

Agile for Medical Devices

A New Day Dawns

Brian Shoemaker, Ph.D.



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- Originally an analytical chemist
- 15 y in clinical diagnostics (immunoassay):
analytical support → assay development → instrument software
validation
- 6 y as SW quality manager (5 in clinical trial related
SW)
- 10 y as independent validation consultant to FDA-
regulated companies – mostly medical device
- Active in: software validation, Part 11 evaluation,
software quality systems, auditing, training

Acknowledgement

Part of this material was developed by Nancy Van Schooenderwoert, Lean-Agile Partners Inc., and is based on her work in coaching teams in lean methods for high-quality software development.

Nancy Van Schooenderwoert
Lean-Agile Partners, Inc.
162 Marrett Rd., Lexington, MA 02421
781-860-0212
NancyV@leanagilepartners.com
<http://www.leanagilepartners.com>



Lean-Agile Partners

A New Day Dawns

- **Why all the fuss?**
- *Has Agile worked at other device co's?*
- *What makes Agile acceptable?*
- *How about risk, usability, design reviews?*
- *What pitfalls have been overcome, and how?*

Why This Discussion?

- Traditional doc-heavy SW development is expensive, slow, and error prone
- Regulatory bodies rightly concerned with product software vs. safety (OSEL report: 24% of 2011 medical device recalls were for software!)
- Classic belief: tightly controlled process → better engineering
- Agile is highly productive, but seems the antithesis of tightly controlled process



Village Rumors

Too many rumors in the medical device village?

*The standards say we **must** use a waterfall model*

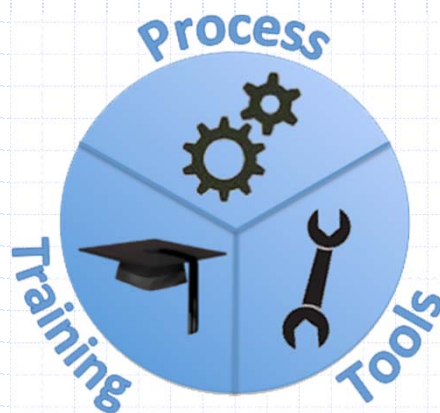
Agile isn't suitable for safety-critical work!

TRUE Agile means you don't plan and don't write documents.

Agile is just an excuse for sloppiness!

The Elements

None of these is sufficient by itself!



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SDMD Attendees using Agile

- Dräger Medical
- Elekta
- Given Imaging
- Medidata Solutions
- Philips Healthcare
- Renishaw
- Siemens
- Systelab Software

INCOSE Agile in HC Conference

- Attendees included reps from:
 - Battelle Memorial Institute
 - Boston Scientific
 - Cook Medical
 - GE Healthcare
 - Medtronic
 - Roche
- All were there to share successes!

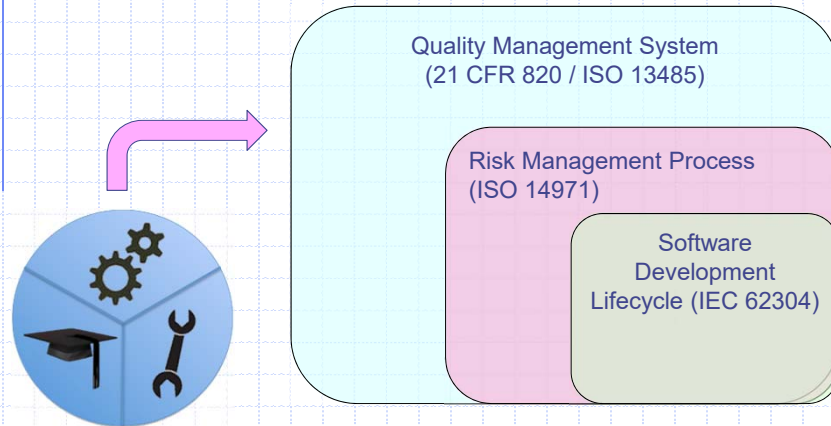
LAP & optical company

- Worked with Scottish co. remotely
- Discussed issues around Agile with both development & testing
- Suggested using Impact Mapping / Story Mapping for new product
- Devised initial impact map based on team's input

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Processes – for Safety



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GPSV & IEC 62304 principles

- Have a Quality Management System
- Use a risk management approach
- Classify software according to safety
- Have processes for known development steps
- Use maintenance processes
- Manage configuration (versions)!
- Follow a problem resolution process

