Agile 4 IEC 62304
XP2013 June 7, 2013 Vienna

For European Medical Product Software Development

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Brian Shoemaker’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)
- 8 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 V’s Background

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

- What would you like to learn today?
- List topics to cover, if time allows
- Set up “feedback door”
Our Assumptions…

Our usual audience knows Medical dev, but not Agile

You know Agile but maybe not Medical development
Course Outline

- The village is full of rumors!
- Understand the MPD Landscape
- Understand the *real* regulatory needs
- Exercises in bringing agility in 3 key ways
  - Understand Regulators as stakeholders
  - Stop strangulation by documentation
  - Find ways to break up the final testing “tail”
- Sample safety-critical project: Tricorder!
- What about hardware?
- Wrap up: Agile is not just acceptable, but better

MPD = “Medical Product Development”
Common rumors

- “Don’t say anything to the regulators. You might give them ideas.”
- “Every change – no matter how small – requires document sign-offs.”
- “A project plan must show every activity in design, development, test”
Role play…

“But FDA requires a waterfall method, doesn’t it?”
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 the FDA guidance!”

Brian, a seasoned development lead who has reviewed all of the FDA guidances, is unperturbed – he knows poor Mary has a misconception, talks her through the real FDA requirements, and shows her how all of the documents will be generated in this project.
Our Project: Kidney Dialysis units “next generation”
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. (...)

From IEC 62304
IEC 62304 – from Contents

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Ultrasonic Device Project Timeline

- Transducer communication
- Noise reduction
- Image processing
- Measurement
- Calibration
- User Interface
Ultrasonic Device Project: UI Timeline

- Image Display
- Device Control
- Pattern Matching
- Patient Data Entry
- Order Retrieval
- Workflow
- Reporting

User Demo
Capture Knowledge as Work Evolves

- Story 1
- Story 2
- Story 3
- Story 4
- Story 5
- Story 6
- Story 7

SRS

SDS

Product

V&V

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MPD = “Medical Product Development”
The old MPD way is broken!


MPD = “Medical Product Development”
Software Related Recalls

Note: Figures are from FDA's medical device recall database (for US recalls). The Class 1 recalls are multiplied by 10 so they are readable on the same scale as total recalls.
How MPD is different

- Some MPD is software on standard computers, or on stable hardware
  - Example: hospital workflow, patient tracking

- Some MPD is new S/W and H/W
  - Example: Respirator, X-Ray machine

- But all MPD wrestles to varying degrees with 3 issues…

MPD = “Medical Product Development”
Build the right thing!  
Build the thing right!

Customers  
Regulators

Agile management practices  
Agile technical practices

Code, H/w

Regulatory people are an additional set of stakeholders!
MPD Landscape – 10,000 m (2)

Build the right thing!  Build the thing right!

Customers  Team  Code, H/w
Regulators

Agile management practices

Agile technical practices

(Validation)  (Verification)

Heavy documentation acts as straightjacket for all!
MPD Landscape – 10,000 m (3)

Build the right thing!  Build the thing right!

(Validation)  (Verification)

Customers
Regulators

Team

Code, H/w

Product iterations

Final Test

Verification can take a year!
First you need background…

You must know:

- What the regulatory stakeholders’ roles are
- Concept behind the regulations
- What is *really* required of documentation
- Who, How, & Why of Final Testing

*These are covered in depth in the next section*
MPD Landscape – 1,000 m (1)

Quality Management System (ISO 13485)

Risk Mgmt Process (ISO 14971)

S/W Dev Lifecycle (IEC 62304)

Level of Concern

A. No injury
B. Slight injury
C. Life-critical

Safety plan, and Development Plan

Usability (IEC 62366)

• As a driver of design
• As a guide to evaluate your design

Key:

A

B

A influences B
Purpose of Validation

- Show regulators that our product is safe
- To do this we must:
  - Know who the user is
  - Know what environment it will be used in
  - Know what the product is supposed to do
- All these must be documented!

Document this!
Purpose of Verification

- Show regulators that our product is safe
- To do this we must:
  - Know who the user is
  - Know what environment it will be used in
  - Know what the product is supposed to do
- All these must be documented!

