


Revisit: Agile Adoption for Regulated Medical Software

Software Design for Medical Devices

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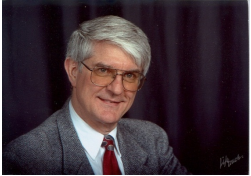
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Who We Are


Brian Shoemaker

- *Originally an analytical chemist*
- *15 y in clinical diagnostics: analytical support → assay development → instrument software validation*
- *6 y as SW quality manager (5 in clinical trial related SW)*
- *13 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 Van Schooenderwoert


- *Originally an electronics and software designer*
- *15 years safety-critical embedded systems development experience*
- *Since 2002: Agile coaching of teams and managers in regulated industries*
- *Industries: Aerospace (Flight simulation), Medical Devices, Sonar Weaponry, Scientific Instruments, Industrial Controls, Financial Services*
- *BSCE (Computer Engineering) from Rochester Institute of Technology*
- *Active in Agile New England & Agile Alliance; speaker at conferences worldwide*



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Reconsider Agile!

- **The Agile debate continues**
- Experience: Agile = safety / quality
- What are the keys to applying Agile?
- SW / HW can both be Agile
- Sum it up

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Rumors about ...



*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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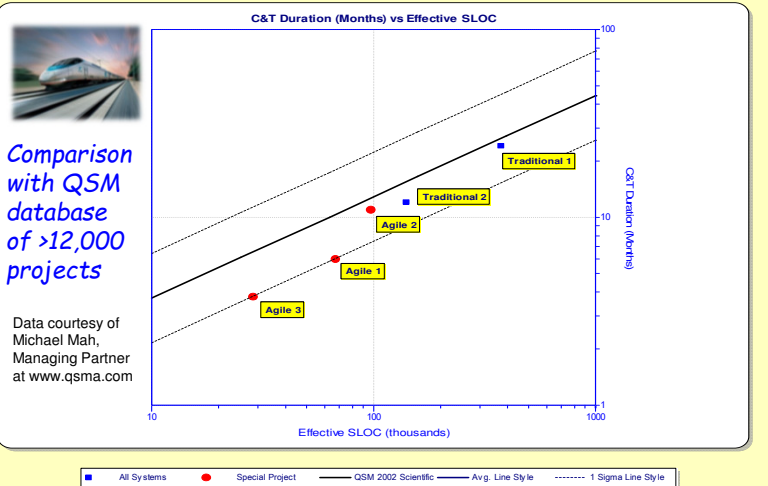
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Time to Market – Canadian MDev Co





Comparison with QSM database of >12,000 projects

Data courtesy of Michael Mah, Managing Partner at www.qsma.com

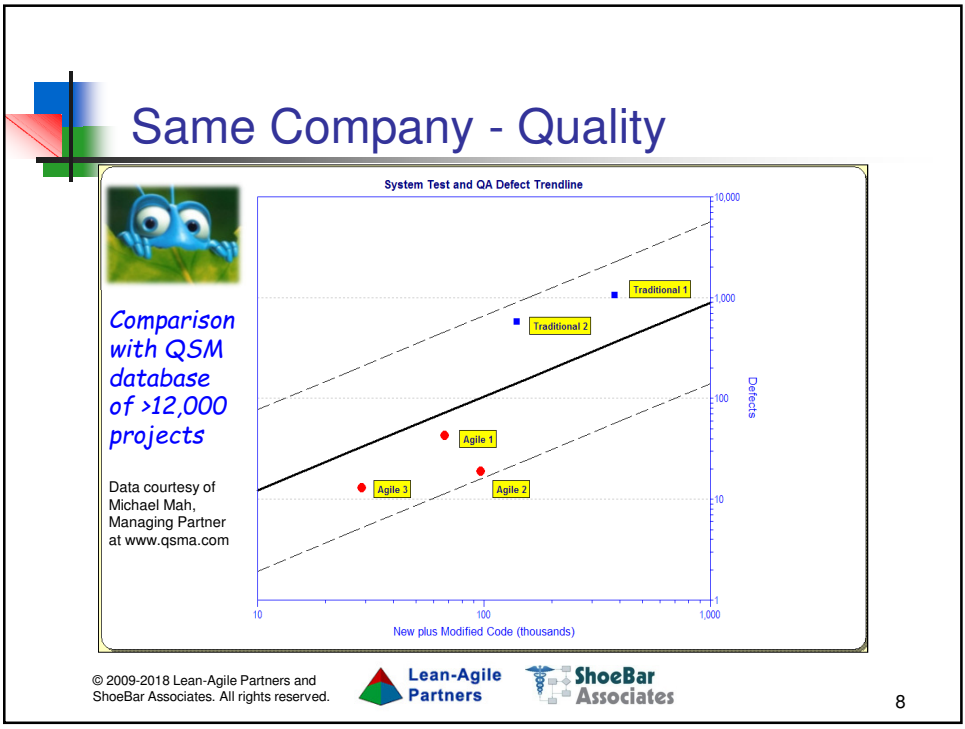


Project Type	Effective SLOC (thousands)	C&T Duration (Months)
Agile 3	~30	~3
Agile 1	~60	~5
Agile 2	~100	~8
Traditional 2	~150	~12
Traditional 1	~300	~25

