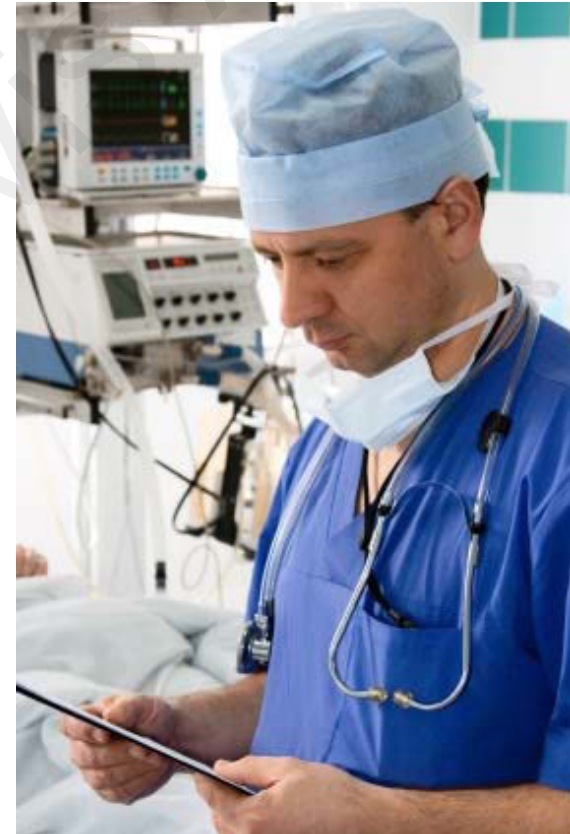

Agile software development for Medical Devices



Robert.Ginsberg@qadvis.se
Tel: +46 760 199 469

Short presentation of me

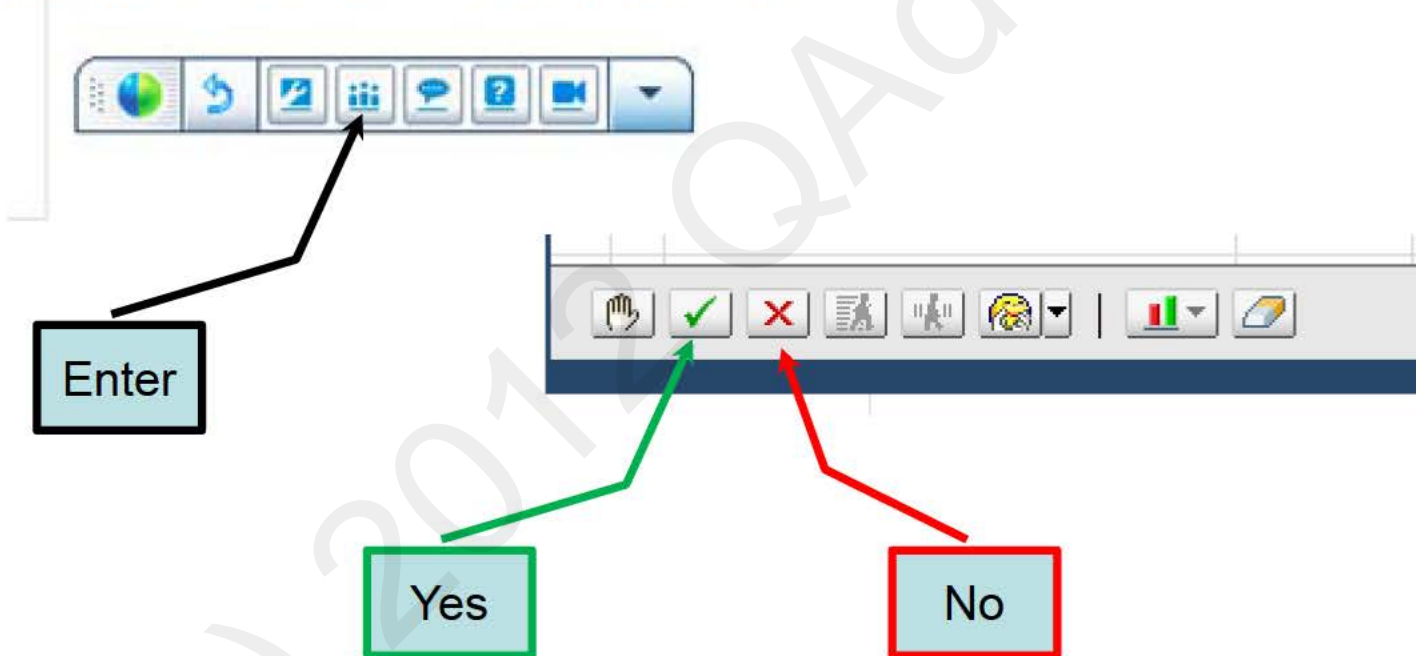
Robert Ginsberg

- 26 years in SW
- 17 years in Medical Device SW
- Participated in approx 20 audits, FDA, MDD, etc.
- Co-author of IEC/ISO 62304
- Lean believer 😊. Implemented agile software methods at two large medical companies



