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# How Three Medical Product Companies Became Agile and Compliant: CASE Studies

*Agile New England chapter of ACM*
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# Intro

## 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*

## Brian Shoemaker

- *Co-author of Agile Methods for Safety-Critical Systems*



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# Three Case Studies

## Efficiency for Survival


**Inpeco** - Lab Automation Systems

*Milan, Italy*

## Agile Long-View Planning


**Sanofi** – Pharma Med Device Group

*Cambridge, MA, USA*


## All Levels Agile


**Bluefruit** - S/W for embedded systems

*Cornwall, UK*



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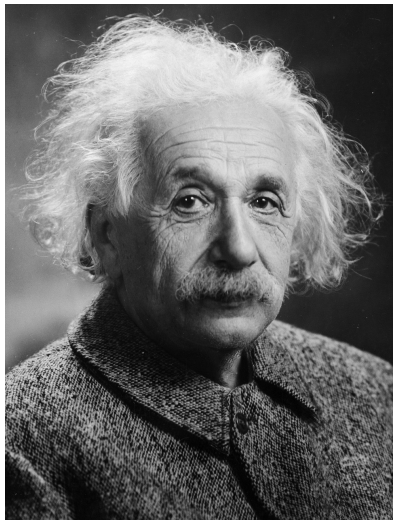
# Learn by examples…

"Example isn't another way to teach, it is the only way to teach." - A. Einstein





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# Medical: Two Key Challenges

- Persistent belief: Agile not allowed
  - Traditional QA view: Agile = disorganized, undocumented
- “Check the boxes” mentality
  - Create a detailed SOP and you’re done
  - Processes always top-down



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# Agile is *not* prohibited!

- You must work to predetermined requirements – but they can be predetermined at any time! Just *not* after-the-fact!
- Your work must be done under the control of a Quality Management System (QMS), and you must show evidence that it was
- Refer to AAMI TIR45:2012 - "Guidance on the use of AGILE practices in the development of medical device software"
- You don't need to be a regs expert to follow the case studies we will see

Note: AAMI = Association for the Advancement of Medical Instrumentation



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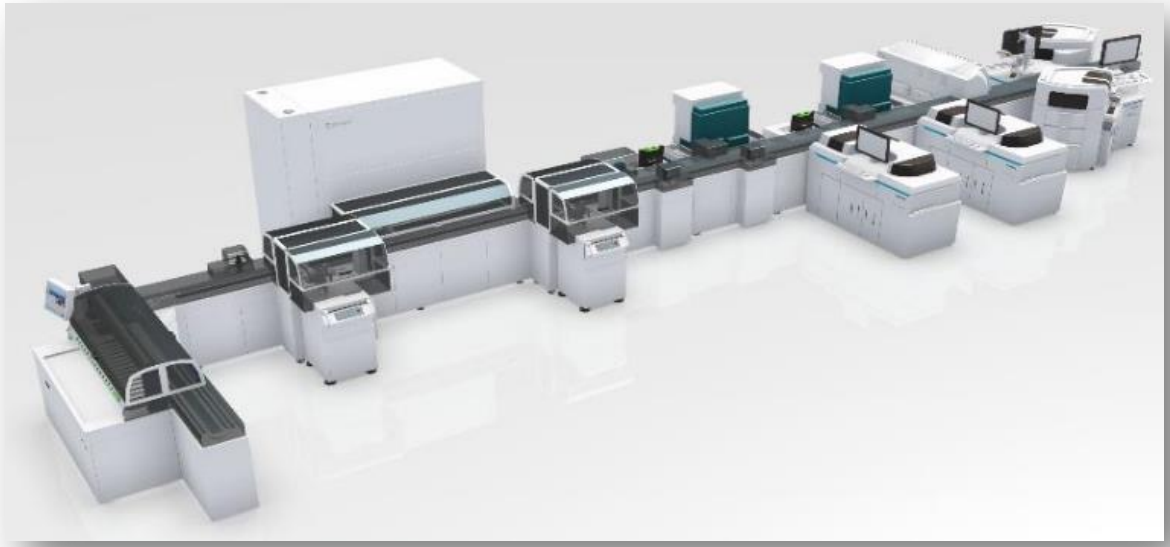
# Case study 1: Inpeco

## Efficiency for Survival

Dominant player in the market for clinical laboratory automation systems. A typical system can process thousands of blood samples per day.  Each customer Installation is unique.




