Accelerating Innovation Effectiveness: Model-Facilitated Collaboration by Regulators, Technical Societies, Customers, and Suppliers

28th Annual INCOSE
International Symposium

Delivering Systems in the Age of Globalization

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- **Abstract**: Society benefits from innovation across the dimensions of life, including advancements in aviation and ground transportation, medicine and health care, production of food, energy, communication, and information systems, distribution of products and services, and other evolving systems. In many of these areas, society also depends upon effective regulation to protect us from undue risks involving safety, credibility, and other aspects.
- Sometimes we hear questions of whether the systems of regulation are effective in their balance of reward and risk to society. Not so well known are the collaborative efforts by regulators and technical professional societies (ASME, INCOSE, others) to advance new frameworks in which the expectations of regulators and innovators are recognized on behalf of the society both serve.
- This panel will discuss some contemporary efforts, beyond traditional standards-making of earlier generations, including the perspectives of engineering societies, regulators, and enterprises. The discussion will include consideration of how computational models are changing this environment, and ask questions about the implications for future innovation, and the practical issues of sharing regulatory and industry models and patterns. Part of a continuing conversation intended to engage more of our communities in these efforts.

Panel Session Time Line

- Introduction of the session topic and panelists (15 minutes)
- Initial position from each panelist (75 minutes total)
- Attendee & panel discussion of this subject (30 minutes)

Innovation and Regulation

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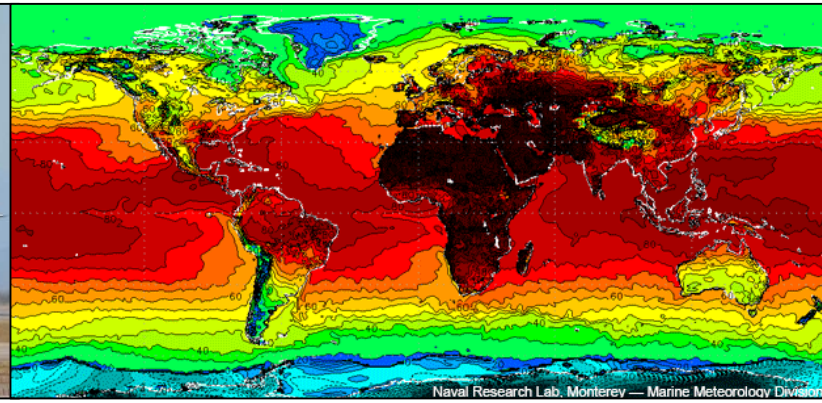

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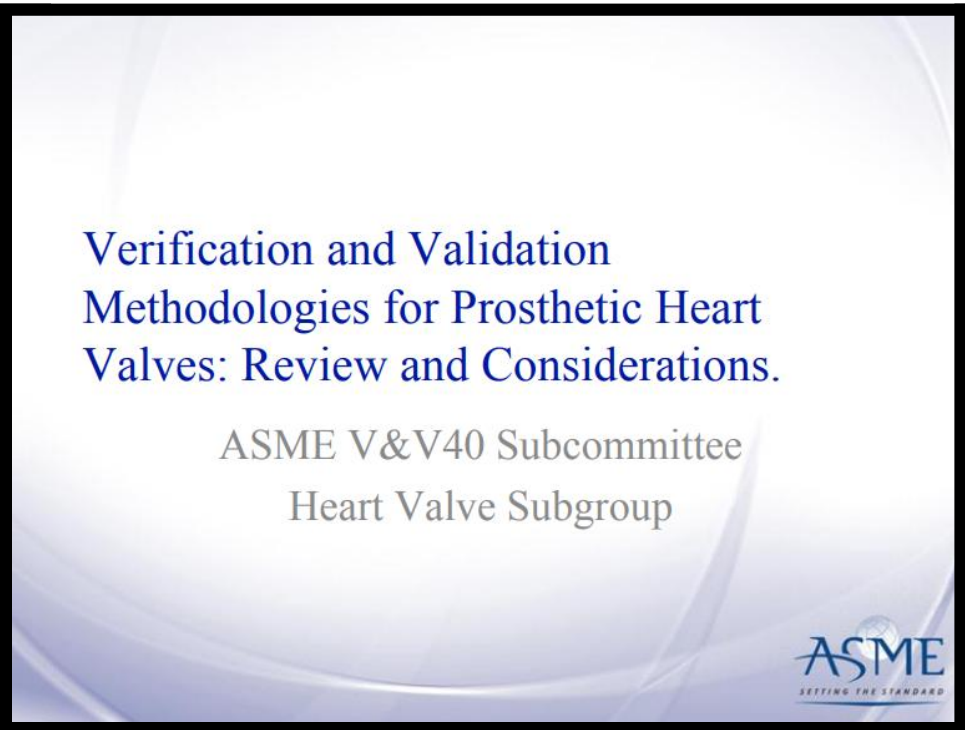

