

Agile for Medical Device Software Development

Where Competitiveness, Compliance, and Quality Meet

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ShoeBar Associates



MedTech Intelligence MedDev SW, 21.-22. March 2017

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.

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Who I am

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

Thesis

Properly understood and applied, an Agile approach can breathe new life into the medical device industry from all three perspectives: competitiveness, compliance, and quality.

Competitiveness, Compliance, Quality

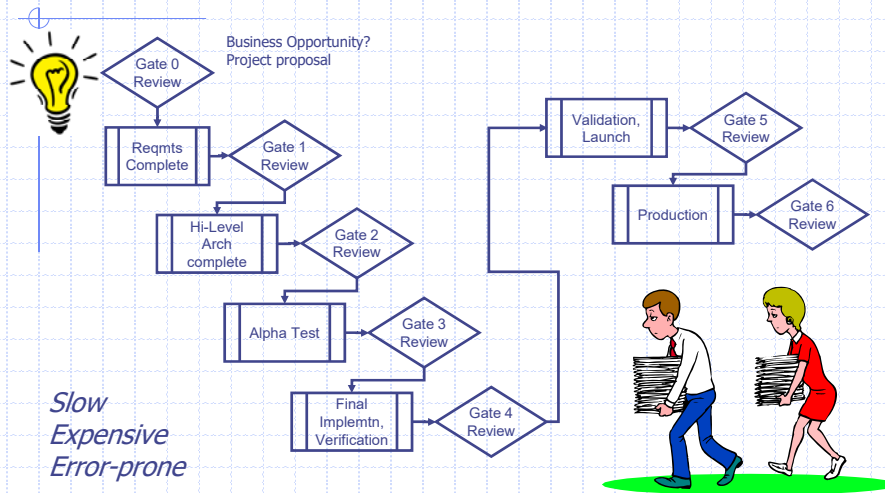
- What Agile is – and isn't
- *Real companies ARE using Agile - and benefiting*
- *Translate the Agile foundation into practices*
- *Iteration works well for risk, usability, and design reviews*
- *Recognize and avoid the pitfalls*

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Classical Process



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The rumors are false!

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!

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Agile Manifesto – Read Closely!

Manifesto for Agile Software Development

We are uncovering better ways of developing software by doing it and helping others do it. Through this work we have come to value:

- 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.

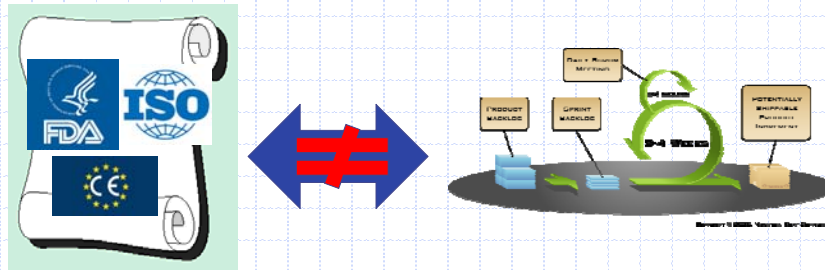
<http://agilemanifesto.org/>

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Contradiction?



Differing *Focus*

- **Agile perspective:**
Maximize delivery of customer / stakeholder value
- **Regulatory perspective:**
Quality
Safety
Effectiveness

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:



