider security as quality within an overall program of collaborative risk management within the healthcare ecosystem.

CASE STUDY: STAKEHOLDER VALUE MODEL AND COMPARTMENTAL DECISIONS MATRIX

Author: Randall Russell, Ex Nihilo Systems

Theme: Healthcare Delivery

Time: Wednesday May 01, 2019, 01:00 PM

Room: Lindbergh

Applying lessons learned from medical device technical development project informed and enabled a strategic technology initiative for realized stakeholder value in a cross functional solution design, development and implementation. Discussion of context, objectives, challenges and resolutions. Presentation of methods and analytic tools to demonstrate the optimal solution space in a constraint exposure.

SAVING COST AND SCHEDULE THROUGH EARLY-PHASE SYSTEMS ENGINEERING

Author: Mark Fiebig, Philips Healthcare - Emergency Care and Resuscitation

Theme: Systems - General

Time: Wednesday May 01, 2019, 01:00 PM

Room: Ballroom 1

Philips Healthcare Emergency Care and Resuscitation develops and markets automated external defibrillator (AED) systems and accessories. Since Philips AEDs have an array of use cases and users, from medical professionals to lay users, early-phase systems engineering is especially critical in establishing groundwork for product requirements. This presentation is a case study that highlights the benefits of upfront system engineering, specifically in determining user stories to bound a product's working environment. The case study relates to product development of an AED carrying case for aviation applications. Through discussion of the lessons learned during development, the presentation will emphasize best practices that reduce development costs, improve product quality, and minimize design iterations after release to market.

USING QUALITATIVE SYSTEM ANALYSIS OF HEALTHCARE SYSTEMS & HUMAN FACTORS TO IDENTIFY OPPORTUNITIES FOR MEDICAL DEVICE DESIGN

Author: Samuel Alper, Bold Insight

Theme: Healthcare Delivery

Time: Wednesday May 01, 2019, 01:30 PM

Room: Lindbergh

Understanding how people interact with systems can lead to better design of medical devices and connected technologies. This is because system analysis methodologies can identify situations in which people lack support within an organization or a system to some degree – and these situations often highlight user needs that are partially or fully unmet. For example, one could examine the process a patient follows leading up to surgery and note areas that are difficult for the patient. Each difficulty encountered by the patient may indicate an opportunity for a new, or an improved, medical device or connected technology to better support the patient and the healthcare system. In this presentation, we will discuss methodologies for analyzing a system and the types of insights that can come from understanding how people interact with systems.



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GETTING STARTED WITH TOOLS AND REQUIREMENTS MANAGEMENT

Author: Paul Kostek, Base 2 Solutions

Theme: SE skills and Tools

Time: Wednesday May 01, 2019, 01:30 PM

Room: Ballroom 1

In today's engineering environment the need for requirements and requirements management is a given. Good requirements help keep projects on track, ensure the needs of the customer/user are met and provide a baseline for the V&V team. A good process and tool can prevent scope creep as changes are managed and traced. This talk will describe best practices in getting started with requirements management tools. While many tools are introduced as silver bullets, the reality is the introduction of a process and tool takes time, effort to learn, and impacts processes. Schedules will likely expand and not compress on the first project to use a tool. I'll walk through an example of how introducing SE can help a company focus on results and create an efficient process to document projects and build the required deliverables (DHF/DMR) to support an FDA audit.

CHALLENGES OF SCALE IN MEDICAL DEVICE DEVELOPMENT -OR- THE CARE AND FEEDING OF DESIGN CONTROLS

Author: Bryan Simmons, Medela, LLC (Sponsored by Cognition)

Theme: Sponsor

Time: Wednesday May 01, 2019, 02:15 PM

Room: Ballroom

Many factors with broad scale can affect the systems approach to developing and marketing medical device products. These include organizational size and maturity, device risk profile, device complexity, product volume, product market and others. Recognizing these factors and applying simple principles can help the systems engineer foster an environment for the timely and economic development of high-quality cost-effective medical device products.