Prove this!
Build a Tricorder: 3 Functions

- BIO: Biological
- GEO: Geological
- MET: Meteorological
How we’ll Validate

- We must:
  - Know who the user is
    - Star Fleet medical and science personnel
  - Know what environment it will be used in
    - Alien planets, and aboard ship
  - Know what the product is supposed to do
    - BIO: Biological – Diagnose injury, disease; vital signs
    - GEO: Geological – Ident. Rock types, stability, forecast
    - MET: Meteorological – Meas. Current and future planetary weather conditions

- All these must be documented!
How we’ll Verify

- We must **Prove** that the product does:
  - What the product is supposed to do
    - BIO: Biological – Diagnose injury, disease; vital signs
    - GEO: Geological – Ident. Rock types, stability, forecast
    - MET: Meteorological – Meas. Current and future planetary weather conditions
  - All these must be documented!
Validation + Verification, controlled

Project Plan document

Build the right thing!

(Validation)

Customers

Regulators

Team

Agile management practices

Build the thing right!

(Verification)

Code, H/w

Agile technical practices

Project Report document (4)

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30
Docs must tell the product’s story

Build the right thing!

Build the thing right!

Customers

Team

Code, H/w

Req

Test

Des

Trace

Risk Anal.

(Validation)

(Verification)

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3 ways you can help

- Address the real needs of regulatory stakeholders
- Show team and regulatory stakeholders Agile docs practices
- Help all to keep final testing from becoming ‘integration hell’
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- Wrap up: Agile is not just acceptable, but better
Who *are* those guys?

- RA professionals interact with govt agencies and Notified Bodies
- QA has a bigger role in medical dev companies than in commercial S/W
# Reg. Affairs Stakeholders

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
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<tbody>
<tr>
<td>RA Director</td>
<td>Ensure our projects get smooth regulatory approval, and no recalls</td>
</tr>
<tr>
<td>RA Specialist</td>
<td>Responsible for content of submission documents:</td>
</tr>
<tr>
<td></td>
<td>• 510(k) or Premarket Approval doc (USA – to FDA)</td>
</tr>
<tr>
<td></td>
<td>• Approval submission (Europe – to Notified Body)</td>
</tr>
<tr>
<td>RA Associate</td>
<td>Keep files updated as product changes occur; watch for impacts to reg. submission documents</td>
</tr>
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</table>
# QA Stakeholders

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<td>Ensure our quality processes are effective and obey company policies</td>
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</table>
| QA Specialist     | Above the project level, ensure Standard Operating Procedures (SOPs) are followed, and are in line with actual practice: “Walk the talk, and Talk the walk”:  
  • The right records are kept  
  • Intended quality is being achieved  
  • Participate in deciding which processes to use (i.e. we do not pass inspection by ‘fluke’) |
Risk Analysis and Planning

- All the traditional approaches still apply
  - Fault tree analysis
  - FMECA (Failure Modes Effects & Criticality Analysis)
  - Many others
- Just do them iteratively!
- Standards even say that:
  - ISO 14971, Sect 3.1
  - ISO 14971, Annex B ← “Process needs to be iterative”
Lifecycle Documentation

- Shown – typical. Not all docs needed for every project
- Not shown: *traceability*
- Safety mitigations in S/W must be included in requirements
- Purpose:
  - Allow review of complete design
  - Ensure nothing is overlooked, esp. if safety impact
- Arrows: *conceptual* relations, *not time!*

Diagram:

- System Reqmts -> S/W Reqmts -> Architec Design -> Code -> Unit/Integ Test -> System & Failure Test
- Acceptance Test
V-Model Distributed

- Avoid bundling whole project into 1 V-model

- Use V-model as structure for each level: Release, Iteration, Story, Task
Regulatory Documentation

- Docs provide evidence (not documented = not done)
- Design control elements of ISO 13485 are the inspector’s basis for evaluation
- IEC 62304 and ISO 13485 outline typical tasks, not specific required documents
- Key concerns for documentation:
  - Complete, consistent, unambiguous
  - Hazards evaluated, mitigations defined
  - Traceability established
  - Information sufficient for maintenance
A single iteration – in docs

