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Model-Based Design & Certification

Application to medical domain

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Key Take-aways

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➔ 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

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- 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.

Clinical Nutrition

I.V. Drugs

Infusion Therapy

Medical Devices/ Transfusion Technology

Biosimilars

Where we are

~ 65 ● Sales and Marketing Organizations

~ 70 ▲ Production Sites and Compounding Centers

~ 20 ■ Research and Development Centers

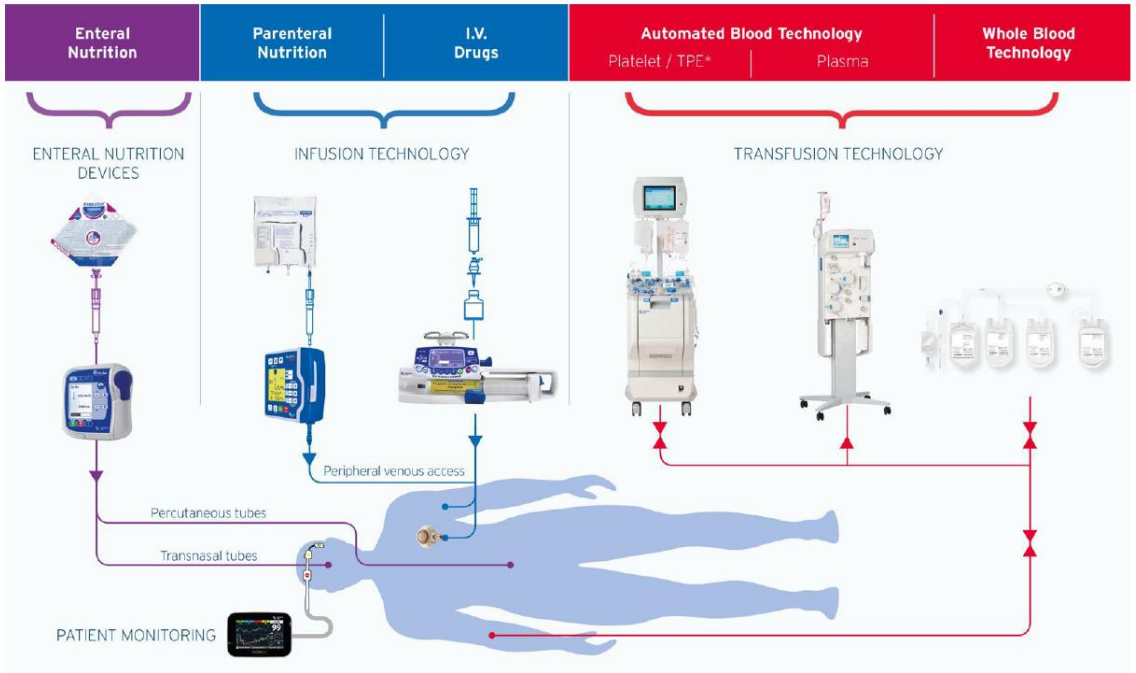
What we do

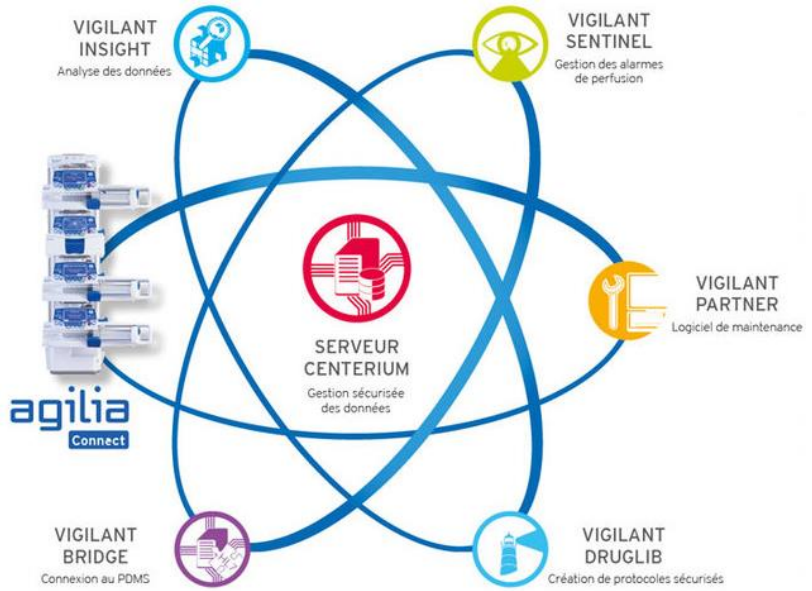

Infusion Devices


Disposables


Enteral Devices


Software Solutions





What we do

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Multi-channel infusion system

