Model-Based Design & Certification

Application to medical domain

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Key Take-aways

- Adoption of Model Based Design for Product development
- Change from Prototyping to Production Code Generation for IEC62304
- Leverage MATLAB / Simulink tools for Embedded Software development
Who we are

- Global healthcare company specializes in lifesaving medicines and technologies for infusion, transfusion and clinical nutrition.
- Our products and services are used to help care for critically and chronically ill patients.
Where we are

~ 65  ●  Sales and Marketing Organizations
~ 70  ▲  Production Sites and Compounding Centers
~ 20  □  Research and Development Centers
What we do

Infusion Devices | Disposables | Enteral Devices | Software Solutions

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What we do

Multi-channel infusion system

**Orchestra®** Infusion Station

**Agilia®** Connect range (mono-channel infusion)
MBD for Product Development

System

Product Specification
Simulation
Rapid Prototyping

Product Integration & Verification
Test Bench

SW
HW
Mech

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MBD for Product Development

- Simscape for plant models
- Stateflow for algorithm models
- Simulink Project with SVN
- Testing with Simulink VnV
- Cont. Integ (Matlab Unit Test & Jenkins)
- Code Generation (Embedded Coder)
MBD for Product Development

Jan. 2013
License Simulation

June 2013
Rapid Prototyping

2014
On-Target Rapid Prototyping

2015
Test bench and Emb. Sw to support R&D

Stateflow
Simulink
VnV

Simscape

Simulink Report Generator

Embedded Coder
Goals and Challenges

Knowledge (pump / algorithms)  
Skills (modeling, design control)

Leverage our MBD experience  
Better Quality, Cost, Delivery

No reuse of prototypes between Quality, Cost, Delivery of Sw dev

Time to market constrains

Process  
Establish new process and integrate it to our SOP  
Establish new tools

People  
Create collaboration between “C/C++” and “MBD” developers  
Change MBD mindset from prototyping to software safety

Product  
Give confidence to project, management and QA stakeholders  
Deliver on Time!
Our path to certification

Mathworks Consulting Services

- Audit of our MBD practices
- Gap analysis with IEC 62304
Our path to certification

IEC 62304 Certification Kit
- Software development plan
- Risk assessment and tool validation

Sw Architecture
- C/MBD development team
- Training Plan

Agile method
- Release Plan

Support of Mathworks for reviews of
- SDP (Certification kit, modeling rules)
- Architecture
- Training Plan
Our path to certification

MBD Adoption

Process Assessment

Change Preparation

Execution on pilot project

Our path to certification involves several key steps:

1. **MBD Adoption**
   - Specification
   - Architecture Planning

2. **Process Assessment**
   - Static Model Analysis, Unit test, Integration test
   - Design verifier checks, Polyspace analysis, Back-to-back testing

3. **Change Preparation**
   - Code generation

4. **Execution on Pilot Project**
   - Peer review
   - Transfer of generated code

**Tools Used**
- Jira Software
- Bitbucket
- Bamboo
- Polyspace

**Result**
- Static Code Analysis
- Unit test
- Integration test

**Application**
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Our path to certification

1. **MBD Adoption**
   - Modeling
   - Functional Testing
   - Model Verification (Static Analysis)

2. **Process Assessment**
   - Generated Code Verification (Back to back testing)
   - Model Verification (Peer-reviews)

3. **Change Preparation**
   - Project Review
   - Tool coaching
   - Project Review
   - Tool coaching

4. **Execution on pilot project**
   - Full Scope
   - More complex models / functions
   - 2/3 simple models / functions

**Process** + **People** + **Product** = Mathworks Support

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Our path to certification

- MBD Adoption
- Process Assessment
- Change Preparation
- Execution on pilot project
- 2nd Project

- Process
- People
- Product

- Mixed C/MBD development tasks
- Ramp up new resources
- Project duration reduced by 50%
- Efficient maintainability during verification phase
- Less defect in development phase
- Fast Start thanks to
  - Reused components
  - Reused patterns

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Conclusion

- **Learning & Recommendations**
  - Change management acting on the 3 «P» (Process, People, Product) is key
  - Break the walls between teams
  - Agile methods + Model-Based Design + Continuous Integration is powerful
  - Benefit of MBD for medical devices development (it is recognized by FDA)
  - Mathworks can guide you to do it right
Conclusion

- **Forward-looking plans**
  - Improve our existing MBD process
  - Reuse this methodology for other pieces of our systems
  - Study synergies between our MBD experience for our MBSE (Model-Based System Engineering) approach => System Composer Toolbox
Question

Thank you