Strategies for Improving Effectiveness and Efficiency of your Quality Management System

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Organizer : GlobalCompliancePanel

Venue :

Location : TBA Boston, MA United States,
BOSTON, MA, US, ZIP: 02128

This two-day seminar will cover the essentials of an effective yet efficient Quality management system for medical device companies. An efficient and effective Quality System can be a competitive advantage for companies by leading to improved Quality and compliance as well as optimizing the cost of Quality. This seminar will get you started in setting up just such a Quality System. We'll discuss the "case for Quality" and how you can use compliance, not as an end itself, but as a means to improved Quality and reduced cost of non-compliance.

In this webinar, we will discuss:

- Regulatory Expectations
- How to plan, structure, and implement a Quality System
- Common problems and lessons from 483 and Warning Letters
- Red-flags that your QS is not effective
- Six essential capabilities for an effective and efficient QMS
- Risk analysis and management techniques
- Process control and performance monitoring
- Culture, Management Responsibility, and maturity
- Strategies for improvement
- Improvement techniques

Why you should attend:

This seminar will help you understand regulatory requirements and how to translate them into a Quality System that is both effective and efficient. You'll learn how to plan, structure, and implement a Quality System specific for your business needs. We'll explore the capabilities that every medical device company needs to ensure Quality products and a compliant Quality System. We'll discuss how to define your current situation and create a Quality strategy and plans. Will discuss methods to identify, prioritize, and analyze risks. Then, we will move on to continuous improvement, Six Sigma, and Corrective and Preventive Action to address issues within your Quality System. You'll learn how to effectively communicate and escalate risk as well as monitor performance and progress.

This seminar can help you get your Quality System off to a good start and avoid common problems including MDRs, recalls, 483s, and Warning Letters!

The expectations for Quality and compliance continue to increase. We will discuss changing regulations and expectations and what you can do to prepare for them. This seminar will allow you to interact personally with an industry expert with over 30 years' experience in medical devices. The instructor has worked in manufacturing, design, Quality and compliance at industry leaders like GE, Johnson and Johnson, and Medtronic. She has traveled throughout the world developing, auditing, and improving quality systems.

Learning Objectives:

Using interactive discussion and exercises, students will understand the regulations, context, and history of Quality System regulations. They will learn concepts and techniques for developing a Quality Management System that is both effective and efficient. They will come away with key concepts, practice in these concepts, and extensive course notes for future use and reference

- Quality System Expectations
- Characteristics of an effective QMS
- Characteristics of an efficient QMS
- Roles, responsibilities, capabilities
- Quality leadership and a seat at the table
- Vision, Strategy, and Planning
- Case for Quality
- Red Flags and warning signs
- Improvement tools and techniques
- Inspection preparedness and management
- Best Practices

Who Will Benefit:

- Quality Systems Specialists
- Document Control Specialists

- Quality and Compliance Specialists
- Auditors
- Auditor Managers
- Compliance Managers
- Quality Managers
- CAPA Specialists
- Quality and Compliance directors for Medical Device companies
- General Managers and Executives wanting to use Compliance and Quality as a competitive strength

Day 1 Schedule

Overview

Introductions
Regulatory expectations
Quality Systems requirements for medical devices
Quality System structure and writing SOPs
Break
Roles and Responsibilities
Management Responsibility and a Culture of Quality
Management Review

Lunch Break

Key Capabilities for Success
Metrics and performance monitoring
An effective auditing program is a key to self-awareness

Day 2 Schedule

Maturity Modeling
Value proposition for Quality

Break

CAPA, investigation, and root cause analysis - essentials for improvement

Lunch Break

Risk Management for Compliance
Creating a strategy and quality plan

Break

Inspection preparedness and management

Speaker

Susanne Manz

Quality and Compliance Expert / Auditor for Medical Devices, Manz Consulting, Inc.

Susanne Manz,MBA, MBB, RAC, CQA is an accomplished leader in the medical device industry with emphasis on quality, compliance, and Six Sigma. She has an extensive background in quality and compliance for medical devices from new product development, to operations, to post-market activities. While at industry leaders like GE, J&J, and Medtronic, Susanne worked in various world-wide roles including Executive Business Consultant, Worldwide Director of Quality Engineering, Design Quality, and Director of Corporate Compliance. She has traveled extensively throughout the world conducting audits and helping companies to understand and improve their Quality Management Systems. Susanne is a Presidential Scholar and has a BS in Biomedical Engineering and an MBA from the University of NM. She earned her Black Belt and Master Black Belt certifications while at Johnson and Johnson. Susanne also holds Regulatory Affairs Certification (RAC) from RAPS and is a Certified Quality Auditor by the American Society for Quality. She has also served as a judge for the ASQ ITEA awards. Susanne has now established a consulting business, Manz Consulting LLC, with a mission to provide services to help medical device companies achieve world-class quality and compliance.

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