INCOSE
Healthcare Working Group

4th Annual Systems Engineering in Healthcare Conference

April 19-20
Minneapolis, MN

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Agile Quality Systems

INCOSE Conference Abstracts

Establishing a System for Medical Device Security Risk Management

Steven Abrahamson, GE Healthcare, Mike Seeberger, Boston Scientific, Matt Russo, Medtronic, Bill Hagestad, Smiths Medical

Managing security risk within medical devices is a complex problem with significant implications within the global healthcare infrastructure. 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. This problem can best be solved by viewing security as a system encompassing various disciplines including engineering, quality, regulatory, product management, and others. Furthermore, this system must encompass multiple manufacturers, healthcare delivery organizations, regulators, and other stakeholders. This panel of industry experts will discuss best practices in developing a system of medical device security.

Designing Secure Medical Devices

Ken Hoyme, Boston Scientific, Rick Brooks, Battelle

A secure medical device must start with a considering security within the design and development of a device. Risk management standards can be used as an approach for assessing risks and applying appropriate security controls to manage those risks. Effective implementation of the controls, and secure development practices will help ensure that the device can be securely operated while providing patient care. This session will focus on industry best practices for applying these techniques.

Security Assurance and Vulnerability Disclosure

Matt Russo, Medtronic, Bill Hagestad, Smiths Medical

Medical device security does not end when a product is designed and manufactured. Anticipating management of security risk throughout the useful life of the device is perhaps the most important element of the security risk management system. For a device to be operated securely, it must be free of vulnerabilities that may provide a threat actor the opportunity to compromise the device or hospital network in some way. The manufacturer must ensure that prior to delivery to a customer, the device goes through an assurance process to identify and remediate any vulnerabilities. Then, during the life of the device, the manufacturer must actively monitor for any newly identified vulnerabilities and manage these within the installed base via a responsible process for disclosure and remediation. This session will look at some best practices that have been applied by leading medical device manufacturers.

A Shared Responsibility - Securing Connected Medical Devices

Mike Nelson, Digicert

In recent years, as cybersecurity has increased in importance due to public disclosures of medical device vulnerabilities, many in the industry are asking whose responsibility is it to secure the millions of connected devices coming into the healthcare ecosystem? In this presentation, Mike will discuss why securing medical devices needs to be a shared responsibility and will discuss what healthcare providers and medical device manufacturers are doing to secure these devices.

Eric Cosman, OIT Concepts LLC

Cyber Security for Automated Health Care Systems

The health care industry employs an increasingly complex portfolio of automated devices and systems for diagnosis, patient monitoring, and treatment. These systems are assembled using sophisticated networks for information sharing and control.

The information contained in these systems, and the technologies employed, make them susceptible to a variety of cyber-related risks. Mitigation of these risks requires combination of reduction of removal of vulnerabilities and application of compensating countermeasures. This is possible through the application of comprehensive cybersecurity standards.

Such standards have been developed for industrial automation and control systems. These standards can also be applied in any of several other industries, including medical care.

This presentation describes the application of the ISA-62443 and IEC 62443 international standards to medical systems, using a combination of context-specific interpretation and assessment of implications for key roles.

Scaling Agile to the Enterprise – Pitfalls and Practices addressed with the Scaled Agile Framework

Doug Stewart, 321 Gang Inc.

Agile is seen, correctly, as a means to achieving better results developing Software and in Systems development. In the small, agile practices and defined methodologies have been supporting good results for over a decade. As practices are scaled to value stream, portfolio, and enterprise levels each organization struggles at the point of including groups like Human Resources, Finance, Business Controls, and Compliance. This presentation will describe practices to address these growing pains with the Scaled Agile Framework and with more traditional agile methodologies.

Industrialized Agile Quality: Leveraging ISO Standards to Deliver Business Agility with World Class Quality

Robert Gormley and Chad Simonson, Trissential/SQS USA

Digital disruption pushes healthcare organizations into becoming more nimble in the marketplace. By intelligently leveraging ISO16085, ISO25010, and ISO25012 to focus quality goals around product quality, quality in use, and data quality in the context of risk, healthcare organizations can solve the challenge of business agility without sacrificing quality. In this presentation, we learn about each of these standards and how to pragmatically apply them in the development of your industrialized agile quality process.

Agile Product Development for Digital Medicines

Eli Snell, Proteus Digital Health

Proteus Digital Health invented Digital Medicine, a new category that measures medication treatment effectiveness, helps physicians improve clinical outcomes and patients reach health goals. Together, with leading health systems and pharmaceutical companies, we're bringing this new digital solution to healthcare providers, thereby increasing access to better insight, optimized therapies and lower costs.