Short survey

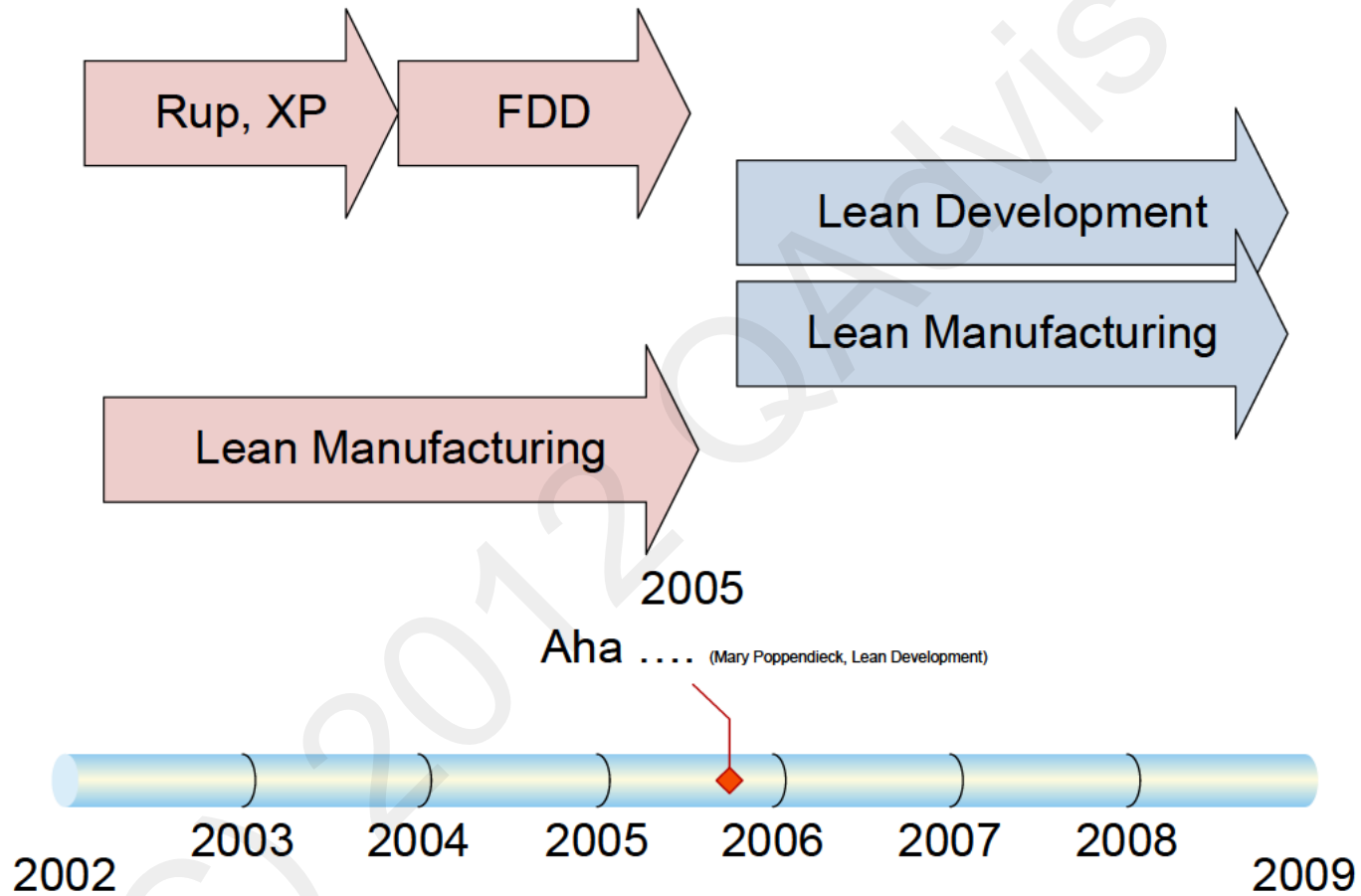
Who has worked hands on with agile methods for software?



