INCOSE Healthcare Working Group

4th Annual Systems Engineering in Healthcare Conference

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

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Challenges in Computational Model V&V for Systems Engineers
Audience Participation

- Take 3-5 minutes to fill in the following form and pass it in
  - I see that (who)
  - Could create better / do a better job at (what)
  - During (when)
  - Because right now they (why)
  - *[optional]* I think we could help them by: (how)

During the 25 minute panel presentations the results will be tabulated and presented. A 30 minute discussion of the results will follow.

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- *[optional]* I think we could help them by: (how)

- I see that (my manager)
- Could create better / do a better job at (helping me manage my career)
- During (my annual review)
- Because right now they (focus on a salary discussion alone)
- *[optional]* I think we could help them by: (scheduling a separate development plan discussion)

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Challenges in Computational Model V&V for Systems Engineers

Chris Unger - Moderator's Introduction

- Why are system design decisions so challenging? Are they more difficult for Medical Devices than other industries? Are they more challenging than decisions in other engineering disciplines?

- Systems problems are hard due to ambiguity
  - SE decisions tend to compare "apples to oranges" (function vs. cost, time to market vs content)
  - SE considers vague things (acceptable levels of artifacts, ease of use, risk vs. benefit of a feature)
  - SE decisions don't have clear owners (subsystem vs. system…ie thermal; systems vs. program…ie time to market; product vs. systems…ie performance specifications, feature content)
- A key step that is often skipped is framing a problem and interviewing stakeholders. Then, before jumping to an answer, identifying the design options and decision criteria.
- Tools used to manage systems design decisions are 'over-kill' for most of the decisions

Challenges in Computational Model V&V for Systems Engineers

Carissa Black

CRITICALITY, # PEOPLE AFFECTED

TIME, COST OF ACTIVITY

Prototype & Test	Trade Study	Brainstorming	System-Level Review	Engineering-Level Review	Peer or No-Review
• Need to 'feel' or 'see' • Difficult to model • Likely emergent behavior • *(Physical Item, Notes/Record)*	• Need input / consensus from many • Non-trivial pros/cons • Conflicting priorities • *(Records & In-Person Meet)*	• Need reassurance that concepts were compre-hensive • Ideas from many • *(Record & Presentation)*	• Need to communicate/ weigh cross-discipline impacts • Foundational to design • *(Sys Arch., Design Review)*	• Need to review with experts • Strong alternates • Impacts other part of design • *(Eng. Review, Design Desc.)*	• Need to choose • Design-level decision within expertise of designer • *(Design notebook)*

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Challenges in Computational Model V&V for Systems Engineers

John Uittenbogaard

- Systems Engineering decisions are difficult because they often involve trade-offs that result in a negative impact to one part of the system for the benefit of the whole system. System-wide decisions require a systems view and systems thinking which not all engineers or managers have.
- Systems problems need to be approached in a logical, disciplined, and timely manner:
  - Define the problem and identify the information that will be needed (understand your timeline)
  - Identify the stakeholders and understand their perspectives (include them in the decision-making process)
  - Define the decision-making criteria
  - Develop options and understand the system-side implication of those options
  - Document the decision including the rationale.
- Force any challenge to decisions into a discussion about the rationale to gain a deeper understanding of the concerns – Actively listen to critics – don't take it personal

Challenges in Computational Model V&V for Systems Engineers

John Uittenbogaard

- Systems Thinking
  - Knowing the inter-related effects among subsystems, components, users, environment, …
  - Knowing the overall objective (including priorities if there is more than one objective)
  - Are we addressing a symptom or do we understand the system well enough to get to the root cause?