Competitiveness, Compliance, Quality

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SDMD Attendees Using Agile

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

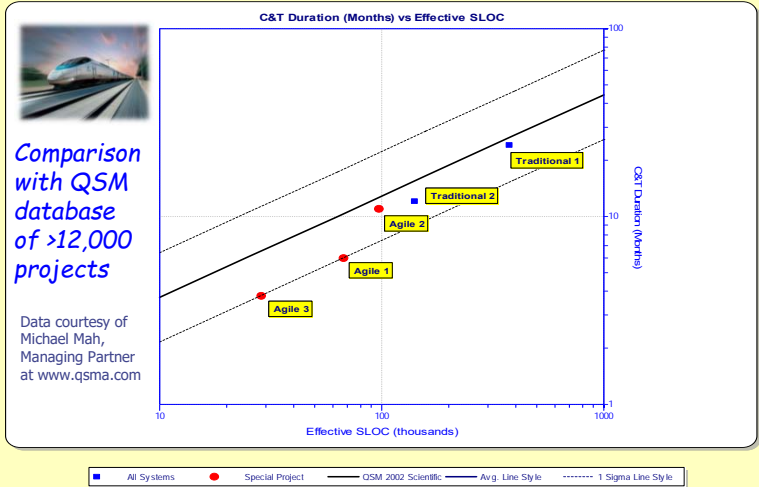
INCOSE Agile in HC Conference

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

We've worked w/ others

- Clinical trial data mgmt software (2 companies)
- ICU aggregated-data risk prediction SW
- Histology / pathology networked slide imaging & assessment system
- Clinical diagnostics
- IVUS
- Optical measurement systems

Time to Market – Canadian MDev Co

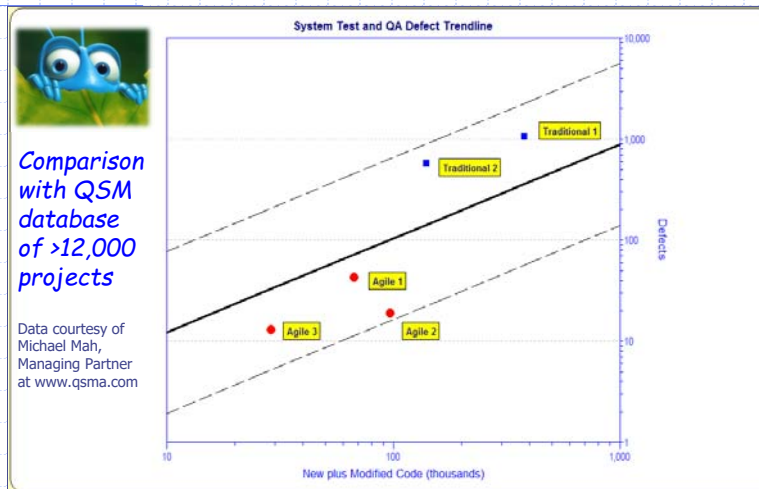


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Same Company - Quality

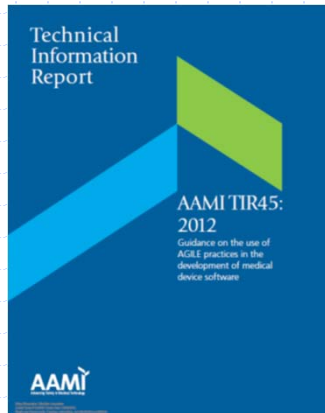


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AAMI TIR 45 – Valuable Discussion



- Document issued in August 2012
- Discusses how Agile approach, regulatory demands can coexist
- Authors came from industry, Agile community, regulators

Competitiveness, Compliance, Quality

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12 Principles Support the Manifesto

- Satisfy customer: deliver software which has value.
- Welcome changing requirements.
- Deliver working software frequently.
- Business and development must work together throughout.
- Allow motivated individuals to get the job done.
- Communicate face-to-face!
- Working software is the primary measure of progress.
- Develop at a sustainable pace.
- Being Agile also means technical excellence and good design.
- Keep it simple - maximize what you **DON'T** do.
- Self-organizing teams produce the best work.
- Teams must regularly reflect and adjust how they work.