Lean



Time line

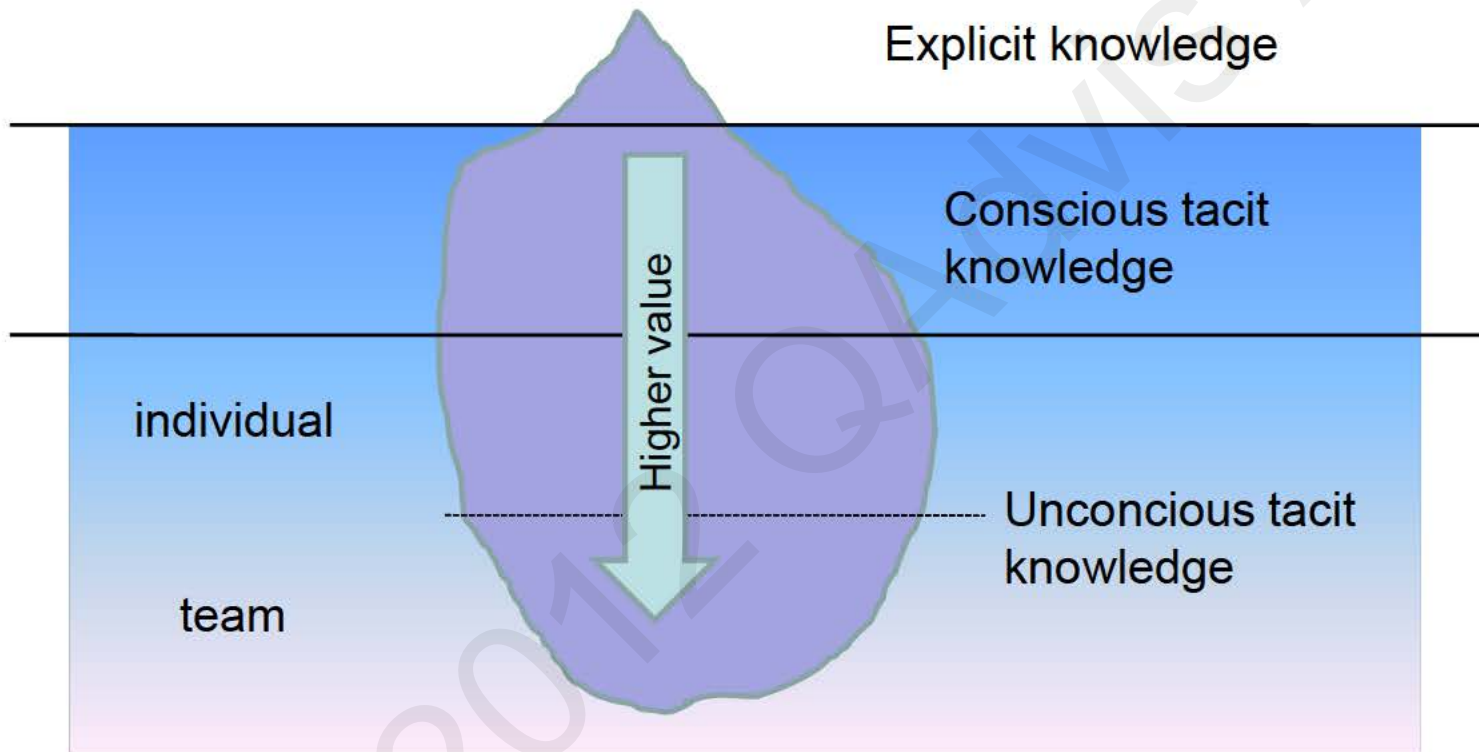


Why Lean – challenges to conquer?

To meet challenges such as:

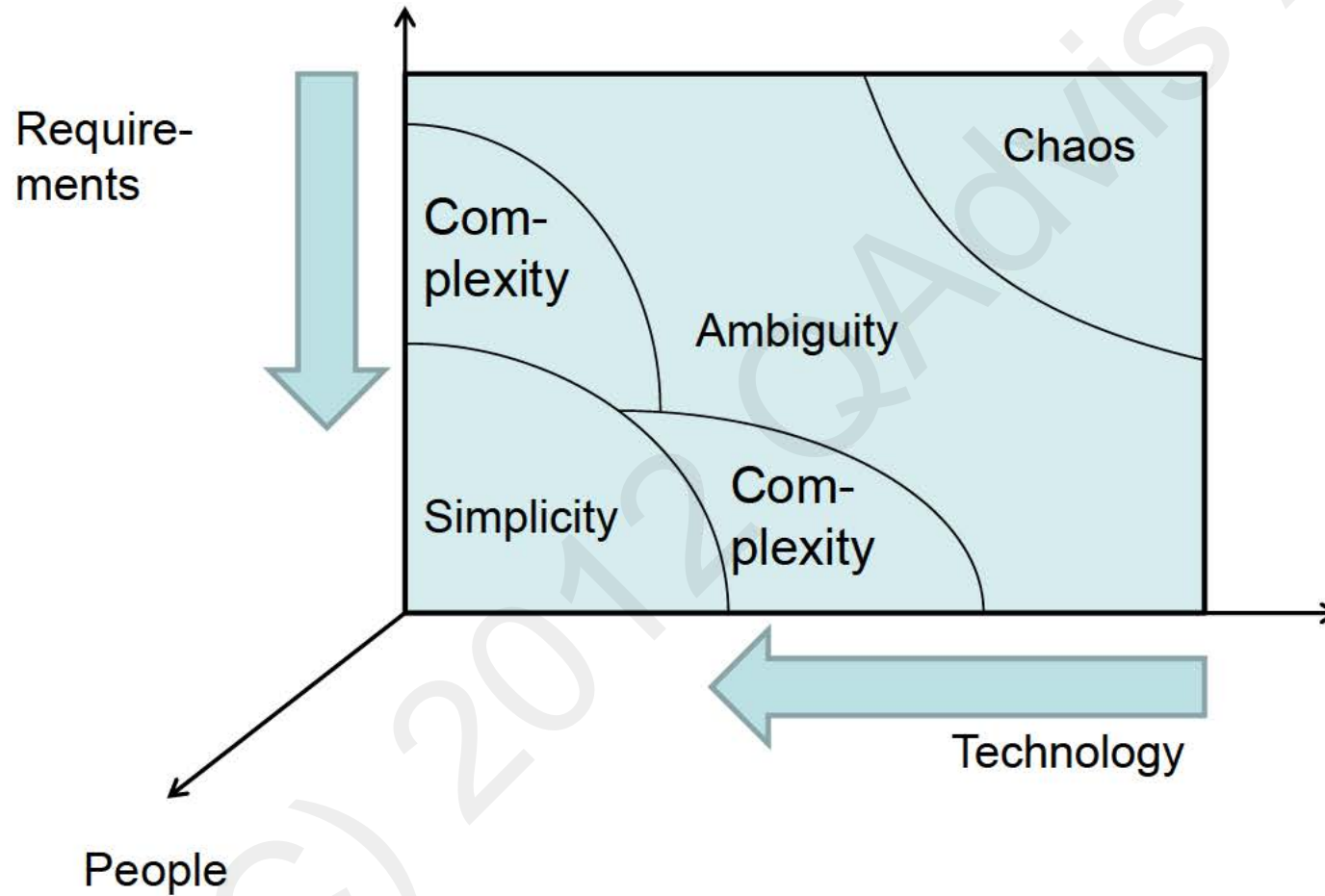
- Ever increasing innovation pace
 - Managing increasing complexity
 - Being an attractive employer
-

Innovation, are we taking care of the knowledge?



