



# Agile Adoption for Regulated Medical Software: Business and Regulatory Impacts

This one-day introductory course, intended for managers, quality, regulatory, and other roles besides 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 and Brian 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 - as well as in 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

# Summary of this course:

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 both quality and safety are improved when the development team is agile, and that regulatory requirements can still be met. 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 the village rumors
- Understanding the REAL regulatory requirements
- Agile is a mindset, not a canned method
- Fitting together hardware and software development, and being Agile in both
- Applying Impact Mapping and Story Mapping practices to chart the way
- Bringing everyone on board, not just software
- Applying Agile to larger scale organizations / projects
- Metrics - how to use them and what to avoid

Rather than focus on any methodology class (Scrum, Kanban, Crystal, XP), this course aims to build understanding of the fundamentals which underlie all 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.

## Who should attend?

- Regulatory specialists
- Functional managers - Software, Test, Hardware
- Other development specialists (mechanical, engineering, other)
- Project managers (especially for cross-functional teams)
- Software Developers
- Business Analysts, requirements analysts
- Product managers
- Portfolio Managers

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

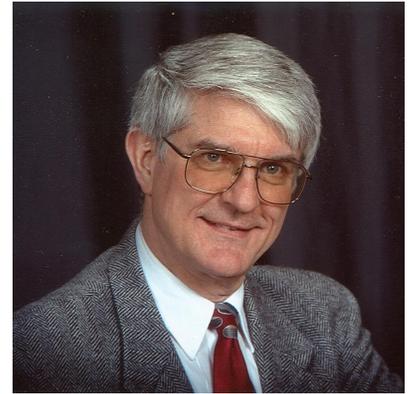
This course can be presented in-house, with examples and issues specific to the host company so as to address your issues directly.

# Course Instructors:

## Brian Shoemaker

bshoemaker@shoebarrassoc.com

- *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)*
- *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*



## Nancy Van Schooenderwoert

nancyv@leanagilepartners.com



- *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*

In addition to presenting courses and workshops, Nancy and Brian have collaborated to:

- Coach medical device companies in their specific Agile initiatives
- Use distance coaching for targeted occasional help
- Advise companies on the quality/regulatory impact of their Agile transition
- Give presentations at conferences world wide

[www.shoebarrassoc.com](http://www.shoebarrassoc.com)

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