Orchestra® Infusion Station



Agilia ® Connect range (mono-channel infusion)


MBD for Product Development

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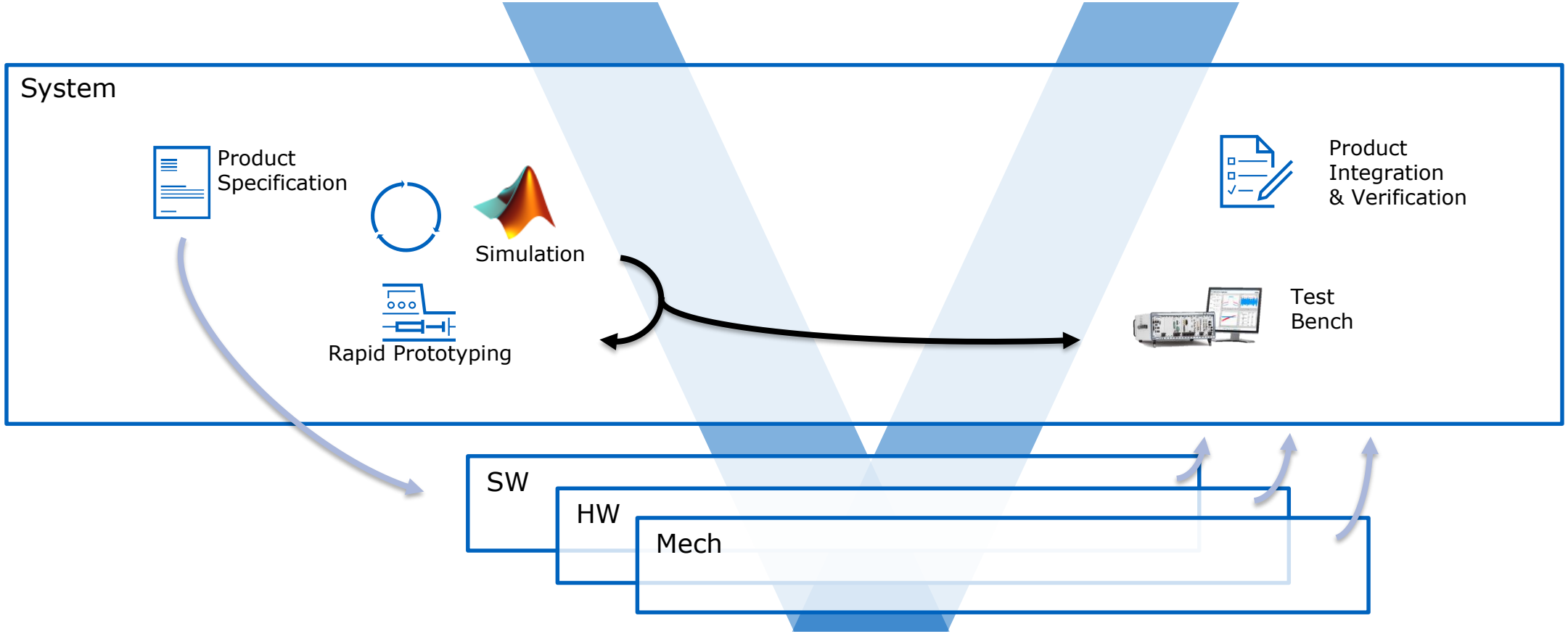