RISK MANAGEMENT AND RESILIENT DESIGN IN AN AGILE SETTING

Author: Joel Hutchinson, Product Manager JAMA Software

Theme: Sponsor

Time: Wednesday May 01, 2019, 02:45 PM

Room: Ballroom

With a high cost to failure and increasing complexity, System Engineers in a medical and healthcare setting have a unique opportunity to advance the traditional Risk Management process with a Systems of Systems approach and incorporate Resilient design into their models. We'll tackle best practices for doing Risk iteratively and accounting for resiliency, human factors, cybersecurity and other challenges. The audience will learn:

- Best practices for incorporating Risk Management into your Agile systems approach
- Approaches to Resiliency and challenges to extending the traditional approach to Risk Management
- How to remove silos and tunnel thinking when considering Risk in a Systems of Systems context

THE JOURNEY CONTINUES: SCALING AGILE DEVELOPMENT PROCESSES FOR MULTIPLE THERAPEUTIC AREA SOLUTIONS

Author: Eli Snell, Proteus Digital Health

Theme: Agile Methods

Time: Wednesday May 01, 2019, 03:45 PM

Room: Ballroom 1

A few years ago, Proteus Digital Health embarked on a journey of agile transformation. We developed processes that were compliant with regulations and standards and that aligned with agile principles to develop our Discover product, a digital medicine platform. Now, we face a challenge of scale. We need to develop multiple therapeutic area solutions in parallel and continue to invest in a configurable platform to support additional solutions in the future.

21ST CENTURY CHINESE CYBER WARFARE

Author: Bill Hagestad II, Medtronic

Theme: Cyber Security

Time: Wednesday May 01, 2019, 03:45 PM

Room: Ballroom 2

21st Century Chinese Cyber Warfare will provide the audience with a firsthand, field-experienced view into the People's Republic of China's use of networked systems as a strategic weapon system. The Chinese call it the "Chinese Dream", as of late, China's President Xi Jinping is advocating for Made in China 2025 - audience members will learn about the political, cultural, historical and linguistics facets that comprise China's Quest for Informatization. Key elements of China's Informatization strategy will be covered including the People's Liberation Army's combined cyber arms capabilities; the secretive Ministry of State Security (MSS) 1,000 China Experts Plan and of course the cyber espionage efforts of State Owned Enterprises such as Huawei and ZTE. Mr. Hagestad will bring you face to face with Chinese hackers based within the People's Republic of China. You will never leave your computer unlocked after this exciting presentation 21st Century Chinese Cyber Warfare.

THE EVILS OF HEALTHCARE FRAGMENTATION AND SE SOLUTIONS AT KP

Authors: Bohdan Oppenheim, Loyola Marymount University and Michael Kanter, Kaiser Permanente

Theme: Healthcare Delivery

Time: Wednesday May 01, 2019, 03:45 PM

Room: Lindbergh

The presentation will describe the evils of fragmentation in healthcare and will demonstrate solutions in both smaller reactive care situations using selected SE tools, as well as the "big bang" approach to integration of preventive and chronic care at Kaiser Permanente using the "Complete Care" approach.



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PERFORMING TRADE-OFF ANALYSIS WITHIN AN MBSE ENVIRONMENT

Author: Matthew Hause, PTC

Theme: MBSE

Time: Wednesday May 01, 2019, 03:45 PM

Room: Wright

A trade-off study consists of “comparing the characteristics of each system element and of each candidate system architecture to determine the solution that best globally balances the assessment criteria. The various characteristics analyzed are gathered in cost analysis, technical risks analysis, and effectiveness analysis.” (NASA 2007). Trade-off analysis is the set of techniques by which the “Best” solution is found for the customer weighing up cost, risk, effectiveness and other parameters. The weighting or importance of these parameters depends on the system goals and priorities, which are derived from stakeholder needs, which are gathered from stake-holders. As always good system solutions are derived from good systems engineering. Defining a decision framework that reflects competing goals, needs, priorities, parameters and architectures in a clear and understandable way. Orthogonal Variability Modeling (OVM) provides the ability to model systems and software products, their variation points, mutual exclusions, and product dependencies resulting in product lines. Through this modeling technique, fully supported by the MBSE toolset, engineers can see their options and conflicts, (if any exists), and to pick their end desired product. Options can then be selected based on user goals, a configuration generated, and trade-off analysis can take place on the resulting model using analysis techniques such as simulation, comparison with physical systems and physics based analysis tools.

