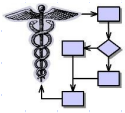


Agile 62304 Mini-Plays

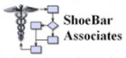
Nancy Van Schooenderwoert

Brian Shoemaker

Agile Software Development for Healthcare,
Berlin Germany

Brian's Background

- 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)
- 7 y as independent validation consultant to FDA-regulated companies – mostly medical device
- Active in: software validation, Part 11 evaluation, software quality systems, auditing, training



Nancy's Background

- 15 years safety-critical systems experience
- 10 years agile team coaching
- 3 years agile enterprise coaching
- Industries: Aerospace, Medical Devices, Sonar Weaponry, Scientific Instruments, Financial Services
- Electrical Engineering and Software Engineering, embedded systems

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Three mini-plays will illustrate widespread misconceptions in regulated healthcare businesses about the regulatory attitude toward Agile methods:

#1: "But the regulators require a waterfall method, don't they?"

#2: "But Agile doesn't have hazard analysis!"

#3: "What about design reviews?"

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Act #1

"But the regulators require a waterfall method, don't they?"

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Scene #1

Scene: Mary, the head of Quality Assurance, has just come to Brian in a panic. "But we're supposed to follow a waterfall development method – it's right there in IEC 62304!"

Brian, a seasoned development lead who has reviewed all of the standards, is unperturbed – he knows poor Mary has a misconception, talks her through the *real* requirements, and shows her how all of the documents will be generated in this project.

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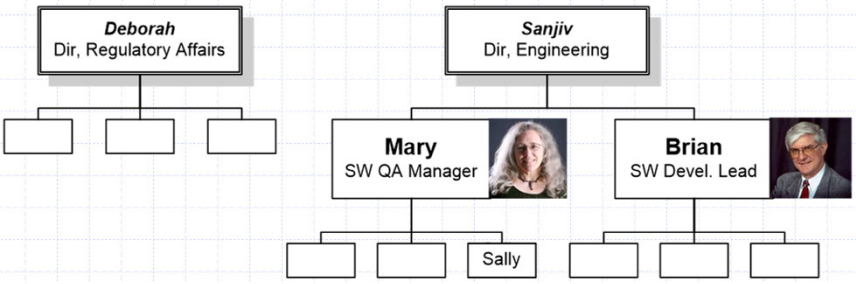
Our Characters



Our Project: Kidney Dialysis units "next generation"

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From IEC 62304

Introduction

This standard does not prescribe a specific life cycle model.
The users of this standard are responsible for selecting a life cycle model for the software project and for mapping the processes, activities, and tasks in this standard onto that model.

Annex B (informative)

Guidance on the provisions of this standard
The purpose of this standard is to provide a development process that will consistently produce high quality, safe medical device software. To accomplish this, the standard identifies the minimum activities and tasks that need to be accomplished to provide confidence that the software has been developed in a manner that is likely to produce highly reliable and safe software products. (...)

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From IEC 62304

Annex B (cont.)

This standard does not require a particular software development life cycle model. However, compliance with this standard does imply dependencies between processes, because inputs of a process are generated by another process. For example, the software safety classification of the software system should be completed after the risk analysis process has established what harm could arise from failure of the software system.

Because of such logical dependencies between processes, it is easiest to describe the processes in this standard in a sequence, implying a "waterfall" or "once-through" life cycle model. However, other life cycles can also be used.

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From IEC 62304

5.1.1. Software Development Plan

The manufacturer shall establish a software development plan (or plans) for conducting the activities of the software development process appropriate to the scope, magnitude, and software safety classifications of the software system to be developed. The software development life cycle model shall either be fully defined or referenced in the plan (or plans). (...)

NOTE 1. The software development life cycle model can identify different elements (processes, activities, tasks, and deliverables) for different software items according to the software safety classification of each software item of the software system.

