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Mitigating and Managing Risk for Medical Devices in Compliance with ISO 14971

Instructor: Lena Cordie

Date: Thursday, 8 June 2017 | Time: 11:30 AM PDT, 2:30 PM EDT | Duration: 90 Minutes

This webinar explains the application of Risk Management for medical devices using ISO 14971. It explains the flow of information from the Risk Management Plan to the Risk Management Report, looking at important terms including Hazard and Risk and explaining how to use each one. The program describes development of a Risk Evaluation form that implements the requirements of ISO 14971. You will gain an understanding of the impact that ISO 14971:2012 has on the decision making process when manufacturing medical devices.

Objectives of the Presentation

ISO 14971 is the de facto standard for medical device risk management. It requires more than just Risk Assessment or an FMEA. Your Risk Management program should be able to answer these questions easily. If not, then your team needs to attend.

- Do you have a documented method to combine frequency and severity to calculate risk?
- Do have a formally approved Risk Management Plan that applies to your medical device?
- Do you apply risk reduction methods in the correct order?
- Have you documented the risk verification in the Risk Management Report?
- Does your manufacturing process control, especially validated processes, regularly update you Risk Management File?
- Have you integrated you complaint system with the Risk Management File to evaluate your frequency and severity estimates?

Why Should you Attend

This course provides the attendees with an overview of ISO 14971 and implementation tips for an effective system for managing risk. We provide an overview that shows each of the elements of a Risk Management system and how they fit together. This approach helps the participant understand the essential structure and the required elements.

We will look at the elements of Risk Management, including the required documents. This includes: A risk management plan, risk evaluation documentation, risk verification activities, risk management report, risk management file, obtaining production information and linking complaints to provide post-production information.

You will learn when written procedures are required, when (and how) to name designated individuals, when (and how) to formally designate units, and the records you must keep.

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Areas Covered

- An overview of ISO 14971 to place the presentation in context
- Key risk management terms & definitions
- FDA requirements for risk analysis as part of design validation
- Incorporating risk management throughout the design control process
- The risk management process in ISO 14971:2007 and the EU variant in EN ISO 14971:2012
- The GHTF guidance document on risk management principles
- Describe relevance of ISO 14971 and the ISO 13485 revision
- Developing a Risk Evaluation Matrix for your product
- Failure Modes and Effects Analysis (FMEA)
- Fault Tree Analysis (FTA)
- Hazard Analysis and Critical Control Point (HACCP)

Who will Benefit

People in the following roles can especially benefit from the knowledge in this webinar:

- Validation professionals
- Design Engineers
- Project Managers involved in Design and Development
- Quality Engineers assigned to validation activities
- Quality Auditors
- Managers
- Quality staff assigned to Customer Complaints or CAPA management
- Systems engineers responsible for developing requirements
- Software developers
- Test Engineers
- Regulatory Affairs

Topic Background

As the ISO 13485 standard provides a benchmark for medical device manufacturers to plan and manage quality processes throughout the entire product management cycle, ISO 14971 acts as an "addendum standard" that stipulates the planning and administration of risk-management processes within the same environments.

The FDA and many additional regulatory bodies throughout the world recognize ISO 14971 risk management standards as a world class risk management criterion and often audit to the same. In Europe, many regulations have been harmonized to ISO 14971, which makes the standard highly applicable/relevant across the global medical device community.

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Webinar Cost :-

$250.00 Live Session	$375.00 Recorded Session	$500.00 Training CD	$1250.00 Corporate Live Session

$500.00 Live Session + Recorded Session	$625.00 Live Session + Training CD

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Instructor Profile:

Lena Cordie has over 20 years of quality and project management experience including 10 years in project management at Target Financial Services and 11 years as director of operations at Key Surgical, a medical device company focused on sterile processing, personal protection, and OR products. In this position she was responsible for overseeing all quality and regulatory functions, production, product procurement, and order fulfillment.

As a consultant at Qualitas Professional Services, LLC, Ms. Cordie now focuses on helping companies implement quality management systems, UDI solutions for labeling and FDA GUDID submissions, and providing validation, documentation and project management resources to global medical device companies.

She is an active member of AAMI (Association for the Advancement of Medical Instrumentation) - serves as a voting member of many sterilization standards committees and co-chairs the terminology committee; ISO (International Organization for Standardization) - serves as a US representative and participates in ISO/TC 198 (ISO 17664 & ISO 11139) and ISO/TC 210 (ISO 13485 & ISO 15223) working groups; and RAPS (Regulatory Affairs Professionals Society) - serving as chairperson of the RAPS Twin Cities Chapter.