Two years ago, we embarked on a journey to redefine our product development practices to adopt agile principles and ensure compliance with relevant regulations, standards, and guidance. This session describes the journey to an agile product development life cycle for the development of digital medicines at Proteus.

TerumoBCT's Agile Journey

Wayne Phillips and Megan Morgan, TerumoBCT

TerumoBCT is a leader in Blood Component Technology. As a technology software organization in the health care industry, TerumoBCT operates within a closely defined regulated environment through entities such as the FDA and other regulatory agencies. In order to improve transparency and predictability during software development while maintaining a high level of quality, TerumoBCT has sought to improve all aspects of software development through the adoption of Agile Software Methodology. This is our story.

Use of Agile & Lean methods to develop X-Ray Analytics Application

Mohamed Ali Hamadeh, GE Healthcare

The presentation will describe how we used Agile & Lean methodology to design, develop, test and deploy an "early version" of the X-ray analytics application at a beta customer site. The application allows radiologists to quantify and measure the rate at which X-ray images are rejected and the reason for those rejects.

We then describe how early deployment within a clinical environment (Radiology department at an academic institution) proved essential to: 1. Identify specific installation challenges not exposed in engineering (networking, security) 2. Test the scalability of the application to handle data volumes in a healthcare facility.

3. Get 1st hand customer feedback & insights regarding additional features and improvements to existing one to address end user needs.

We then describe how items above were accounted for and addressed in a 1st commercial release of the application.

Agile – Stage Gate Management (ASGM): NPD Implementation practices from global firms developing complex, physical products

John Salvato, Michigan Technological University

Global firms that design and manufacture physical products have used traditional Stage Gate frameworks to manage New Product Development (NPD) for years. Recently, some of these firms have adopted Agile techniques, long used in the IT and Software worlds, in an attempt improve NPD performance. A sneak peak of a ground-breaking study to inductively develop theory from qualitative interview data on how firms manage NPD using ASGM for physical products delivers insights to the implementation practices.

Aligning the Language of Systems Engineering and Agile

Kelly Weyrauch, Agile Quality Systems LLC

It's been said for a long time that Agile is not just for Software, yet hardware and big-systems companies are slow to adopt Agile methods. Part of the problem is language - the language of Agile is well-established for software, but in the domain of big-systems development, Agile models are sometimes viewed as contrary to the guidance provided by the ISO 15288 Systems Engineering Standard. At this session we will explore how the language of Agile and Agile scaling frameworks can align with the methods of Systems Engineering. 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.

Non-Functional Requirements (NFR) in Agile

Balasubramanian Swaminathan, GE Healthcare Digital

Nonfunctional Requirements (NFRs) describe aspects of the system that do not map onto a single piece of functionality. Essentially, they're constraints you need to operate within. System attributes such as security, reliability, performance, maintainability, scalability, and usability. They serve as constraints or restrictions on the design of the system across the different backlogs. Nonfunctional requirements are critical as Business requirements like epics, features, and user stories. They ensure the usability and effectiveness of the entire system. Failing to meet any one of them can result in systems that fail to satisfy business, user, or market needs, or regulatory needs.

Modeling and Simulation at GE Healthcare

Chris Unger, GE Healthcare

This paper gives an overview of the state of system modeling at GE Healthcare. We describe the intermediate term vision and the gaps that exist today. Several example applications of computed modelling for medical devices from different domains are presented, along with benefits achieved (faster development, reduced iterations, higher quality, and lower cost designs). The challenges we have faced in introducing more comprehensive approach to systems modeling are discussion, along with recommendations some evolving standards that may help to frame the organizational challenges.

Closing the Loop on Medical Device Systems Simulation

Marc Horner, ANSYS, Inc.

Great products are composed of great individual components that are increasingly assessed from every possible physical perspective. But optimally designed components do not necessarily result in optimal systems. Computational modeling is recognized by both industry and regulatory agencies as an alternative to physical testing, but has historically been used in silos with minimal collaboration between various design disciplines and engineering departments. The rise of multi-domain, system simulation and digital prototyping platforms are enabling multi-specialty teams with diverse backgrounds to work in unison to achieve a deep understanding of integrated product behavior. A multi-domain model of the drug delivery sub-system of an insulin pump has been developed and will serve as an example of the potential for digital collaboration to transform the product development process.