NOTE 2. These activities and tasks can overlap or interact and can be performed iteratively or recursively. **It is not the intent to imply that a specific life cycle model should be used.**

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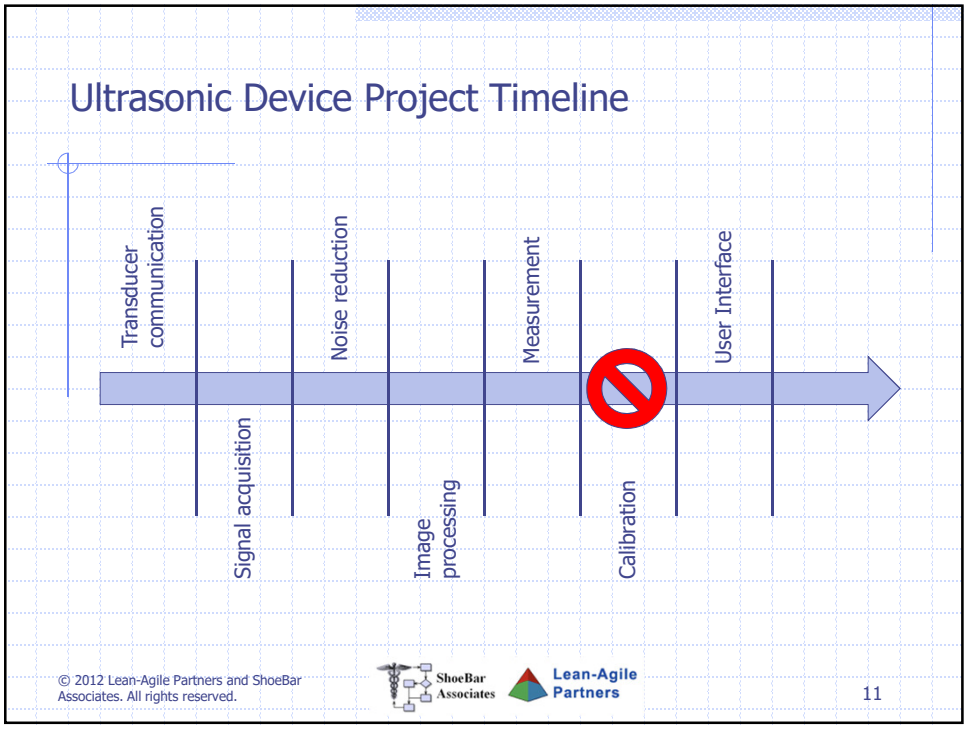
Ultrasonic Device Project Timeline
Transducer communication
Signal acquisition
Noise reduction
Image processing
Measurement
Calibration
User Interface
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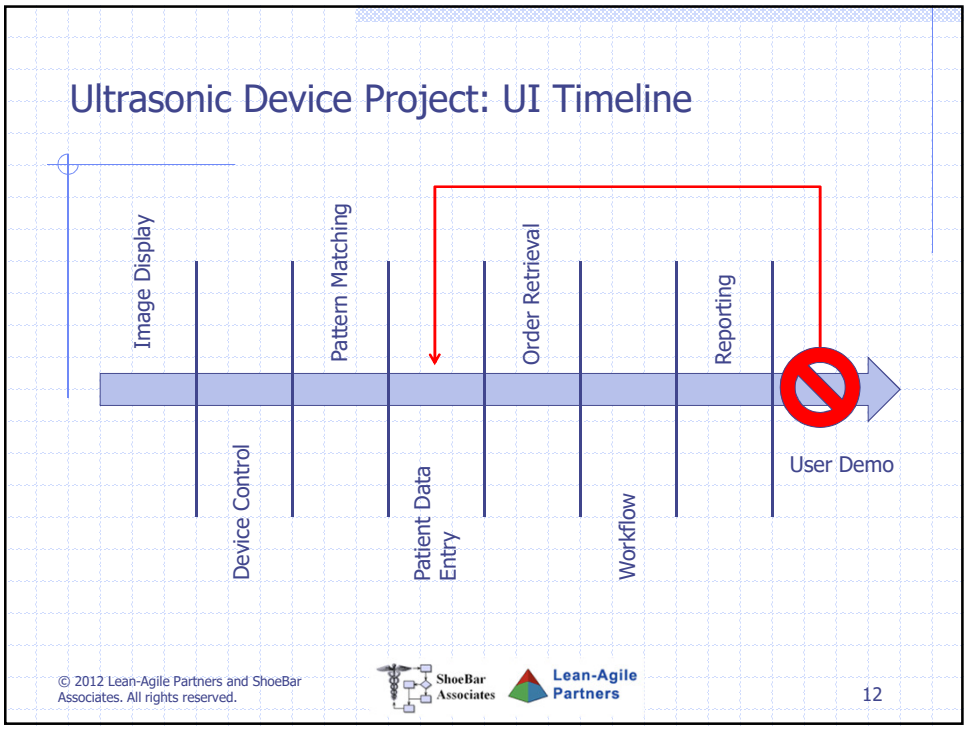
Ultrasonic Device Project: UI Timeline
Image Display
Device Control
Pattern Matching
Patient Data Entry
Order Retrieval
Workflow
Reporting
User Demo
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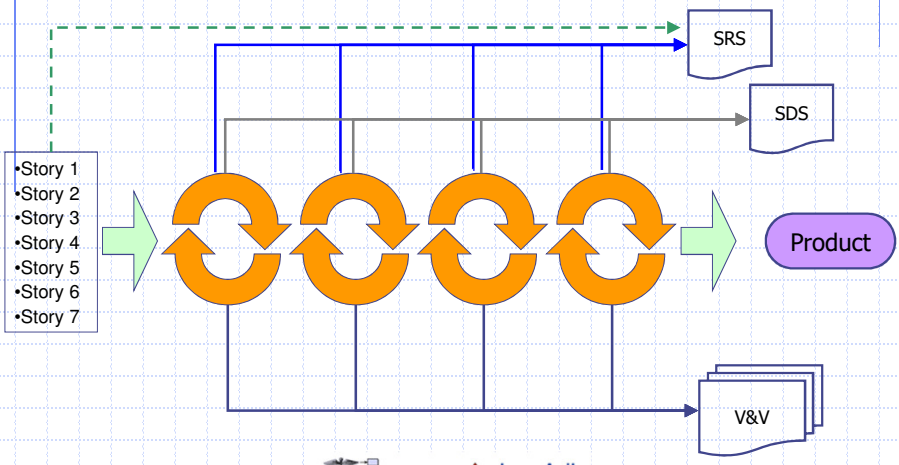
Capture Knowledge as Work Evolves