**Inpeco** - Lab Automation Systems

*Milan, Italy*



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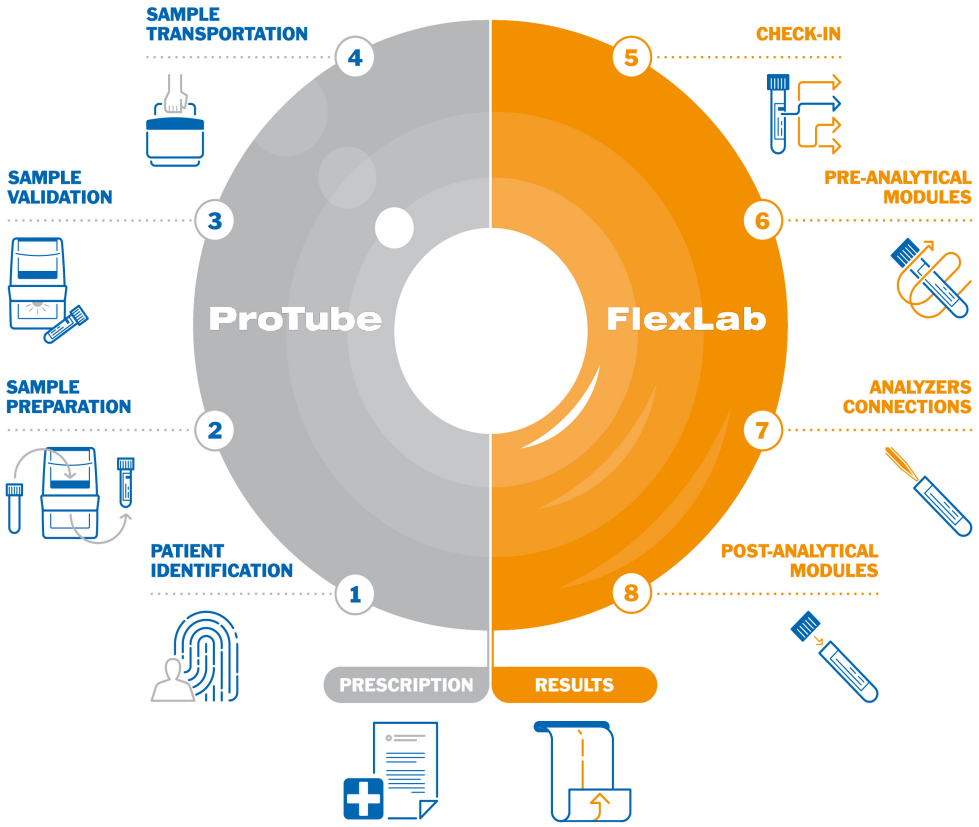
# Inpeco – Processing

***Total Testing Process***



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# Inpeco – The Problem(s)

The clinical laboratory automation world was changing:

- Cybersecurity - needing rapid patches to keep up
- New external sales force creating distance to their customers
- Customer requirements changing even faster than before
- New regulatory initiatives expected from the EU



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# Inpeco – What they did

- Tried to start Agile in all development groups at once – *failed!*
- They took time to study the experiences & successes of other companies
  - Asked their teams to envision a more effective way to work together than the old silos
  - They formed cross-functional teams around features or automation modules (Teams included developer, tester, QA person)
  - Teams tested what they created, supported by QA
  - Teams chose tools that would help them work together – Jira, Jenkins

# Inpeco – What they did

Company had a simulator they had commissioned for helping customers to envision the laboratory set-up they want built.