MBD for Product Development

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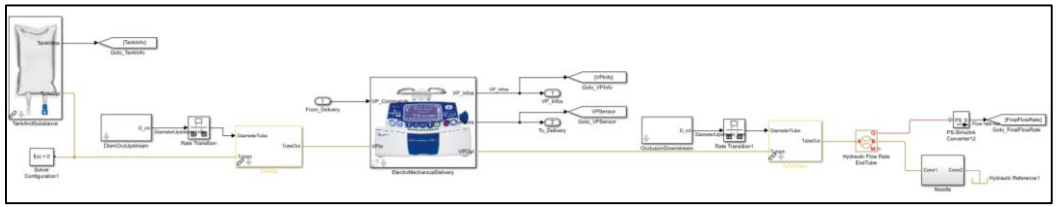
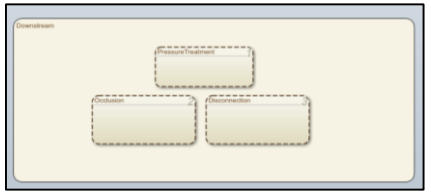
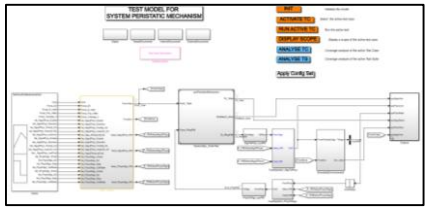
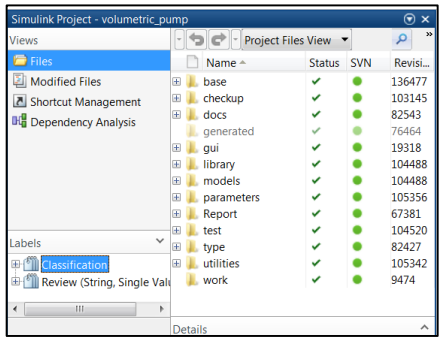
- ✓ Simscape for plant models
- ✓ Stateflow for algorithm models
- ✓ Simulink Project with SVN
- ✓ Testing with Simulink VnV
- ✓ Cont. Integ (Matlab Unit Test & Jenkins)
- ✓ Code Generation (Embedded Coder)









MBD for Product Development

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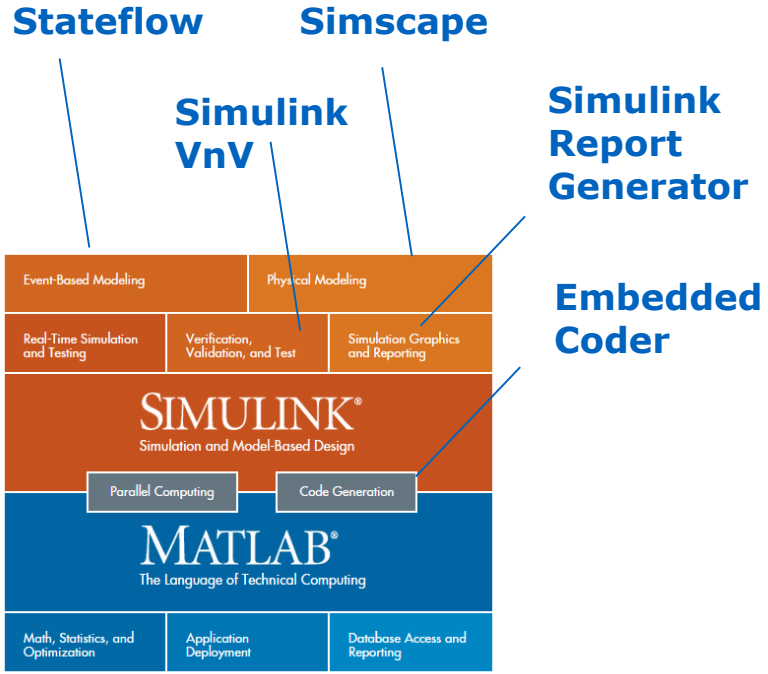
Jan. 2013
License Simulation

June 2013
Rapid Prototyping

2014
On-Target Rapid Prototyping

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



Goals and Challenges

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

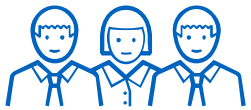
No reuse of prototypes between
Quality, Cost, Delivery of Sw dev

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 !