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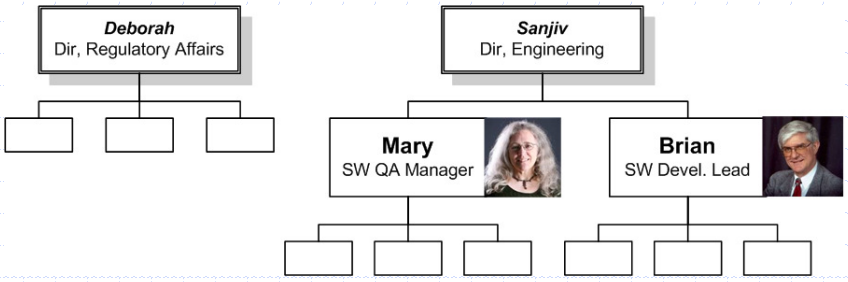
Scene #2: Improv

Scene: Improv on theme –

But the regulators require a waterfall method, don't they?



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Take-aways

- 62304 carefully avoids stating that it requires waterfall or any other lifecycle model
- "Predetermined specifications" can be broad goals – and we ***always*** start with goals
- Too much design up front results in broken schedules, not better products
- Frequent product demos to customer / users are a way to ***reduce risk***

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Act #2

"But Agile doesn't have hazard analysis !"

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Scene #1

CEO Nancy has just received an urgent message from Joe, her newly-hired head of Regulatory Affairs, saying the Dialysis project has not done a Hazard Analysis.

Mark is a seasoned QA leader and has been instrumental in the 2-month old Agile adoption program begun by the Dialysis product manager, Dan.

In this episode, the CEO asks Mark what's going on here, and how to move forward with Joe.

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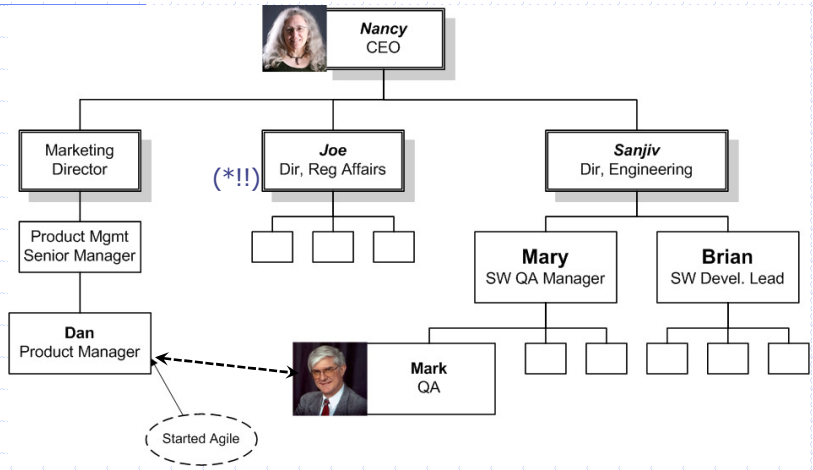
Our Characters