A = Implement stories & develop tests;  
B = Approve stories as implemented

- Iter Plan
- Demo
- Finish docs

**A**
- Update SDS & traceability
- Update test suite, test rpt
- Update project plan, forecast
- Document design review
- Update usability summary & risk mgmt
- Adjust SRS, test plan, traceability for de-scoped stories

**B**
- Re-eval risks & update
- Est future stories & tests
- Compose future stories
- Add to SRS, traceability
- Risk Mgmt
- Hum Fctrs
- SDLC
- QMS

Stories → SRS

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Guidance / Stds docs: symbols used

- Quality Management System (ISO 13485)
- S/W Dev Lifecycle (IEC 62304)
- Risk Mgmt Process (ISO 14971)
- Usability (IEC 62366)
- Medical Elect. Equip. (IEC 60601-1)
- 21 CFR part 820 (The QSR)
- General Principles of SW Validation
- Applying Human Factors and Usability...
- Guidance on Pre-Market Submissions...
Usability Assessment

- 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?**
FDA guidance on V+V

- Your RA folks may show you this...

- FDA reprinted this figure from a company adapting the FDA guidance to waterfall process!
- In the same doc, FDA recommends concurrent engineering...

“CONCURRENT ENGINEERING. Although the waterfall model is a useful tool for introducing design controls, its usefulness in practice is limited. The model does apply to the development of some simpler devices. However, for more complex devices, a concurrent engineering model is more representative of the design processes in use in the industry.”

Source: FDA, Design Control Guidance for Medical Device Manufacturers, p. 5 (This doc is from 1997! Therefore it is referring to industry practice that predates the Agile movement.)
QUIZ: Regulators’ real needs

True or false? [5 minutes]

1. At the end of each iteration, each technical lead person must sign-off the System Design Spec for the features implemented.

2. If stories were developed interactively, the only sign-off needed at iteration end is between team and product owner, who represents stakeholders.

3. At the end of each iteration, ISO 13485 requires that QA must formally sign-off the System Test Plan.

4. Iteration planning must include an up-front definition of all major hazards, although their mitigations can be implemented in later iterations.
Exercise: Stakeholders needs

- Revisit the role play… [15 min.]
  - Mary (QA Director) questions s/w preparedness
  - Brian tries to explain…
  - Your (audience) role: Help Brian make his case
  - Can you clear up Mary’s misconception so that she fully understands?
Debrief group role-play

- Were you able to convince Mary of your view?
- Can you show that you and Mary are interested in achieving the same goal?
- What did you find difficult (or easy) about this discussion?
Negotiation basics

- Knowing the regs is not enough
- You need to negotiate successfully

Our mission today is to equip you with BOTH
- Content (regs, needs), and
- Ways to align people (negotiate)
Method (from Getting to Yes)

- Separate the people from the problem
- Focus on interests, not positions
- Invent options for mutual gain
- Insist on using objective criteria

Example, Negotiation methods

- Separate the **people** from the problem
  - General: “The kitchen is a mess.”
  - Medical products: “I can’t make heads or tails out of your design document.”
Focus on interests, not positions

- General: Israel / Egypt discussion about Sinai Peninsula. Israel: security; Egypt: sovereignty. Agreement: Egypt took control, agreed not to station tanks near Israel.

- Medical products: RA Specialist wants all requirements frozen at project start. S/W says only freeze at each iteration. Agreement: Both have an interest in obeying regs. Regs say verification = “predetermined spec has been met” – you can pre-determine at start of each iteration.
Negotiation methods - #3

- Invent **options** for mutual gain
  - General: Iraqi farmers planted on land, but oil co. moved in and ordered them out. Mediator asked oil co. how long it would to take to prospect and be ready for drilling – 3 years! Can farmers plant / harvest in meantime? Yes.
  - Medical products: help fill this in!
Negotiation methods - #3 (cont’d)

- Invent **options** for mutual gain
  
  - Medical products example:
    
    - both 21 CFR Part 820 and ISO 13485 call for design reviews, but traditionally these are difficult to organize, take many hours, and result in nasty surprises. Agile teams conduct frequent demos, for customers as well as management
    