Our path to certification

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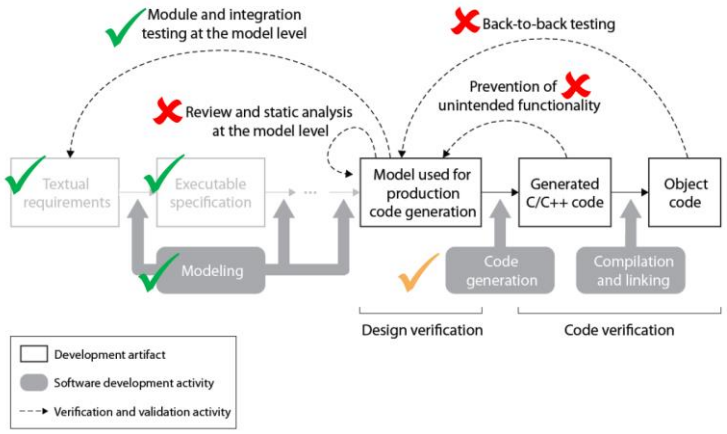
MBD Adoption → **Process Assessment**

Mathworks Consulting Services

➔ Audit of our MBD practices
➔ Gap analysis with IEC 62304



IEC 62304 Gap Analysis

Processes	Gap	Effort
5.1 Software development planning	+++	low
5.2 Software requirements analysis	+	low
5.3 Software architectural design	++	med
5.4 Software detailed design	+	med
5.5 Software unit implementation and verification	+++	high
5.6 Software integration and integration testing	+	low
5.7 Software system testing	-	n/a
5.8 Software release	-	n/a
6 Software maintenance process	+	low
7 Software risk management	+	low

Our path to certification

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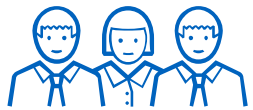
MBD Adoption → Process Assessment → **Change Preparation**

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*

Our path to certification

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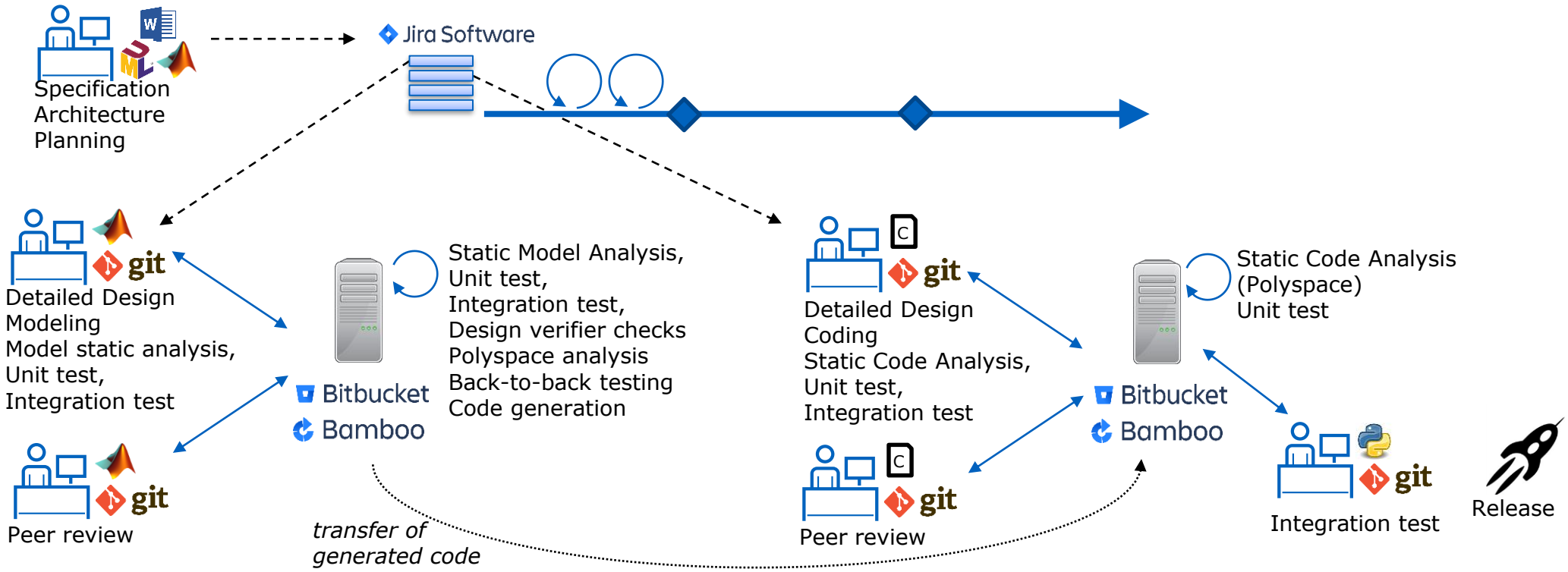
MBD Adoption → Process Assessment → Change Preparation → **Execution on pilot project**