The Medical Device Digital Thread

Matthew Hause, PTC

The INCOSE Integrated Systems Engineering Vision 2025 describes how future systems engineering tools will facilitate systems engineering practices as part of a fully integrated engineering environment. The Systems Engineering Modeling Language Version 2 (SysML V2) initiative at the OMG envisions a systems engineering eco-system where the different tools interoperate and work together to achieve unified product development throughout the engineering and product lifecycle. A shift towards an integrated, digital engineering environment enables rapid transformation of concepts and designs to digitalized virtual prototypes and then to physical prototypes through the application of additive manufacturing technologies, such as 3D printers. Implementing this vision will require an integrated suite of tools, technologies, and standards to support the full systems engineering and product lifecycles from requirements to design to implementation and maintenance. MBSE models are digital and executable, and using a simulation engine, they can shift risk towards early stages of project development as the asset can be tested before it is built. IoT allows us to convert physical assets to virtual information. MBSE can be used to fuse the gap between the physical and the virtual, allowing comparison and analysis between the physical systems and their virtual counterparts in real-time. This creates an opportunity to blend the two, into what we might call the Digital Asset or Digital Twin; a physical system tightly-coupled with a digital replica, and associated digital tools. Once connected and integrated, we can then migrate functions from the physical to the digital to reap benefits. Having a digital counterpart or equivalent of the system opens the door to performance optimization through emulation and simulation, without putting the real assets at risk. Service Lifecycle Management (SLM) solutions combine IoT platform technology with service solutions. Together, these comprise an integrated closed loop systems engineering toolset. This presentation will describe this digital thread using a medical device example.

Model Credibility for Embedded Control: Applying ASME VnV40

William Schindel, ICTT System Sciences, and Marc Horner, ANSYS, Inc.

This talk will discuss a white paper being authored to illustrate the applications of ASME VnV40 to medical devices that include embedded control. There is an historical subject of control systems applied in uncertain situations, but our subject here is uncertainty, risk, credibility as they apply to the model of the resulting system. VnV40 provides a set of related principles, and this discussion summarizes how they apply whenever embedded control is part of the subject system.

Systems Design Decisions for Medical Devices: What Makes them Difficult?

Chris Unger, GE Healthcare

The panelists will discuss their organization's approaches to systems decisions and trade studies. Systems design decisions are inherently cross-functional; which therefore means that the boundary between systems decisions, business decisions, and pure 'functional' decisions is ambiguous. Also, systems decisions inherently involve tradeoffs and sub-optimizing some stakeholder's needs, which makes closure problematic. Finally, the level of process and documentation rigor should be tailored to the decision, and how to do that is unclear. While the panel presents the audience's problem statements will be collected and assessed.

Bridging the Gap Between Research and Practice: Building an Enterprise Knowledge Translation System to Optimize Military Healthcare

Aaron Sawyer, Engility

The Military Health System (MHS) is a complex and global enterprise comprised of research and development, provider education and training, and operational environments ranging from hospitals to austere field settings and combat zones. Engility's Knowledge Translation (KT) capability seeks to bridge the gap between research and practice in the MHS by detailing organizational processes and pathways to maximize efficiency, optimize and integrate health care practice, and make data-informed decisions. Systems engineering (SE) approaches provide a way to overlay and infuse KT best practices across MHS's fragmented collection of systems to drive efficiency and get evidence-based tools to providers faster. Substantial changes are underway to centralize and integrate many parts of the MHS under the Defense Health Agency (DHA), including deployment of a new electronic health record system which will enable data-driven decision making. However, most of these changes are siloed within vertical organizational units, and there is no enterprise system by which to integrate across the MHS. We are mid-way through a multi-year e ort to deliver an enterprise system of systems infrastructure to meet this need. Thus far, we have developed a comprehensive KT model and tested it within one segment of the organization. To scale that e ort, we are employing model-based systems engineering tools and will be running enterprise scenario testing to arrive at a well-defined, data-driven system of systems to enable research-practice integration. This presentation will provide an overview of this work, share lessons learned to date, and discuss applicability to other large health systems.

A Systems Design Control Process for Medical Device Software Development

Joseph Akyeampong and Erik Arthur, Medtronic

The need to make healthcare accessible to more people and the demand for more personalized treatment are among the factors pushing the medical device market and expanding technologies. As healthcare technologies advance, software has become an important part of healthcare products, integrated widely into digital platforms that serve both medical and non-medical purposes. These advancements place pressure on medical device manufacturers to accelerate design and production to get products to market safely, efficiently, and effectively. This presentation focuses on a Systems Engineering design process based on the FDA Design Controls for developing new medical device software for Medtronic's neuromodulation medical devices, with the aim of providing a design template for effective medical device software development.

Improving Operating Room Design Through Innovative Systems Engineering Methodology

Anthony Millan, Johns Hopkins University

In traditional operating room design, independently developed components are federated into a system that satisfies the wide range of users' needs. However, this approach comes with interoperability, scalability and adaptability challenges, and yields systems that are not optimized for top-level functionality. Shifting the focus of operating room design using a systems architecting perspective allows the designer to address these issues at the system level and before the individual components are selected. This presentation will highlight ongoing research that explores how a design method developed to revolutionize military systems engineering could be leveraged to improve operating room design as well as other fields, and discuss future research opportunities to apply these concepts to real design problems. Participants are invited to join the discussion to share ideas that could shape future research in operating room optimization from a systems architecting perspective.