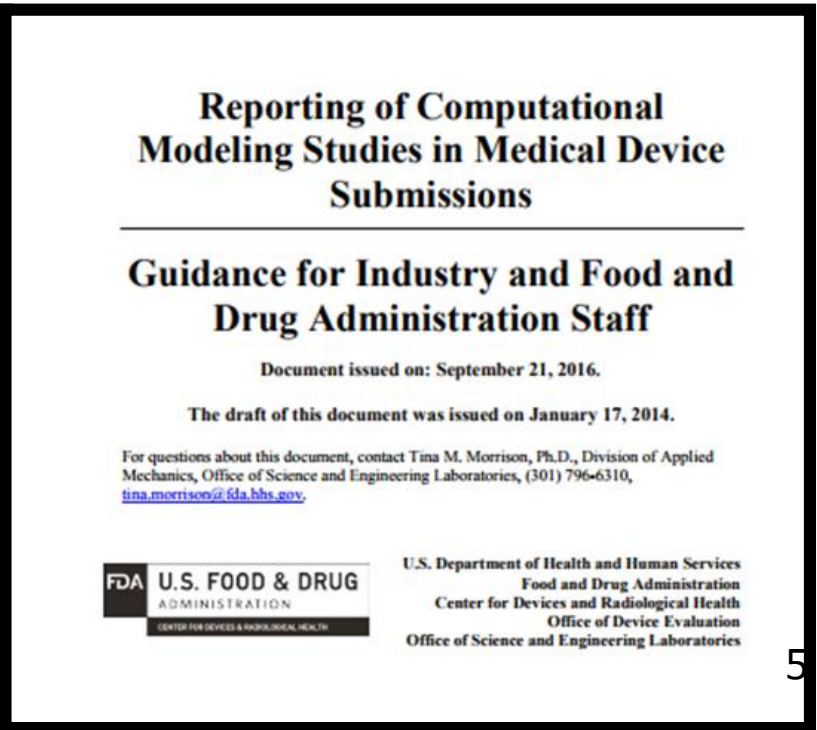

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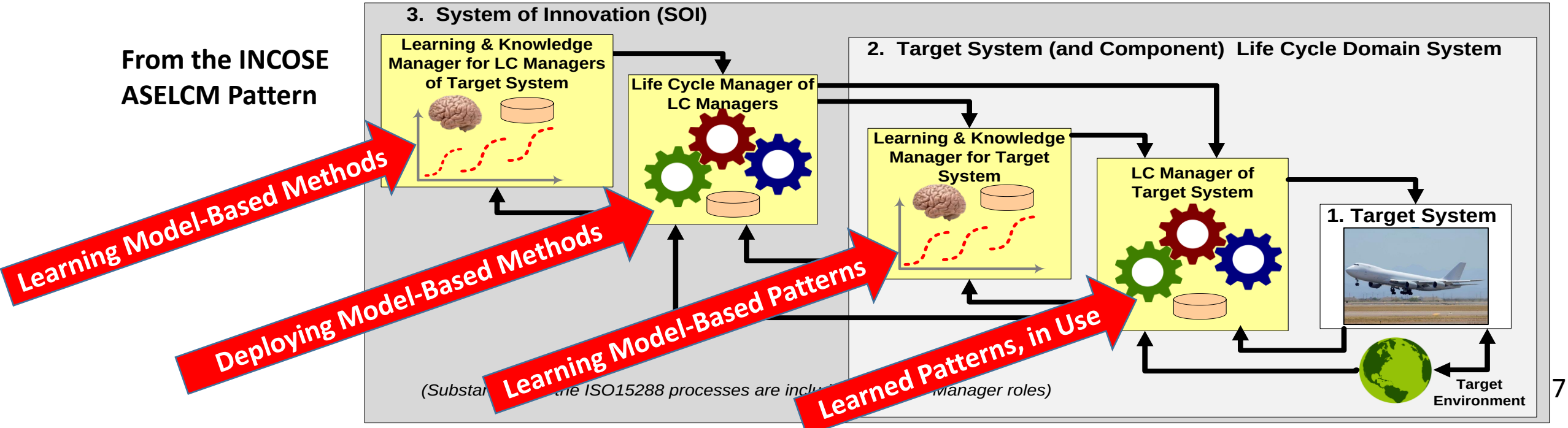
Innovation and Regulation