## Lab System Simulator

Integration Tests Enabler

Time Saving

Configurable

Huge tube workloads

Complex Env. in-house simulation

- Automation & Lab Users full emulation
- Complex environment simulations
- Huge tube workload simulation
- Accellerated simulations



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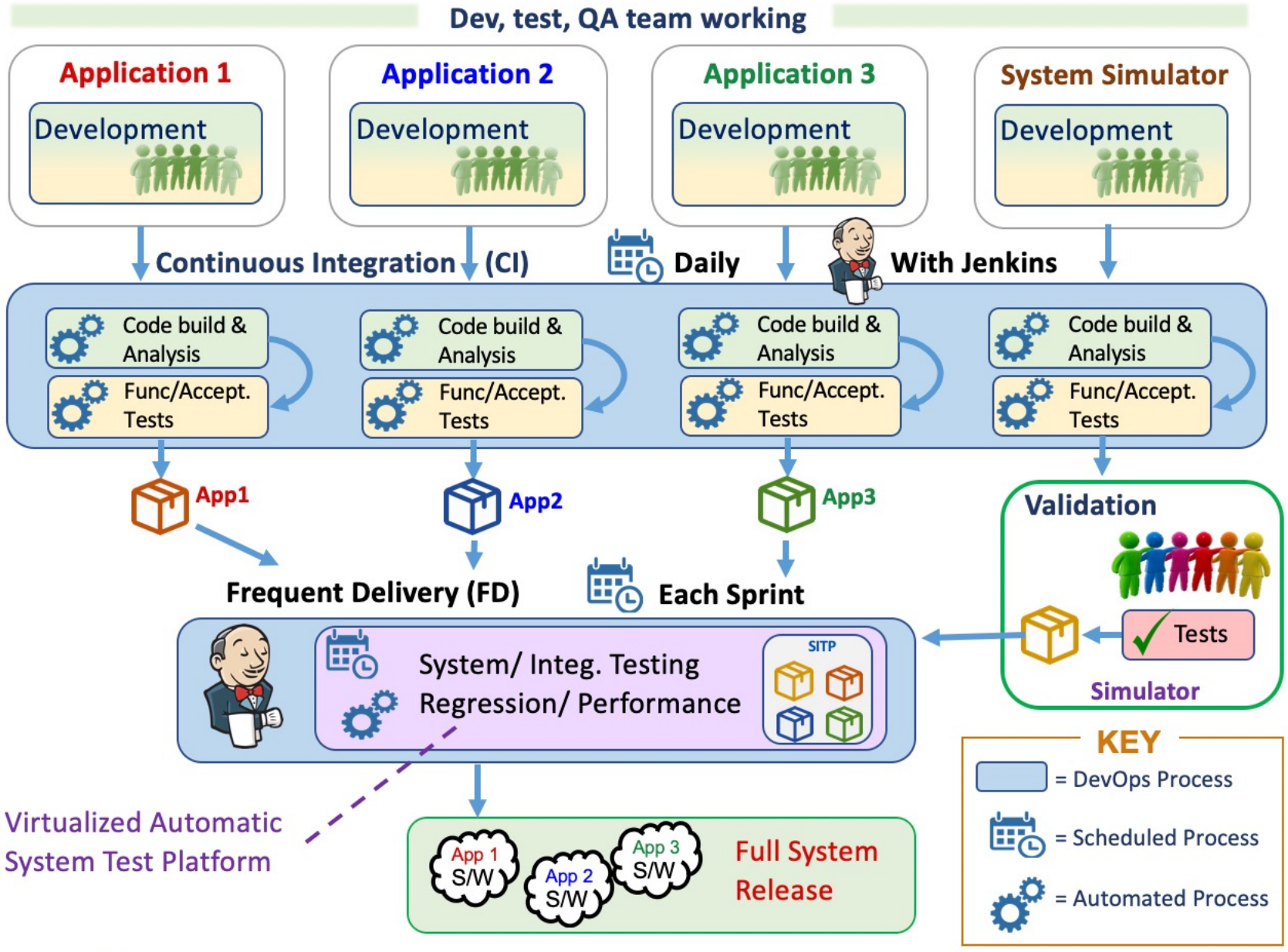
# Inpeco – What they did

Agile leaders began to use the lab simulator to try out design ideas.