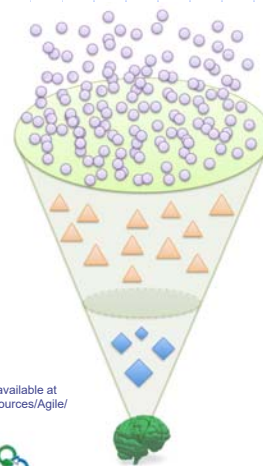
Paraphrased from <http://agilemanifesto.org/principles.html>

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The Mindset – 3 Levels



- Agile is a mindset**
[that in software world is]
- Established through 4 values**
- Grounded by 12 principles, &**
- Manifested through many many different practices**

- | | |
|---|--|
| <ul style="list-style-type: none"> Product vision Empiric planning Activity (relative) estimation Size (small (unit)) estimation Planning poker Circle rotation Value-based documentation Incremental product backlog User stories Progressive elaboration Personas Story maps / MMF Story slicing Acceptance tests as requirements Short iterations WIP limits Early and frequent releases Backmapping Velocity-based planning and commitment Iteration planning / iteration backlog Release planning / Release backlog Time based functions Adaptive (multi-level) planning Risk handling Team structure of V7 / DT Roll-based systems Slack Sustainable pace | <ul style="list-style-type: none"> Frequent face-to-face Team charting Cross-silo collaborative teams Self-organizing teams Cross-functional teams Transparent leadership Task prioritizing Generalizing specialists Tracking progress via velocity Burn-up/Burn-down charts Refactoring Automated unit tests Coding standards Incremental/evolutionary design Automated builds Test-retain build Monitoring technical debt Version control Configuration management Test driven development Pair programming Spike solutions Continuous integration Incremental deployment Simple design End of iteration hands-on UAT Automated functional tests Automated developer tests (unit tests) Exploratory testing Software metrics |
|---|--|

Credit: Ahmed Sidky, "The Agile Mindset", available at <http://www.softed.com/assets/Uploads/Resources/Agile/The-Agile-Mindset-Ahmed-Sidky.pdf>

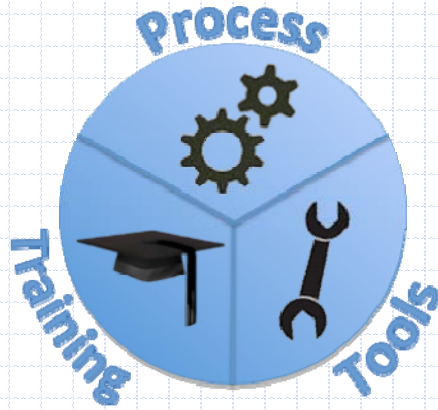
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The Elements

None of these is sufficient by itself!

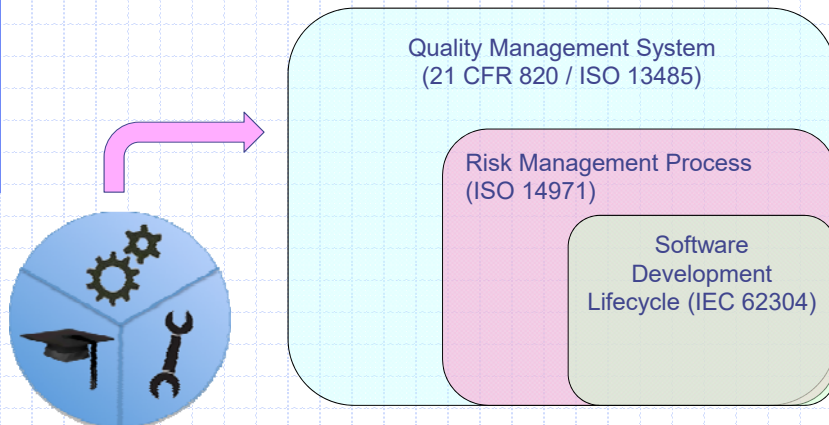


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Processes – for Safety



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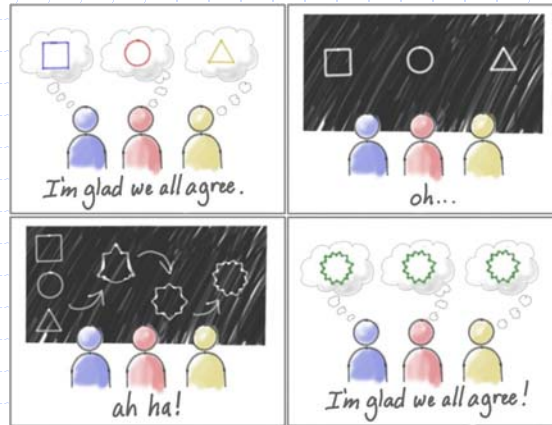
GPSV & IEC 62304 principles

- 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

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

The Goal: Shared Understanding!