    - if we document each demo with a memo to file, these could all be considered mini-design reviews, and the one major review need only come at the end of the development project.
Negotiation methods - #4

- Insist on **objective criteria**
  - General: Fixed-price house construction contract: reinforced concrete foundation, but depth not stated. Contractor: 2 feet enough; purchaser believes 5 feet more typical. What are standards for this area and type of building?
  - Medical products: help fill this in!
Insist on **objective criteria**

Medical products example:

- Medical system recently filed involved microscope / scanners to take images of slides with stained tissue, and stations (on a network) where docs evaluate images
- Color rendering on stations was a concern; in manufacturer’s validation test, multiple pathologists given multiple slides with known cell components.
- Number of cell components correctly identified: objective measure of viewing station’s correct color rendering
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- What about hardware?
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MPD = “Medical Product Development”
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MPD = “Medical Product Development”
Top 7 Myths of Regulatory Stakeholders

- You must complete the design before you build
- You must document and approve all your requirements before you start your design work
- Developers will build the wrong things unless we prescribe every detail for them
- You cannot meet a fixed deadline unless you know all your specifics ahead of time
- A plan has to define explicitly all the activities (design, development, test) that will be carried out
- We are required to review and sign a document any time we make any change
- A design review only ‘counts’ if all stakeholders are present and there is a complete and through review of the entire design
Story 1 “Audit trail”

“The Deployed Analytics server shall log user activities for auditing purposes.”
Story 1 evolved…

- Title: Audit Trail
- Story: As a Hospital IT System Administrator, I want to log user activities so that I can ensure HIPAA Compliance.
- C.O.S. (Conditions of Satisfaction)
  - Capture the following:
    - User
    - Actions
    - Date / time
    - Parameters
Exercise: Hazard analysis

- HIPAA* requires healthcare providers to keep certain Protected Health Information confidential.

- Consider: what is this audit trail feature supposed to accomplish and why?

- Now consider: what unwanted consequences could result if this feature fails to perform correctly?

*Health Insurance Portability and Accountability Act
Exercise: Hazard analysis

- “Story 1” has been refined as shown. Now it’s time to analyze hazards that may be associated with it.
- Form groups of 3 or 4

  - Pro – ‘All hazards have to be identified at project start.
  - Con – Hazards and mitigations can be identified during project.
  - Neutral – Ensure fairness, courtesy

Discuss until instructor signals. Then rotate positions.
Chart your Role’s pro/ con

- On a flip chart, note the significant pro and con arguments for each role you played

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<tr>
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Exercise debrief

Did you use any of these negotiation methods?

- Separate the **people** from the problem
- Focus on **interests**, not positions
- Invent **options** for mutual gain
- Insist on using objective **criteria**

Comments? Reflections?
Course Outline

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  - **Stop strangulation by documentation**
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- Wrap up: Agile is not just acceptable, but better

MPD = “Medical Product Development”
Why the test first?

“Experience is a hard teacher because she gives the test first, the lesson afterward” – Vernon Law
1. At the end of each iteration, each technical lead person must sign-off the System Design Spec for the features implemented.

2. If stories were developed interactively, the only sign-off needed at iteration end is between team and product owner, who represents stakeholders.

3. At the end of each iteration, ISO 13485 requires that QA must formally sign-off the System Test Plan.

4. Iteration planning must include an up-front definition of all major hazards, although their mitigations can be implemented in later iterations.
Exercise: Docs only at end?

- “Since the system is changing all the time, let’s leave all documentation till the end.”
- Form groups of 3 or 4
  - Pro – ‘All docs should be generated at end of project’.
  - Con – ‘No. Docs must be present throughout’.
  - Neutral – Ensure fairness, courtesy
  - Discuss until instructor signals. Then rotate positions.
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Comments? Reflections?
Consider: Do good documents result if we try to write them after everything else is done?
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Story 2 “Patient Prioritization”

- Title: Patient Prioritization
- Story: As a Director of Respiratory Therapy, I want to know the top 10 respiratory patients having the most potential for harm.
- Conditions of satisfaction:
  - “Harm Index” rating bumps patients to top of list
  - Report displays info for prioritization/sorting on the report
Story 2 evolved...