Eventually teams were able to make the simulator able to fully simulate the s/w design, isolated from actual h/w.

Soon it became a test bed for all the s/w in all the lab machines



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# Inpeco – Results

- A common Jenkins pipeline is set up and running
- Daily continuous integration and bi-weekly sprint-based DevOps cycles are in place
- Automation Testing framework integration is at 50% coverage
- The simulation system runs up to 30k tubes/day, producing GBs/day of data log to be analyzed
- 1 month: platform delivery cycle for patches
- 3 months: system delivery cycle for full solutions

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# Case study 2: Sanofi

## Agile Long-View Planning


**Sanofi** – Pharma Med Device Group

*Cambridge, MA, USA*

Sanofi's medical device software group in Cambridge, MA has built Agile iterative planning and feedback into its overall process with the aim of meeting both business and medical needs efficiently.

- Sanofi's product is software as a medical device, or SaMD*
- Assists diabetic patients in managing blood glucose levels and their physicians in tracking and directing patient care.
- Product "ecosystem" - Mobile app, wearable monitor device, web portal for physicians, database

* SaMD: Software as a Medical Device



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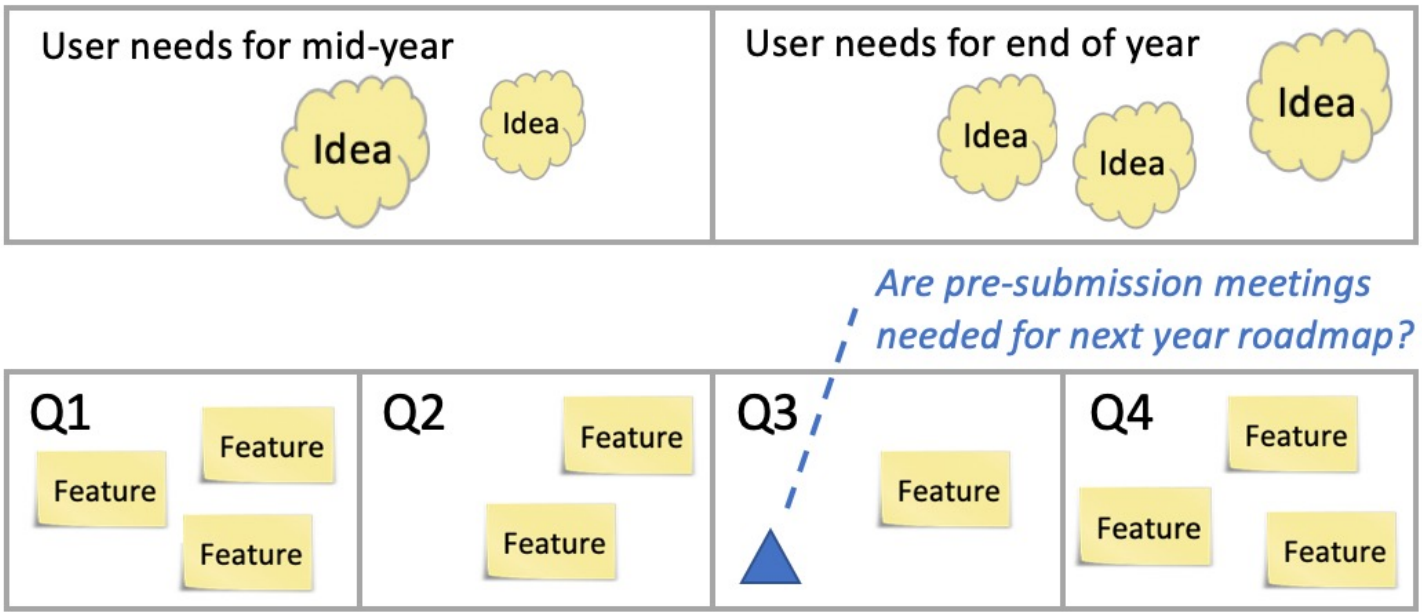
# Sanofi – The Problem(s)