THE AGILIZATION OF ROCHE DIABETES CARE

Authors: Michael Schoemaker and Brad Markisohn, Roche Diabetes Care

Theme: Agile Methods

Time: Wednesday May 01, 2019, 04:15 PM

Room: Ballroom 1

Due to the high levels volatility in our environment, Roche Diabetes Care is taking the initiative to move from a traditional development model to Agile. While the initial focus is on R&D, changes are happening across the organization with many areas outside of R&D looking for ways to participate in agility. This talk will focus on:

- Factors driving change
- Our path towards agility
- Challenges and successes

DECISION-DRIVEN PRODUCT DEVELOPMENT

Author: Matthew Hause, PTC

Theme: MBSE

Time: Wednesday May 01, 2019, 04:15 PM

Room: Wright

Product Line Engineering (PLE) is the engineering and management of a group of related products using a shared set of assets and a means of design and manufacturing. PLE can include system and software, assets and involves all aspects of engineering including electrical, electronic, mechanical, chemical, etc. PLE is normally considered after the product has evolved and complexity becomes too much to manage. Leveraging PLE from the very beginning will identify cost savings and commonality and provide a natural means for product evolution. Orthogonal Variability Modeling (OVM) provides a natural decision set allowing engineers to perform trade-offs for specific customers and guide system development along the most effective route. This paper will describe Model-based Product Line Engineering, the process for creating product lines, and the benefits of this approach. Finally, it will show how the adoption of MB-PLE early on in the development lifecycle provides more benefits without the potential disruption and re-engineering that can be involved when it is adopted later on in the lifecycle.

A PRIEMER ON SYSTEM THREAT MODELING

Author: Dan Lyon, Synopsys

Theme: Cyber Security

Time: Wednesday May 01, 2019, 04:45 PM

Room: Ballroom 2

Threat modeling is an activity that is required to ensure systems are designed with security in mind, yet there are many different definitions for 'threat modeling'. This session will provide an overview of threat modeling methodologies as well as a deeper view of Synopsys' threat modeling methodology. Attendees will learn the importance why security is a systems problem and how to decompose a system into a security architecture that can be analyzed for potential weaknesses.

IMPACT OF VALUE BASED HEALTHCARE ON THE MEDICAL DEVICE INDUSTRY

Author: Michele Zorowski, m.zoro Consulting LLC

Theme: Healthcare Delivery

Time: Wednesday May 01, 2019, 04:45 PM

Room: Lindbergh

Delivery of Care is quickly changing from a fee for service to fee for outcome known as Value Based Care. This will have an enormous impact on the medical device industry and the products that we develop, how we market, and how we sell. More stakeholders (patient, physician, hospital, insurers, CMS, caregivers...) compels us to understand the real needs and values so that we can deliver products that provide the desired improved patient outcomes. It is truly a systems of systems challenge. This presentation provides a look at the changing landscape. It includes actual case studies and industrial examples providing a lens into the impact of this change. We will discuss current strategies and tactics and future trends.

MACHINE LEARNING, DEEP LEARNING - THE ALGORITHMS ARE THE SIZZLE, THE SYSTEMS ENGINEERING IS THE STEAK

Author: Steve Zielinski, Boston Scientific

Theme: Systems - General

Time: Wednesday May 01, 2019, 04:45 PM

Room: Wright

This presentation will focus on the role systems engineers play in the creation of AI/Machine Learning/Deep Learning systems. Machine learning models are becoming table stakes in the healthcare field. Are you ready? The headlines declaring the next advance in AI/Machine Learning/Deep Learning for healthcare are frequent and attention grabbing. The articles beneath the headlines typically focus on the architecture of the neural network that generated the results. What is frequently missing is a description of the system needed to generate the data, train the network, and evaluate the results. This presentation will cover some of the basics of machine learning and deep learning (neural network architectures, the back propagation algorithms) and then move on to describe the systems that must be in place to train, maintain, and evaluate the central algorithm. We'll discuss the role of systems engineers in constructing this ecosystem. We'll also talk about some of the cutting edge examples of AI/ML/DL in healthcare.