Our path to certification

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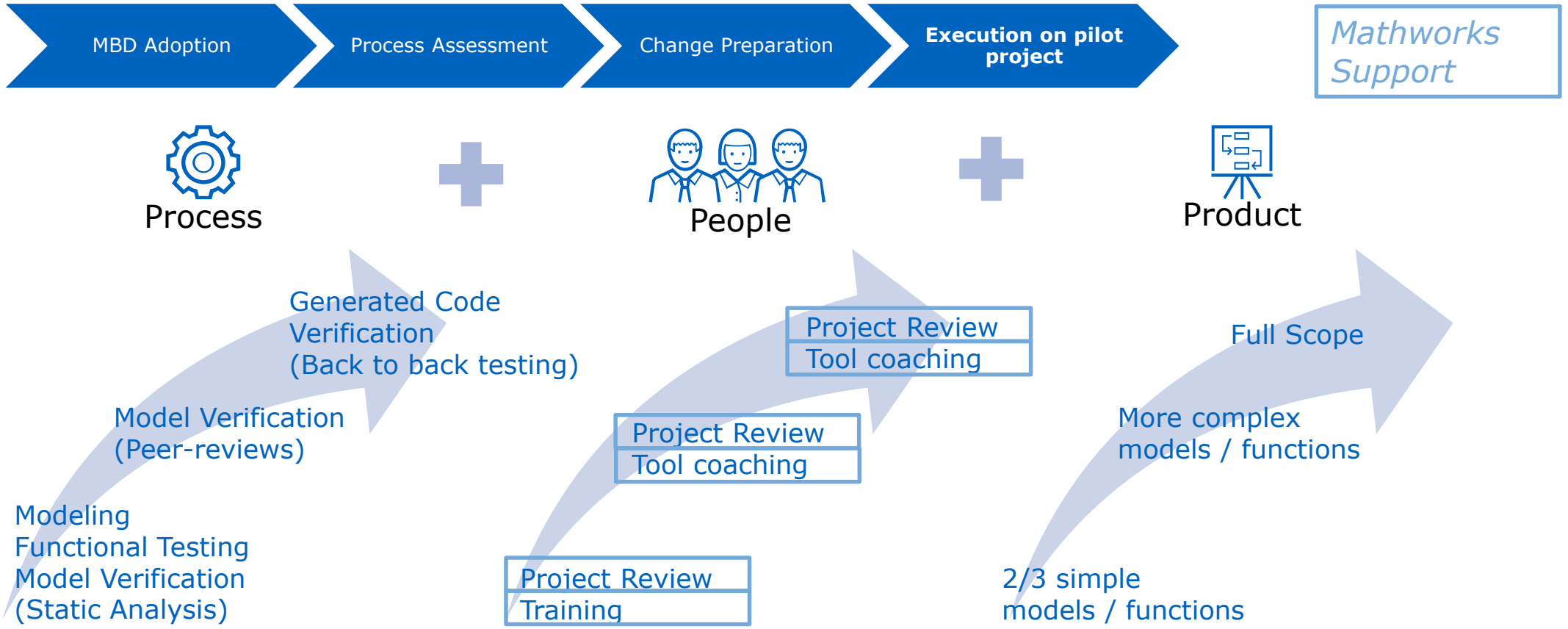

Our path to certification

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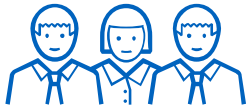
MBD Adoption → Process Assessment → Change Preparation → Execution on pilot project → **2nd Project**

Process



People

Product

Mixed C/MBD development tasks

Ramp up new ressources

Project duration reduced by 50 %

Efficient maintainability during verification phase

Less defect in development phase

Fast Start thanks to
- Reused components
- Reused patterns

Conclusion

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- **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

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- **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 ?

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Thank you