Source: Bartholomew, David. Sharing Knowledge. David Bartholomew Associates, 2005

”The thorniest problem we have with software is its complexity” Mays, IBM 1994



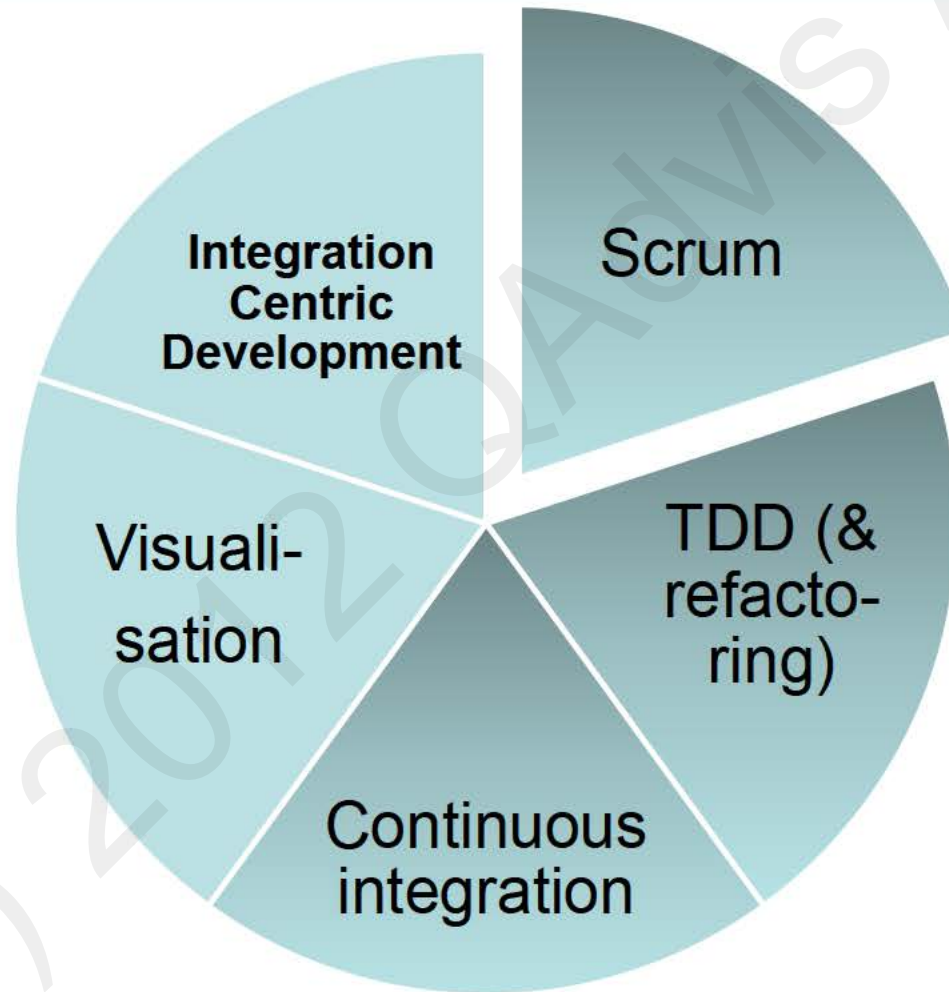
People, how do we attract the best?



Why Lean – gains

- Higher quality and productivity
 - Better usage of the total knowledge in your organization
 - Higher level of innovation
 - Higher focus on value added activities
 - Feedback loops and focus on impediments
-

The Lean tool box for Sw



Very short introduction to SCRUM



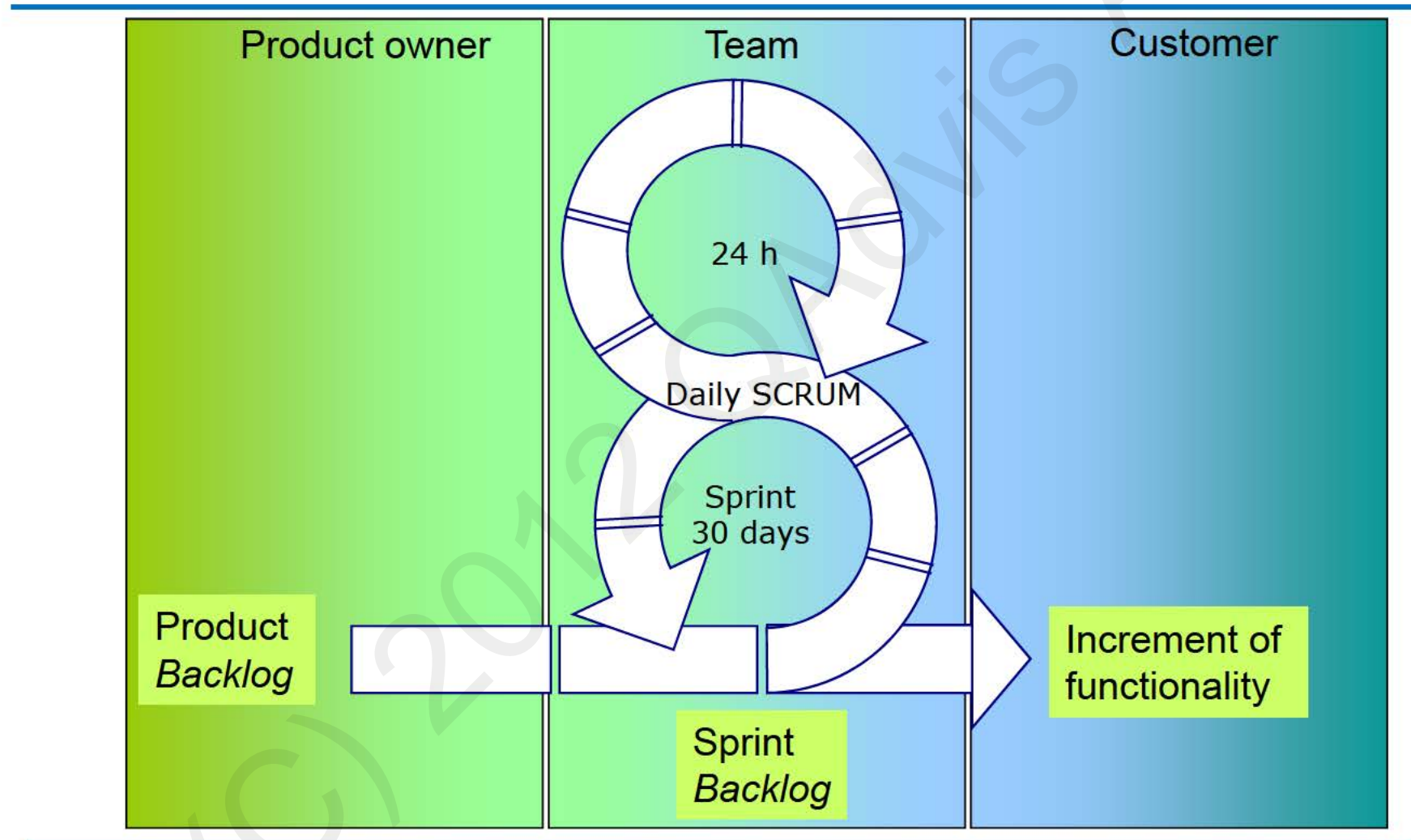
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SCRUM!!

