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Webinar on

Establishing a Robust Supplier Management Program

Learning Objectives

- *Review Supplier Management Regulatory Guidance*
  - *ISO*
  - *ICH*
  - *FDA*
  - *EU*
- *Elements of a Robust Supplier Management Program*
  - *Standard Operating Procedure (SOP) example*
  - *Quality Agreement template review*
  - *Initial qualification*
  - *Onboarding*
  - *Monitoring / Scorecards*
  - *Development*
  - *Phase-Out*

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Areas Covered

Review of Risk Analysis Tools and Recent Audit Observations

Review an example FMEA classifying different suppliers by criticality

Review recent FDA audit observations applicable to supplier management

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This course will also include a discussion on how to utilize risk-based quality tools to determine supplier classification.

PRESENTED BY:

Ms. Thomas has over two decades of cGMP hands-on industry experience in both pharmaceutical and medical device manufacturing operations.

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On-Demand Webinar

Duration : 90 Minutes

Price: $200

Webinar Description

Regulatory expectations are clear about manufactures' responsibility regarding supplier quality oversight. All regulatory agencies agree that pharmaceutical and medical device manufacturers are responsible for ensuring their suppliers adhere to quality standards, maintain compliance with regulatory requirements and consistently meet established expectations. Therefore, it is essential pharmaceutical and medical device organizations develop and implements a robust supplier management program.

A robust program is one that utilizes a comprehensive life-cycle approach that manages suppliers from initial qualification through phase-out. In other words, from cradle to grave. A robust, yet efficient, supplier management program is one that also utilizes a risk-based methodology to determine supplier criticality and the required level of oversight.

This course will review regulatory guidance governing Suppliers; as well as, all the elements of a robust supplier management program; including, initial qualification, supplier performance monitoring and scorecards, supplier audit options, and quality agreement requirements. An example Supplier Management Standard Operating Procedure (SOP) and Quality Agreement template will be reviewed during the course.

This course will also include a discussion on how to utilize risk-based quality tools to determine supplier classification. An example supplier risk assessment will be reviewed during the course. Finally, in order to understand the real-life consequences associated with non-compliant supplier management programs, recent FDA audit findings will be reviewed and discussed.

Who Should Attend ?

QA Manager s and Associates responsible for supplier management

Supply Chain Managers and Associates

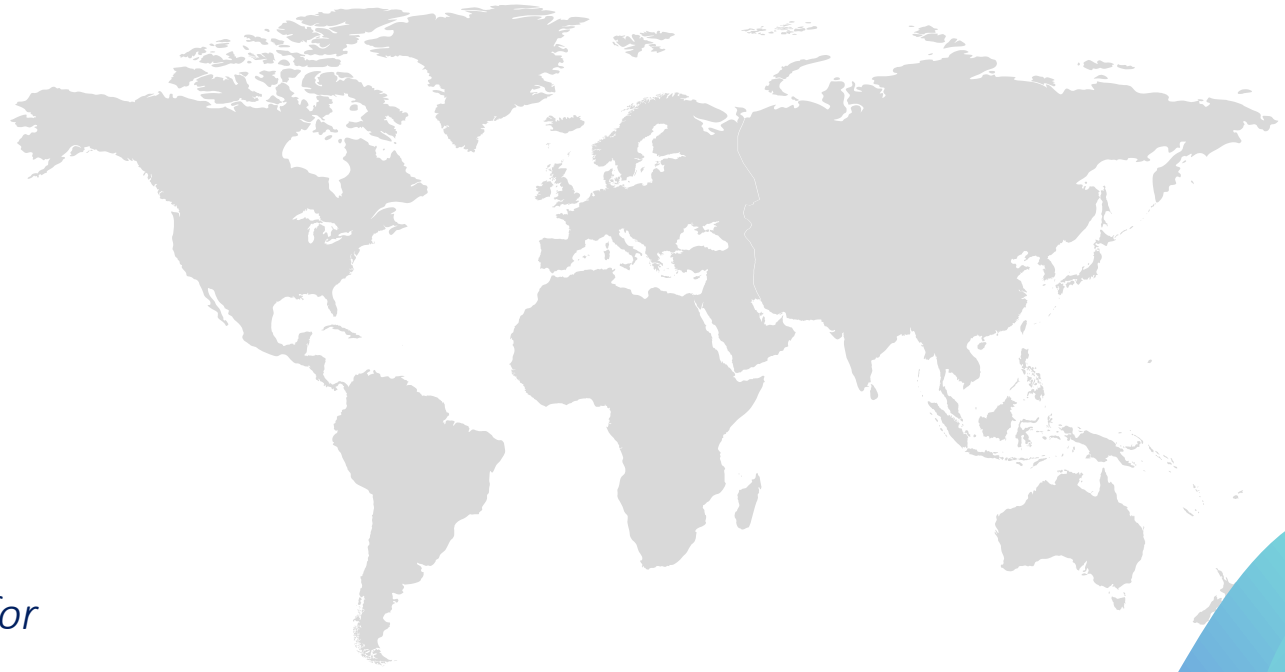
Operations Managers

Managers and QA personnel from Contract Manufacturing Organizations (CMOs)

Regulatory and quality professionals working for US companies that are considering foreign suppliers

Suppliers outside the US looking to US-based clients

QA/QC/Compliance/Regulatory affairs professionals



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