

Medical Device Agile Systems Development Workshop

Logistics

- November 20, 2015
- IBM Schaumburg, Illinois
- 15 Attendees (Roche, GE Healthcare, Agile Quality Systems, Battelle, Baxter, ICTT System Sciences, IBM)

Focus was on Agile Systems development processes

- Agile methods applied concurrently to multiple disciplines
- Includes electronic, mechanical, and firmware design of a system
- Synchronization of Agile processes on each discipline

Problem Statement

- Agile and Lean Enterprise Startup methods are state of the art methodologies which allow organizations to thrive in environments of rapid change
- The AAMI TIR 45:2012 AAMI “Guidance on the use of agile practices in the development of medical device software” describes how to apply Agile principles to software in the world of medical device regulations.
- We lack best practices and guidelines on how to leverage the benefits of adaptive and iterative methodologies for programs involving both SW and HW in the medical field.

What is the Essence of Agile?

Agile Manifesto

- Individuals and interactions *over processes and tools*
- Working software *over comprehensive documentation*
- Customer collaboration *over contract negotiation*
- Responding to change *over following a plan*
- *That is, while there is value in the items on the right, we value the items on the left more.*

Hard to argue with the above principles, though the details are constrained by medical regulations & you would need to change “software” to “systems”

A simple view, from Jennifer Pahlka, Founder and Executive Director, Code for America. Former Deputy United States Chief Technology Officer

- **Agile is:**
 - Iterative
 - Customer focused
 - Data driven

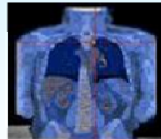
“Disrupting Politics As Usual”, The Commonwealth Club, Jan 8th, (<http://www.commonwealthclub.org/events/2016-01-07/disrupting-politics-usual>)

Agile at GEHC

Chris Unger

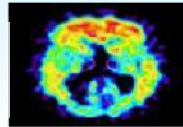
Broad Based Diagnostics

Diagnostic Imaging



- CT, PET/CT
- MR

Medical Diagnostics



- Contrast agents
- Molecular diagnostics

Clinical Systems



- Ultrasound
- Critical care systems

Information Technology & Services

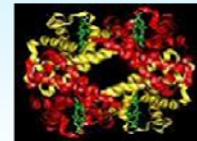


- Electronic medical records
- Revenue cycle



- Performance solutions
- Multi-vendor services

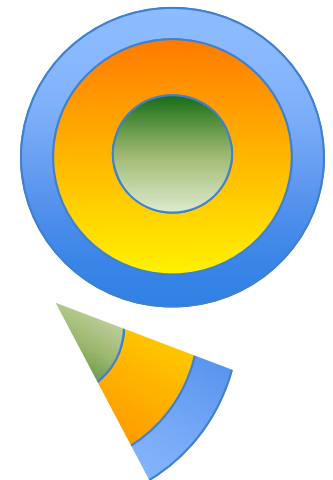
Life Sciences



- Discovery systems
- Protein separations

Why Agile Software Development Methodology?

Program Challenges	Agile Strategies
<p>Quality</p> <ul style="list-style-type: none"> • Need continuous customer and performance feedback to ensure needs are met. 	<ul style="list-style-type: none"> • Frequent demo's, VoC. • Integrate cross functional team into the development process
<p>Predictability</p> <ul style="list-style-type: none"> • Need to estimate the work in the way we are doing it. • Need to have a continuous progress measurement system to be sure we are on track. 	<ul style="list-style-type: none"> • Decompose work into quarterly program increments...focus on customer expectations • Close monitoring and tracking of progress • <i>Automated testing</i> and "Definition of Done"
<p>Speed</p> <ul style="list-style-type: none"> • Need to re-prioritize quickly to address risks, support the hardware teams, test, VoC, etc. 	<ul style="list-style-type: none"> • Work is done in slices, not layers. • <i>Short 2 week sprints of focused activity to create a software development assembly line</i>
<p>Scalable</p> <ul style="list-style-type: none"> • Need to partition the work to scale up the number of teams. 	<ul style="list-style-type: none"> • Teams are self organizing and supported with dedicated execution, technical, and product functionality oversight.