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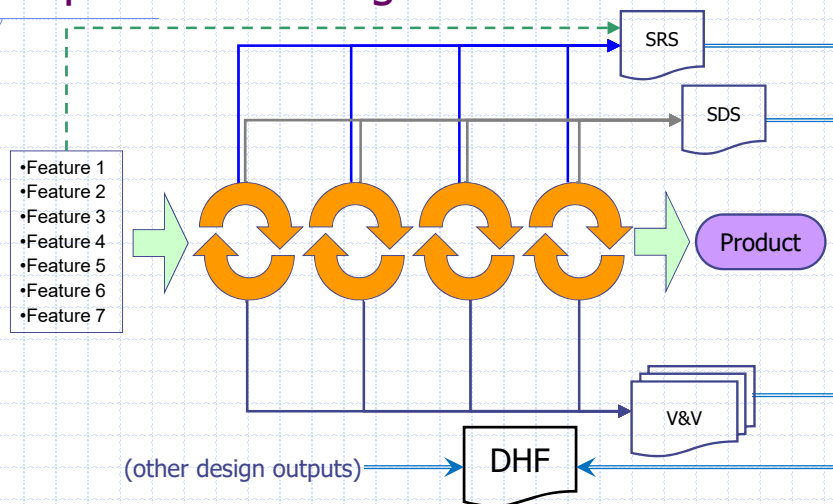
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What's NOT in GPSV or 62304?

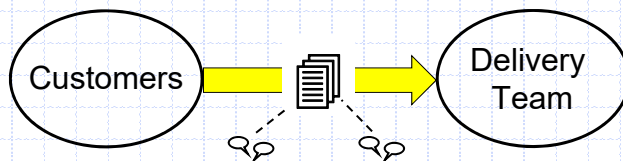
- No prescription for how to accomplish requirements
- No specific required software life cycle
- Particular documents not specified – *what* to cover, not *where* to cover

Capture Knowledge as Work Proceeds

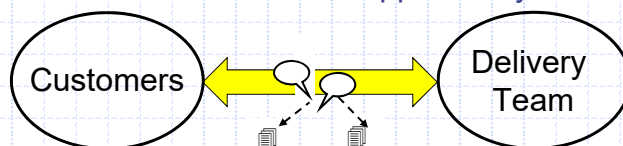


Documents as Output

- From **Document-centric**, supported by Conversation



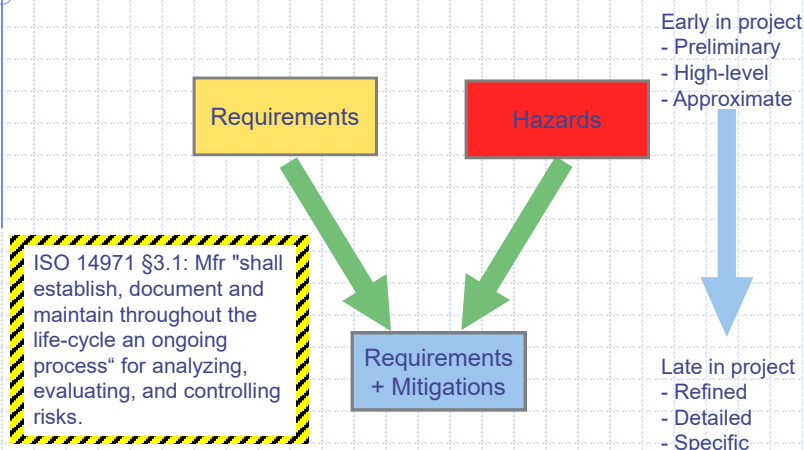
- To **Conversation-centric**, supported by documents



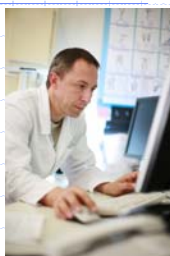
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Risk Management *MUST* Iterate



Who are you designing for?

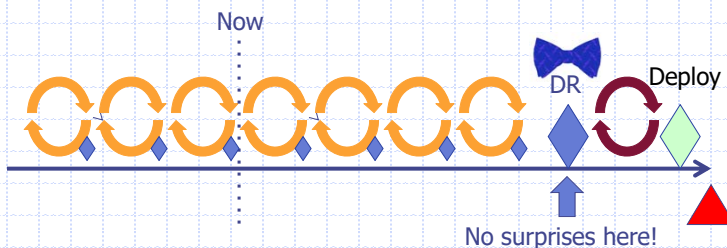


- Who will actually operate your system?
- Do you know what jobs they have to do every day? Where and under what conditions?