GRRRR! GRRRR! GRRRR!!

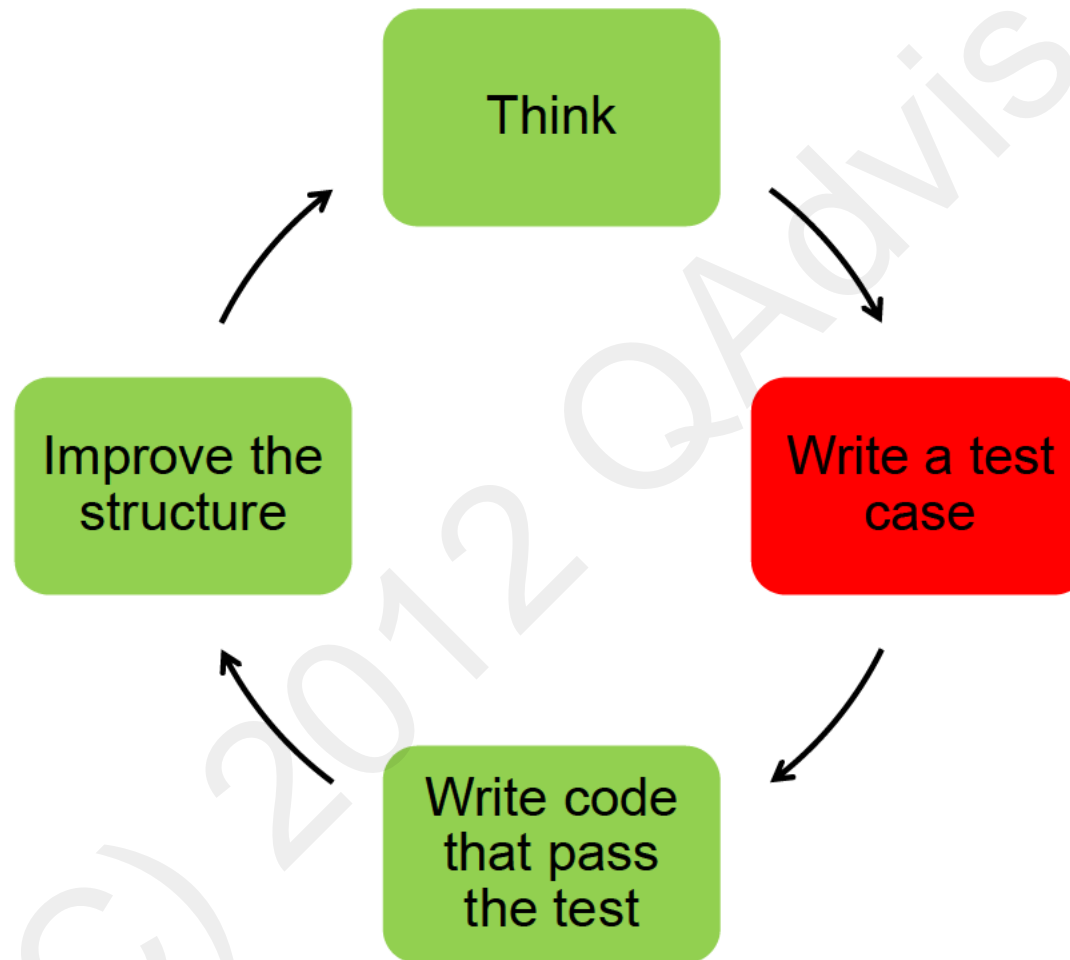
SCRUM



Scrum (7 ± 2)