Source: Patton, Jeff, and Peter Economy, *User Story Mapping: Discover the Whole Story, Build the Right Product*, Sebastopol CA, O'Reilly Media Inc, 2014.

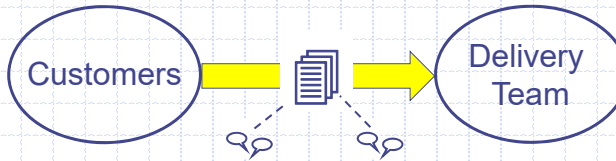
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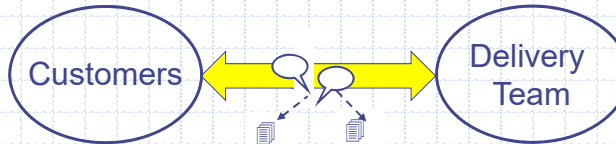


Shift the Communication Medium

- Document-centric, supported by Conversation



- Conversation-centric, supported by documents



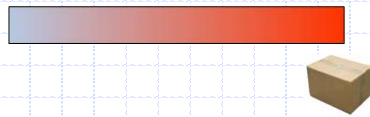
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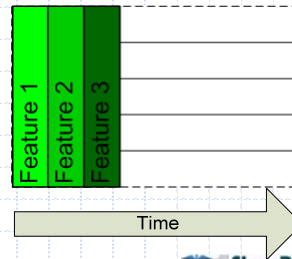
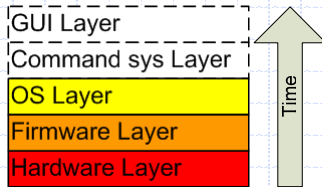
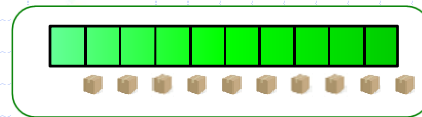


Mindset: Deliver Working Increments

X Not This:



✓ But This:



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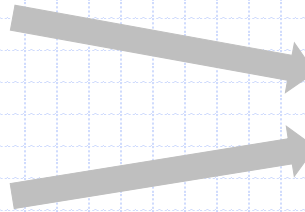


Design – Chunk the Work

- All the project will get done – just not all at once



Initial architecture
– minimal detail!



- Many ways to carve the work up
- Some make it easier to do

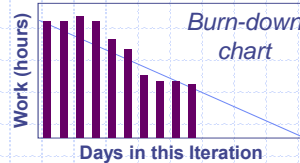
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Track work as it proceeds

- Status reporting is not separate from team's own way of tracking their work



Each day:

- Team estimates hours remaining for each task
- All remaining hours are summed
- That total is today's data point on burn-down chart

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Define – and enforce – “Done”

When can we say with confidence that a story is DONE?