- CoS: Factors in patient vulnerability include:
  - Trend of configurable ventilator values
  - ABG data
  - Ideal weight
  - Age
  - Days on ventilator
  - Notification history
  - Patient demographics

*Problem! Could not state algorithm for decision from these parameters.*
Question to customer: If you had a list of patients and these parameters for each, could you rank their potential for harm?

Answer: Yes!

Decision: We’ll create several scenarios using realistic data. You’ll rank them, and then developers will derive the algorithm. We will need iterations (with you) to resolve edge cases.
Exercise

- How might you develop an algorithm to prioritize patient vulnerability?
- How can you know whether it is complete and correct?
- How can you develop tests if your system is still in flux?
Exercise: Test only at end?

- “We must have a single final test stage so we don’t refine our solution too closely to one data set.”
- Form groups of 3 or 4
  - Pro – ‘One final test stage only!’.
  - Con – ‘We need multiple final test stages’.
  - Neutral – Ensure fairness, courtesy
  - Discuss until instructor signals. Then rotate positions.
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**MPD = “Medical Product Development”**
Build a Tricorder: 3 Functions

- BIO: Biological
- GEO: Geological
- MET: Meteorological
But there are unknowns

- Some of the science is only lab-proven
- Not sure we know all the hazards
- Need to decide what to build first

Therefore...

- We’ll use a feasibility stage
- If that’s positive, we’ll commit to development
Sample project - Tricorder

- Prep – Discuss and explore possible product idea
- R&D – Commit effort to driving out big unknowns

Prep | R&D | Development

Match mkt need with what we think we can build

Feasibility phase to drive down risk

Functionality increment
Knowledge increment

Commitment to develop product

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Sample project - Tricorder

- ‘Prep’ asks: Can we build something the market wants?
  - If YES, set MVP* and go to R&D
  - If NO, then exit (no go)

- ‘R&D’ asks: Are risks low enough now for development to proceed?
  - If YES, set next milestones, go to Dev
  - If NO, then judge whether to exit or continue on with R&D

* MVP = Minimum Viable Product

Trigger points for “go/no-go” decisions
Why use ‘R&D’ stage?

- Need to explore
- Too many unknowns
- Cannot make a delivery commitment

**Strategies to reduce product development risk**

- Explore using as little labor as possible
- Commit fully to development for at least the MVP*
- Explore using labor but as little *hardware* as possible

* MVP = Minimum Viable Product
How we’ll plan Tricorder HW

- ‘Prep’ – get training, set up tools, etc.
- ‘R&D’ – Prep has identified 3 possible approaches for Tricorder electronic architecture
  - Multi-core processor vendor A
  - Traditional, vendor A
  - Traditional, vendor B
- Explore all paths; narrow down to one for Development

We are not sure if any of these 3 approaches will work, though we may have high confidence in one of them.
R&D activity spans disciplines

- Electronic architecture is one dimension that has alternate architectures to explore…
  - Multi-core chip from vendor A
  - Main processor+ PLD from Vendor A
  - Main processor+ PLD from Vendor B

- Also parallel paths for Mech/Materials
  - Try new Pi-Tanium self-cooling housing (bleeding edge)
  - Use modified prior chassis + upgraded “Iso-kool” blocks for circuit board cooling (safer choice)
Regulatory Output for Tricorder

- Risk Mgmt Plan
- Verificn/Validn Plan
- Project Plan
- Mktg Rqmts
- Proj Summary
- Risk Mgmt Rpt
- Test Rpt
- Usability Rpt
- Design Rvw Min
- SRS
- SDD
- Risk Analysis
- Tests, Trace
- Usability Eval
- Design Revs
Medical Product lifecycle

“All models are wrong, but some are useful.” -- George E. P. Box

Typical lifecycle used in medical SW, HW development

Note: Another relevant quote from G.E.P. Box: “Since all models are wrong the scientist cannot obtain a "correct" one by excessive elaboration. On the contrary following William of Occam he should seek an economical description of natural phenomena. Just as the ability to devise simple but evocative models is the signature of the great scientist so overelaboration and overparameterization is often the mark of mediocrity.” George E. P. Box (1976) *Science and Statistics* Journal of the American Statistical Association, Vol. 71, No. 356. (Dec., 1976), p. 791
Terminology can vary…

