INCOSE Healthcare Working Group
5th Annual Systems Engineering in Healthcare Conference
May 1-2, 2019
Minneapolis, MN

Dynamic Systems Modeling and Simulation

for Medical Device Design and Development

A Model-Based Design approach to solving systems engineering problems in Medical Device development

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MathWorks

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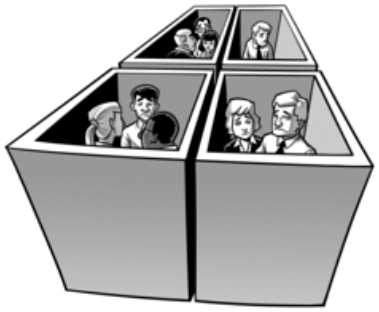
Why is medical device development hard? … and take too long?

- Safety Critical Products?
  - Class 2/3 (/4) Devices are more safety critical
  - Risk analysis, mitigation
- Complex Design?
  - Multi-domain systems
  - Requirements to Prototype to Final Product
- Compliance to Regulation?
  - FDA, IEC 60601, IEC 62304, ISO 13485,
- Compartmentalized Development Process?

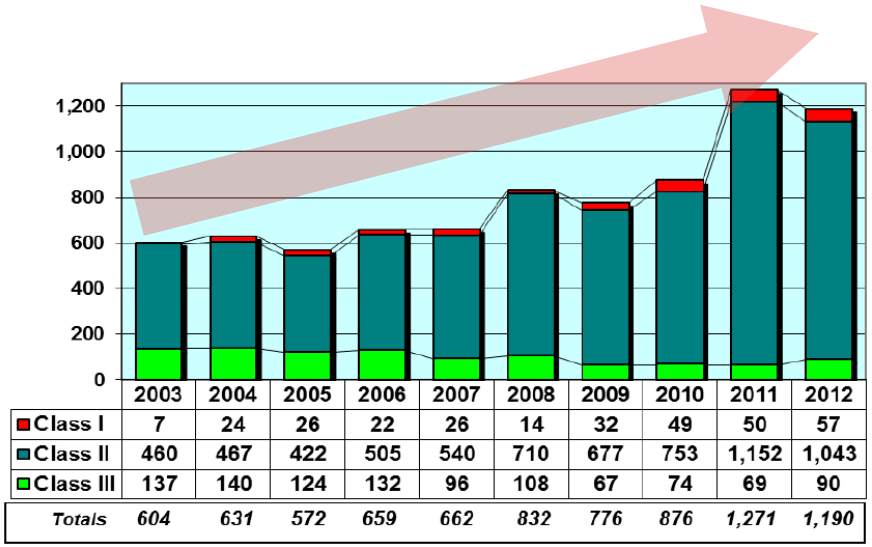
ISO International Organization for Standardization

IEC INTERNATIONAL ELECTROTECHNICAL COMMISSION

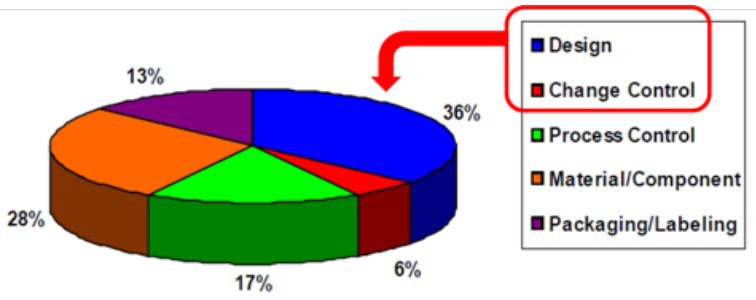


But…Why are there so many recalls?