Challenges in Computational Model V&V for Systems Engineers

John Uittenbogaard

- Decision Making Process
  - Problem
    - Do you know what the problem is and why it's a "Systems" problem to solve?
  - Stakeholders
    - Who is responsible for making the decision?
    - Who can provide input/data?
    - Who do you need to get agreement from (how do you attain agreement)?
    - Who needs to be informed of the decision
  - Options
    - Have we considered different ways to solve the problem?
  - Feedback
    - Listen carefully – do you understand the feedback/concerns
  - Document Decisions
    - Formality of documentation is dependent on the situation (& organization/culture)
    - Rationale must be captured (Criteria & Supporting Information)
  - Tools
    - Use to support your needs, Tools don't make the decision, you do

Challenges in Computational Model V&V for Systems Engineers

John Uittenbogaard

- Active Listening/Feedback
  - Understand that people speak in their own “language”
    - e.g. System-ese, Electrical-ese, Mechanical-ese, Software-ese, Program Manager-ese, Customer Language, Materials, Risk, …
  - Communicate with other’s in their native language to increase understanding

Challenges in Computational Model V&V for Systems Engineers

Tony Raike

Trade space evaluations

- The ability to know when and how to conduct trade studies are a sign of an organization's maturity.
- Development teams often spend excessive amount of time debating the merit of alternative solutions. Worst, they select solutions that are not optimal due to various reasons.
- Unfortunately, many development teams do not know when design decisions need a formal trade study process. Start with the critical decisions of the development:
  - Impact the project schedule
  - Have a significant impact on system performance, functionality, or requirements
  - Have a significant business impact – regulatory, legal, and/or end-users.
- The value of trade study process is the clarification of available options against the problem statement.
- The evaluation of risk for problem statement which includes schedule (time to market), technical (performance, functionality, requirements, feasibility), cost (customer vs COTS, Dev't NRE, total cost of ownership), and business (VOC, supplier management, strategic) criteria.
  - Record the rational for score for each criteria.
- When development teams conduct trade space evaluations, they always come out more knowledgeable about the target design space.

Trade Study Example

Evaluation Criteria		Section Weight	Criteria Weight	Option 1			Option 2			Option 3		
				Value	Score	Wtd. Score	Value	Score	Wtd. Score	Value	Score	Wtd. Score
Technical	Technical feasilibility and risk	10.0%	2.5	L	10.0	25.0	ML	7.5	18.8	M	5.0	12.5
	Data transfer performance		2.5	ML	7.5	18.8	H	0.0	0.0	H	0.0	0.0
	Integration to SoS		2.5	L	10.0	25.0	H	0.0	0.0	M	5.0	12.5
	Upgrade-ability		2.5	H	0.0	0.0	ML	7.5	18.8	L	10.0	25.0
Schedule	Time to market	40.0%	20.0	L	10.0	200.0	M	5.0	100.0	H	0.0	0.0
	Milestone B decision		20.0	MH	2.5	50.0	L	10.0	200.0	ML	7.5	150.0
Cost	Development costs - NRE	20.0%	10.0	MH	2.5	25.0	M	5.0	50.0	MH	2.5	25.0
	Custom vs COTS		5.0	L	10.0	50.0	ML	7.5	37.5	M	5.0	25.0
	Reliability/serviceability Cost		5.0	L	10.0	50.0	M	5.0	25.0	ML	7.5	37.5
Management	Customer Satisifaction	30.0%	15.0	M	5.0	75.0	L	10.0	150.0	L	10.0	150.0
	Strategic technology development		10.0	L	10.0	100.0	L	10.0	100.0	M	5.0	50.0
	Requires Key Resources		5.0	L	10.0	50.0	ML	7.5	37.5	M	5.0	25.0
Overall Assessment		100.0%	100.0			669			738			513

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Presentation Recap

Systems design decisions are hard since they **tend** to be

- complex,
- ambiguous,
- and have numerous and varied stakeholders with competing interests

There isn't an easy and standardized process to reduce the 'art' of decision making to a precise discipline

Your Thoughts

- Is medical device development more challenging than other industries?
- Would a standardized approach (process or tools) help? Can we leverage INCOSE standards?
- How much of the challenge comes down to influencing and communication skills (not purely technical)?
  - How would a team or individual go about developing those skills?

Questions?

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Thank you for attending!

Share your experiences at #HWGSEC

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