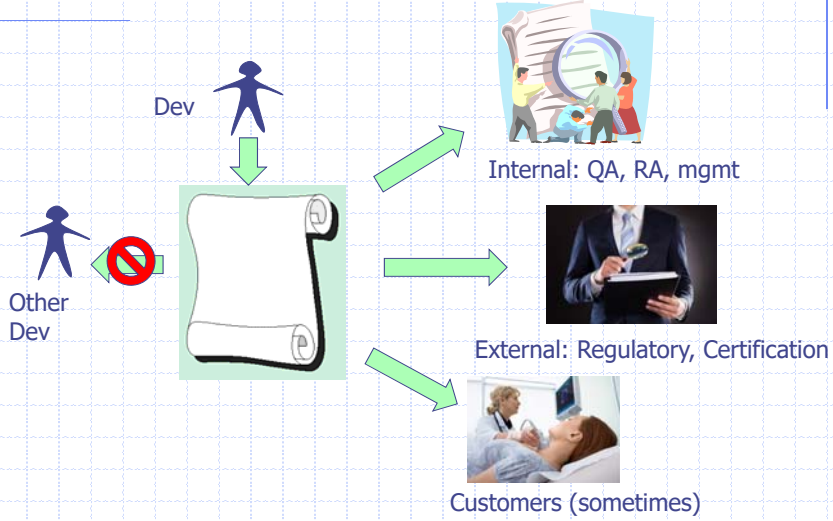
- When the story is refined and accepted (and documented).
- When the code is implemented & checked in.
- When the implementation is unit tested.
- When system / functional tests have passed.
- And??

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Documentation – Not for the team

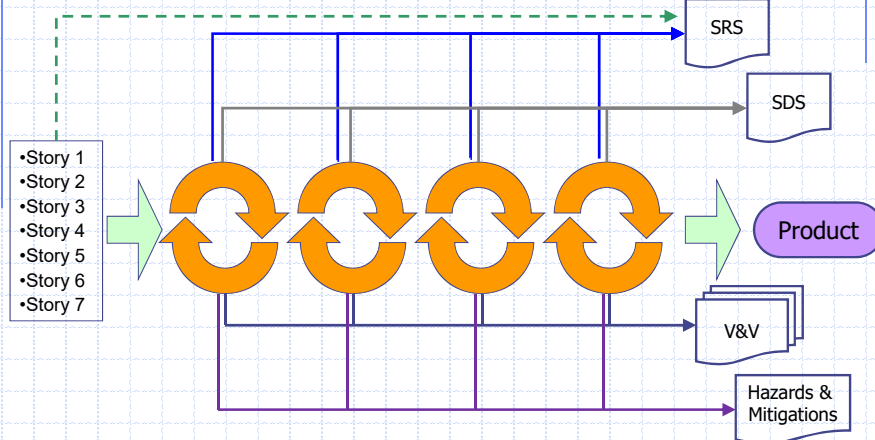


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Documents: Capture As You Work



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Pairing – for code and more



Pairing can be used effectively for requirements, design, and testing as well as coding. Benefits include:

- Better designs
- Effective training / mentoring
- Reduced risk of knowledge loss
- Improved quality via constant review

Pairing can also serve as peer review if the company addresses regulatory concerns:

- Established acceptance criteria
- Defined reviewer qualifications
- Documentation of results

Pairing as a form of peer review (as part of the overall verification process) must satisfy the same requirements as any other method of peer review, addressing the considerations described above.

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Mob Programming . . .



Photo courtesy of Woody Zuill.

It started in 2011 in San Diego...

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Productivity

How can we be productive
with 5 people at one computer?



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Photos courtesy of Woody Zuill.

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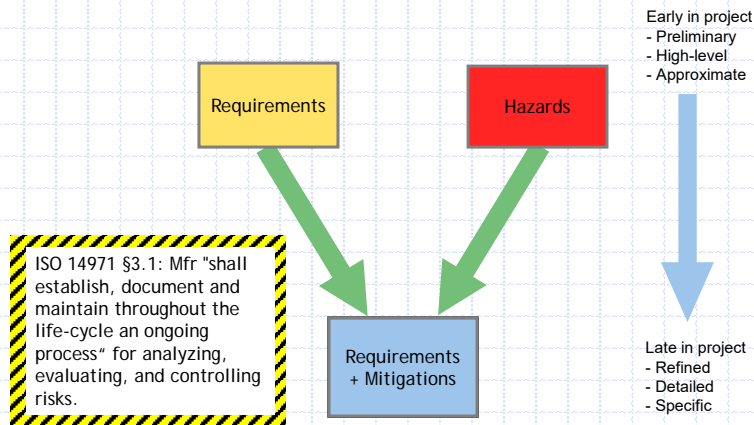
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Risk Management MUST Iterate