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Example: Mobile Spectrometer

- Audited for **medical** application – blood analysis (initial customer in agriculture)
- Real-time data readouts with laboratory accuracy
- Technology risks: 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 iterations
 - 51 s/w defects post-unit-tests, 3 yr. total



Spectrometer system
"GMS"

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Agile - Quality

Team	Defects/FP	Process
Follett Software (1)	0.0128	Agile, XP co-located
BMC Software (1)	0.048	Agile, Scrum distrib.
GMS (2)	0.22	Agile, XP for embedded
Industry Best (3)	2.0	traditional
Industry Average (3)	4.5	traditional

Co-located agile XP team achieved 100X the defect performance of the best traditional waterfall teams!

1. M. Mah, "How Agile Projects Measure Up and What This Means to You", Cutter IT Journal vol 9, no. 9, Sep 2008.
2. N. Van Schoenderwoert, "Embedded Agile Project by the Numbers With Newbies", Agile 2006 conference report.
3. Capers Jones, "Software Quality in 2002: A Survey of the State of the Art", presentation to Boston SPIN, Oct 2002

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Mindset, not cookbook

NOT this:

But this:

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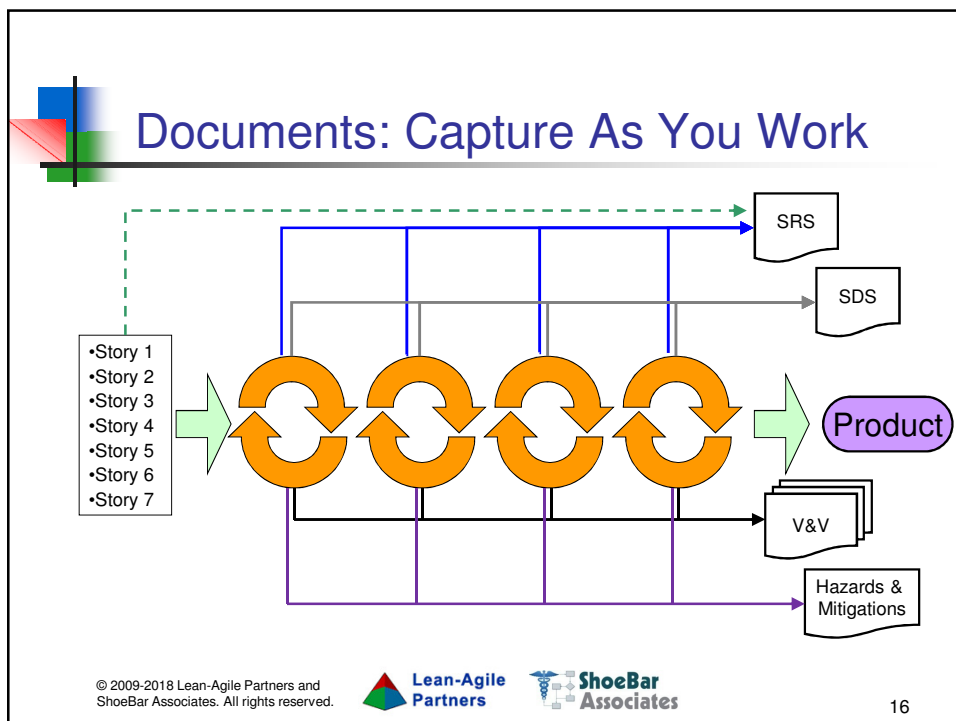
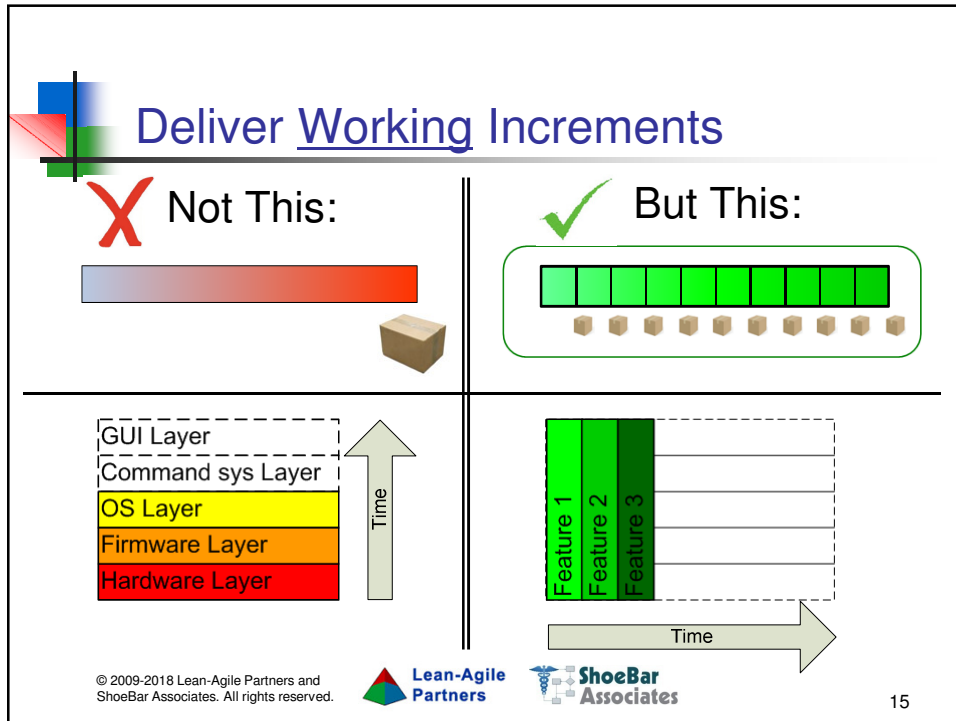
The Goal: Shared Understanding!

