Safety Certification in medical device systems

HCSS Conference

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About me.

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Assistance is also available from the Division of Small Manufacturers, International and Consumer Assistance, http://www.fda.gov/cdrh/industry/support.

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Origins of safety culture

- First there was Disaster.
- Then came evolution.
- Then came “experience”.
- Then came “rules of thumb”.
- Then came “guilds”.
- Then came “standards”.
- Then came “risk management”.
- Soon there will be “models”.

The trajectory of safety evolution

- Food
- Fire
- Mechanical
- Biological
- Electrical
- Logical
- ……

Safety engineering canons

- Margins of performance
- Redundancy
- Durability of materials and composition
- Risk management within the use context

But these are still primitive 20th Century concepts in the broad field of systems engineering!

There remains a ‘trust gap’ which Certification seeks to bridge.

We need to be able to make a prototype or a ‘virtual prototype’ of any complex system before we can establish trust.

Virtual prototyping seeks to prospectively model certain salient properties of complex systems within a defined use context and to ‘certify’ that they will work in the physical world.

For many device aspects

- Consensus standards published by professional Standards Development Organization (AAMI, ISO, IEC, ASM, ASTM, etc) can provide these ‘touch points’.
  - Proven in use ‘rules of thumb’
  - Based on experience and industry best practice
  - Evidence based, defined terms, test methods, etc
- For very innovative aspects there may not yet be a consensus standard.
  - Intellectual property concern$
  - Unpublished/un-reviewed new science
  - Limited empirical evidence only

So how to deal with innovative aspects?

- Modeling and simulation of the materials, properties, methods and processes may provide some insight (trust) into the suitability for a specific narrowly construed context of use while experience is accumulated.

- With experience comes data, and trust and eventually a consensus agreement (standard).

But this insight does not mitigate risk, it illuminates it!

- For modeling and simulation to be a useful tool in gaining insight into the risks of an innovative approach, the manufacturer must trust the model and know the limits of its applicability and those aspects of its use-context which have good peer reviewed data.
- And remember “Trust is not transitive”
  - If Tom trusts Dick and Harry trusts Tom, it does not mean Harry trusts Dick!

So how do we fix the trust gap for models and simulations

- That's easy!
  - We wait for convincing data from the field which provides evidence of trustability
  - Sorry….That could take years and lives!

So how do we fix the trust gap for models and simulations

- That's easy!
  - We just trust the market!
  - Sorry….Safety is not an emergent property

So how do we fix the trust gap for models and simulations

- It's really not so easy!
  - We develop an industry consensus about those models whose essential micro-functionality we can agree about
  - That might not take very long.

  - These will be quite narrowly construed and may leverage the experience we have with their non medical use.
  - We consider them with respect to specific devices and iterate as we accumulate new model properties

Consider a theoretical example

- A stent
  - We have a good Finite Element Model for its strength, flexure, given certain properties of its construction and mesh.
  - We have a good drug elution model for a static coated stent given certain properties of its construction.
- We don't yet know how to combine these two for a model of a femoral stent to see how its flexing adversely affects its rate of elutation and life.

Our theoretical example

- But we already have a lot with just these two distinct narrowly construed models.
- If we could somehow ‘bank’ these two models as canonical models for these narrow properties of this device we could encourage some bright researcher to propose a combinatorial model.
- This simulator can be progressively calibrated against real–life data and real constraints.
- Pretty soon we can begin to do what-if scenarios with new materials, or new placements, on this combinatorial model
- Isn’t that virtual prototyping? Are we not developing a kind of system certification context? But just for the combination of sub-systems at hand.

Back to Virtual Prototyping!

- For VP to be commercially and regulatory useful we need an industry-wide process to be in place to qualify and validate models so they can be built upon and combined.
- We should recognize that they may initially be useful for a single generic device alone since devices have specific intended uses and therefore specific assumptions.
- There may need to be one (or more) common abstract modeling languages adopted
- We need discussions about:
  - What are the system properties which could be modeled this way
  - What are the abstract modeling environments available for certain types of predictive properties (software, elution)

How do we do this?

- In my opinion
  - We can look to the consensus standards management model for many of the processes we should set up to establish a credentialed model ‘catalog’ which might be used in the regulator approval (certification) process.
    - Independent fee based publisher which uses an ANSI accredited review model
    - Committee based review of models and detailed exposition of methods for implementation
    - Wide representation on review committees including regulator, academics, industry and other stakeholders
    - No proprietary IP brought to the model
    - Very detailed scope and well defined boundary of model usage.
    - Regulator recognition process for acceptance
    - Periodic re-review for current applicability

What about proprietary models?

- Models where there is an IP element or where the manufacturer does not wish to share the model
  - The sponsor could follow the broad outline developed by the Consensus Standards publisher for documentation and references and methods for implementation and convey this to the regulator along with other reviewable artifacts required. Such a model would be held confidential. But it would inform the regulator!
  - Not as tractable as the former since it would complicate the review process somewhat.

The fueling of Innovation

- As combinatorial models begin to aggregate and begin to be available in modeling tool sets, so virtual prototyping can emerge as a confidence building tool and sub-system design will reflect the new “faster-better-cheaper” methods of product realization.

- This should spur innovation and should tend to favor cost containment and time to market while reducing the uncertainties in regulatory review.

Thank you

- Questions?