Supplier Management in FDA- and ISO-regulated Industry

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Organizer : Global Compliance Panel

Venue :

Location : DoubleTree by Hilton Hotel San Diego Downtown 1646 Front St, San Diego, CA 92101, USA,
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Supplier qualification and assessment is required in both the QSR regulations and ISO standards. Many companies spend a great deal of time and money in pursuit of compliance. Many companies can spend significantly less time and money, and still be in control of their suppliers and in compliance with the regulations. This class will review the QSR and ISO requirements for supplier evaluation, including defining the types of suppliers that require evaluation. The QSR/ISO requirements for supplier assessment will be defined as well. Attention will be paid to inclusion of risk management in across both supplier qualification and assessment, implementation of which will allow your company to devote value-added resources to these efforts. Significant time will be spent on discussion of the topic of supplier nonconformance, including how and when to issue the dreaded Supplier Corrective Action Request. Your supplier nonconformance handling process must be nonconfrontational, or even better, collaborative. If your company is too demanding of your suppliers, you risk alienating them or even worse losing them - try explaining that to your supply chain folks.

Why should you attend

Notified bodies and the FDA cannot require your suppliers to meet the quality system regulations, so they must make sure you are exercising sufficient control over those suppliers. You must make sure your supplier management and system meets all required regulations and guidance documents, especially for outsourced processes such as contract manufacturing, sterilization and testing, and also for critical suppliers. Sure, you depend on your suppliers to provide you with goods and services, but can your system prove that you have sufficient control over your suppliers to assure auditors and regulatory agencies that your product is safe and meets all your requirements? Your supplier management program can be in compliance, but is it cost effective? If not, your unquantifiable overhead costs may be out of control. Is your supplier management program collaborative with your suppliers? If your company is too demanding of your suppliers, you risk alienating them or even worse losing them - try explaining that to your supply chain folks!

Areas Covered in the Session:

- Supplier Selection
    - Review of FDA requirements
    - Review of ISO requirements
    - Types of suppliers that must be qualified
    - Defining critical suppliers
    - Outsourced processes
    - Recommended Practices
    - Documentation requirements
    - Use of Risk Assessment
    - The Quality Agreement
    - Common Pitfalls
- Supplier Assessment
    - Review of FDA requirements
    - Review of ISO requirements
    - Case Study: A Hypothetical Supplier Assessment
    - Recommended Practices
    - Documentation requirements
    - Use of Risk Assessment
    - Common Pitfalls
- Supplier Nonconformance
    - Types of supplier nonconformances
        - Best Practices for Notification
        - Best Practices for Handling
        - Trending
        - Evaluation of Supplier Response
        - Tracking effectiveness
    - Supplier Corrective Action Requests
        - Pre-notification?
        - Best Practices for Issuance
        - Followup
        - Evaluation/Acceptance of Supplier Response
        - Tracking effectiveness
- Workshop: Review of Supplier Responses: Acceptable or UNacceptable?

Who Will Benefit:

This webinar will provide valuable assistance to all regulated companies that are interested in implementing and maintaining a supplier management program that is both compliant and cost-efficient. The employees who will benefit include:

- Supply chain management
- Buyers
- Purchasing management
- CAPA Coordinators
- Regulatory management
- QA management
- Executive management
- Internal auditors

Please contact the event manager Marilyn below for the following:
- For Registrations Please call +1 929.900.1853
- Discounts for registering 5 or more participants.
- If you company requires a price quotation.
Event Manager Contact: marilyn.b.turner(at)nyeventslist.com
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