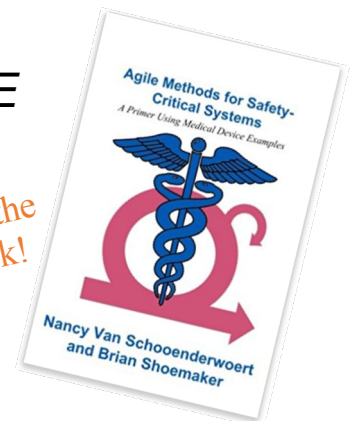


FULL DAY TRAINING COURSE

Agile **Intro** for Regulated Medical Software

Business and Regulatory Impacts

Based on the
new book!



This introductory course, intended for managers, quality, regulatory, and other roles in addition to software development, presents the information you need in order to plan your transition to an Agile approach. Whether you are brand new to Agile, or have tried Agile and found your approach isn't giving the hoped-for results, this course will fill in what you need to know.

Instructors Nancy Van Schooenderwoert and Brian Shoemaker have presented multiple workshops and courses to medical device audiences since 2009. They combine depth of experience in the Agile and engineering fields: hardware and software development, Agile coaching, regulated software for medical products, software quality, regulatory concerns, documentation, risk management.



Here's what course attendees are saying...

“ We are about to start using Agile and we were attending SDMD [Software Design for Medical Devices conference], so it was the perfect moment and the right training.”

- Ramon Alonso, Software & Communication Engineer, Kiro Grifols

“ As a leader/manager in the organization, the course has been great to have a broader understanding of the Agile mindset.”

- Rebecca Stead, Sr. Vice President - Operations & Development, STRATEC Biomedical UK, Ltd.

“ I find the workshop you give very easy to follow and I appreciate the references also. Every year I pick up on some new things to try and take back to my teams.”

- Grayson Marpes, Director, Compliance and Governance, Infor



www.leanagilepartners.com



www.shoobarassoc.com

Agile Intro for Regulated Medical Software

Course details

The Agile approach is well established in other industries, and adoption of Agile in medical device development has been increasing in the past five years. Experience is showing that Agile teams achieve higher quality and safety than before, while still meeting regulatory requirements. By walking through a safety critical project, Nancy Van Schooenderwoert and Brian Shoemaker delve into several key areas for applying Agile methods in the medical device context, including:

- ▶ Countering myths and preconceived ideas about Agile methods
- ▶ Understanding the *REAL* regulatory requirements
- ▶ Agile is a mindset, not a canned method
- ▶ How to choose an Agile pilot project
- ▶ Agile in hardware and software development
- ▶ Applying Impact Mapping and Story Mapping practices to chart the way
- ▶ How to move from traditional specs to Agile stories
- ▶ Bringing *everyone* on board, not just software
- ▶ Applying Agile in larger organizations / projects
- ▶ Metrics - how to use them; what to avoid!

Rather than focus on any methodology (e.g. Scrum, Kanban, Crystal, XP), this course aims to build understanding of the fundamentals which underlie all Agile methods, so that teams can determine their own blend based on what works in their context, and address the issues which inevitably come up in Agile adoption. Practical illustrations will be demonstrated by use of specific tools, but the tools themselves are not the focus. Interactive exercises reinforce what you learn, as you get to know colleagues in other companies. You won't be struggling to stay awake!

Who should attend?

- ▶ Regulatory specialists
- ▶ Functional managers - Software, Test, Hardware
- ▶ Product / Project managers
- ▶ Technical leaders
- ▶ Business Analysts, Requirements Analysts

This will be an introductory course, and makes no assumptions about previous knowledge or experience with the Agile approach.

Course Instructors

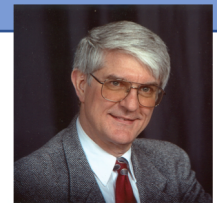


Nancy Van Schooenderwoert

- ▶ 15 y safety-critical embedded systems development experience, as Electronics and Software designer
- ▶ Agile coaching of teams & managers in regulated industries since 2002
- ▶ Industries: Aerospace, Medical Devices, Sonar Weaponry, Scientific Instruments, Industrial Controls, Financial Services
- ▶ Active in Agile New England & Agile Alliance; speaker at Agile-related conferences worldwide

Brian Shoemaker

- ▶ Originally an analytical chemist
- ▶ 15 y in clinical diagnostics: analysis 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



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This course can be presented in-house, with examples and issues specific to the host company so as to address your issues directly.