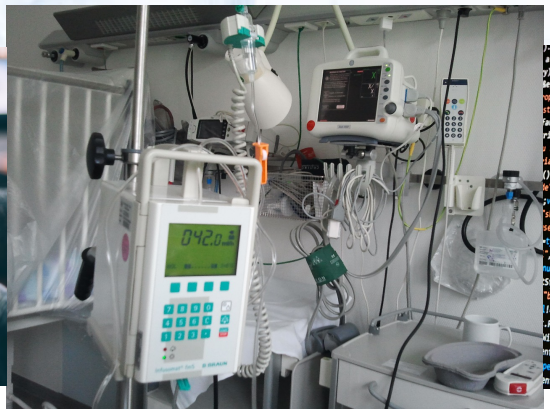
FULL DAY TRAINING COURSE

Agile Next Steps for Regulated Medical Software

Your company has accepted the concepts of Agile and you've started one or more projects which use the approach. You're making good progress, but you want guidance on getting the most out of this new method. In particular, you're looking for how to document your project, how to address risk management, how to coordinate hardware and software efforts, and how to work in human factors engineering (none of which classically seems to fit the Agile mindset).

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…

> *"One of the best courses I've been on. Great combination of theory, exercise, and personal accounts…. Brilliant. I now have something to take back to Oxford. Thanks!"*
>
> - John Garratt, Analyst, Mirada Medical

> *"The delivery technique is excellent (e.g. the presentation slides, activities, team discussions, play games, powerful questions, etc.). Thanks."*
>
> - Wenjin Li, Medical Device QA Mgr

> *"The exercise of moving the tasks from dept to dept and to 'Ship It' was a great example and really gave us some ideas we can use to help explain the idea to non-dev management. Plus ... it wakes everyone up."*
>
> - Grayson Marpes, Director, Compliance and Governance, Infor

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Course details

Picking up the thread from the introductory course, this session explores topics essential to any regulated medical product company applying an Agile approach for development. You'll come away with a deep understanding of ways to avoid the false dichotomies that pit expediency against larger business needs - you'll see how actions at the team level can improve overall flow of the work, and keep technical complexity from crippling later progress. You will also learn practical ways to address special needs of medical device work (such as documentation, risk management, hardware, or human factors...) without sacrificing any of the benefits Agile brings. Course topics include:

- Lean Flow in a Medical Device Example
- Handling Complexity
- Applying Agile Beyond Software
- Documentation in Agile
- Risk Management within Agile
- Where does Human Factors Engineering fit?
- Agile Leadership and the Organization

Each topic is reinforced through interactive exercises that all attendees can participate in, and most can be brought back to your workplace and used with the rest of your team members.

Our focus is on the core principles and practical ways to use them rather than on any one Agile methodology or framework. Our approach is compatible with Scrum, XP, and other Agile methods, and is based on experience working with a variety of medical device teams.

Who should attend?

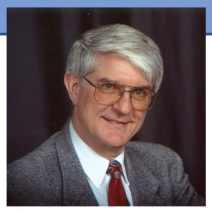
- Regulatory specialists
- Functional managers - Software, Test, Hardware
- Product / Project managers
- Technical leaders
- Business Analysts, Requirements Analysts

This is an intermediate course, and makes an assumption that attendees have either attended our introductory course, or have been involved in their company's Agile adoption program for at least 6 months.

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.