TDD, Test Driven Development



Continuous integration


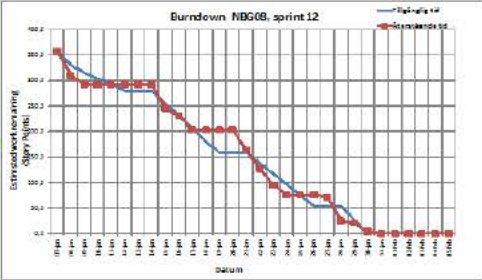



Code is

- Delivered
- Built
- Tested
- Deployed

over and over again,
thanks to tool support



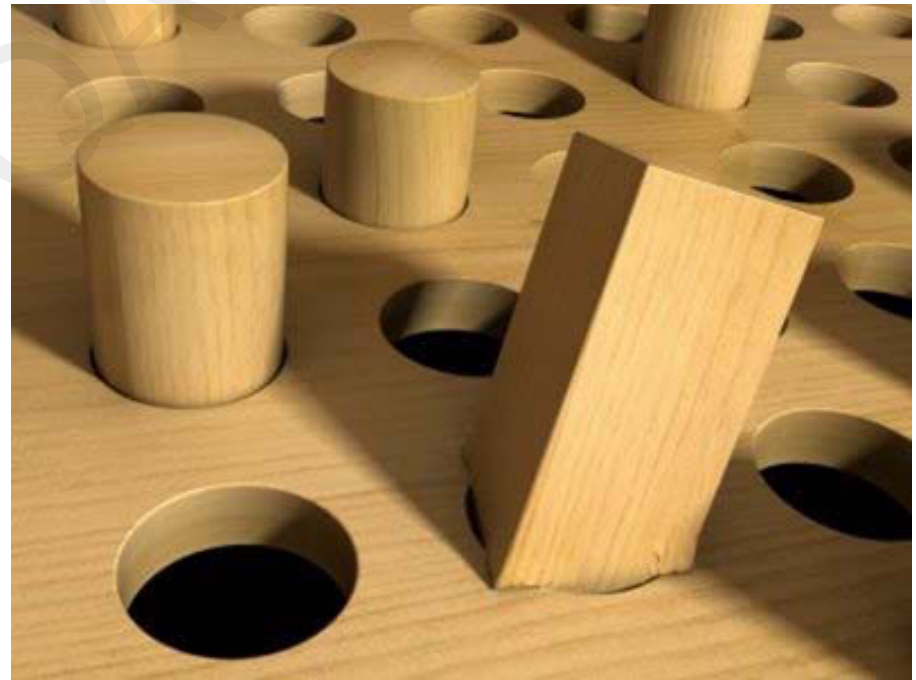
Visualization

| Not Started | Ongoing | Done! :o) | Estimated man-hours | Remaining man-hours | Burndown |
|--|---------|--|---------------------|---------------------|--|
| <div data-bbox="232 501 483 667"> <p>VoV Rapport</p>  </div> | | <div data-bbox="757 526 900 612"> <p>VoV Rapport</p> </div> | 83h | 57h | <div data-bbox="1473 539 1953 820">  <p>Burndown NBG08, sprint 12</p> <p>Estimated work remaining (blue line)</p> <p>Actual work remaining (red line)</p> <p>Y-axis: Estimated work remaining (h)</p> <p>X-axis: Datum</p> </div> <p>Sprint Goal Focus: 75%</p> <div data-bbox="1496 1104 1895 1270"> <p><u>Descope</u> <u>Next Item</u></p> <div data-bbox="1496 1155 1662 1270"> <p>Dokumentation</p> </div> <div data-bbox="1711 1155 1868 1270"> <p>FMLS</p> </div> </div> |
| <div data-bbox="224 695 470 861"> <p>Mobsat</p>  </div> | | | 18h | 10h | |
| <div data-bbox="224 900 483 1066"> <p>FMG</p>  </div> | | | 14h | 10h | |
| <div data-bbox="224 1098 483 1264"> <p>Dokumentation</p>  </div> | | | 34h | 30h | |
| <u>Total</u> | | | 149h | 107h | |

Integration Centric Development

Focus on early integration to:

- Mitigate risks
- Keep focus on the product
- Get early customer feedback

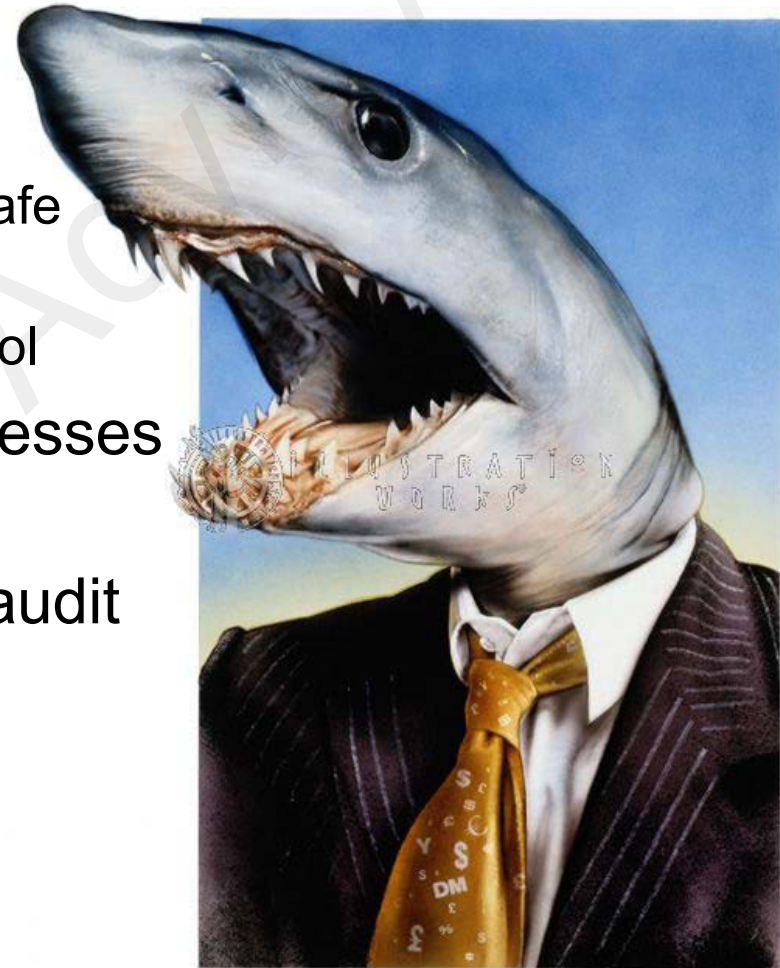


Going agile, impediments

- Affects many key roles in the company and may cause uncertainty and "turf war"
 - There is usually an outer framework, that the agile approach has to comply with
 - Difficult to establish the product owner role
 - Hard to get requirements, developers and testers to go in the same pace
 - Sets high expectations on people
-

Authorities, what do they say?

