

Evolution of the Quality Management System - How to go from Surviving to Thriving

Date : Feb 22, 2018 - 09:00 AM - Feb 23, 06:00 PM

Event URL : <http://www.sfbayeventslist.com/events/evolution-of-the-quality-management-system-how-to-go-from-surviving-to-1516038238>

Organizer : GlobalCompliancePanel

Venue : WILL BE ANNOUNCED SOON

Location : 1 Main St,
Los Angeles, CA, US, ZIP: 00000

Using lecture, discussion, and exercises, this 2 day seminar will focus on taking your QMS from surviving to thriving. We'll move from understanding the regulatory requirements, how to create your QMS structure, process thinking, and developing your improvement strategy. We'll discuss tools and techniques for improvement and how to measure your progress.

Why you should attend:

Many companies struggle to establish and maintain a Quality Management System (QMS) that is both efficient and effective. An ineffective QMS leads to disastrous consequences such as medical device reports, recalls, 483s, and warning letters. An ineffective QMS can result in serious consequences for your customers leading to dissatisfaction, serious injury, or even death. It is imperative that medical device companies can effectively establish a QMS.

And an inefficient QMS results in wasted time, money, and missed opportunities. In this 2-day seminar, we will use lecture, exercises, and discuss to learn the fundamentals of a Quality Management System and how you can take your program from surviving to thriving. A thriving QMS can help you achieve your compliance objectives and improve product quality, leading to higher customer satisfaction and business results.

Areas Covered in the Session:

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- Essentials of an effective QMS
 - Essentials of an efficient QMS
 - Quality is not an Organization
 - Key Capabilities
 - Maturity Modeling
 - Vision, Strategy, and Quality Planning
 - Improvement Tools
 - Best Practices
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Who will benefit:

- Quality Systems Specialists
- Quality and Compliance Specialists
- Auditors
- Quality and Compliance Managers and Directors
- CAPA Specialists
- Project Managers
- Supplier Quality Engineers and Auditors
- Quality Engineers
- Management Representatives
- General Managers

Day 1 Schedule

Lecture 1:

- Regulatory expectations for a QMS
 - Lessons Learned from 483s and warning letters
 - Common problems and simple solutions
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Lecture 2:

- QMS Structure
 - Roles and Responsibilities
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Lecture 3:

- Management Responsibility, Culture of Quality, Risk Management
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Lecture 4:

- Key Capabilities for success

- Maturity Modeling
- QMS Evolution

Day 2 Schedule

Lecture 1:

- Metrics, internal Audit
 - Cost of Quality
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Lecture 2:

- Quality Leadership
-

Lecture 3:

- Vision and Strategy
 - Quality Planning
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Lecture 4:

- Improvement Tools and Techniques
- CAPA and RCA

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 GE, J&J, and Medtronic, Susanne worked in various world-wide roles including Executive Business Consultant, Worldwide Director of Quality Engineering, Worldwide Director of Design Quality, and Director of Corporate Compliance. 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 with a mission to provide services to help medical device companies achieve world-class quality and compliance. For more information, visit www.ManzConsultingInc.net.

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

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