- Alternate terms for the lifecycle stages…

<table>
<thead>
<tr>
<th>Prep</th>
<th>R&amp;D</th>
<th>Development</th>
<th>Final Test</th>
<th>Deploy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concept, Vision, Planning, Definition</td>
<td>Feasibility, Discovery, Definition</td>
<td>DevOps, Delivery</td>
<td>Qualification, Indep. V&amp;V</td>
<td>Release, Launch</td>
</tr>
</tbody>
</table>

- By any name, these are recognizable stages in medical product development prior to moving to Agile methods
Phase gates are problematic

- Locking all product features to the same level blocks flow of value

- Some or all these transitions are locked down by heavy-weight process activities – “Phase Gates” – in most organizations
Agile unlocks the phase gates...

- Because some stories are ready to move forward before others – why block them?

- But what about controls?
- We move them to the *story level* – where they work better!
Agile controls at the story level

Each story goes through the main phases of Prep → Final Test
Early stories more on Prep and R&D content, etc.
Phases have fuzzy boundaries

- Some R&D (feasibility) work can start before all of Prep stories are completed
- There will be smaller R&D work all through Development, etc.
- Therefore, these phases blend from one to the next

Remember - It’s just a model!
Safety-critical lifecycle overview

- A typical example of medical product development

Variations...

- First release of newly-invented implantable device
- Eighth-generation upgrade of mature med device
- HW upgrade project for med dev, done by Agile team
MPD lifecycle: another view
Agile MPD lifecycle - Tricorder

Most of ‘Final Test’ has been integrated into iterations

$\text{Prep} \quad \text{R&D} \quad \text{Development} \quad \text{F T D.}$

Internal release

Limited release

Public release
‘Prep’ phase

Can we build something the market wants?

- Explore scenarios
- Research
- Discuss
- Analyze
- Do R&D step
- Exit

- Risk Mgmt Process (ISO 14971)
  - Draft risk management plan
- Quality Management System (ISO 13485)
  - Draft project plan
  - Draft marketing reqmts
- S/W Dev Lifecycle (IEC 62304)
  - Draft development plan
‘R&D’ phase

- Share new knowledge
- Agree Stories, milestones
- Run Experiments
- Analyze

Are risks low enough now for development* to proceed?

- Do Dev step
- Exit

* Development of MMF, something more?

- Risk Mgmt Process (ISO 14971)
  - Identify main hazards
  - Determine mitigations

- Quality Management System (ISO 13485)
  - Finalize project plan
  - Draft verificn/validn plan(s)

- S/W Dev Lifecycle (IEC 62304)
  - Establish initial dev backlog

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‘Dev’ phase

- Will customers buy this? Is this better than other use of these resources?
- Agree Stories, Milestones
- Integrate, test
- Build features
- Deliver, Get cust. feedback
- Continue Dev
- Exit

**Risk Mgmt Process (ISO 14971)**
- Iterate on hazards & mitigations

**Quality Management System (ISO 13485)**
- Document traces incrementally
- Draft summary report

**S/W Dev Lifecycle (IEC 62304)**
- Document rqmts, design incrementally
- Develop tests incrementally
- Each iter demo is design review
‘Final Test’ phase

- **Risk Mgmt Process (ISO 14971)**
  - Document residual risks

- **Quality Management System (ISO 13485)**
  - Finalize summary report

- **S/W Dev Lifecycle (IEC 62304)**
  - Conduct / document final test
  - Finalize summary report

---

- Is this ready to ship? Do we know how it will be supported?
- Correct & approve docs
- Execute release

- Review, finalize project docs
- ID docs to finalize; Map submission doc
- Release

- Check project, submission docs, risk mgmt file

---

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## Summary of phases, activities