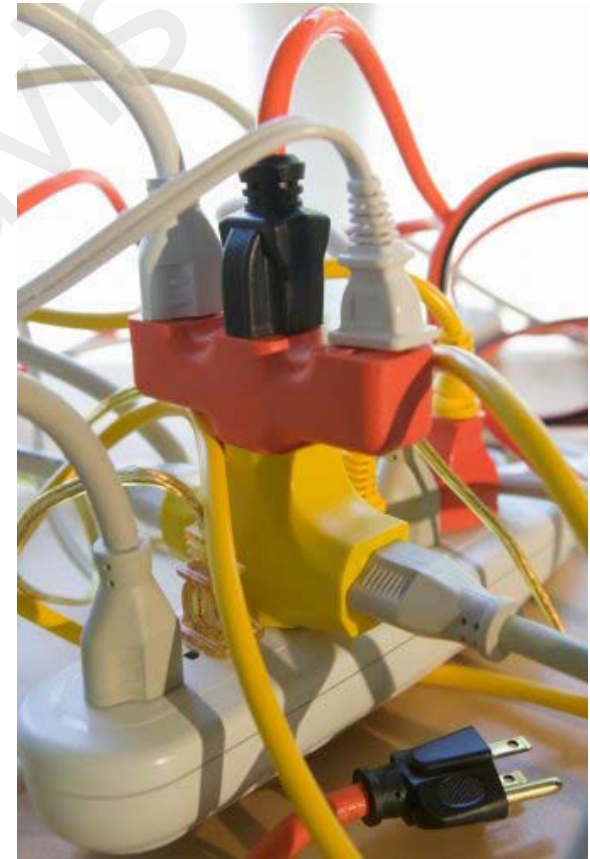
- Wants evidence that we:
 - Have done our best to make a safe product, "Risk management"
 - That we are In-the-state-of-control
- Manufacturer decides on processes and tools used
- Must be easy and efficient to audit



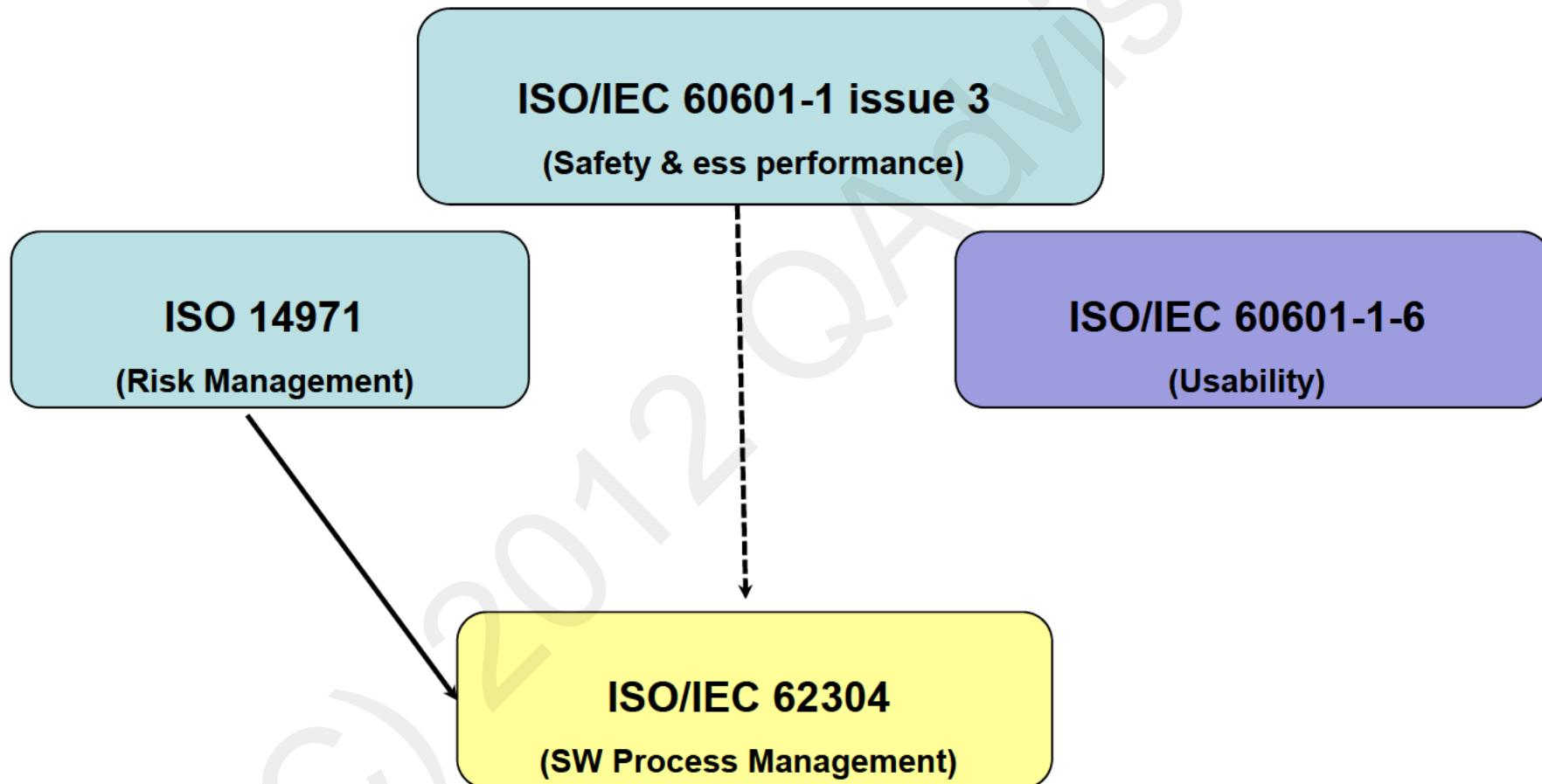
Can standards help?

