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Supplier Management for Medical Device Manufacturers

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Organizer : GlobalCompliancePanel

Venue : Hilton Zurich Airport

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

Supplier selection and management is one of the critical issues for medical device manufacturers. Suppliers provide materials and services to the device manufacturer, which means that they can be critical to performance and delivery of your device. Neither the FDA nor your notified body regulates your suppliers (with a few exceptions). They expect you to have an effective process to ensure your suppliers perform in the regulatory environment.

How well do you understand the requirements for supplier management?

Could you pass a regulatory audit or inspection without any issues?

This course delivers the tools, templates, and methods to help participants implement an effective and efficient supplier management program.

This two-day hands-on course provides a clear understanding of the underlying principles of supplier management. The course uses exercises to solidify understanding. In addition, the course uses FDA Warning Letters to illustrate the points and help you learn from others. As part of the practical implementation, the course includes receiving acceptance activities, outsourced processes, process validation at the suppliers' location, supplier auditing techniques, and supplier issues in management review.

The course uses the Global Harmonization Task Force (GHTF) framework, but expands it to cover other issues and techniques important in effective implementation.

Why should you attend:

Since FDA regulations do not allow them to audit your suppliers unless they make finished medical devices, they require that you have sufficient control over them. But from time to time the FDA makes a reinterpretation of what this means. This happened within the last f 5 years, so if you supplier management program is older than that, you need to make major changes in you supplier management program. This is why the Good Manufacturing Practice (aka Quality System Regulations) is called cGMP. The C stands for current, meaning what the FDA considers the current state of the art in the areas they regulate. Also European Notified Bodies also periodically update their expectations, and for suppliers this happened with the publication of a guidance document by the Notified Body Operations Group (NBOG).

This seminar will go into the details of the NBOG supplier guidance document and a GHTF (Global Harmonization Task Force) guidance that describes the current FDA expectation on supplier management.

One of the major things introduced in these guidance document, is the concept of Risk, and the use of identified risks as part of the evaluation and monitoring of suppliers.

This seminar will review requirements and expectation of the FDA and European Notified Bodies for supplier management, and then how to incorporate these into your own supplier management process.

Areas Covered in the Session:

- Understand FDA QSR and ISO 13485 requirements for supplier management
- Creating a Risk-based Multi-tier supplier classification system
- Understand when suppliers have to register and list with the FDA
- Defining and using supplier Metrics
- Explain the link between design control and purchasing data
- Develop an risk-based supplier management process
    - Incorporating supplier regulatory and safety risk
    - Incorporating supplier business risk
- Create supplier measurement and monitoring systems
- Understand the how to develop and implement supplier controls
- Create a risk based Value-added system for supplier audits
- How to prepare yourself and your contract manufacturer for unannounced audits from your Notified body
- Creating acceptance criteria and understand how that fits into your supplier control process

Who will benefit:

- Quality Managers
- Quality Engineers
- Audit Managers
- Supplier Engineers

- Internal quality auditors
- Supplier auditors
- Quality associates
- Quality Specialists
- Regulatory Compliance Managers

Day 1 Schedule

Lecture 1:

Introductions

Lecture 2:

Fundamentals Regulatory Requirements

- FDA Requirements
- ISO 13485 requirements
- Understanding the role of the Global Harmonization Task Force Guideline
- Understanding NBOC Guideline and why it should be used

Lecture 3:

Planning the Supplier Management Program

- Supplier Classification
- Supplier QA agreements what are they and why are then

Day 2 Schedule

Lecture 1:

Planning Supplier Selection

Lecture 2:

Potential Suppliers

Lecture 3:

Supplier Selection

Lecture 4:

Implementing Supplier Controls

Lecture 5:

Monitoring, Measuring, and Evaluation

- Periodic Monitoring
- Re-evaluations

Lecture 6:

Supplier Audits - where do they add value

- Planning your supplier audit schedule
- How Notified Body unannounced audits affect your contract manufacturer
- What you should do to prepare yourself and your contract manufacturer for unannounced Notified body audits

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Lecture 7:

Feedback and Communication

- Supplier meetings: Partnering with Key suppliers
- Supplier Corrective Actions

Lecture 8:

Evaluating your current program to see how it measures up to regulatory Expectations

Betty Lane

Founder and President, Be Quality Associates, LLC

Betty Lane has over 30 years' experience in Medical Device quality assurance and regulatory affairs. She is the founder and President of Be Quality Associates, LLC, a consulting company helping small and medium sized medical device and diagnostic companies implement and improve their quality systems. Her work enables companies to manage their business in compliance with FDA and ISO 13485 requirements, as well for quality system requirements for other geographic area such as Europe and Canada. Her background in digital systems engineering enables her to facilitate quality system processes for design controls and software validation. Her areas of expertise include training, auditing, supplier management, document and records management, design controls, and software validation.

Betty's training experience includes over 25 years of training on all aspects of ISO 13485, the ISO standard for Medical Device - Quality Management Systems - System Requirements for

regulatory purposes, and FDA Quality System Regulation - Medical Devices; Good Manufacturing Practice (cGMP), in companies where she worked as manager or director, and for AAMI, ASQ biomedical division, and ASQ sections. She has taught courses in medical device and biotechnology quality and regulatory affairs as an Adjunct at Northeastern University, Boston, MA. Betty is active in her local section of the *American Society for Quality and is also a member of the Association for the Advancement of Medical Instrumentation (AAMI), The Society of Women Engineers and the IEEE.* Betty has degrees in engineering from Rensselaer Polytechnic Institute (RPI), and an MBA from Northeastern University.

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

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