<table>
<thead>
<tr>
<th>Phase</th>
<th>Plan</th>
<th>Do</th>
<th>Check</th>
<th>Act</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prep</td>
<td>Research</td>
<td>Discuss</td>
<td>Analyze</td>
<td>Explore scenarios</td>
</tr>
<tr>
<td></td>
<td>Agree stories, milestones</td>
<td>Run experiments</td>
<td>Analyze</td>
<td>Share new knowledge</td>
</tr>
<tr>
<td>R&amp;D</td>
<td>Agree stories, milestones</td>
<td>Build features</td>
<td>Intergrate and test</td>
<td>Deliver, get cust. Feedback</td>
</tr>
<tr>
<td>Dev</td>
<td>ID docs to finalize; Map submission doc</td>
<td>Review, finalize project docs</td>
<td>Check project, submission docs, risk mgmt file</td>
<td>Correct &amp; approve docs, Execute release</td>
</tr>
<tr>
<td>Final Test</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Lifecycle we recommend

- A company before moving to Agile…
  - Prep
  - R&D
  - Development
  - Final Test
  - Deploy

- Same company after starting Agile practices…
  - Prep
  - R&D
  - Development
  - Final Test
  - Deploy
  - Iter.s produce knowledge
  - Iter.s produce features

- Same company after improving Agile practices…
  - Prep
  - R&D
  - Development
  - Final Test
  - Deploy

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Course Outline

- The village is full of rumors!
- Understand the MPD Landscape
- Understand the *real* regulatory needs
- Exercises in bringing agility in 3 key ways
  - Understand Regulators as stakeholders
  - Stop strangulation by documentation
  - Find ways to break up the final testing “tail”
- Sample safety-critical project: Tricorder!
- What about hardware?
- Wrap up: Agile is not just acceptable, but better

MPD = “Medical Product Development”
Lean, Agile and Hardware

- Problem statement
  - Lean: “How do we manufacture with small capital?
  - Agile: “How do we hit a moving target during software/systems development?”

- Solution (in both cases)
  - Inspect and adapt
  - Deliver in small increments
  - Aim for highest possible quality
Grain Monitor System (GMS)

- Measures protein, oil in corn, wheat, etc. in seconds
- Based on new science, new CPU, new OS port, new NIR sensor, new algorithm…
- Agile team delivered 1st field units in 6 months
- In 3 years – 60+ s/w iterations, approx. 9 electronic iterations, approx. 5 mechanical iters.
Grain Monitor Teamwork

- Productivity 292% of comparable teams
- Quality 2000% above industry norm

Bugs - sorted by Severity level and time found

<table>
<thead>
<tr>
<th>Severity Level</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Totals</th>
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</thead>
<tbody>
<tr>
<td>Critical</td>
<td>🌟🌟🌟</td>
<td>🌟🌟🌟</td>
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<td>Moderate</td>
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<td>Cosmetic</td>
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<td>🌟🌟🌟</td>
<td>🌟🌟🌟</td>
<td>13</td>
</tr>
</tbody>
</table>

S/W Releases

Year 1 | Year 2 | Year 3

Hardware Evolving…

1. EVAL-1
2. EVAL-2
3. EVAL-3
4. EVAL-4
5. Pre-production-A
6. Pre-production-B
7. Production-A
Texas Instruments, Germany: Integrated circuit design to tape-out in Agile “vertical slices”

Tobias Leisgang reports reduction of cycle time to 1/12th
- Deliver FPGA prototype to customers to try out before silicon is produced
- Repeat at each iteration

Developed own grass-roots Agile process
- Cross-functional teams
- Iterations – settled on 4-week length
- Estimation & Planning
- Daily Standups
- Retrospectives

Agile Hardware Lessons

- Mech. + elec. h/w create containers for s/w
- Devel is controllable but not fully plannable

*Must inspect and adapt!*

**Mechanical H/W**
- Circuit boards
- PLDs
- Micro-switch settings
- Pin-compatible chips
- Components
- Housings
- Special materials

**Software**
- User settings
- App s/w
- Operating Sys

**Flexibility**

**Time**

Slower iterations for the less flexible items
Course Outline

- The village is full of rumors!
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MPD = “Medical Product Development”
Quality Management System (ISO 13485)

S/W Dev Lifecycle (IEC 62304)