What's Different About Hardware?

Lead times are longer in HW

- Modification of design output based on user feedback is much slower – however this is improving due to both mechanical and electrical rapid prototyping
- Product increments are dependent on external suppliers (or external labs)
- Harder to drive 'zero technical debt' on defects. Can drive to root cause and then schedule the fix based on lead times.

Fewer 'modular tasks' that can be completed in 2 weeks (sprints)

- Hard to 'complete' parts of a board or mechanical structure independently...
- Many interdependencies (power, grounding, thermal, board space, cross-talk...)

Team members are less "generic"

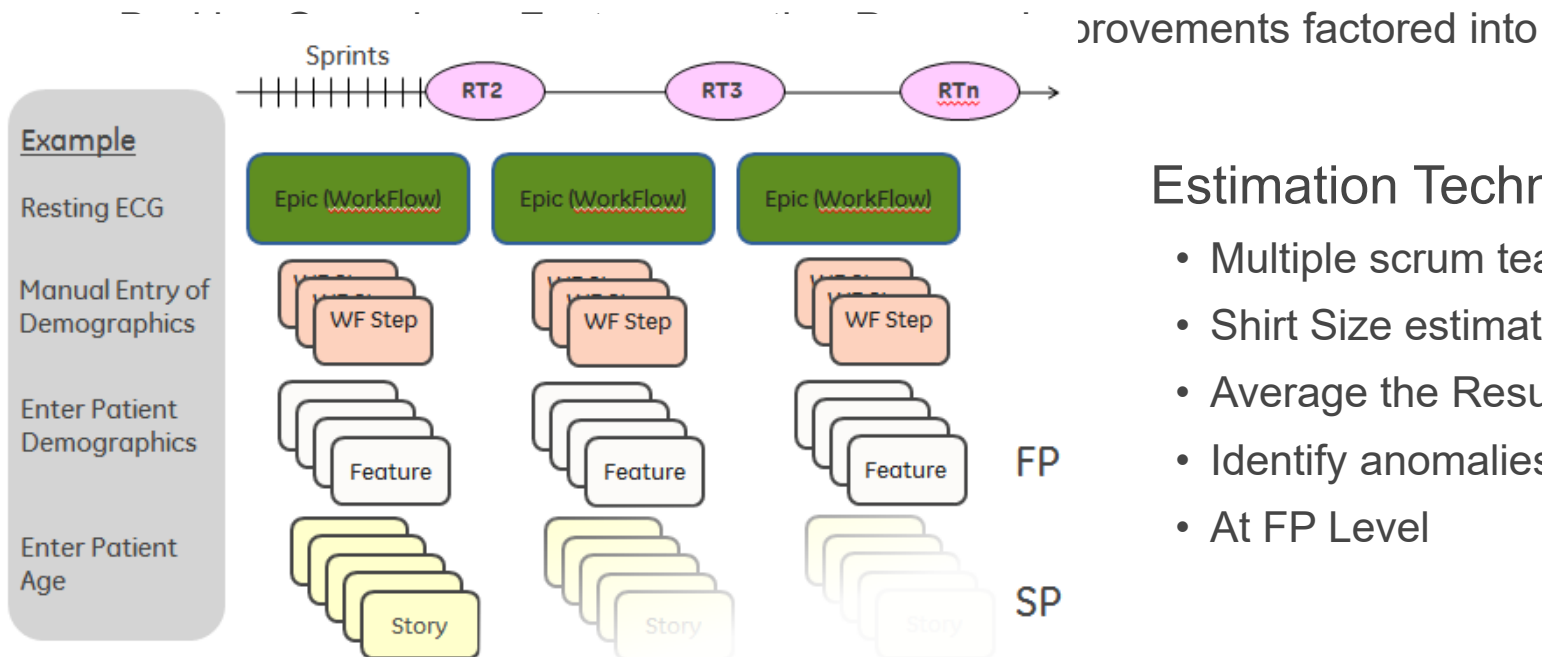
- Mechanical/electrical developers, board layout/designers, technicians, etc.
- Reduces ability to share tasks

What's the same?