- FDA has been deeply involved in development of both 14971 and 62304
- Those will affect and in the long run replace several of the current guidelines from FDA

No standard can override QSR!



62304 in relation to other standards



62304 content

- Based on 60601-1-4 and AAMI 68
- Defines minimal levels for process activities
- Aligned with FDA's expectations and terminology
- Takes different approach than 61508 – manufacturer best suited to choose best processes, techniques and tools

*Biggest home work for many companies:
Integrated SW risk management*

Integrated risk management

- Focus of effort and money
 - Traceability **risk measures – reqs – verification** is a key issue
 - Enables efficient documentation
 - Tool support is critical when combined with agile approach, e.g. configuration management
 - Several agile techniques are recognized and encouraged by FDA, e.g. Test Driven Development, Design-by-contract, Misra, etc
-

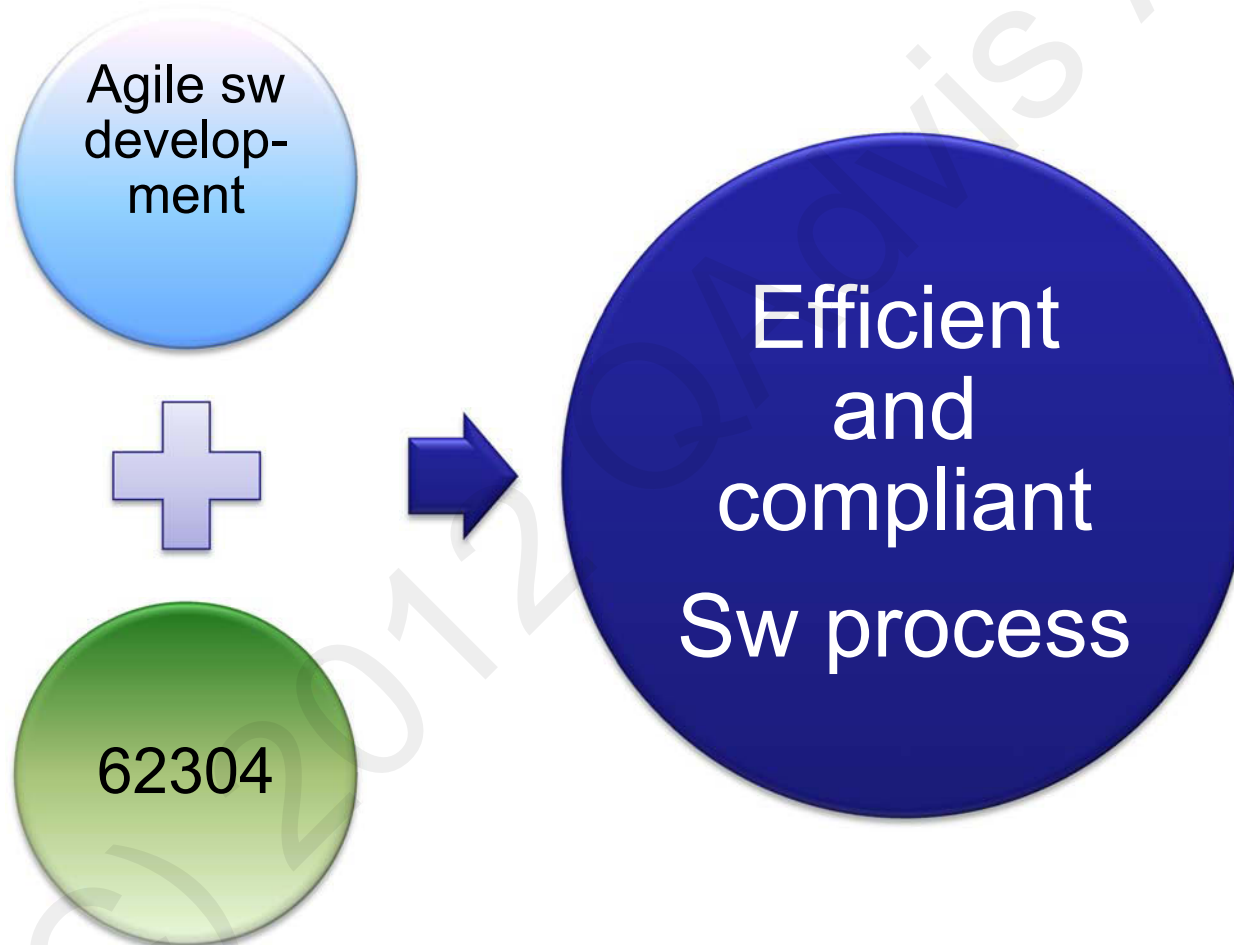
Agile - hands on, where to start?

- Cross functional teams
 - Visualization, sprints, backlog
 - Pair programming
 - Test Driven Development
 - Continuous Integration
 - Integration Centric Development
-

Going agile, recommendations

- Start in small scale -> evaluate -> adapt
 - Create a good mix of *Top down* and *Bottom up* implementation
 - Visualize impediments and progress !!!
 - Invest in training
 - Communicate, communicate, communicate ...
-

Summary



Qadvis contact details

Qadvis is a consultant company for Quality and Global Regulatory for Medical Devices.

Contact:

www.qadvis.com

info@qadvis.com

Tel +46 8 601 01 05
