Global CompliancePanel

Netzealous
Knowledge, a Way Forward…

2-day In-person Seminar:

Documenting Software for FDA Submissions

Washington, DC

August 10th & 11th, 2017

9:00 AM to 6:00 PM

Price

Price: **$1,295.00**

(Seminar for One Delegate)

Register now and save $200. (Early Bird)

Register for 5 attendees

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~~$6,475.00~~

ENROLL

***Please note the registration will be closed 2 days (48 Hours) prior to the date of the seminar.*

Brian Shoemaker

Brian Shoemaker consults for healthcare products companies on computer system validation, software quality assurance, and electronic records and signatures. He has conducted validation both on product software and on internal software, developed software quality systems, audited software quality processes (including agile methodology), and evaluated 21 CFR Part 11 compliance. He has had clients in clinical diagnostics, medical device engineering, medical imaging, medical-device fabrics manufacturing, contract lyophilization, clinical trial software, dental prosthetics, and bone-repair implants.

Overview :

When medical device companies consider Agile development methods, they often run into the key criticism that Agile groups produce little to no documentation, and that Agile stands in contradiction to the lifecycle standards outlined in IEC 62304. In fact, those principles - have clear processes for quality management system, risk management process, software maintenance, configuration management, and problem resolution - actually augment rather than contradict the Agile manifesto.

The Agile approach helps companies avoid hearing bad news late in a project, by delivering incrementally, integrating regularly, and leaving room for learning as the user stories are refined. In addition, it provides real information on progress and project speed to stakeholders outside the development group.

Agenda:

Day One

Lecture 1: Are Agile and medical device standards contradictory?

Lecture 2: What is the value of documentation?

Lecture 3: What do the regulatory bodies require?

Lecture 4: Consider the software documentation required for an FDA submission

Why you should attend:

Agile methods are appearing more and more in regulated health-related applications. The teams carrying out this development must work both rapidly and flexibly, since they are obligated to satisfy not only their business management, but also the patients and caregivers, and, of course, the regulatory bodies who must approve their products. Teams must document all aspects of their development - requirements, design, tests, hazard analysis, usability, and traceability. How do we achieve all that and remain Agile?

Many companies struggle with meeting all these expectations; software-related product recalls and failed companies are the legacy of traditional, sequential methods.

How can we gather these as development proceeds, while minimizing overhead? How can we assure that inputs are reviewed and approved, without getting mired in the document signoff spiral? How can we address design reviews without bogging down the team in long, droning meetings? How can we capture traceability as a natural outcome of our work?

Experience is showing, and the AAMI Agile report (TIR 45) has stated, that when Agile is properly applied in the context of a quality system and robust safety risk management, its emphasis on nimbleness and ongoing learning can be reconciled with regulatory expectations of well-documented development.

Day Two

Lecture 1: Where do most companies get bogged down?

Lecture 2: Iteration works well for risk, usability and design reviews

Lecture 3: Practices are the bridge

Lecture 4: The core values align

Documenting Software for FDA Submissions

Group Participation

10%	2 Attendees to get offer
20%	3 to 6 Attendees to get offer
25%	7 to 10 Attendees to get offer
30%	10+ Attendees to get offer

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1. Credit Card: Use the Link to make Payment by Visa/Master/American Express card click on the register now link
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Kindly get in touch with us for any help or information.

Look forward to meeting you at the seminar

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