Implementing AAMI-TIR45 in Medical Devices

INCOSE Agile Conference

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Agenda

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3. Capability Building
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    2. Process and Framework
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4. Retrospective

Introduction

Speakers

Madhu Expedith, GEHC, Senior Agile Leader for GEHC

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Madhu has more than 16 years of combined experience in Agile Transformation and Coaching, Program Portfolio Management, IT Strategy Consulting, Process and Quality Consulting, Business Process Re-engineering, and Software Engineering. Madhu has worked extensively on programs with leading Medical Devices, Healthcare, Pharmaceutical, Retail, Finance, Automobile, Telecom and Oil & Gas firms in United States of America and Canada. Madhu holds a Bachelor's degree in Chemical Engineering and Technology from University of Madras and holds various certifications and has numerous publications.

Sergey Korabelnikov, GEHC, Program Director in MRI unit

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Sergey has 25 years of software development, functional leadership and project/program management experience in companies ranging from a seed-money startup to one of the world largest medical device manufacturers. Introduction of Scrum and Scaled Agile Framework practices into medical device software and system development is one of the focal points on his current assignment in GE Healthcare, MRI. Sergey holds a Master's degree in Computer Science (IT) from one of Moscow Universities and is CSM and CSPO certified.

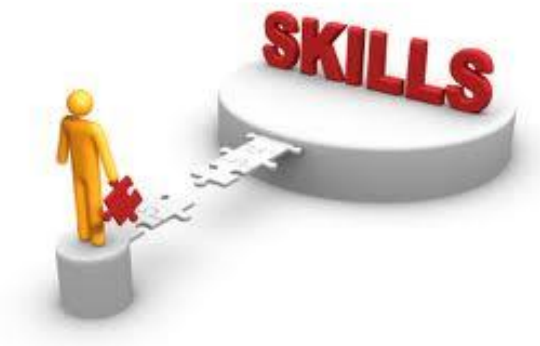
Context

Setting the Context

- Exploring Agile as part of Continuous Improvement
- Understanding FDA's perspective
- Implementing AAMI:TIR45

Capability Building

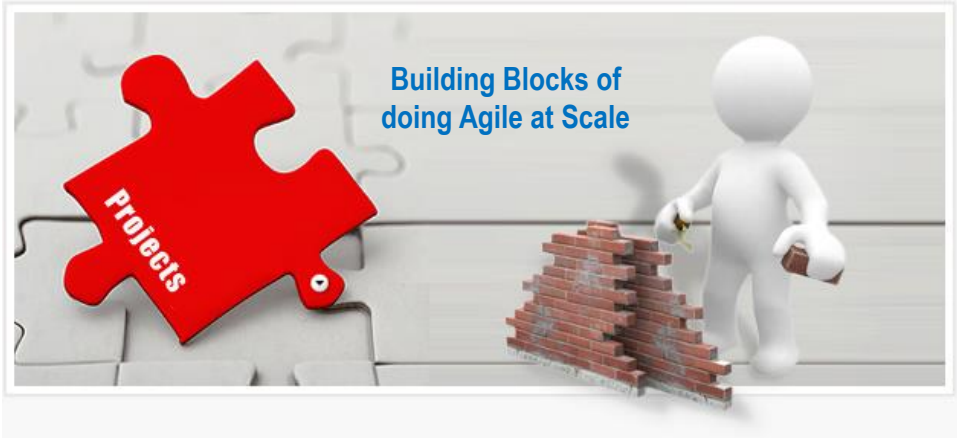
People and Coaching



- Agile is a cultural and mindset change
  - Agile is hands-on application of Lean Thinking
- Building truly cross-functional teams is more challenging in Medical Devices
- Building Program Level Capabilities
  - Agile Systems team
  - DevOps
  - UX

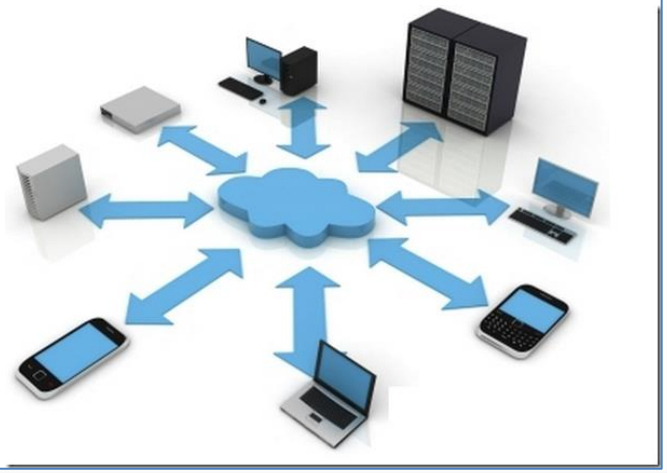
Process and Framework

- What does Agile at Scale mean in Medical Devices?
- Value Stream Mapping and Achieving Business and Quality Milestones
- Managing Design Inputs, Design Outputs and Design History Files (DHF)



Technology and Infrastructure

- Agile Engineering Tools: Automation and Continuous Integration
- New Tools to support DHF in Agile and managing existing Tools
- Architectural Runway



Retrospective

What did we learn?

- When Organizations embark on adopting Agile in Medical Devices in accordance with AAMI:TIR45 Guidance they are signing up for a major Org. Change initiative
- Treat the Regulators as another Customer / Persona
- Focus on the Dynamics and Mechanics will follow
- Applying Lean / Agile to Software has its benefits. However, an Organization will reap maximum benefit if the all the other cross-functional areas such as hardware, magnets, manufacturing, systems, coils etc. also adopt Lean / Agile philosophy
- Agile / Scrum in Hardware is a reality
- Complexity is multi-fold with Globally Distributed Teams

Thank you