- Iterative/planning (precise planning for next few weeks, detailed planning for next quarter, rough planning for the project)
- "Daily Stand-ups" – currently meeting 3 times/week
- Create completion criteria at the Sprint, Feature, Epic levels and develop using vertical slices of functionality
- Do continuous integration and test automation at all levels (unit, item, system)
- Perform as much verification as possible in each Release Train; Collocate and embed testers with the developers

Hybrid Approach to Systems Programs

- Software uses Scaled Agile Framework, Hardware uses PERT planning
- Program Estimation at different time horizons
- Backlog Grooming – constrained by critical HW interdependencies
- Assessing Progress Against Plan – Updating future plans
 - Historical velocity estimates



Estimation Techniques

- Multiple scrum teams
- Shirt Size estimates
- Average the Results
- Identify anomalies
- At FP Level

Remaining Technical Challenges

Agile Scope and Requirements Management

- Tying scope to effort and market impact in an iterative/learning culture
- Incorporating lead times and technical risks into requirements phasing
- Changing the “planning” culture

Agile, Compliant, Efficient Documentation Practices

- Minimizing overhead of managing revisions and change control

Distributed team members

- Few programs are fully collocated

Harmonizing Terminology Across Corporate Initiatives

- Lean Startup, Marketing Functional Excellence, Design Thinking...

Various Agile Approaches

Kelly Weyrauch

Agile for Early Phase Feasibility – “Project Backlog”

- Background
 - Medtronic – Multi-year SW project, 1 Feasibility Team. Motivation to shorten typical Feasibility from 6 months to 1
 - Smiths Medical – 5 Concurrent Feasibility Teams. Motivation to jump start a platform project that is stuck in Feasibility for 3 years.
- A more pragmatic approach to Early Phase Feasibility
 - Team & Business is ready to commit to a **definition** and a **schedule** that has an acceptable level of **risk** and reasonable **levers to manage** the development phase.
 - Accepting
 - We know just the right amount of definition and design
 - And just the right amount of plan/schedule
 - Knowing the risks of being wrong about either
 - And having ability to manage the risks as we go

Agile for Early Phase Feasibility – “Project Backlog”

- A “Project Backlog” and Sprinting to produce the Product Backlog
- Definition Stories
 - “Product Owner & Dev Team understands the scope/definition of _____ so that we can have an acceptable Product Backlog & Release Plan.”
 - Output is Stories on the Product Backlog, with Acceptance Criteria & Initial Estimates + Risk Attributes
 - Possible Output is Stakeholder Expectations, System/Subsystem Requirements, Validation Strategies
- Implementation/Design Feasibility Stories
 - “Dev Team understands impact of design decisions for ____ so that we have Acceptance Criteria and Estimates for Backlog”
 - ____ = Technology, Arch & Interfaces, Functional Decomposition, ...
 - Output is Stories on the Product Backlog, with Acceptance Criteria, better estimates on other Stories
 - Possible Output is Requirements, Architecture, Design Docs, Verification Strategies

Backlogs & Time-Boxes for non-Software

- Backlogs
 - Emphasize VALUE TO DELIVER (not work to be done)
 - Consider “Decisions” as a valuable thing
 - Use the Story Pattern
<Someone>
Can do <something>
To achieve <some goal, benefit, value>.
 - “Purchasing needs a decision on the <product standard we will adhere to> so they can narrow the vendor list for evaluation.”
 - “Purchasing needs a decision on the <component selection> so they can select vendors and begin purchasing process.”
 - “Vendor needs decision on the finish for the part to provide us with their lead-time requirements for the final part.”