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THE DIGITAL TRANSFORMATION OF HEALTHCARE

Author: Kathy Frisbee, Veteran's Health Administration

Theme: Keynote

Time: Thursday May 02, 2019, 08:00 AM

Room: Ballroom

Digital technologies are rapidly transforming the way health care is delivered. There is a growing recognition that traditional health care delivery determines only a small fraction of health, and a system's virtual health strategy must address more than delivering access to care. It needs to account for the other factors that impact health - socioeconomic factors, physical environment, health behaviors, health care. The alignment of health information technologies produces a consistent experience for users, and increasing engagement means that now health depends on more than just appointments with a provider. To avoid disruption, and reduce barriers to care, old models must be updated to accommodate digital health trends and technologies, while also being prepared for what's next. The emergence of digital health has changed the way patients engage and will continue to for the foreseeable future. Digital health technologies allow for better self-management, capturing of patient-generated data, remote monitoring and communications with a specialist. Users today expect innovative options for receiving care and more convenience. Providing tools that foster user's participation in their health care, improves care coordination between health teams and users, and brings healthcare to patients when and where they need it, makes it easy for the patient to easily get the care they need and improve their quality of life.

USING SYSTEM ENGINEERING METHODS IN AN AGILE DEVELOPMENT FRAMEWORK

Author: Kelly Weyrauch, Agile Quality Systems, LLC

Theme: Agile Methods

Time: Thursday May 02, 2019, 10:00 AM

Room: Ballroom 1

Agile development methods are not just for software. The value from Agility can be achieved in the development of any system, including big-system development that also gets value from applying system engineering methods. At this interactive session we will discuss systems engineering methods are applied with the Agile development framework. This is for Agile proponents (Coaches, ScrumMasters, organizational leaders) and product development leaders (Systems Engineers, Hardware and Software Engineers, and Product Quality Engineers) who want to realize the value of Agile methods and Systems Engineering concepts working well together.

HOW USING SIMULATION IN HEALTHCARE CAN REDUCE COST & IMPROVE QUALITY

Author: Chad Jackson, American College of Chest Physicians

Theme: Healthcare Delivery

Time: Thursday May 02, 2019, 10:00 AM

Room: Lindbergh

This presentation will detail how the American College of Chest Physicians has used creativity and discipline to develop true innovation in medical education over the past 11 years to improve the practice of 21,000 its pulmonary, critical care and sleep physician members. Over the last decade and more, CHEST has engineered and created in its two Innovation Laboratories, software integrations and hardware solutions where none have existed, filling the gap in commercially available products to allow increased educational and training opportunities for lung health professionals in training and practice. Using a mix of internally developed low, medium and high fidelity simulation as well as novel training techniques such as gamification, virtual and augmented reality, to reduce the cost of training physicians and advanced practice professionals, which in turn has allowed them to improve their practice, and ultimately improve patient outcomes. This presentation will be presented by Chad Jackson, MS, RRT, FCCP who is the Chief Innovation Officer and Vice President of Market Growth for CHEST.