Changes in the business environment, including:

- Need to deliver SaMD faster than before they went Agile
- Stakeholders have much longer-term expectations
- Pressure to complete the overall product definition so sprints can happen
- Once a design has regulatory ok, it's harder (more expensive) to change

# Sanofi – What they did

- For the nearest 6 -12 months, use broad feature ideas in the backlog
- For 6 months out and later, refine into user stories; use story point estimation, planning poker to plan the releases



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# Sanofi – Example

During the 6-12 month “look ahead” period:

- Decide whether a feature needs more data: e.g. human factors testing; medical affairs expert input; a research study

Current product is intended for diabetes patients who are maintaining their insulin levels.

Desired new feature “basal titration” is for those who are not at a maintenance state. It will compute changing dosage levels and instruct the patient on when and how to dose.



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# Sanofi – Example continued

The two use cases are fundamentally different: basal titration is a stepping-stone to to the maintenance feature for the same patient.

- Internal reviews came up with two possible designs.
- If using non-Agile process they would
  - Have high level discussions to pick one of the designs
  - After 6 months in the field, might learn it had real problems
- Instead they did:
  - Took two prototype versions to 10 patients and 10 physicians in Boston for a formative study

# Sanofi – Results

- The Boston study gave them confidence to select one of the designs
- This allowed them to avoid investing too heavily in early verification activities – a common and costly mistake for medical device companies
- Their style of road-mapping
  - Let them accommodate the regulatory processes that are outside their control
  - Gave them clear data on which to base their design choice, and for evidence the work was done within their QMS

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# Case study 3: Bluefruit

## All Levels Agile

Embedded software specialists, over 70 employees, based in Cornwall, UK. Born Agile. Customers in automotive, industrial, and more recently in medical devices. Growth driven by high quality.

- Founded in 2000
- All projects use Agile development – no exceptions
- Much lower employee turnover than s/w industry average


**Bluefruit** - S/W for embedded systems

*Cornwall, UK*



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# Bluefruit – The Problem(s)

As any company grows, more structures and layers are added. These can easily get in the way of *empowerment*, which is a core Agile value for founder Paul Massey.

In practice, empowerment means:

- Avoid creating situations where management has to overrule teams to safeguard a larger or longer-term interest
- Don’t give up on the larger benefit; help everyone see that benefit and win their buy-in



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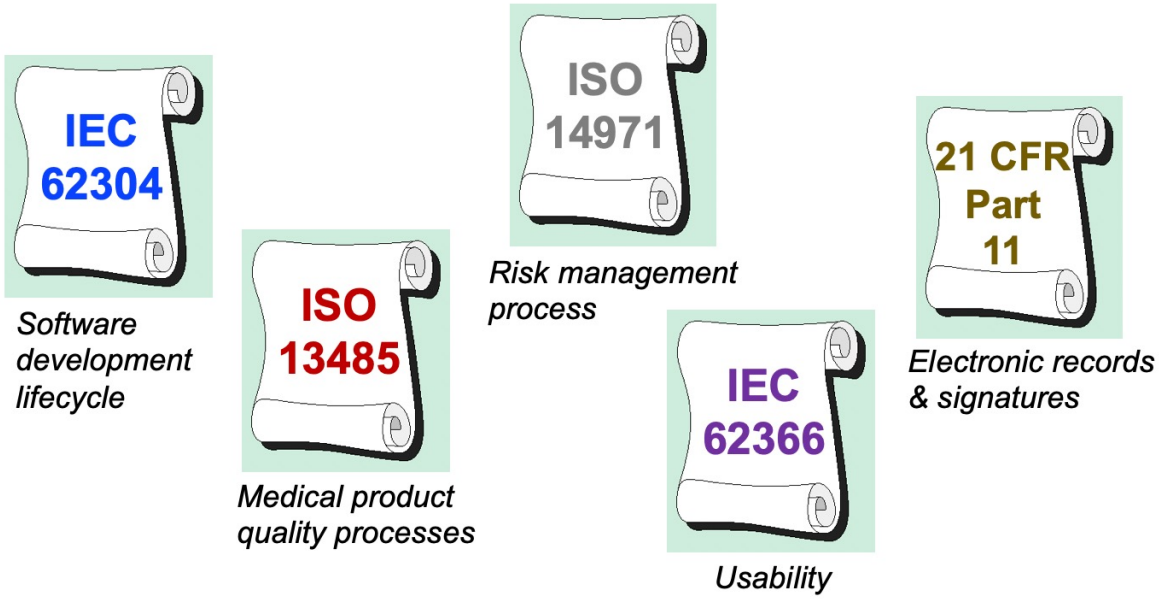
# Bluefruit – Example issue