- # of Recalls **doubled** since 2003
- Increasing # of Class 1 and 2 recalls



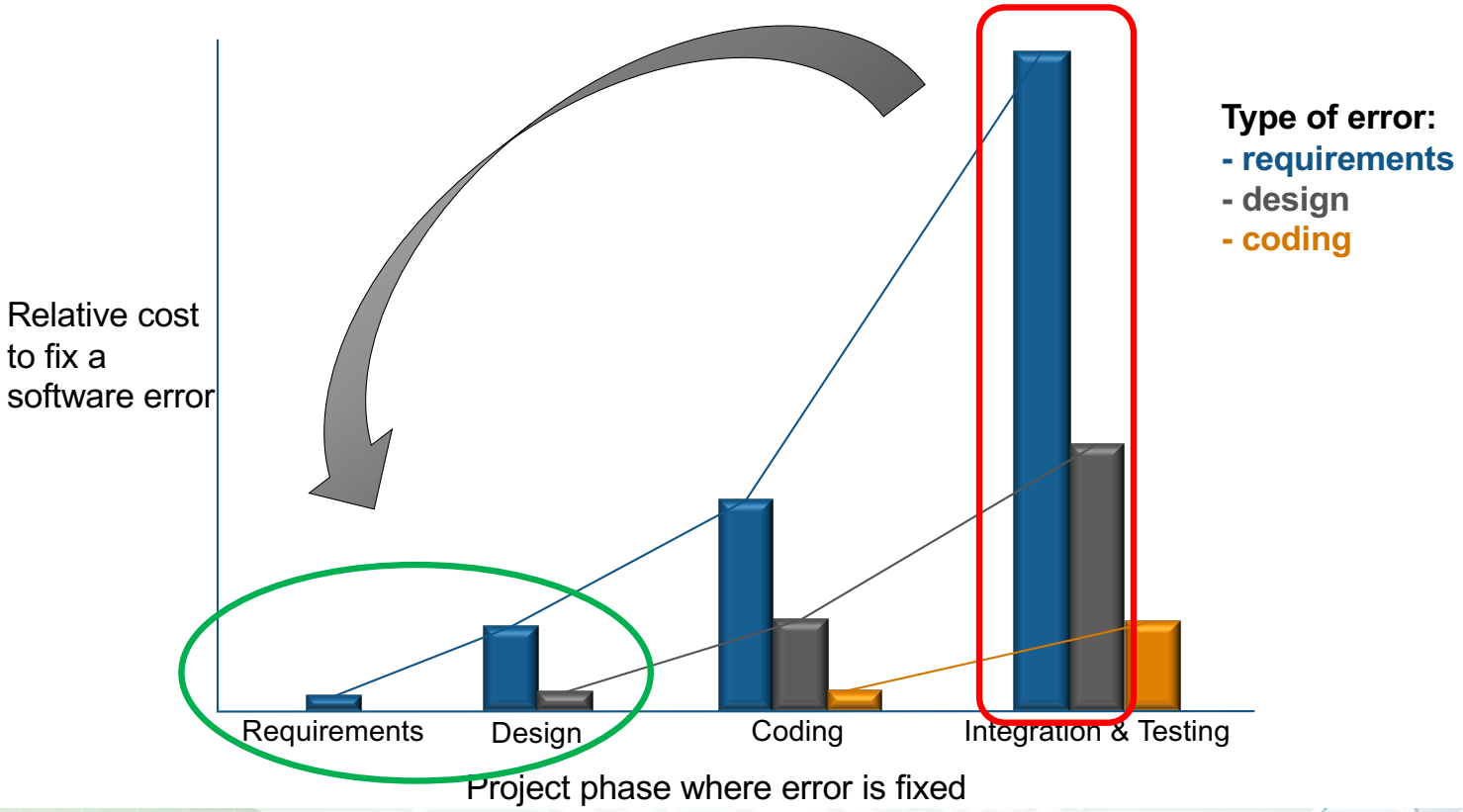
	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Class I	7	24	26	22	26	14	32	49	50	57
Class II	460	467	422	505	540	710	677	753	1,152	1,043
Class III	137	140	124	132	96	108	67	74	69	90
Totals	*604*	*631*	*572*	*659*	*662*	*832*	*776*	*876*	*1,271*	*1,190*



Source: Medical Device Recall Report FY 2003-FY2012, CDRH, Office of Compliance, FDA

