Compliance Online
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2-Day In-Person Seminar

Supplier and Contract Manufacturer Management

By: **Peggy Kwoka,** Senior Consultant, Quality GMP Solutions, LLC

Location: Orlando, FL | February 6-7, 2020

SPEAKER

Peggy Kwoka, Senior Consultant, Quality GMP Solutions, LLC

Peggy Kwoka has more than thirty years of experience in pharmaceutical, cosmetic consumer health and medical device industries including twenty years in Quality Assurance management and consulting. She has managed or provided expertise for more than ten US FDA inspections.

Peggy is currently working with pharmaceutical companies to develop effective quality systems through her consulting firm, Quality GMP Solutions, LLC. She focuses on improving her client's manufacturing and quality processes to enhance their regulatory compliance profile. She previously held quality assurance management roles at Colgate-Palmolive Company and GlaxoSmithKline.

AREAS COVERED

- The benefits and components of a supplier management program
- Regulatory requirements for managing suppliers and contract manufacturers
- Strategic decision making for good supplier management
- How to manage risk and reduce the costs associated with having suppliers
- The steps involved in selecting and onboarding a supplier
- Developing good supplier relationships including managing improvement and nonconforming events
- Writing effective and useful quality agreements
- Reviewing supplier performance and making performance-based decisions
- How to perform a desktop assessment and a supplier audit (and when to use each)
- Managing supplier transitions

COURSE DESCRIPTION

Effective management of suppliers and contract manufacturers is an integral component of a quality management system. Suppliers are an integral part of the supply chain and, therefore, the process of production and delivery should by understood and supplier relationships developed and improved. Supplier failures can increase the cost of poor quality through excess inventory, downtime, additional testing, and customer satisfaction. On the other hand, a significant strategic advantage can be gained by excellent supplier management. One of the seven quality principles of ISO 9001 is to build relationships with suppliers because it is a critical component of sustained success.

Pharmaceutical and medical device manufacturers have a mandated responsibility for ensuring the suppliers meet regulatory requirements and produce good quality product. FDA regulations CFR 210 and 211 require pharmaceutical companies to assure the quality of the product they put into interstate commerce regardless of where it or any of its components were manufactured. The Q10 Pharmaceutical Quality System Guidance provides additional details on the agency's expectations for supplier management. For Medical Device Manufacturers, 21 CFR 820.50 places the burden on the purchasing company to establish purchasing controls. European regulations similarly require effective supplier quality management.

This 2-day course will cover managing a supplier for the entire lifecycle of the relationship, beginning with identification and qualification of a supplier and continuing through building a relationship, risk management, ongoing assessment (including auditing) and finally planning for an exit. The course will show attendees how to use risk assessment for ranking suppliers and reducing the number of audits that are necessary to effectively manage suppliers. Strategies for determining whether a supplier will be sole source will be included. Exercises will help attendees develop their own supplier scorecard based on the requirements of their company and do develop quality agreements that will ensure clear lines of communication. Attendees will take away strategies for the ongoing monitoring of supplier process performance and for managing nonconforming incidents and changes.

AGENDA

Day 1 (8:30 AM – 4:30 PM)

8:30 AM - 8:59 AM Registration. Meet & Greet.

9:00 AM -10:00 AM

- Introduction and Objectives for the course
  - What are your expectations
  - Agenda for the course
- The Benefits of Effective Supplier Management
  - Case studies discussion
- Key Components of a Supplier Management Program

10:00 AM - 10:10 AM Break

10:10 AM -11:00 AM

- Understanding Regulatory Requirements and Standards for Supplier and Contract Manufacturer (CM) Management
  - United States Food and Drug Association (FDA) regulations and guidances
  - European Union (EU) directives and guidelines
  - International Standardization Association (ISO) standards
  - Examples of regulatory findings

11:00 AM -12:00 Noon

- Group Activity to Understand and Meet Regulatory Requirements
- The Cost of Poor Quality from Suppliers and CMs

12:00 Noon -1:00 PM Lunch

1:00 PM -1:50 PM

- To Purchase or to Manufacture In-house?
  - Cost benefit exercise on making the decision to outsource
- Strategic Management of Suppliers
  - Developing a strategic plan based on your company and environment

1:50 PM - 2:50 PM

- Risk Management – A Lifecycle Approach
  - Template for a risk assessment
  - Case study with risk assessment exercise

2:50 PM - 3:00 PM Break

3:00 PM - 4:00 PM

- Selecting a Supplier or Contract Manufacturer
  - Obtaining information on suppliers
  - Tools for making the selection
  - How to use your strategic plan to make decisions
  - When to use a sole source supplier
- Supplier qualification

4:00 PM - 4:30 PM Daily Wrap-up and Discussion

AGENDA

Day 2 (8:30 AM – 4:30 PM)

8:30 AM - 8:59 AM Meet & Greet.

9:00 AM -10:00 AM

- Seminar Objectives Review
- Building a Relationship with Your Supplier or CM
  - Onboarding
  - Communications and documents

10:00 AM -10:50 AM

- Making your Supplier Quality Agreement a Great Resource
  - Quality Agreement Template
  - Development of a Quality Agreement
  - Using your Quality Agreement

10:50 AM –11:00 AM Break

11:00 AM -12:00 Noon

- Monitoring Your Supplier's Performance to Reduce Risks and Costs
  - Template for a supplier scorecard
  - Activity on supplier performance monitoring
  - Managing nonconforming events

12:00 Noon -1:00 PM Lunch

1:00 PM -2:00 PM

- Partnering with a Supplier or CM for Improvement
  - Group improvement activity

2:00 PM -2:10 PM Break

2:10 PM -3:30 PM

- Supplier Assessments
  - desktop assessments
  - supplier audits

3:30 PM -4:00 PM

- Handling Supplier Transitions

4:00 PM - 4:30 PM

- Seminar Closeout

LEARNING OBJECTIVES

- Understand the benefits of effective supplier management
- Learn about the regulatory requirements for supplier management
- Understand how to develop a strategy for suppliers based on your supply chain
- Be able to analyze the cost of manufacturing vs. purchasing
- Understand how to select a supplier or contract manufacturer
- Understand the basics of building a supplier relationship
- Be able to develop a quality agreement that provides valuable guidance
- Learn how to perform risk assessments on suppliers and how to make decisions based on that assessment
- Learn how to develop a plan for supplier performance monitoring
- Understand how to manage failures and how to work with a supplier for improvement
- Understand the methods of supplier assessment and when to apply each
- Learn techniques for auditing a supplier and for follow-up and closure of the audit
- Learn how to effectively manage supplier exits and the transition to a new supplier

Registration Form

Registration Information:

- **Register Online**. Click Here Use your American Express, Visa or MasterCard.
- Get your group to attend the seminar at a discounted price call +1-201 871 0474.
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Seminar Topic: Supplier and Contract Manufacturer Management

Date & Location: .Orlando, FL | February 6-7, 2020

Attendee Details: $1699 per registrant

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Attendee 1			
Attendee 2			
Attendee 3			
Attendee 4			

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