COBBLESTONE

COURSE ID 2826

Ensuring Your Supply Chain through Supplier Qualification

DIRECTED BY

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90 MINUTE

ACCREDITED COURSE

Course Topics Include:

- Qualification Methodology & Tools
- FDA Regulations
- Principles of Risk Assessment

about the course

The Covid-19 pandemic highlighted the significance of effectively managing pharmaceutical and medical device supply chains. Previously hidden or overlooked vulnerabilities in the supply chain led to production disruptions and, in some cases, product shortages. To ensure regulatory compliance and sound business practices, supplier qualification is the foundation of effective supply chain management for pharmaceuticals and devices.

Our practical, 90-minute accredited training will cover the essential elements of a robust and compliant supplier qualification process for FDA-regulated industries. With an emphasis on applying risk management techniques, participants will learn how to effectively evaluate and qualify suppliers.

who should attend

This practical online training will benefit professionals and associates in the Pharmaceutical, Biotechnology, Medical Device, and Cosmetics industries including:

• QA/QC	• Auditors
• Regulatory Affairs	• Operations
• Purchasing/Material Management	• Outsourcing Project Managers
• Supply Chain	• Tech Services
• Managers of CMO's	

learning objectives

Upon completion of this course, you will be able to:

- Explain the criticality of Supplier Qualification from a business and regulatory perspective
- Analyze your firm's Supplier Qualification System to confirm adherence to current industry standards and FDA requirements
- Apply principles of Risk Assessment in managing your firm's Supplier Qualification Process

course outline

Review of Learning Objectives

Module 1: Regulatory Requirements for Supplier Qualification

- US FDA Drug GMP's
- ICH
- IPEC Guides
- EU GMP's
- US Medical Devices (QSR's)
- ISO

Module 2: Qualification Methodology

- Material vs Supplier Qualification
- Selection of Qualification Team
- Risk based, tiered approach
- Defining the "type and extent of control" of each supplier.
- Qualification criteria/Qualification Plans
- Methodology/Procedures
- Requalification criteria
- Transitioning to a more comprehensive system

Module 3: Qualification Tools & Monitoring Systems

- Notification of Change Agreements
- Audits
- Surveys/Questionnaires
- Master Service & Quality Agreements
- Supplier Monitoring
- Who is ultimately responsible? The sponsor or vendor?
- Summary

Question and Answer Session

Assessment Opportunity

course instructor

Frank Carroll, Carroll Pharma Consulting, LLC, Pharmaceutical Operations/Supply Chain.

Frank Carroll is currently an independent pharmaceutical operations/supply chain consultant and Principal of Carroll Pharma Consulting, LLC. He has over 25 years' experience in the Pharmaceutical, Device, Biologics, and Biotech industries in many aspects of operations including commercial and clinical product manufacturing and supply chain; purchasing; strategic alliance management; implementation of advanced project management systems; MRP/ERP systems; and senior operations management. He has held senior consulting positions at Pharmatech Associates and senior management positions at Zosano Pharma, Genitope Corp., Alpha Therapeutics, McGhan/Inamed Corp., Collagen Corp., and Bayer AG.

He has earned certifications from APICS (CPIM), ASQ (CQE), and Zenger-Miller as a certified trainer. He has instructed/directed numerous courses for the Center for Professional Advancement, instructed courses for APICS CPIM certification, and was a faculty member at Indiana University at South Bend in Continuing Education programs. He received his B.Sc. degree from The Ohio State University and MBA and MSBA degrees from Indiana University at South Bend.

Accreditations

International Accreditors for Continuing Education and Training (IACET)
Cobblestone has been approved as a CEU Accreditor by IACET and awards CEUs for participation in qualified courses. Cobblestone has demonstrated that it complies with the ANSI/IACET Standards and is authorized to offer IACET CEUs for its programs. CEUs will be awarded for participation in Cobblestone's courses at the rate of .1 CEU per contact hour upon successful completion of the entire course and 70% accuracy in the required Learners' Assessment. A minimum score of 80% is required for all courses within a Cobblestone Certification Program. This course offers a total of 1.5 contact hours, or .2 CEUs. For further information, visit www.iacet.org

Regulatory Affairs Professional Society (RAPS)
Cobblestone is committed to enhancing the ongoing professional development of regulatory affairs professionals and other stakeholders through appropriate regulatory affairs learning activities and programs. Cobblestone has agreed to follow RAPS- established operational and educational criteria. This course may be eligible for up to 12 credits towards a participant's RAC recertification upon full completion. The requirements and standards for recertification are developed and administered by the Regulatory Affairs Certification Board (RACB), which manages all areas of the RAC program. Additional information about RAC is available on the RAPS website at RAPS.org/rac.