Late Errors Cost More

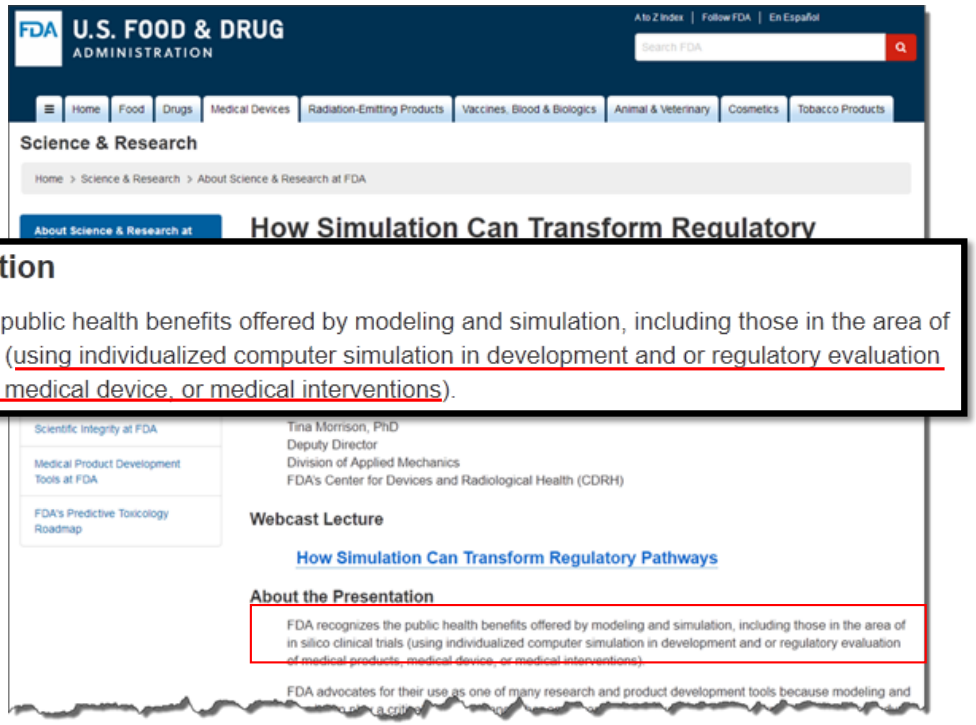
Source: *Return on Investment for Independent Verification & Validation, NASA, 2004*



Solution: Modeling and Simulation

Dynamic system modeling & simulations

- Model-Based Design and Systems Engineering has been increasingly used by other regulated industries for decades
  - Aerospace
  - Automotive
  - Industrial Machinery
  - Medical Devices
- FDA actively promoting closer look at Modeling and Simulation technologies to accelerate innovation and increase safety



