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EVENTS LIST

ISO 13485:2016 Implementation Workshop

Date : Mar 01, 2018 - 09:00 AM - Mar 02, 06:00 PM

Event URL : http://www.sfbayeventslist.com/events/iso-13485-2016-implementation-workshop-mar-2018

Organizer : GlobalCompliancePanel

Venue :

Location : 407, Squire Rd
Revere, MA, USA, ZIP: 02151

The medical device industry is in the midst of major change, with the publication of the FDA's UDI Regulation, the first revision to the ISO Quality Management Systems standard in over a decade, and the upcoming changes to the EU's Medical Device Regulation expected to be passed later this year. All of these events have far reaching effects on Quality Management Systems so it is critical to understand what has changed with in ISO 13485: 2016 in order to create a comprehensive quality plan for your organization to ensure continued compliance and certification.

This interactive session will include lectures, roundtable discussions and activities all aimed at understanding key strategies and identifying specific actions to effectively improve Quality Management System Compliance. The program will also include detailed, step-by-step guidance on how to develop, implement and maintain strategies in order to achieve a specific goal. Participants will want to come to the sessions with a thorough knowledge of improved company strategies and a willingness to discuss aspects of it in a confidential learning environment.

Why you should attend:

Quality management systems are now, more than ever, a requirement rather than an option for sustainable businesses, both for increasing internal efficiency and for creating a competitive advantage. The easiest route for establishing a QMS is to base it on a proven method rather than starting from scratch. Medical device service providers, contract manufacturers, service providers and OEMs will benefit from implementing quality systems based on ISO 13485.

The first part of the seminar will provide you with training on quality systems and the

requirements of the revised standard. The second day will focus on developing a plan for implementation and will provide helpful tools you can take back to your organization to kick-start the project.

Areas Covered in the Session:

- Gaining an understanding of the relationship between standards and quality management systems
- Understanding the basic principles of a quality management system
- Incorporating the Plan-Do-Check-Act approach
- Identifying the critical elements of a quality system
- Creating a documentation structure that is consistent with the system requirements
- Assessing and applying risk throughout the quality system
- Comparing the requirements of ISO 13485 to the FDA QSR
- Understanding the differences between ISO 9001, ISO 13485: 2003 and ISO 13485: 2016
- Understanding the QMS requirements of the proposed EU Medical Device Regulation that are not in ISO 13485: 2016
- Establishing a plan for implementing the revised requirements of ISO 13485: 2016

Who will benefit:

Executives, Directors, Senior Managers and Functional Managers from the Medical Device Industry with responsibilities in the following areas. We encourage the participation of more than one person from each company to facilitate the creation and implementation of your action plans.

- Quality associates
- Quality managers
- Document Control coordinators
- Project Managers
- Regulatory Affairs professionals
- Middle management in regulated industries
- Independent service organizations

Day 1 Schedule

Lecture 1:

Anatomy of a Quality Management System

- Detailed review of all Clauses within the Standard
- Policies and Procedures designed to drive safety and compliance
- Supporting Documents and Databases covering operating procedures, staff training, and data management

- Operational Procedures guiding regulatory compliance, management involvement, and overall control of critical business functions
- Monitoring and measuring of quality processes and operational outcomes affecting product quality and patient safety
- Compliance and Improvement programs for audit, inspection, and clinical information

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Lecture 2:

Gap Analysis of ISO 13485: 2003 to ISO 13485: 2016

- Increasing efficiency, cutting costs, and monitoring supply chain performance through increased supplier controls
- Increased requirements for design control
- Covering new requirements for complaint handling, regulatory reporting and unique device identification

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Lecture 3:

Application of Risk

- Ensuring all operational procedures are following a risk based approach
- Discussion of risk mitigation techniques and implementation
- Identifying ways to make medical devices safer and more effective

Day 2 Schedule

Lecture 1:

Identification of Documentation Requirements

- Utilizing new Medical Device File requirements for each family or line of devices
- Reporting requirements to regulatory authorities
- Enhancing product design and development through validation and design transfer
- Preparing all necessary material for a Quality Report

Lecture 2:

Monitoring & Measurement of the QMS

- Validating software implementation into the manufacturing process and/or quality system
- Establishing evaluation procedures based on audit and quality reports
- Creating a system of checks and balances to analyze QMS success

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Lecture 3:

Creating a Quality Plan for QMS Updates

- Obtaining senior leadership buy in to the new program
- Outlining how to review and improve processes across your organization
- Utilizing efficient reporting protocol and technology
- Identifying new or existing processes and documents affected by the changes
- Evaluating risks to the quality system associated with the QMS updates

Lena Cordie

Quality & Regulatory Consultant, Qualitas Professional Services, LLC

Lena Cordie has over 20 years of quality and project management experience including:

- 10 years in project management at Target Financial Services
- 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 labelling 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
- RAPS (Regulatory Affairs Professionals Society) - serving as chairperson of the RAPS Twin Cities Chapter and a member of the RAPS EU Committee
- AHRMM Learning UDI Community

Please contact Marilyn Turner: Phone: +1 929 900 1853 Email: marilyn.turner [a] nyeventslist.com for registrations

Event Categories :