Our Project: Kidney Dialysis units "next generation"

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Joe's Email to CEO

Subject: Concerns for Dialysis project Hazard Analysis

I have serious concerns about the so-called Agile process that the Dialysis project team is using. Were you aware of this? They did not do a full hazard analysis before beginning the project. In my view this is an accident waiting to happen. This is not something I want to end up explaining to our Notified Body.

As you know, at my previous company we had a complete mess going on in the name of 'Agile'. I may be stepping on some toes by coming directly to you on this, but I'm sure you can appreciate the urgency…

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CEO Nancy Talks to Mark

Scene: After a meeting

Who: Nancy talks informally with Mark…

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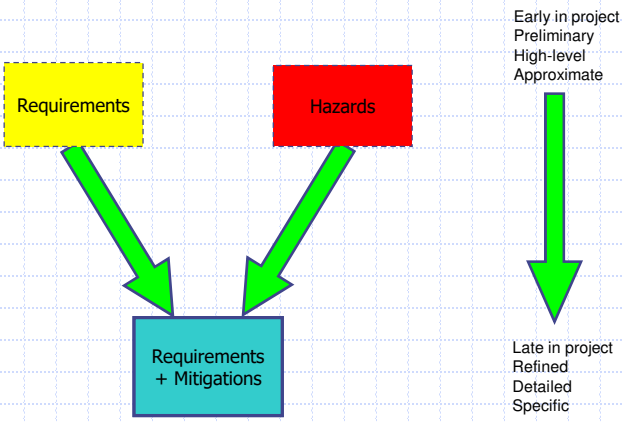
Reqmts / Hazards: Converging Analyses

ISO 14971: "Evaluate risks early and often"



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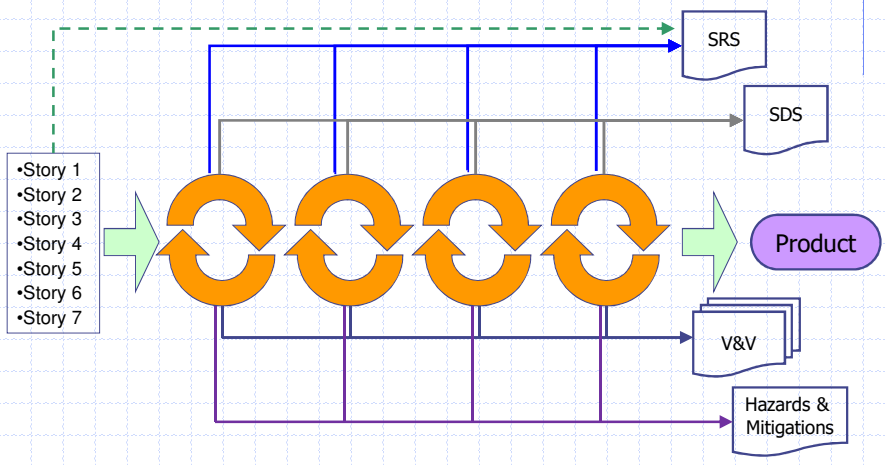
Accumulate Understanding



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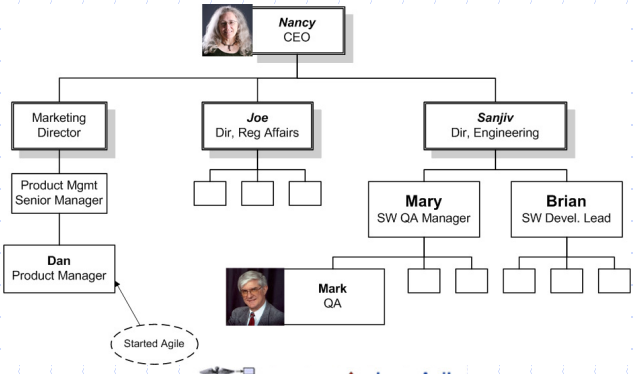
Scene #2: Improv

Scene: Improv on theme –

But Agile doesn't have hazard analysis !