Arguably the most dramatically impactful example of extended group-wide learning process, during the last three centuries, is the edifice of the physical sciences:

- The language of its “lessons learned” repository is that of explicit quantitative models—specifically, recurring patterns expressed as general models;
- The credibility of these models (whether wrong, close, or right) is expressed via Model Validation, Verification, and Uncertainty Quantification (Model VVUQ);
- Described in this way, the System 2 and System 3 portions of ASELCM Pattern are models of Group Learning as well its effective (“muscle memory”) application:



Vision for a Collaboration

- **The Setting**: Innovation, particularly in regulated domains
- **The Need**: Streamline the innovation cycle while still achieving regulatory goals
- **The Domains**: Aerospace, medicine, electrical grids, automotive, others
- **The Opportunity**: Enhanced trust shared models that society and regulatory authorities can trust during interaction with enterprises and researchers, streamlining joint processes
- **Achieved Example**: Automotive virtual crash testing
- **Engineering Professional Societies**: These System 3 entities occupy a special place in this ecosystem, by virtue of their ethical commitment, combined with technical expertise:
  - Not the same position as the enterprises, or trade groups;
  - Not the same position as the regulators;
  - Not the same position as the academic research community;
  - But a potentially catalytic collaborator with them all, to accelerate the advancement of this vision to reality.

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Vision for a Collaboration

- **ASME's Model VVUQ Leadership Position**: Attracted participation by INCOSE beginning in 2016, in connection with:
  - ASME's goals and leading position in V&V of Computational Models
  - INCOSE's transformation of SE to a Model-Based Discipline
- Special role played by MBSE Patterns (re-usable, configurable models) in this transformation, and in the tradition of the physical sciences (shared, validated general models, configurable)
- Other engineering professional societies discussing this interest (e.g., SAE)
- Other technical societies and trade groups discussing this interest (e.g., AIAA)
- Public forum discussion and panel interests for:
  - INCOSE Great Lakes Regional Conference 2017 (MN)
  - INCOSE International Symposium 2018 (Washington, DC)
  - INCOSE Great Lakes Regional Conference 2018 (IN)
- Indiana private sector aero/medical team standing up a Virtual Verification Institute (V4I), with ASME collaboration from outset

More than "regulated" domains

- This discussion applies to more than "agency regulated" domains; e.g.:
  - Defense: In the US, the role of the DoD, NDIA, and suppliers, in defense systems innovation;
  - Educational Policy Domain, innovation, and accreditation
  - Government Policy Domain, innovation, implementation
  - Other domains

Panelists--Introduction

- Series of public panels on this subject at 2017-2018 INCOSE conferences: INCOSE GLRC for 2017 (MN), INCOSE IS2018 (DC), and INCOSE GLRC for 2018 (IN).
- At the first (GLRC11) panel, engineering society leaders introduced the conversation, and at this second (IS2018 in DC), they are joined by the regulatory perspective. For the IS2018 panel, those participating are:
  - Moderator: Bill Schindel, Chair of INCOSE MBSE Patterns WG
  - **FDA**: Dr. Tina Morrison, Deputy Director, Division of Applied Mechanics, FDA Office of Science and Engineering Laboratories (DC)
  - **ASME**: Marian Heller, ASME Initiatives Standards & Certification (NYC)
  - **INCOSE**: Troy Peterson, AD for Model Based Transformation
  - **NAVAIR**: Steven A. Donaldson, Head, NAVAIR Aeromechanics Engineering Division
  - **SAE**: Logen Johnson, PE, SAE Aerospace Standards Engineering, SAE International (DC)

Panelists: Dr. Tina Morrison, Deputy Director, Division of Applied Mechanics, FDA Office of Science and Engineering Laboratories

Dr. Tina Morrison is the chair of the new FDA-wide working group on Modelling and Simulation (M&S), in the Office of the Chief Scientist. She has been serving as the Regulatory Advisor of M&S for the Center for Devices and Radiological Health (CDRH) since 2012. In that capacity, she leads the Regulatory Review of Computational Modelling working group, which has developed guidance documents on the use of M&S in the regulatory evaluation of medical devices [1]. She dedicates much of her energy towards advancing regulatory science with M&S because she believes the future of medical device design and evaluation, and thus enhanced patient care, lies with computation and enhanced visualization [2]. She serves as Chair of the ASME V&V Standards Committee on Verification and Validation of Computational Modelling, the Subcommittee V&V40 for Medical Devices, where she is leading the development of a strategy to assess the credibility of computational models [3]. She is also working with a team at CDRH to implement this strategy into the review of submissions that leverage M&S [4]. For seven years, she was a scientific reviewer on a variety of medical device submissions in Cardiovascular Devices. She is the Deputy Director of the Division of Applied Mechanics in FDA's Office of Science and Engineering Laboratories. She is a mechanical engineer who received her PhD in Theoretical and Applied Mechanics from Cornell University in 2006.