https://www.fda.gov/ScienceResearch/AboutScienceResearchatFDA/ucm616822.htm

Multi-domain System Modeling

6 Modeling Patterns

Software Models

TEXT-BASED
Mathematical Algorithms as MATLAB code

DISCRETE-TIME
Digital control, DSP, Image/video

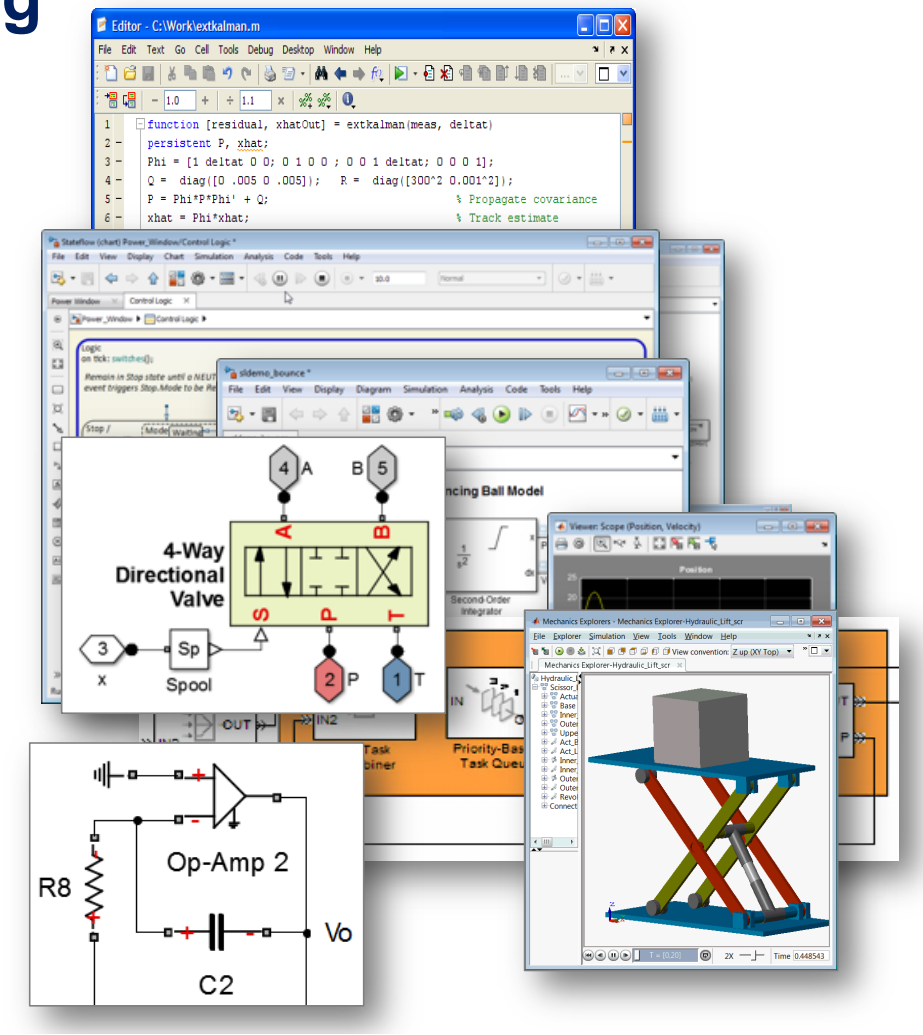
STATE MACHINE MODELS
Control logic, Mode logic

Environment Models

CONTINUOUS-TIME
Dynamic systems, Plant models, Controller models

PHYSICAL
Electronics, Mechanics, Hydraulics, Thermal

DISCRETE-EVENT
Architecture, Latency, Resource, Performance modeling



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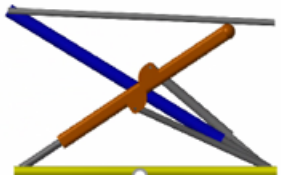
Value of Using Dynamic System Models

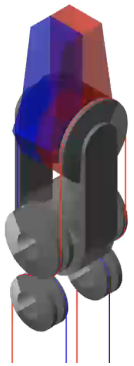
in Medical Device Design

Analyze system behavior & Performance	• **Analyze larger system behavior and performance** through simulation.
Understand Design Tradeoffs	• **Understand and make rapid design tradeoff decisions** across domains.
Iterate Early on Requirements	• **Iterate early on requirements** and design specification.
Identify Component Specs/Sizing	• **Identify and verify component specs/sizing** before building a physical prototype.



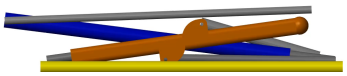
Real-World Examples

Pulley-Based Surgical Tool Tip



Neo-Natal Ventilator
High-Frequency Jet Ventilation

Endoscope Reprocessing & Decontamination Device



Mechatronic Emergency Bed & Stretcher

Case Study – Mechatronic Emergency Bed

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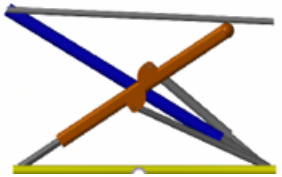

Mechatronic Emergency Bed & Stretcher

Case Study – Instrument Tip for Surgical Robots

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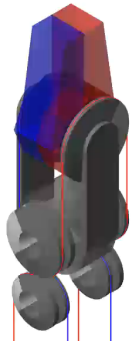