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Take-aways

- There are multiple Agile approaches
- Some attempts at "credentialing," but not ready for prime time
- Developers from non-regulatory work think they can do same thing here – wrong!
- Bandwagon effect: People read a book and think they can do it all
- We're taking nothing on faith; we have an experienced coach

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Act #3

"What about design reviews?"

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Scene #1

Sanjiv, the head of engineering, has approached software technical lead Terri about their software method after the team's first three iterations. Jim, the mechanical engineering lead (who has been against Agile all along), has sent Sanjiv a memo warning that the company will be in trouble because there have been no design review meetings.
Sanjiv: "Terri, I see how your Agile method unfolds, but where do you hold the required design reviews?"

Terri has anticipated this objection, and shows Sanjiv how they satisfy everything the notified body needs.

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Our Characters

Sanjiv
Dir, Engineering

Jim
Mech Engrg Lead

(anti Agile)

Mary
SW QA Manager

Terri
SW Devel. Lead

Ed
Elect Engrg Lead

Our Project: Kidney Dialysis units "next generation"

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ISO 13485 says ...

7.3.4 Design and development review
At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1)
a) to evaluate the ability of the results of design and development to meet requirements, and
b) to identify any problems and propose necessary actions.
Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed, as well as other specialist personnel (see 5.5.1 and 6.2.1).
Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).

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Jim's view

- 3 iterations done, and
- No formal Design Review meetings…
- Therefore not in compliance

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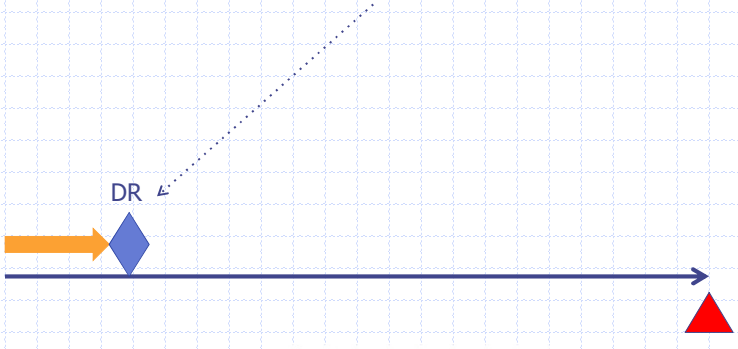
Terri's view

- We used to start with months of design work, then a Design Review…



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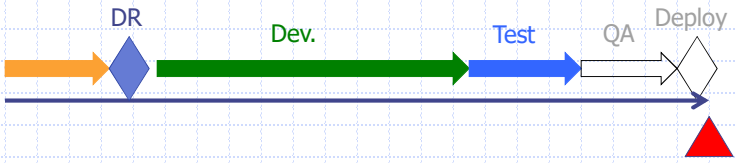
Terri's view

- We used to start with months of design work, then a Design Review…
- Next design freeze, development, Test



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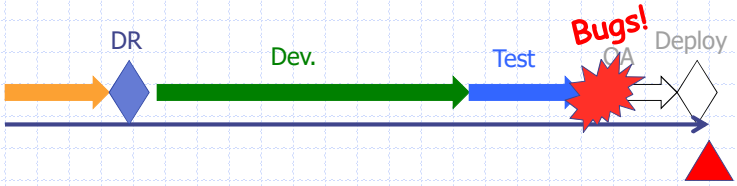
Terri's view

- We used to start with months of design work, then a Design Review…
- Next design freeze, development, Test
- But…



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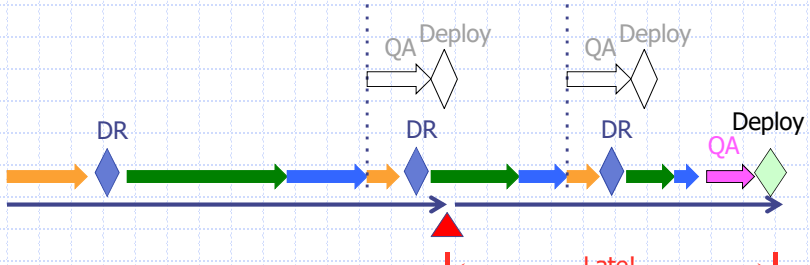
Terri's view

