Patterns Working Group

Advance Planning Summary for Sept. 26-27 Seminar Participants

Virtual Verification, Validation, and Visualization Institute

Introductory Seminar for FDA

- S*Models and S*Metamodel
- S*Patterns
- Model VVUQ S*Pattern
- System of Innovation S*Pattern

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Sept 26-27 seminar, in a nutshell . . .

1. The INCOSE Patterns Working Group has been active over years with model-based patterns, called S*Patterns, based on the S*Metamodel framework, including application to the System of Innovation (SOI), leading to the Agile Systems Engineering Life Cycle Management (ASELCM) Pattern.
2. In the ASME Model VVUQ Standards Committee, we have been applying the above to create a model-expressed standard approach to model VVUQ, advancing traditional prose-based standards.
3. The Model VVUQ Pattern provides INCOSE practitioners a metadata-based asset for model planning or characterization, neutral as to model type, tooling, or domain—a consistent model "wrapper", itself model-based.
4. INCOSE and ASME work has recently been incorporating ASME VV40 draft standard prose-expressed guidance into a model-expressed update to the Model VVUQ Pattern, improving ability to plan, express, and assess evidence in a more uniform manner, as a part of "System 2" of the SOI Pattern.
5. We are pursuing this for a Generic System, a General Medical Device, and a Specific Medical Device.
6. Stimulated by this technical society work, the public-private V4 Institute formed to accelerate growth in related capabilities of V4I Members, using a set of Launch Projects as platforms for collaboration, including inviting regulatory observation and feedback.
7. This seminar is intended to advance your awareness of key elements behind the above.

Contents

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- Objectives of the seminar
- Seminar pre-requisites and pre-reading
- Seminar outline / timeline
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Purpose of this material

- This material is a pre-seminar planning summary for attendees of the planned Sept 26-27 seminar at FDA.
- The basic objectives, scope, timing, and location of the seminar are summarized by this material, along with suggested pre-reading.

Seminar objectives

1. Learn about S*Metamodel we use in INCOSE Patterns Working Group and in our ASME VV50 work, including the Model VVUQ Pattern.
2. Learn about use of S*Patterns we use in the Patterns Working Group to improve leverage of S*Models, and how model VVUQ, group learning, S*Patterns connect.
3. Learn how S*Models/S*Patterns are related to computational models of various sorts, as a kind of metadata about them and the toolchains they inhabit.
4. Review how we are embedding the VV40 structures into the Model VVUQ Pattern, and implications for UQ and otherwise of doing so.
5. Learn about the medical device S*Pattern we are constructing as an example of above, controls and other aspects, UQ aspects, etc.
6. Learn about V4 Institute public projects that V4I invites regulators to observe, collaborate in, or otherwise interact for mutual community benefit.
7. Learn about related FDA perspectives, priorities, concerns, etc.
8. Discuss how related interactions involving additional regulators (e.g., FAA) or their DoD equivalents as well as technical societies might advance the overall practices of virtual life cycle management in the interests of the larger communities and society.
9. Other objectives important to you?

Seminar pre-requisites and pre-reading

- Seminar attendees are expected to already:
  - Be aware of the uses, methods, and contemporary challenges and opportunities of model-based engineering, model VVUQ and related standards, and interests in the use of models in support of innovation and regulated offerings;
  - Be familiar and able to speak to the interests of their organization in the subjects of this seminar;
  - Have read over the seminar Pre-Reading listed in the References.

Seminar Outline / Timeline

- Introductions, objectives, agenda, individual interests and concerns
- Challenges of diversity in domains, models, styles, and approaches, even with standards
- S*Metamodel, S*Models, S*Patterns, PBSE, with examples
- The System of Innovation S*Pattern: System 1, 2, and 3
- The Model VVUQ Pattern and its embedding in the SOI Pattern
- Physics-Based Models, Data-Driven Models, Hybrid Models, System Models
- S*Features, Interactions, States, Roles, Design Components, Attributes, Couplings for:
  - The Model VVUQ S*Pattern, enhanced by VV40
  - Embedded Intelligence (EI) S*Pattern
  - Applying Model VVUQ Pattern to the General System of Interest Pattern
  - Applying Model VVUQ Pattern to the General Medical Device Pattern
  - Applying Model VVUQ Pattern to the Specific Medical Device Model
- Tooling
- V4I Collaboration Projects
- Discussion, issues, next steps

Sept 26 (PM)

Sept 27 (AM)

Seminar materials

- This Planning Summary is not the “Seminar Materials”:
  - Seminar Materials will be provided at the time of the Seminar
- Meanwhile, you are invited to review the seminar Pre-Reading listed in the References:
  - The Pre-Reading is not the “Seminar Materials”, but provides key background.

Seminar logistics and contacts

- Seminar dates / times:
  - Wed, Sept 26 1:00 – 5:00 PM EST (Part 1)
  - Thurs, Sept 27 8:00 – 12:00 PM EST (Part 2)
- Seminar location:
  - _____
- Seminar participation:
  - Contact Dr. Tina Morrison, FDA
  - Email: Tina.Morrison@fda.hhs.gov
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- Seminar provider, contact for content matters:
  - Bill Schindel, ICTT System Sciences, schindel@ictt.com,
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Seminar pre-reading

Download from this link:
http://www.omgwiki.org/MBSE/doku.php?id=mbse:patterns:mbse_patterns_wg_participation_in_fda_pbse_seminar

1. Schindel, W., "INCOSE Collaboration In an ASME-Led Standards Activity: Standardizing V&V of Models", in *Proc. of INCOSE International Workshops*, Jacksonville, FL, Jan, 2018.
2. INCOSE Patterns Working Group, "MBSE Methodology Summary: Pattern-Based Systems Engineering (PBSE), Based On S*MBSE Models", V1.5.5A.
3. Schindel, W., and Dove, R., "Introduction to the Agile Systems Engineering Life Cycle MBSE Pattern", in *Proc. of INCOSE 2016 International Symposium*, 2016.
4. Schindel, W., "What Is the Smallest Model of a System?", in *Proc. of the INCOSE 2011 International Symposium*, International Council on Systems Engineering (2011).
5. Schindel, W., "Got Phenomena? Science-Based Disciplines for Emerging Systems Challenges", in *Proc. of the INCOSE 2016 International Symposium, International Council on Systems Engineering*, Edinburgh, UK. 2016.
6. Schindel, W., "System Interactions: Making The Heart of Systems More Visible", in *Proc. of INCOSE Great Lakes Regional Conference*, 2013.
7. Schindel, W., "Hamilton's Principle and Noether's Theorem as a Basis for System Science", *Proc. of 2018 Annual Meeting of the International Society for the System Sciences*, July, 2018.