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DYNAMIC SYSTEMS MODELING AND SIMULATION FOR MEDICAL DEVICE DEVELOPMENT

Author: Arvind Ananthan, MathWorks

Theme: MBSE

Time: Thursday May 02, 2019, 10:00 AM

Room: Ballroom 2

Complexity is one of the predominant challenges in modern systems engineering and embedded software development. Traditional software development, V&V, and testing methods haven't been able to keep up with the complexity of devices that span multiple domains (SW/mechanical/electrical/fluidic). Model-Based Design and Systems Engineering is considered a 21-century answer to the challenges of adding electronics, control, and embedded software to formerly mechanical designs. In this technical talk, we'll see how dynamic system simulation can help engineers understand and iterate on requirements and behavior of a complex multi-domain software controlled medical device using real-world examples such as emergency bed, neo-natal ventilator, pulley-based surgical instrument, and an infusion pump. Various system/software V&V steps, required as part of FDA or IEC certification process, is integrated within this agile approach wherein requirements traceability, coverage analysis, unit testing, etc. can be performed much earlier in the design cycle (on models and generated code) while documentation of these V&V results is automated through report generation.

AN INTRODUCTION TO MODEL-BASED SYSTEMS ENGINEERING

Author: Matthew Hause, PTC

Theme: MBSE

Time: Thursday May 02, 2019, 10:00 AM

Room: Wright

The purpose of this tutorial is to give an overview of MBSE, its history, goals, and SysML modeling techniques for system engineering activities on a variety of project types and sizes. This will include case studies on best practice, lessons learned and actual ROI from government and industry organizations. It will also have an overview of the Systems Modeling Language (SysML) and Enterprise Modeling. Group exercises will take place after the presentation of each set of concepts to ensure that students understand the concepts. Part 1 : Introduction to MBSE: What is it and why should I care?; MBSE Tools; MBSE and Process Part 2: Model-Based Systems Engineering with SysML: Introduction; SysML Model Elements; Requirements Modeling; Use Case Modeling; Activity Modeling; Blocks and Block Diagrams; Ports and Interfaces Part 3: Interaction Modeling; State Machines; Parametrics; Cross-cutting Constructs; Integration with Requirements Management; Product line Engineering; Summary

IMPROVING THE ECONOMICS OF THE MEDICAL DEVICE VALUE STREAM WITH SCALED AGILE

Author: Cindy Vanepps, 321 Gang, Inc

Theme: Agile Methods

Time: Thursday May 02, 2019, 11:00 AM

Room: Ballroom 1

In a safety-critical system with stringent compliance, complex solutions and contribution by many skill sets and perspectives, why would we consider changing the way we deliver and support our system? When we discuss the economics of agile practices for such systems, the result is often interpreted as cutting corners and therefore introducing risk. This session refutes that interpretation with our practical experiences as well as the science behind the economics.



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IT IS BROKE, HOW MIGHT WE FIX IT? SYSTEMS ENGINEERING AND ECMO

Authors: Drew Pihera, Nicholas Bollweg, Georgia Tech Research Institute and Matthew Paden, Children's Healthcare of Atlanta

Theme: Healthcare Delivery

Time: Thursday May 02, 2019, 11:00 AM

Room: Lindbergh

Extracorporeal membrane oxygenation (ECMO) is a life-saving therapy providing heart and/or lung support when conventional methods have failed and risk of death is high. This conceptually simple technique can improve survival from 25% to nearly 75%, however it is complex to implement, and many patients suffer complications including procedure-related death. Though ECMO has been used since the 1970's on over 100,000 patients, there remains no purchasable ECMO device. The implementation is not standardized, nor FDA approved, and individual centers providing the therapy perform it in a locally dictated manner. Lack of standardization leads to expensive in-house development of execution methods and center-specific tribal knowledge of procedures and systems. This presentation describes ECMO therapy, a selection of human-systems concerns through moments in its history, possible paths for standardization, and potential and realized cost saving opportunities that systems engineering can afford.

TRANSITIONING TO MBSE FOR MEDICAL DEVICE DEVELOPMENT

Author: Geoffrey Cox, Stryker

Theme: MBSE

Time: Thursday May 02, 2019, 11:00 AM

Room: Ballroom 2

Any change in methodology presents challenges. The transition from document based systems engineering to MBSE using SysML has been no exception to the rule, as companies across multiple industries have had mixed results. This presentation discusses the challenges that are common and those that are unique to medical device development. Methods are proposed to monitor and manage the challenges during the transition and beyond.