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Agile adapts well to hazard mitigation

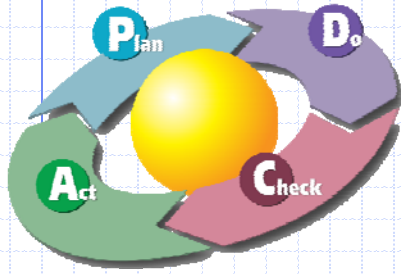
- Early analysis not static – review & revise as iterations proceed
- Users / product owner have multiple chances to uncover hazard situations
- Hazards can be simulated via "mock objects" in test suite
- Flexible, adaptive method can react to hazards learned during development (considered "negative user stories")

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Work iteratively!



- Good risk management is the same as ever – Agile hasn't changed that
- Early analysis is not static – review & revise as iterations proceed

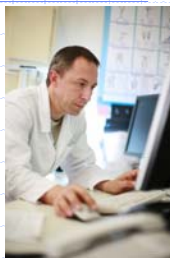
Image: <http://www.bulsuk.com/2009/02/taking-first-step-with-pdca.html>

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Usability – who is this 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?**

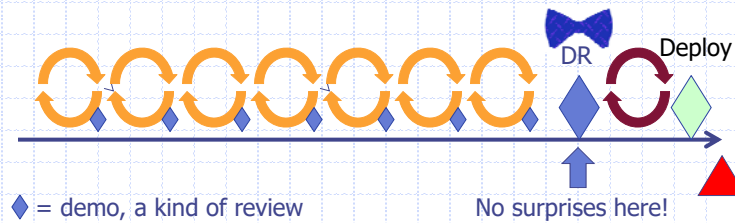
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Design Reviews: Part of the Lifecycle

- *In software development plans, define the reviews that take place, showing that they satisfy regulatory requirements.*
- *Plan formal design reviews to be performed at increment and release boundaries.*



Competitiveness, Compliance, Quality

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Agile: Not just for the SW team!

- Management: review progress, adjust scope
- Marketing: provide frequent input on features and user needs
- Service (as appropriate): provide input on maintenance features
- Mech/Elect Engrg: collaborate / provide prototypes

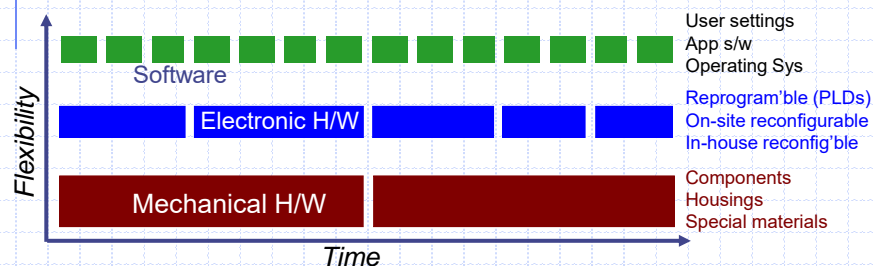
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Hardware **CAN** be Agile

- Less frequent iterations for hard-to-change items
- Aim for *working hardware* at each *iteration boundary*
- Misconception: To be Agile, h/w dev has to fit inside of 2-wk or 4-wk iterations



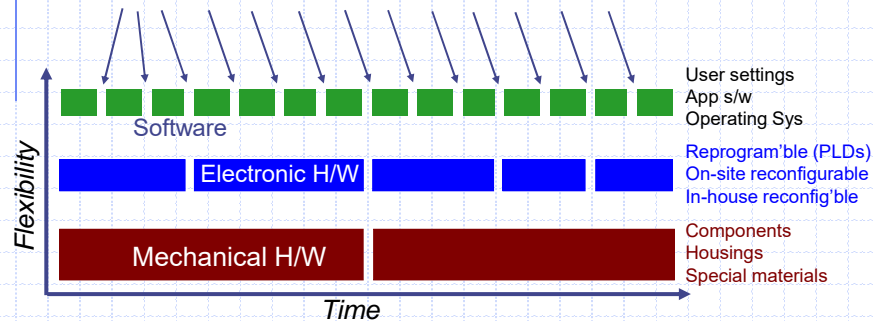
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Sprints: a **LEARNING** Culture

