Software Quality and FDA

The Lean - Agile Way

A live workshop in Medical Software Development using Lean / Agile Methodologies

October 4, 2011, 8:30 AM – 5:30 PM

The Centres at Burlington, 67 S. Bedford St, Burlington MA

Offered in cooperation with MDG Medical Development Group — The Industry's Professional Network

Course Overview

We who develop software for medical applications - medical device software and more - have a safety responsibility to patients and caregivers who will use our product, but also have a responsibility to our managers and our investors to get a usable product out the door on time and within budget. And of course we can't forget that we need to fulfill regulatory requirements!

Many companies struggle with meeting all these expectations; software-related product recalls and failed companies are the legacy of traditional, sequential methods. In this one-day course, we present the basics of software quality for FDA compliance, then show how lean/agile development, properly applied, provides a solution to both high quality and high productivity.

The morning session sets out an overview: where the FDA's concerns lie, what can be changed about traditional development while retaining good practices, and how development teams can be both fast and cost-effective. The afternoon session then delves in depth into each of the key areas of concern: standards and guidance, role of a quality management system, risk management as applied to software, agile project flow, agile planning and team autonomy, and approaches to documentation when using an agile approach.

Join Tony Raymond, Brian Shoemaker, and Nancy Van Schooenderwoert as they present fundamentals of software quality for FDA compliance - with lean and agile principles to resolve quality/safety vs. cost/time.

Who should attend

Product development personnel working on medical device software, including:

- Managers
- Team leaders and technical leads
- Software Developers
- Requirements analysts and business analysts
- Validation and Quality Assurance personnel

What you will learn

- Overview of the FDA regulations
- Which FDA and international standards relate to device software - and what they ***really*** say
- What SOPs are needed in a good software quality system
- How to apply hazard analysis / risk management to medical device software
- How Agile development improves speed and quality without losing FDA compliance

Registration is limited to 30 students, so be sure to register early!

To register, visit http://www.meddevgroup.org/courses

Course Agenda

8:30-9:00 AM	Registration and Networking
Morning Session: Overview	
9:00-10:15 AM	Our responsibility; FDA's concern; what to change and what to keep
10:15-10:30 AM	Morning break
10:30 AM – noon	Cost effective validation; document to suit regulators
Afternoon Session: the depth	
Noon-1:00 PM	Lunch
1:00-2:30 PM	Guidances/standards; Quality Management system; risk management
2:30-2:45 PM	Afternoon break
2:45-4:30 PM	Agile project flow and agile planning
4:30-5:30 PM	Team autonomy and documentation

Course Fee (includes course materials, lunch and snacks):

	MDG Member	Nonmember
Regular (before midnight September 23)	$575	$635
Late (September 24 and after)	$655	$715

Presented by Industry experts

Nancy Van Schooenderwoert
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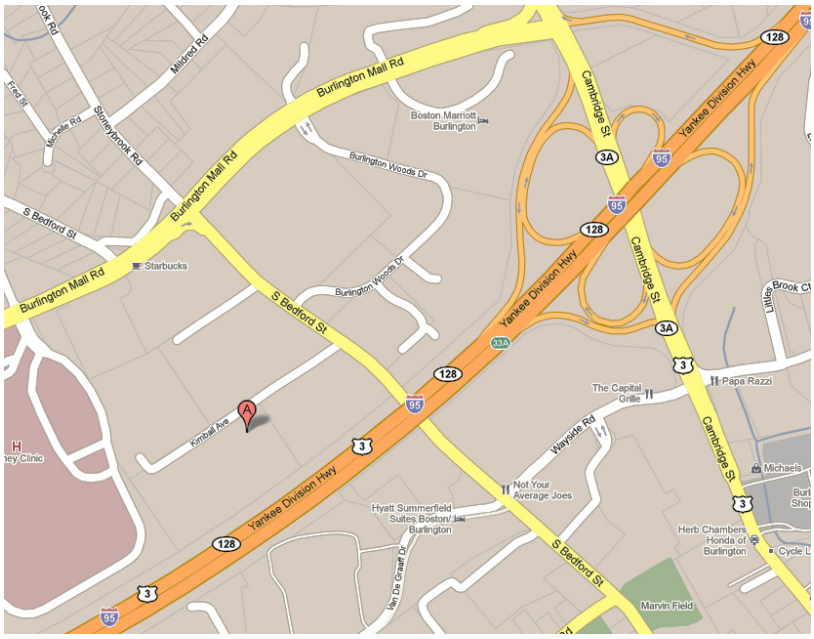
Directions to location:



From 128, take exit for route 3A north.

Turn left onto Burlington Mall Road; go to stop light and turn left onto South Bedford Street.

At blue sign for 67 S. Bedford, turn right and go approx. 200 yards to driveway on left.

Enter the building at the East lobby.