- We couldn't start QA – had to fix bugs
- Then it happened *again!*



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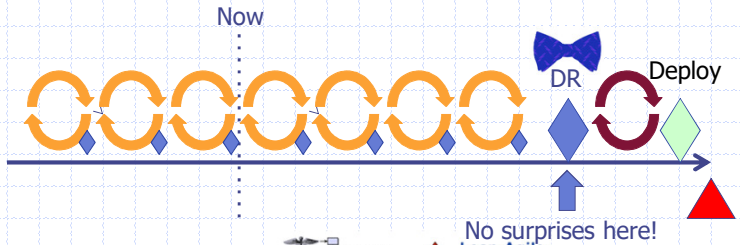
Terri's view

- *Now* we start by learning…
- Each iteration has design, dev, test, demo (♦)
- We'll hold the formal Design Review…



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ISO 13485 says ...

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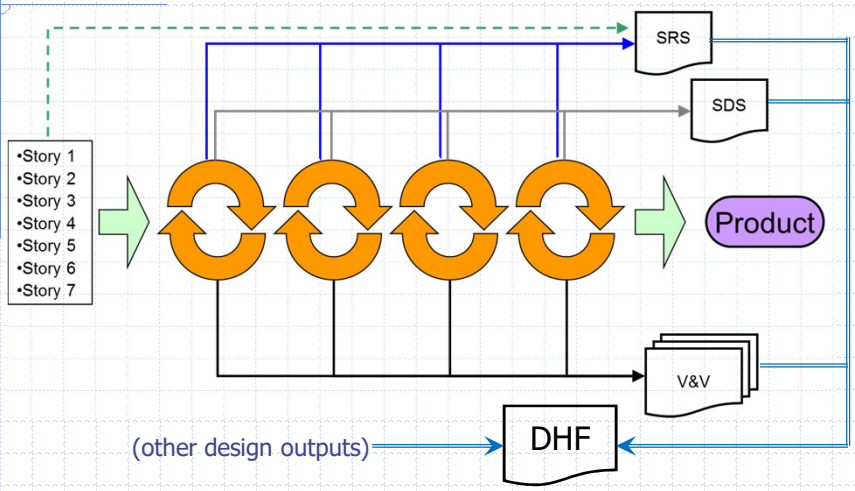
Every Iteration → Reviewable Output



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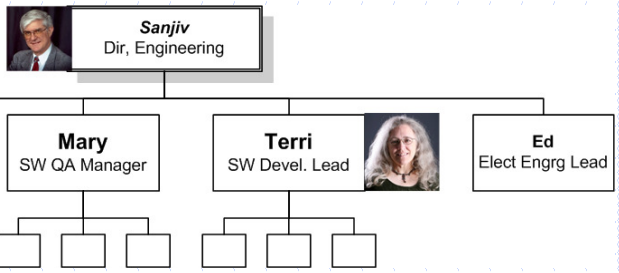
Scene #2: Improv

Scene: Improv on the theme –
What about design reviews?



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Take-Aways

- We skip the initial paper-only design – instead prove our ideas
- Two layers of review: external stakeholders; internal technical
- Incremental review makes better use of reviewers' time
- We still do a final formal design review
  - BUT stakeholders have all seen the elements before, in iteration demos – *no surprises!*

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References

- IEC 62304:2006, **Medical device software - Software life cycle processes**, AAMI, June 2006.
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- ANSI/AAMI/IEC TIR80002-1:2009, **Medical device software - Part 1: Guidance on the application of ISO 14971 to medical device software** (AAMI, 3 September 2009)
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- Association for the Advancement of Medical Instrumentation, AAMI TIR45: 2012 **Guidance on the use of AGILE practices in the development of medical device software**, August 2012.

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Please Fill Out The Survey

Agile 62304 Mini-Plays

Nancy Van Schooenderwoert
Brian Shoemaker

Brian Shoemaker, Ph.D.
ShoeBar Associates
199 Needham St, Dedham MA 02026
781-929-5927
bshoemaker@shoebarassoc.com
http://www.shoebarassoc.com

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

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