System Impact Analysis - A Systems Engineering Best Practice for Change Management

RV Krishnan, SysThink Medical

Nearly all systems in the healthcare and medical device domain undergo changes in their lifetime. The changes are often large and they can get increasingly complex in the case of major enhancements to an existing system. Have you ever been impacted by a change that caused unexpected complications that lurked below the surface? Have you been asked to estimate the e ort for a change proposal that rippled across multiple parts of the system? Have you been challenged to optimize your testing of a change without compromising quality and also provide a sound rationale to support your decision during submission? If you are a systems engineer, system analyst or a project manager looking for a systemic approach and best practice to handle change impact, then this presentation is for you.

This presentation will walk you through a systems engineering framework on how to systematically identify and analyze impact of changes that often ripple across the entire system. It will also discuss how to perform a system impact analysis in a cross-functional team setting, with multiple representatives/functions responsible for their respective areas related to the change.

Building a Medical IoT Platform for a Learning Healthcare System: A Case Study in Systems Engineering

Tracy Rausch, DocBox

The Institute of Medicine released its first report on a learning healthcare system in 2011. Since there subsequent reports and research has occurred. In parallel the Industrial Internet of Things (IIot) has emerged. This presentation will cover the clinical scenarios, requirements, and development of a technology platform based on IIot technologies through the development phases to installation, lessons learned and the pathway forward for a learning healthcare system platform. This presentation includes how cybersecurity and regulatory requirements impacted the design of the system. We will also outline the benefits of real-world data in the design and post market surveillance of the platform.

Unlimited Potential - Leveraging the Power of Mind in Design

Randall Iliff, Eclectic Intellect, LLC

We live in an era of nearly unlimited technology, possess the ability to alter matter to virtually any purpose, routinely play with the building blocks of life itself, and deploy systems that not only span our planet but extend well into space around us. Despite these capabilities – in fact because of them - the role of SE, enabled by the human mind, has never been more important within the design process.

We have moved from a period of scarcity to one of richness and our design logic must respond accordingly. The era of line extension and cost reduction is ending. Now the priority must be to expand our capacity for vision, understanding, agility, and informed risk acceptance. SE and Program Management have a role to play in all of these dimensions.

Introduction to Model-Based Systems Engineering (MBSE)

Matthew Hause, PTC

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.

Improving SE Projects by, "Getting It Right, Right From the Start"

Mike Pafford, INCOSE Chesapeake Chapter

An interactive Tutorial reviewing how Mike Pafford combined best practices from the Lean Startup Method (LSM) and Agile (Scrum) Product Backlog Item (PBI) Development to facilitate three interactive workshops that enabled key stakeholders to collaboratively develop Initial Work Items for a "Micro-Grid Reference Model (uGrid RM) MBSE Project" for Cuyahoga County, Ohio. The three workshops, held at the Johns Hopkins University Applied Physics Laboratory (JHU/APL) between July and September 2017, brought together engineers, managers, and other decision makers from INCOSE, FBI/InfraGard, IEEE, and Cuyahoga County Emergency Management Representatives. As Facilitator for the three day-long workshops, Mike introduced, then led the group in applying, specific LSM and Agile Scrum PBI Development process steps to help them efficiently and collaboratively develop a set of "Focus Mechanism" Initial Work Items they could immediately use for the uGrid RM MBSE project to, "Get It Right, Right From the Start".

The Development Difference - Essential Insight for Understanding and Mastering Innovation Effort

Randall Iliff, Eclectic Intellect, LLC

All projects are challenging, but projects that contain developmental e ort are much more likely to encounter cost, schedule and technical issues. Part of this challenge is inevitable due to the creative aspect of development. The other (and often far larger) portion of the challenge is self-inflicted and arises whenever imposed methods are out of sync with true task needs.

This deceptively simple workshop activity, to date experienced by over 5,000 participants worldwide, is filled with "aha!" moments that will leave you with a much richer understanding of how to master development e ort.

Whether you are a PM, an Engineer, a Senior Manager, an Entrepreneur or an Investor the ability to improve development outcomes is of critical interest. Don't miss this chance to have fun and gain valuable insight into the origin and solution of common development challenges!

Application of Agile to Device Systems Development Tutorial

Kelly Weyrauch, Agile Quality Systems and Cary Bryczek, Jama Software

This hands-on tutorial will teach you how to apply AAMI TIR45. You will learn how agile practices can align with your quality management system, apply effective change management, and utilize iterative development lifecycle practices to satisfy regulatory requirements.