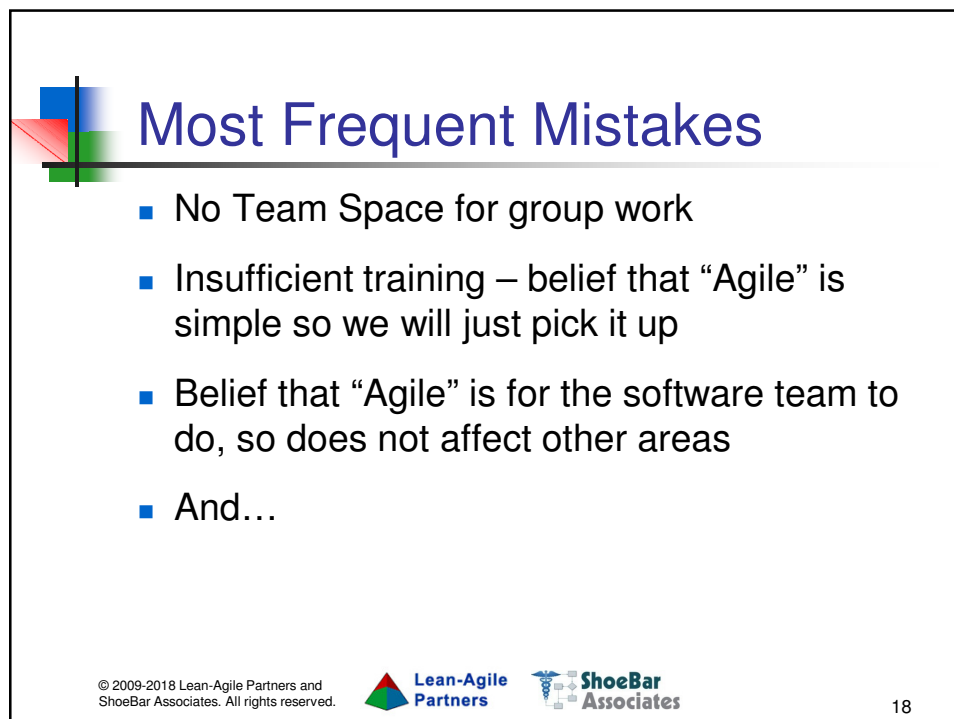
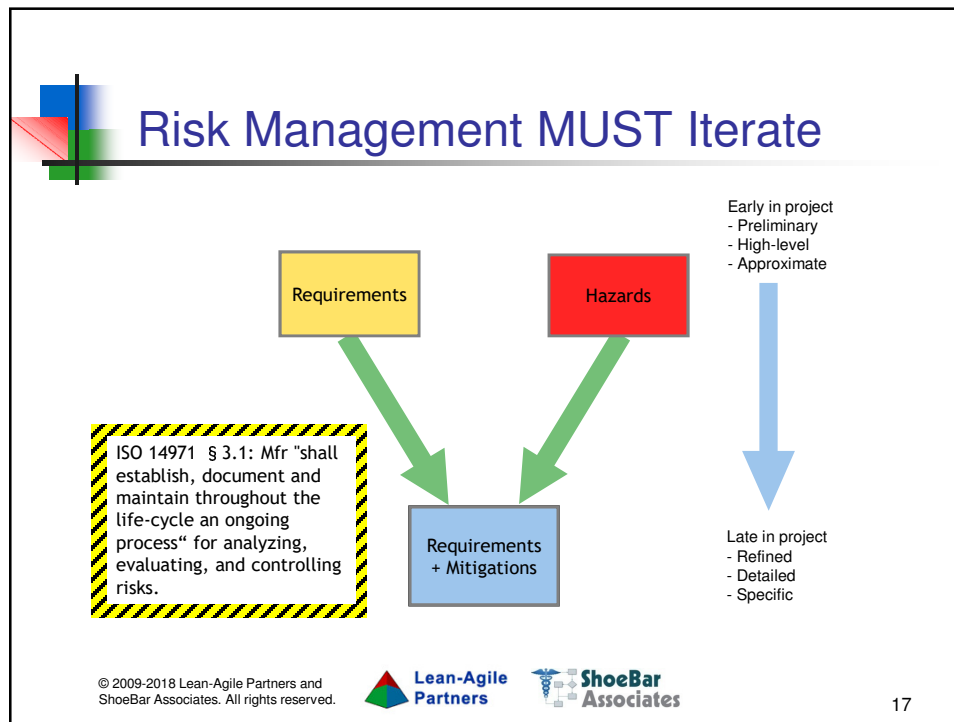
This applies to mechanical, electrical, instructions for use, and risk management issues as much as to software features!