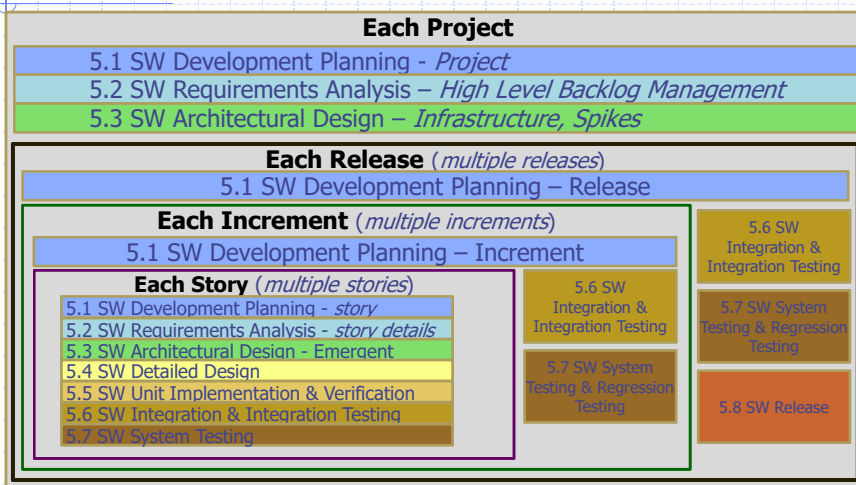
- What will make the device you're designing better than the one they're already using?
- How will you ever really know whether you've met their needs?
- **Could they misuse the system in a way that would hurt or kill the patient, the user, or a bystander?**

Design Reviews in Agile

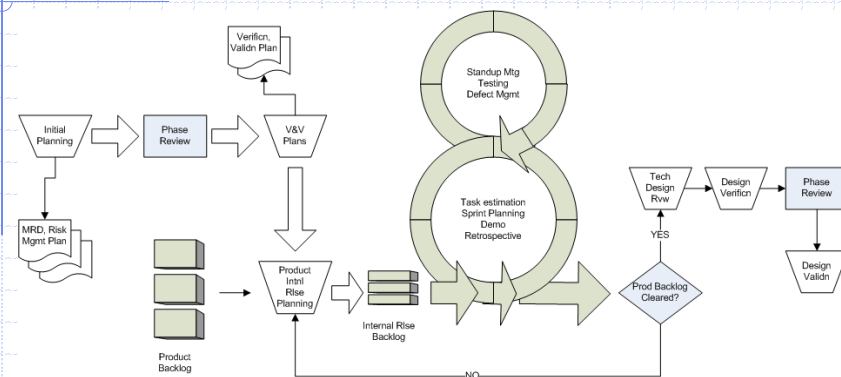
Each iteration has design, dev, test, demo (◆)
 We'll hold the formal Design Review...



Plan at different levels



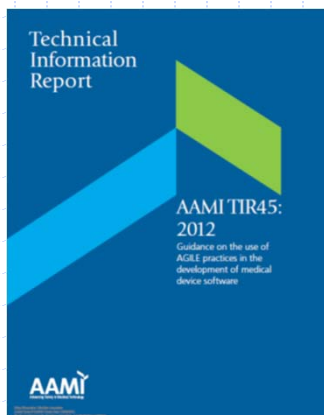
Agile in a Product Lifecycle Process



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Officially accepted



- Published in 2012
- Authors include industry experts, Agile experts, and FDA personnel
- Gives guidance on using Agile methods for medical device SW development
- Covers key concepts and practices

We Can Answer the Objections

- Formal hazard mitigation process?
- Lack of Overall Planning?
- Lack of Structured Reviews?
- Lack of Documentation?

Mindset, not Cookbook

NOT this:



But this:



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Understand and Enforce "Done"

- Core agile behavior → **complete** one story before moving on to the next
- What does done mean?
- Specified, designed, coded, tested, documented, approved, all bugs fixed?
- Testing is crucial
- "Nearly done" distorts velocity → estimates become unreliable
- Done-ness checklist is helpful.

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Essential Elements

- High level product vision
- Access to REAL CUSTOMERS
 - Hospital med techs – Radiologists – Nurses - Patients, e.g. diabetics
- Collaboration across functions
 - SW, HW, UI design, marketing
- Managers need to participate!
 - Remove roadblocks, keep team focus

Other Crucial Elements

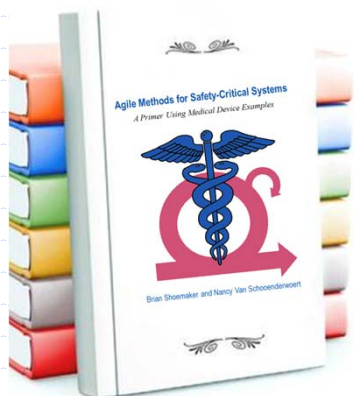
- QA and RA engaged early
- Frequent regression testing (and tools for this)
- Team's work visible to stakeholders
- Regular demos, with feedback, as product emerges

Agile for device development?

- Simple answer: yes
- Discipline is necessary – but that's always true
- AAMI TIR45 endorses Agile methods, outlines approaches

There's More Information!

- Soon to be published



Agile Methods for Safety-Critical
Systems: A Primer Using Medical
Device Examples

By

Nancy Van Schooenderwoert
And Brian Shoemaker

Contact Information

Brian Shoemaker, Ph.D.
Principal Consultant, ShoeBar Associates
199 Needham St, Dedham MA 02026 USA
+1 781-929-5927
bshoemaker@shoobarassoc.com
<http://www.shoobarassoc.com>

