Vendor Qualification and Audit Training

2 HALF DAY INSTRUCTOR LED ONLINE COURSE

COURSE DESCRIPTION

Supplier or vendor qualification is a crucial component in compliance to 21 CFR 111. The FDA requires that manufacturers of dietary supplements must "qualify" each of their vendors but do not provide guidance on how a company is to perform this qualification. Supplier qualification principles also apply to subcontracted services affecting cGMP (manufacturing steps, packaging and labeling, testing and/or calibration services, storage and distribution, etc.) Any supplier qualification program must include two critical components:

- Clearly defined specifications/requirements for all of these goods or services being purchased, and;
- Objective evidence to show that your requirements are being consistently fulfilled.

It is designed for those who already have a basic understanding of dietary supplement GMPs and the knowledge and skills necessary to qualify suppliers.

LEARNING OBJECTIVES

- Regulations that apply to vendor qualification (21 CFR 111)
- Food Safety Modernization Act (FSMA)
- Impact of FSMA on supplier qualification
- Risk assessment and risk management
- Supplier monitoring activities
- On-site audit strategies and requirements
- Managing the audit process effectively before, during and after
- The consequences of noncompliance

WHO WILL BENEFIT

- Management
- Laboratories
- Auditing
- Purchasing
- QA/QC
- Procurement
- R&D
- Legal
- Manufacturing
- Validation

WHY SHOULD YOU ATTEND

The various regulatory agencies have expectations that suppliers and vendors will demonstrate control over their manufacturing processes, validations, and documentation. Quality auditing is the process of checking whether these organizations have implemented what they have stated in written procedures and whether their people are doing what the organizations procedures state they will do.

KNOW YOUR FACULTY

Kelly Thomas, Vice President at America's Quality Operations, has 20 years of hands-on experience in the industry. She has worked with reputed facilities like FDA, EMEA, IMB, JP, and Health Canada. Her core expertise includes computer system validation, equipment process validation, and facilities validation. In addition, she will guide you on implementing a robust quality system, evaluating the KPIs of the facility, and executing high-quality management.

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TRAINING AGENDA

DAY 01

Topic 1: The Benefits of Effective Supplier Management

• Key Components of a Supplier Management Program

Topic 2: Regulatory Guidance Review

Understanding Regulatory Requirements and Standards for Supplier and Contract Manufacturer (CM) Management:

- United States Food and Drug Association (FDA) regulations and guidance
- European Union (EU) directives and guidelines
- International Standardization Association (ISO) standards
- Examples of regulatory findings

Topic 3: The Cost of Poor Quality from Suppliers and CMs:

• How to speak management's language

Topic 4: Strategic Management of Suppliers:

• Developing a strategic plan based on your company and environment

• Risk Management – A Lifecycle Approach:

➢ Template for a risk assessment

• Topic 5: Supplier qualification: Continued on Day 2

• Selecting a Supplier or Contract Manufacturer

• Obtaining information on suppliers

• Tools for making the selection

- Supplier Assessments:
- Desktop assessments
- Supplier audits
- Handling Supplier Transitions

• How to use your strategic plan to make decisions

• When to use a sole source supplier

DAY 02

Topic 5 Supplier qualification:

- Building a Relationships with a Supplier or Contract Manufacturer
- Making your Supplier Quality Agreement a Great Resource:
- Quality Agreement Template
- Monitoring Your Supplier's Performance to Reduce Risks and Costs:
- Template for a supplier scorecard
- Managing nonconforming events
- Partnering with a Supplier or CM for Improvement:
- Tools for improvement

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REGISTRATION FORM

Name **Email**

Organization **Department** **Position**

Phone **Mobile**

Register Online At www.worldcomplianceseminars.com

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Terms And Condition

- Registration shall be reconfirmed only once payment has been made prior to the course.
- Cancellation of participant/s shall be submitted in writing to WCS ten days (10 days) before the course. There is a 50% liability on all bookings once made.
- WCS reserves the right to make alterations to the conference/executive briefing content, timing, speakers without notice. The event may be postponed or cancelled due to unforeseen events beyond the control of WCS. If such a situation arises, we will refund your registration fee or we will try to reschedule the event.