Pulley-Based Surgical Tool Tip

Case Study – Control of Neo-Natal Ventilators

(HFO mode)

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Neo-Natal Ventilator
High-Frequency Jet Ventilation

Case Study – Endoscope Reprocessing SW Design

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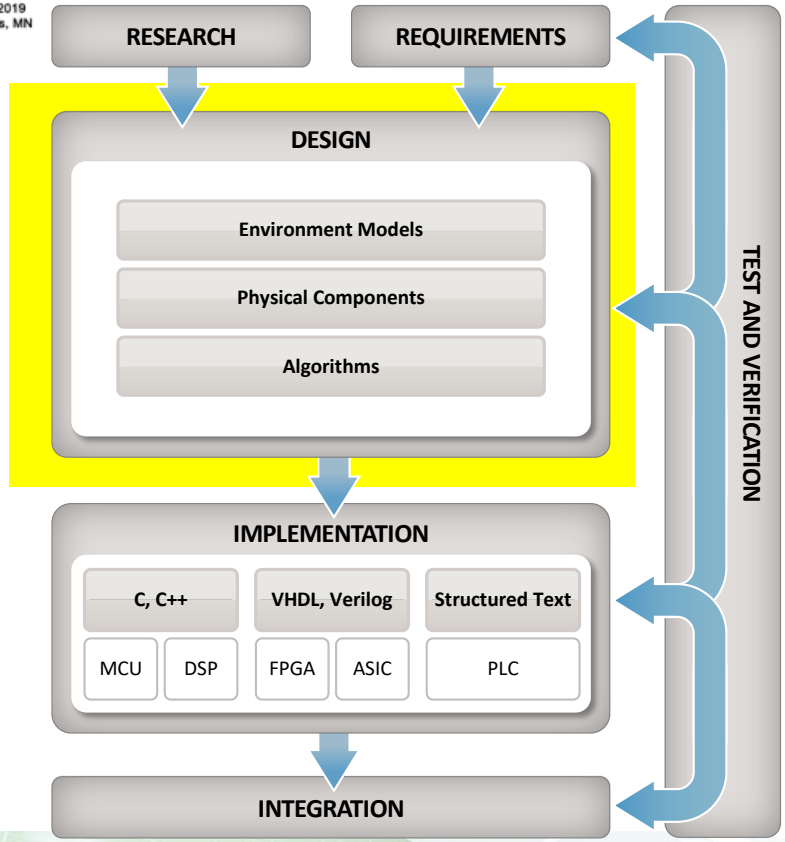
Endoscope Reprocessing & Decontamination Device

Model-Based Design

What was covered in this presentation



Integrates Modeling & Simulation with rest of regulated product development process!

- **Design as Executable Specification**
- **Requirements Traceability**
- **Continuous and early Verification**
- **Document & Report Generation**