3 – Backlogs & Time-Boxes for non-Software

- The Power of the Time-Box
 - Lean (focus, limiting WIP, deliver fast)
 - Decision-Making (last-responsible moment, accelerate learning)
- Problems with the Time-Box
 - Belief: “We can’t break down our Stories that small”
 - Fact: “You can ALWAYS break work, so you can ALWAYS break down Stories”

Other Companies

Battelle, Roche

Battelle Presentation

Rainy Mumper, Clark Fortney & Blake Alberts described the approach that Battelle Memorial Institute takes for their healthcare related projects:

- Up-front work: Initial risk analysis, Marketing specs, Draft systems specs, Fleshed out SW specs, Draft architecture and key interfaces defined
- Went to 3 week sprints to allow time for efficient paperwork generation
- The sprints more do refinement of the requirements than requirements elicitation
- Formal verification is more waterfall near the end.
- Battelle uses three level of planning, similar to the SAFE framework (though they do not use that framework explicitly):
 - *Project Planning*
 - *Release level planning*
 - *Sprint level planning (2 hours)*

Roche Presentation

Will Bishop described how Roche Diabetes Care integrated Agile for projects with hardware and software:

- HW Sprints do not have a fixed length; they drive to a firm definition of done
- HW sprints are normally longer than SW/FW sprints (normally a couple of months)
- Earliest increments are breadboards working, but pretty early they have an end to end functionality.

Workshop Breakouts

Barriers Related to Agile Systems

Entire conference brainstormed possible barriers to adopting Agile for systems

Everyone voted on their favorites and two issues dominated the results

Two breakout teams were formed to work on each of the top two.

[8] Agile team organization (around features, not disciplines) how to do it?

[8] What are the cultural barriers to adoption and best practices to overcome?

[3] Agile lifecycle and 15288 update (also, concept of information debt)

[2] Opportunities to break down work into short but valuable tasks

[2] Framework to determine how to balance architecture phase before feature phase

[1] Portfolio management – how that integrates with the next level down

How to get started? Migration paths for initial deployment

Is there a maturity model for assessing Agile deployment

Hybrid simulations – how to simulate top to bottom to do early verification

Tutorial, testimonials, and/or examples (in “their” language) – training and the AAMI class

What are the best practices on requirements freeze vs. emergent requirements & a learning culture

Breakout 1: Agile team organization

Team structure depends

Define how to measure teams value progress

Person responsible for scrum team interfaces

Interfaces help define scrum team organization

Independent, empowered with customer focus and common goal

Engineers are not interchangeable

Work is demonstrated within Sprint...so organize that way

Breakout 2: Barriers to Adoption

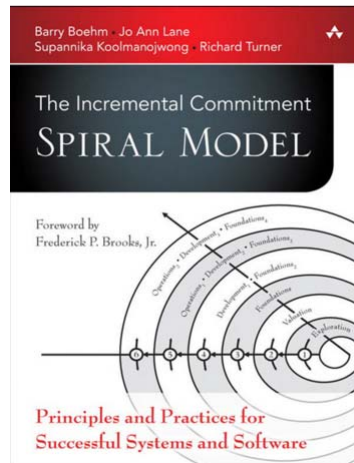
Cultural and Organizational Barriers

1. My type of work is different
2. On a team my skills are deep and unique
3. Depends on trust and transparency
4. With enough analysis we can be predictable
5. Commitment and accountability
6. Desire to direct – command and control
7. Accepting a level of uncertainty
8. Beliefs about cost of change (various system elements)
9. Will regulators accept this? “Ghosts of ‘They’”
10. Misperceptions about Agile
11. Shift in how we specify requirements
12. Stated vs. real requirements
13. How do I fit in?
14. Fear of the unknown
15. Want long term benefits without the short term costs

