BOSTON EVENTS LIST

Applying ISO14971 and IEC62304 - A guide to practical Risk Management

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Organizer : GlobalCompliancePanel

Venue :

Location : Four Points by Sheraton Boston Logan Airport,
Revere,, MA, US, ZIP: 02151

Applying ISO14971 and IEC62304 - A guide to practical Risk Management

Gaps, incorrect or incomplete implementation of safety functionality can delay or make the certification/approval of medical products impossible. Most activities cannot be retroactively performed since they are closely linked into the development lifecycle. Diligent, complete and correct implementation of risk management from the start of product development is therefore imperative. This course will introduce all necessary steps to design, implement and test critical medical devices in a regulatory compliant environment. This course will additionally address the software risk management and the resulting interfaces to device level risk management.

To comprehensively summarize all risk related activities and to demonstrate the safe properties of a device the 'Safety Case' or 'Assurance Case' document is a well-established method to collect all safety related information together in one place. This documentation will most likely become mandatory for all devices (currently only required for FDA infusion pump submissions). This course will introduce the basic concepts and content of safety assurance cases and will illustrate the usefulness for internal and external review of safety related information.

Who will benefit:

The course will introduce the main elements of risk management with emphasis on the application of risk management principles and requirements to the medical device development cycle. Risk management has become the method of choice to ensure an effective and safety oriented device development. International consensus, reflected in globally applicable standard requirements, has led to risk management being a mandatory component of almost any activity in the medical device industry.

The course will emphasize the implementation of risk management into the development and maintenance process. It will use real-life examples and proven tips and tricks to make the application of risk management a practical and beneficial undertaking. This seminar will address the system level issues of risk management as well as the increasingly important software and usability related issues of critical systems. It will help to comply with regulatory requirements with minimized overhead and resource burden. To make the combines effort to design, implement and verify a safe device transparent the concept of an assurance case will be introduced.

The course is mainly based on international consensus requirements such as ISO14971, IEC62366 and IEC62304. It will cover European (MDD), US (FDA) and international risk management requirements from a regulatory and practitioner's perspective.

Following personnel will benefit from the course:

- Senior quality managers
- Quality professionals
- Regulatory professionals
- Compliance professionals
- Project managers
- Design engineers
- Software engineers
- Process owners
- Quality engineers
- Quality auditors
- Medical affairs
- Legal Professionals

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Event Categories :