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

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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

**Tools and Technologies**

- Stateflow
- Simscape
- Simulink VnV
- Embedded Coder
- Simulink Report Generator

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Goals and Challenges

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

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

Leverage our MBD experience
Better Quality, Cost, Delivery

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!

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Our path to certification

Mathworks Consulting Services

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

MBD Adoption → Process Assessment → Change Preparation

**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

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Our path to certification

**MBD Adoption**
- Specification
- Architecture
- Planning

**Process Assessment**
- Detailed Design
- Modeling
- Model static analysis
- Unit test
- Integration test

**Change Preparation**
- Peer review

**Execution on pilot project**
- Jira Software
- Bitbucket
- Bamboo
- Static Model Analysis
- Unit test
- Integration test
- Design verifier checks
- Polyspace analysis
- Back-to-back testing
- Code generation

**Static Code Analysis**
- (Polyspace)
- Unit test

**Peer review**

**Transfer of generated code**

**Release**
Our path to certification

MBD Adoption | Process Assessment | Change Preparation | Execution on pilot project

Process
- Generated Code Verification (Back to back testing)
- Model Verification (Peer-reviews)
- Modeling
- Functional Testing
- Model Verification (Static Analysis)

People
- Project Review
- Tool coaching

Product
- Project Review
- Tool coaching
- Mathworks Support

Mathworks Support

Process
More complex models / functions
Full Scope

People
2/3 simple models / functions
Project Review
Tool coaching

Product
Mathworks Support

Our path to certification

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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

Fast Start thanks to - Reused components - Reused patterns
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