APPLICATION OF SYSTEMS THINKING IN HEALTHCARE QUALITY IMPROVEMENT

Author: Ajay Jayakumar, Mayo Clinic

Theme: Healthcare Delivery

Time: Thursday May 02, 2019, 01:00 PM

Room: Lindbergh

Quality has many dimensions within the domain of healthcare provision. Quality can be explored from the perspective of patient safety, experience and outcomes. It is critical to understand how quality is measured in healthcare in terms of structure, process and outcomes (Donabedian model). Healthcare quality is of high significance and the improvement required to ensure the best healthcare delivery across numerous settings is leveraged by systems thinking.

CASE STUDY OF MBSE IN HEALTH CARE: SYSTEMS MODELING DRIVES STAKEHOLDER ENGAGEMENT FOR EARLY VALIDATION, ROBUST REQUIREMENTS AND RAPID PROTOTYPING

Author: Chris Meeker, Dassault Systemes

Theme: MBSE

Time: Thursday May 02, 2019, 01:00 PM

Room: Ballroom 2

This presentation will use a recent case study to illustrate the value of system modeling for device development in a hospital setting. A process improvement initiative within a hospital had identified the need for a new tool in a laboratory, but couldn't find any existing equipment that met their needs. The process owners had created two potential concepts and were struggling to make them tangible, so they reached out to a Systems Engineer. After translating their initial requirements and concepts into virtual systems models of the designs and operational contexts, the team leveraged model-based systems engineering to engage end-users and other stakeholders in rapid, iterative design development and validation cycles. By modeling and tracing requirements with functional and physical architecture, they quickly clarified original requirements, elicited and incorporated additional requirements, and validated highly refined, ergonomic designs that were 3D-printed and use-tested in the laboratory. The results are a powerful example of how model-based systems engineering can engage stakeholders, driving early and effective product development.

CULTURAL CONSIDERATIONS FOR SYSTEMS ENGINEERING IN HEALTHCARE ORGANIZATIONS

Author: David Walden, Sysnovation, LLC

Theme: SE skills and Tools

Time: Thursday May 02, 2019, 01:00 PM

Room: Ballroom 1

In many healthcare organizations, systems engineering represents a cultural shift from "the way things have always been done" to a fundamentally new way of thinking. This is similar to the cultural shift that mechanical-heritage organizations need to take place from a parts-based, manufacturing culture to a development-based, systems engineering culture. This presentation will discuss the potential conflicts between two healthcare cultures and systems engineering: - Science vs. Systems Engineering - Compliance vs. Systems Engineering First, the key elements of each culture will be examined. Then, these cultures will be contrasted with the cultural aspects of effective systems engineering. Suggestions to overcome these cultural issues will also be discussed.