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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The "Tool Jungle" mistake

you are in charge, not the tools!

Image from Dzone article "Orchestrating ALL the Things!" <https://dzone.com/articles/orchestrating-all-the-things-watch-the-video-of-my>

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Mistake – Preventing Interaction

Management

Engineering

PO / Customers



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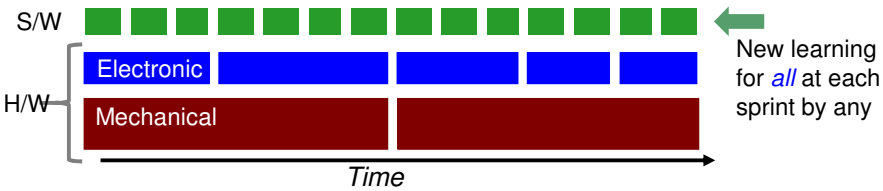
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Issue: Long h/w cycle times

- Many ways to mitigate
 - Simulation
 - Programmable devices – PLD, FPGA... 
- Faster s/w cycles allow s/w team to support the electronics team, e.g. monitor test points



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Mockups / Prototypes!

Mechanical / electrical engineers have designed iteratively for decades ...

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Is it a s/w or h/w problem?

	Target CPU	Desktop PC
System	Full system able to run on target hardware. [The deliverable s/w]	Full system able to run on PC with hardware presence faked.
Domain	Example domain = the OS task that is the math algorithm. Can run alone.	A domain is not the whole system, but is more than a C function.
Unit	C function routine, or C++ class method – the “unit” in ‘unit testing’.	C function routine, with #defines to fake the presence of hardware.

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Mixed team skills

- Story board can be divided...

H/W S/W

We're still *one* team, now with different workstreams visible

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Lanes not independent

- Keep focus on whole features; don't merely fit work to skill siloes

People pair to do their parts of features that span disciplines

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Learning cycles benefit *all*

- Every discipline benefits from the learning by any, at each iteration juncture
- Experience showed that traditional h/w teams benefitted from working with Agile s/w teams – even with different sprint lengths!

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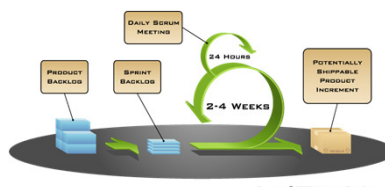
Common Values



Fulfilling medical need
Safety / Effectiveness



Customer Satisfaction
High Quality



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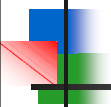
Essential Elements

- 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

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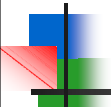
Consider

- No regulatory body requires waterfall
- No regulatory body prohibits Agile
- *Discipline* is a key - documented process, and continuous improvement
- *Good Engineering* is our goal – compliance follows


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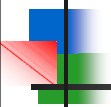
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- Lean-Agile coaching for software and hardware teams
- Safety-critical, regulated coaching is our specialty
- Lean-Agile coaching for stakeholders and senior managers




**ShoeBar
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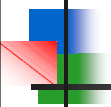
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- Software quality systems
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<https://dzone.com/articles/orchestrating-all-the-things-watch-the-video-of-my>

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Slide 33: Mountain Goat Software,
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Further Info

More examples of Agile hardware: N. Van Schoenderwoert, "Yes, Hardware Can Be Agile!", InfoQ, March 2015, <http://www.infoq.com/articles/hardware-can-be-agile>

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