Should Bluefruit pursue regulatory certifications as a means for attracting business with medical device companies?

- Q: What are “Certifications”?
- A: Certifications and standards are issued by regulatory bodies, and may be the basis for audits



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# Bluefruit – What they did

- Investigated Employee Ownership as a way to keep their company culture Agile
- Decided not to use an outside consultant to create a QMS and get them a certification – that would break empowerment!
- An externally-designed Quality Management System would have rules that teams do not see a reason for, so there wouldn't be genuine buy-in
- Their first medical device client had a problem with FDA
  - Hardware was ok'd but s/w was not created within a QMS
  - No choice but to rewrite the s/w!

# Bluefruit – First Med Dev

- Quality, *not certs*, attracts first client
- Client found Bluefruit by inquiring about s/w quality processes (Bluefruit had no certifications*)
  - Use of BDD, TDD
  - Pair programming
  - Blind hiring process, etc.
  - All served to show that Bluefruit had a genuine bottom-up QMS

* Since Bluefruit is not the device manufacturer, they are not required to have certifications.



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# Fear of doing harm

- Hesitation… then they saw the code
  - *"It kind of drew our team in, and so rather than feel anxious about that kind of responsibility, making sure that people couldn't come to harm if we get this wrong, it was more like if we don't help these folks out, people ARE going to come to harm!" – Paul Massey*
- Concerns about the extra responsibility, and regulatory paperwork bureaucracy melted away
  - Teams gained even more confidence in their Agile coding; were excited to add the higher value they could bring
  - Morale boost!



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# Empowerment is Key

*If it's my project, if it's something that I'm championing — whether part 11, or in the past, it's been BDD or TDD —*
*I've always said to myself that if the team doesn't buy in, then we're not doing it.*

*It's not happening.*

*And I'm absolutely committed to that.*
***The onus is on me to get that buy-in.***

Paul Massey, Founder of Bluefruit Software

*Note: "Part 11" is a regulation on electronic records & signatures*



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# Bluefruit – Results

- Company has moved to employee ownership – to preserve its Agile culture
  - Internal benefit: changes which take years for other companies took only a few months *because their culture was already one of accountability & quality*
- Saw *Surprise Benefits* for customers:
  - Less chance a competitor will buy Bluefruit, due to legal (emp. ownership) barriers to a sale → more business!
  - No outside shareholders means that no extra layer of costs is built-in to customers' projects → more competitive!

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# Summing Up

- Understanding the principles is not enough
- Understanding the context is not enough
- You need to choose/create the practices that are best able to realize a *principle* in your *specific context*
- In each case study they took ownership for steering their own path to Agility



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# Case Studies book


## Agile Methods for Safety-Critical Systems

***Case Studies of Medical Product Companies***

Follow-up to our earlier book *Agile Methods for Safety-Critical Systems: A Primer Using Medical Device Examples*.

Complete info:

http://agilemethodsforsafetycriticalsystems.com/



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# Our Services


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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

Where to get AAMI TIR45:2012
https://webstore.ansi.org/standards/aami/aamitir452012r2018
(cost is $266)