Panelists: Marian Heller, ASME Initiatives Standards & Certification

- Marian Heller is a mechanical engineer and staff secretary for two of ASME's V&V (verification and validation) standards development committees: V&V 20 Verification and Validation in Computational Fluid Dynamics and Heat Transfer; and V&V 50 Verification and Validation of Computational Modeling for Advanced Manufacturing. Marian serves as Business Development Manager of Healthcare at ASME, exploring ways for ASME to provide greater support to the bioengineering and healthcare industries and increase the positive impact of mechanical engineers. She is also a facilitator, supporting ASME's roadmapping and gap analysis workshops.

Panelists: Steven A. Donaldson, NAVAIR Aeromechanics Engineering Division Head

- Steven Donaldson currently serves as the Head of the Aeromechanics Engineering Division at the Naval Air Systems Command. This national engineering division is comprised of approximately 160 personnel responsible for delivering aeromechanical engineering products and services for all acquisition and sustainment engineering activities for Naval Aviation. He is responsible for the planning, direction, and execution of the Research and Engineering efforts related to the development and sustainment of Naval Aviation assets across the technical disciplines within the division including Applied Aerodynamics, Stability & Control, Aircraft Performance, Flight Controls, Store Separation, and Flight Vehicle Modeling and Simulation.
- Mr. Donaldson currently serves on the Board of Directors for the Department of Defense (DoD) High Performance Computing Modernization Program Computer Research and Engineering Acquisition Tools and Environments (CREATE) Air Vehicles Project whose charter is to develop and deploy computational engineering tools that address the needs of the air vehicle acquisition programs across the DoD.

Panelists: Troy Peterson
INCOSE AD for Model-Based Transformation

- Troy Peterson is a Vice President and Fellow with System Strategy, Inc. (SSI) where he is providing consulting services to help clients conceptualize and design for the deep interdependencies inherent in today's cyber-physical systems. Before joining SSI, Troy was Booz Allen's Chief Systems Engineer and a Booz Allen Fellow. Prior to this Troy worked at Ford Motor Company and as an entrepreneur operating a design and management consulting business.
- Troy is INCOSE's Assistant Director for Transformational within INCOSE and is the champion for accelerating the transformation of systems engineering to a model based discipline. Troy is also co-chair of the MBSE Patterns WG and Past President of the INCOSE Michigan Chapter.
- Troy has led several large projects in the delivery of complex systems and has instituted several methodologies to speed innovation. His experience spans commercial, government and academic environments across all product lifecycle phases. He has been appointed to several boards to improve engineering education and application. Troy is also a frequent speaker at leading engineering conferences.
- Troy received his BS ME from MSU, his MS in TechMgmt from RPI and an advanced graduate certificate in Systems Design and Management from MIT. He also holds INCOSE CSEP, PMI PMP and ASQ SSBB certifications

Panelists: Logen Johnson, SAE International, Aerospace Standards

- Logen Johnson is an Aerospace Standards Engineer with SAE International base out of Washington, DC. In this role, Logen is responsible for supporting standards development operations for SAE's aerospace standards program. This includes working with the US and global aerospace community on new standards development as well as global strategy and outreach for SAE. Prior to joining SAE, Logen worked with other standard organizations in DC and he holds a BS degree from Wentworth Institute of Technology in Electromechanical Engineering.

Panel Moderator: Bill Schindel

- Bill Schindel is a member of the ASME standards team writing guidelines for verification, validation, and uncertainty quantification (VVUQ) essential to regulatory submissions across aviation, medical devices, and other domains. Also a member of INCOSE, Bill chairs the MBSE Patterns Working Group of the INCOSE/OMG MBSE Initiative. He is president of ICTT System Sciences, and has practiced systems engineering for over thirty years, across multiple industry domains. Bill serves as president of the INCOSE Crossroads of America Chapter, is an INCOSE Fellow and Certified Systems Engineering Professional, and a member of AIAA and ASEE.

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