Level of Concern
- A. No injury
- B. Slight injury
- C. Life-critical

Safety plan, and Development Plan

Risk Mgmt Process (ISO 14971)

Usability (IEC 62366)
- As a driver of design
- As a guide to evaluate your design

Key:
- A influences B

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Relationship Among Standards

**Quality System: ISO 13485 / 21 CFR 820**
- Design Controls
- Documentation Controls
- Quality Records

**ISO 14971**
- Risk Management
- All medical devices

**IEC 62304**
- Medical Device SW - Lifecycle
- Medical device S/W

**IEC 60601-1**
- Medical Elect Eqpt. – Basic
- Safety, Essential Performance

- Risk mgmt plan
- Methodology
- Risk mgmt file
- Requirements
- Architecture
- Design
- Verification
- Validation
- Traceability
- Change Control

**Risk mgmt**
- Methodology
- File

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TIR 45: Important discussions

- Regulatory perspective and Agile perspective need not exclude each other.
- Incremental / evolutionary is a valid lifecycle.
- A crucial concept is the idea of "DONE".
- One benefit is ample opportunity for customer feedback.
- Another benefit is verification throughout.
- Design reviews are a natural activity.
- Documentation can be generated incrementally.
“Before we used Agile methods, we had high final quality but spent much effort on defect cleanup in later steps.”

“After going Agile, each step in our process kept defects very low – unpredictable debugging period is gone!”

BEFORE
Poor internal quality – much rework

AFTER
Better quality controlled process
Points to remember

- No regulatory body requires waterfall
- No regulatory body prohibits Agile
- V-model arrows are relations, not time!
- You must demonstrate conformance to pre-determined requirements, but you can pre-determine them at any time
Thoughts for the Coach

- Fear of Agile = fear of sloppiness
- MPD badly needs better S/W dev
- Agile *can* be used for MPD
- MPD focus: *safety* (usability → safety)
- Docs for MPD prove what was done
- For Agile in MPD, include doc, risk eval, usability eval
Contact us

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Brian Shoemaker
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Guide to regulatory documents and how to use them
Guidance / Std.s docs symbols used

- Quality Management System (ISO 13485)
- S/W Dev Lifecycle (IEC 62304)
- Risk Mgmt Process (ISO 14971)
- Usability (IEC 62366)
- Medical Elect. Equip. (IEC 60601-1)
- 21 CFR part 820 (The QSR)
- General Principles of SW Validation
- Applying Human Factors and Usability...
- Guidance on Pre-Market Submissions...
FDA References

- FDA: Design Control, Medical Devices (March 11, 1997)
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070627.htm

- FDA: General Principles of Software Validation (Jan 11, 2002)
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085281.htm

- FDA: Premarket Submissions, Software Contained in Medical Devices (May 11, 2005)
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- FDA Draft Guidance: Applying Human Factors and Usability Engineering to Optimize Medical Device Design (June 22, 2011)
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm259748.htm
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- ISO 13485:2003 (2nd ed) Medical devices – Quality management systems – Requirements for regulatory purposes
- ISO 14971:2007 (2nd ed) Medical devices – Application of risk management to medical devices
- IEC TIR80002-1:2009, Medical device software - Part 1: Guidance on the application of ISO 14971 to medical device software
- AAMI TIR 45:2012 Guidance on the use of AGILE practices in the development of medical device software
- IEC 62366:2007 Medical devices – Application of usability engineering to medical devices
IEC80002-1 as bridge

IEC 62304
SW lifecycle
risk based

ISO 14971
Med dev risk mgmt

IEC TIR80002-1
SW risk mgmt
SW concerns, examples

Incorporates text of ISO 14971
Discusses software considerations for each section
“Magic” Incantations

Guidances are clear: no specific lifecycle required
- GPSV sec. 4.4, 5.1; IEC 62304 introduction, 5.1.1 Note 2, Annex B sec. B.1.1

Standards say analyze risk iteratively:
- ISO 14971, sec. 3.1, A.2.1; IEC TIR 80002-1, 4.1

Quality regs: document activities, but lockstep order not specified
- 21 CFR Part 820.30; ISO 13485 sec. 7.3