- Each junction gives tangible baseline each person sees
 - Enables peer-to-peer work, less need for hierarchy



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Know the Objections & Benefits

Points to counter:

- Lack of defined requirements
- Lack of structured review/release cycles
- Lack of documentation

Advantages to offer:

- Ability to resolve incomplete / conflicting requirements
- Ability to reprioritize requirements (mitigations) as system takes shape
- Many chances to identify hazards (controls not frozen too soon)

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Dispel the Myths

- 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

Beware the "But"

- Have you ever heard "We're Agile but . . .
- " . . . Detailed requirements are written and approved before iterations begin" or
 - " . . . We don't conduct demonstrations" or
 - " . . . After all features are implemented, we conduct an integration sprint" or
 - " . . . We use every [Nth] iteration to catch up our documentation" or
 - " . . . Software isn't runnable until many iterations into the project"

Approaches like these are ***Agile in Name Only***

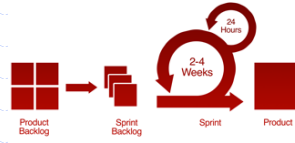
Plans – Avoid the Bottleneck

Formal – high level



Goals
Resources
Milestones
Deliverables

An Agile team will find that they need more than a backlog and release strategy to cover some of these planning topics. They now will have to write formal plans around such subjects as testing (at all levels), risk management, and software configuration management. A good way to remain Agile is to document the high-level strategy / resources / schedules / milestones and use the story creation / backlog / increment / release management to plan and execute detailed tasks. Together, they form the software development plan for a project.

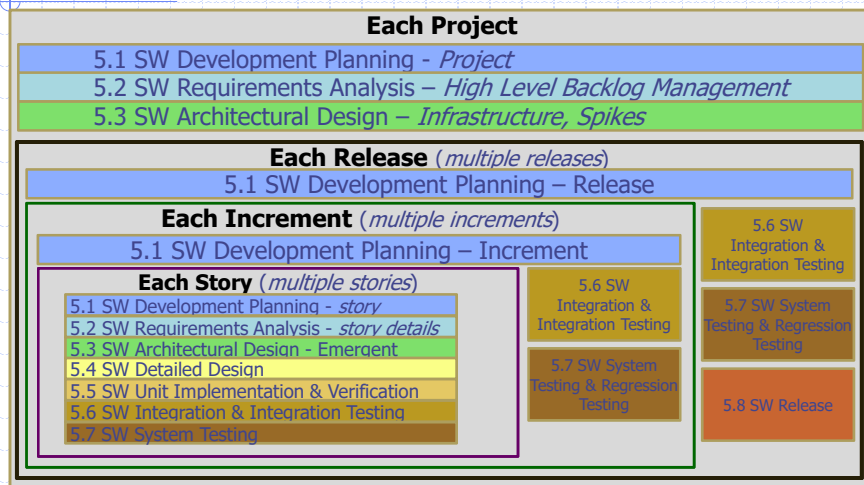


Less formal
(emergent details)

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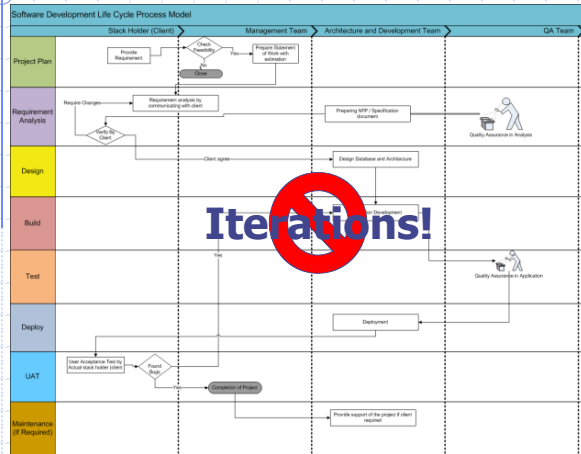
Plan at Multiple Levels



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Restrictive Product Development Process?