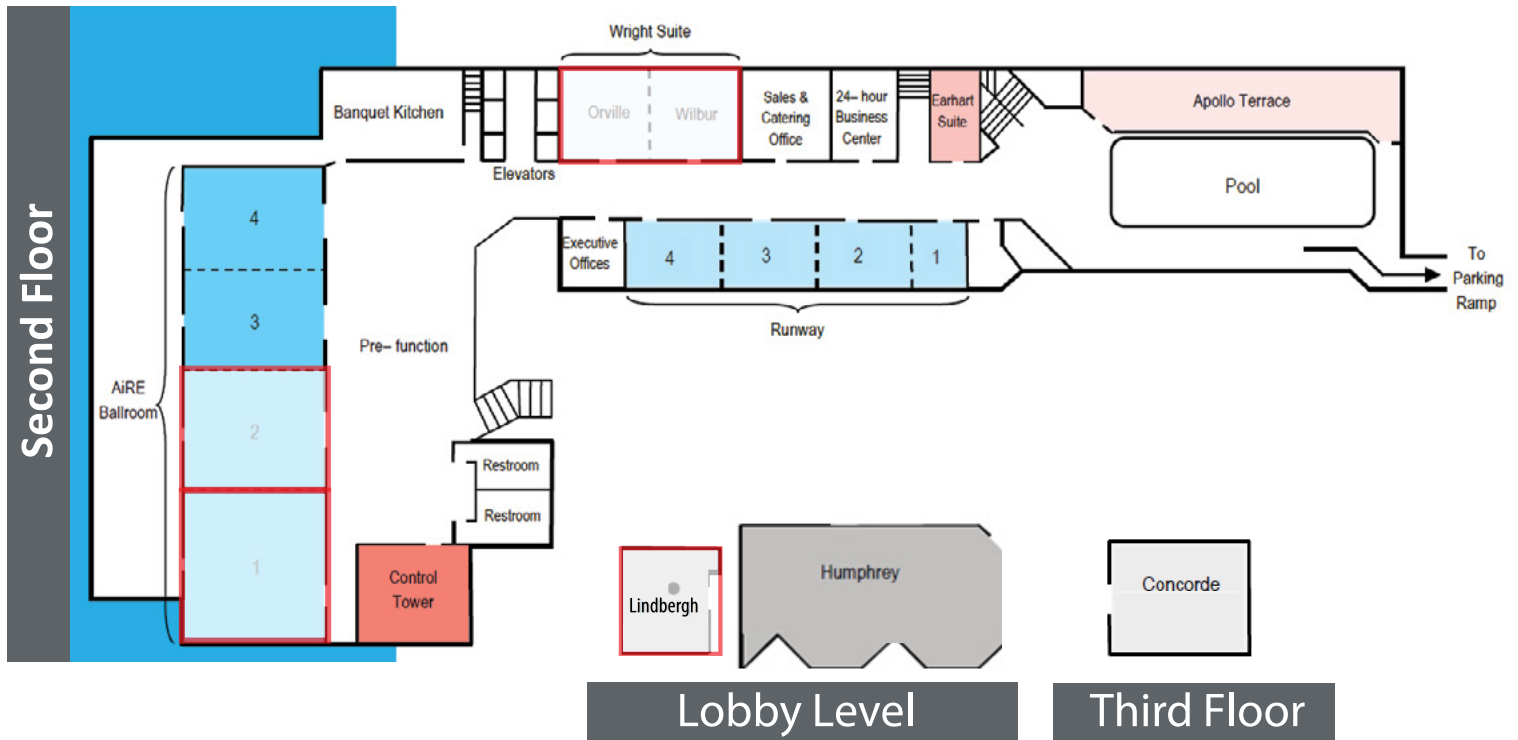


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MEETING ROOMS



SCHEDULE

1-May			
Ballroom 1	Ballroom 2	Lindbergh	Wright
Breakfast			
Introductions			
Keynote: Gary Strong			
Break			
Healthcare Delivery	Cyber Security	SE Skills, and Tools	Agile Methods Tutorial
Lunch			
Healthcare Delivery	Cyber Security	SE Skills, and Tools	Agile Methods Tutorial (continued)
Break			
Sponsor Presentations			
Break			
Healthcare Delivery	Cyber Security	Agile Methods	SE Skills, and Tools / MBSE
Day Adjourns			
JAMA Reception / Happy Hour			
Banquet			

2-May			
Ballroom 1	Ballroom 2	Lindbergh	Wright
Breakfast			
Keynote: Kathy Frisbee			
Break			
Healthcare Delivery	MBSE	Agile Methods	MBSE Tutorial
Lunch			
Healthcare Delivery	MBSE	Agile Methods	MBSE Tutorial (Continued)
Break			
Unconference			
Conference Retrospectives			
Conference Adjourns			

PROGRAM COMMITTEE:

Cary Bryczek , Kendra Kreutz, Marc Horner, Phyllis Larson, Bob Malins, Mark Ridgley, Ajay Thukral, Vijay Thukral, Chris Unger (Co-chair), Beth Walden, Kelly Weyrauch (Co-chair), and Michele Zoromski.

WEBSITE:

<https://www.incose.org/hwg-conference-2019/>

PROGRAM DESIGN:

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