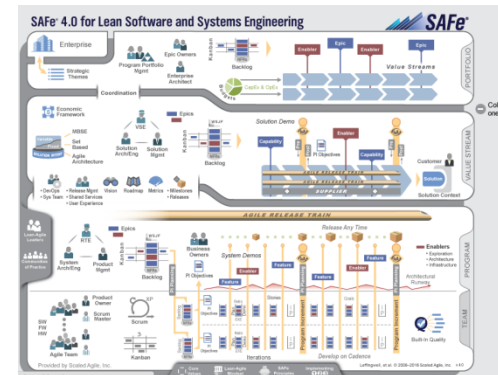
Change Techniques

- A. Educate all levels of the organization (1-3)
- B. Functional manager need to understand their role (13, 5, 7, 3)
- C. Change roadmap / playbook – may take years (set expectations) (1-13)
- D. Agile approach to change process (backlog, sprints) (11, all)
- E. Examples of waterfall disasters/boondoggles in “our” organization (14, 10)
- F. Lenses through which failure is seen/interpreted (14, 10)
- G. Rolling wave planning (4, 7, 11)
- H. Show how things are currently happening in organization which are good are actually Agile things (14, 13, 10)
- I. Cite other companies or other teams within our company that are doing it (14, 13, 9, 7, 8, 3, 1)
- J. Improved visibility to stakeholders (All)

More Resources



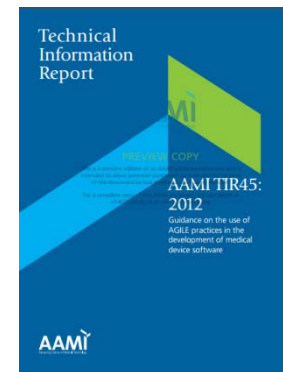
The Incremental Commitment Spiral Model: Principles and Practices for Successful Systems and Software, Boehm et al.



Scaled Agile Framework 4.0 (<http://www.scaledagileframework.com/>)



http://www.omgwiki.org/MBSE/doku.php?id=mbse:patterns:patterns_challenge_team_mtg_01.30-31.16



AAMI TIR-45: 2012
http://my.aami.org/aamiresources/previewfiles/TIR45_1208_PREVIEW.PDF

INCOSE Conference on Agile Systems in Health Care

The Health Care Working Group of the International Council on Systems Engineering (INCOSE), with support from the INCOSE Agile Systems Working Group and System Patterns Working Group

Monday, May 23, 2016 at 8:30 AM - Tuesday, May 24, 2016 at 5:00 PM (CDT)
Schaumburg, Illinois



Conference on Agile Systems in Health Care

Ticket Information

TICKET TYPE	SALES END	PRICE	FEE	QUANTITY
Conference Participant	May 23, 2016	\$100.00	\$0.00	1

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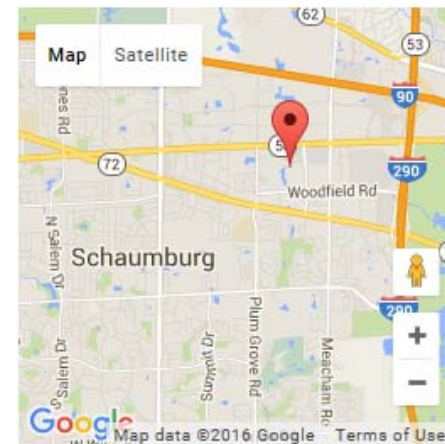
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Event Details

ADVANCING THE AGILITY OF GENERAL SYSTEMS IN THE HEALTH CARE DOMAIN: The International Council on Systems Engineering (INCOSE www.incose.org) is concerned with complex hybrid systems of all types--including interacting people, equipment, materials, software, and their environment. Although the software development community has advanced the practice of agile development of software, the system-level opportunities and challenges of agility are much broader than software alone. This conference is about the current landscape, examples of progress in agility for more general systems, and the road ahead. It builds on an earlier conference held in 2015.

When & Where



American Society of Anesthesiologists
1061 American Lane
Schaumburg, Illinois 60173

Monday, May 23, 2016 at 8:30 AM -
Tuesday, May 24, 2016 at 5:00 PM (CDT)

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