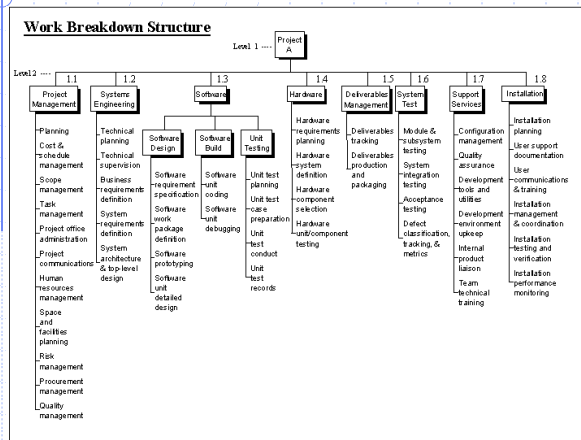
- Development SOP like this?
- Can't change all at once
- Look for deviations / exceptions clause
- Start with one or a few projects

Figure source: www.amipatelit.com/tag/sdlc-diagram

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Upfront Plans – Excessive Detail



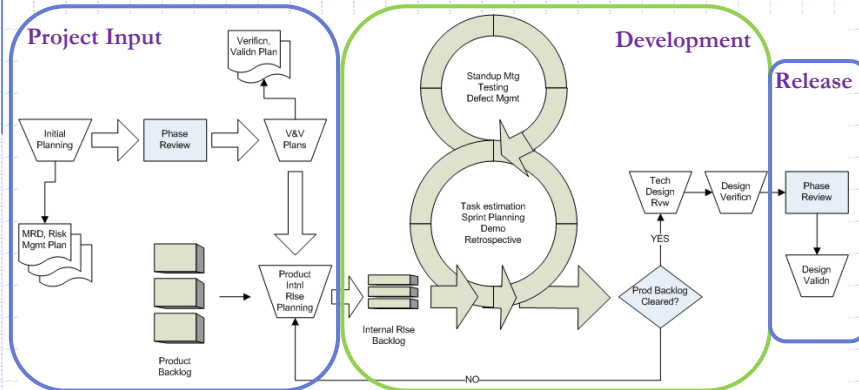
How can details for all stages of a project be planned before the specifics are explored and known?

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Get Lifecycle Model Out of the Way

Allow flexibility in the development process, while still requiring the important gates to begin and end a project.



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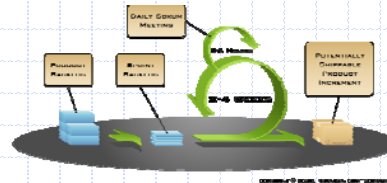
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Common Values



Fulfilling medical need
Safety / Effectiveness



Customer Satisfaction
High Quality

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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

Consider

- No regulatory body requires waterfall
- No regulatory body prohibits Agile
- *Discipline* is a key - documented process, and continuous improvement
- V-model arrows are relations, not time!
- *Good Engineering* is our goal – compliance follows

Key Points

- 
 ■ Fear of Agile = fear of sloppiness
- 
 ■ Devices badly need better S/W dev
- 
 ■ Agile **can** be used for med devices
- 
 ■ Device focus: safety (usability → safety)
- 
 ■ Docs prove what was done
- 
 ■ Agile for med devices: include doc, risk eval, usability eval as deliverables

References

- AAMI TIR45:2012 "Technical Information Report: Guidance on the use of AGILE practices in the development of medical device software", Association for the Advancement of Medical Instrumentation, August 2012. (available at <http://my.aami.org/store/>)
- Patton, Jeff, and Peter Economy, *User Story Mapping: Discover the Whole Story, Build the Right Product*, Sebastopol CA, O'Reilly Media Inc, 2014.

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