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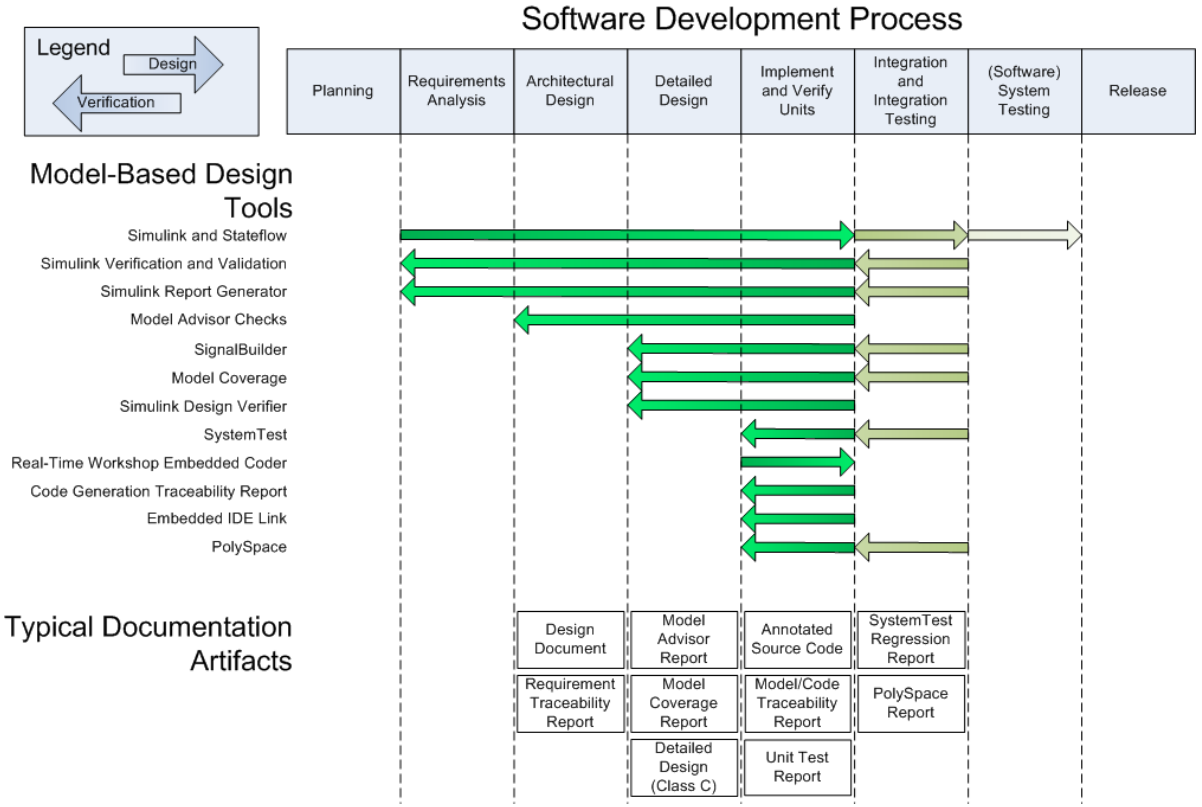
Mapping Model-Based Design to IEC-62304



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itk ENGINEERING

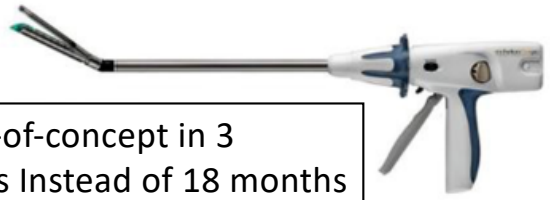
"Without modelling Controller development would've taken twice as long!"
2x faster + *IEC Certification achieved*

PHILIPS

"Design changes in VHDL 80x faster **(from 1 week to 30 minutes)**"

Ethicon Endo-Surgery

New Powered ECHELON FLEX™ Stapler



"Proof-of-concept in 3 months Instead of 18 months **(6x improvement)**"

imt. making ideas work

"Manual work reduced by 80% **(from 2 weeks to 2 days)**"
IEC certification granted

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Preceyes – Eye Surgery Robot

Preceyes Accelerates Development of World's First Eye-Surgery Robot Using Model-Based Design

"MATLAB and Simulink provided a single platform that supported our complete workflow and all the components and protocols we needed for our robotic system. That enabled us to quickly develop a safe, real-time device, ready for clinical investigation."

— *Maarten Beelen, Preceyes*

The PRECEYES Surgical System. The system manipulates the instrument that enters the eye and is controlled using the motion controller on the left; the surgeon operates with the other hand manually. Image copyright and courtesy Preceyes.

Challenge

Develop a real-time control system for robot-assisted surgical procedures performed within the human eye

Solution

Use Model-Based Design with MATLAB and Simulink to model and simulate the control system and use Simulink Coder and Simulink Real-Time to deploy it to a real-time target

Results

- Core controller developed by one engineer
- Patient safety assured
- Road map to industrialization set

https://www.mathworks.com/company/user_stories/preceyes-accelerates-development-of-worlds-first-eye-surgery-robot-using-model-based-design.html

Questions?

medical@mathworks.com

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Thank you for attending!

Share your experiences at #HWGSEC