COBBLESTONE

COURSE ID 1714

# Qualification and Management of CMO's

(Contract Manufacturing Organizations)

DIRECTED BY

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

12 Hours

ACCREDITED COURSE

- Use of Risk Management with CMO's
- Aligning CMO & Corporate Strategies
- Regulatory Aspects-US & EU
- Assessing Contractor Capabilities
- Qualification of CMO's
- Developing Effective Requests for Proposals/Quotes
- Best Practices in Outsourcing Project Management
- Contracts: Supply Agreements/Quality Agreements
- Current CMO/Outsourcing Issues
- Resolving Common Supplier/Contractor Problems

## about the course

Every pharmaceutical company hopes to obtain their desired expectations when it comes to important relationships with their Outsourcing Partners. This intensive course examines the root causes of critical issues that can arise within these relationships which are much broader and deeper than the technical capability to perform a process.

This intensive 12-hour, accredited course, delivered over three consecutive days examines the strategic and tactical outsourcing processes of selecting, monitoring, and managing an outsourced operation. It includes a review of domestic and international regulatory requirements and operational aspects including the role of the quality system. An in-depth discussion of risk-based supplier and material qualification processes, supplier selection, supplier monitoring, contracts/agreements, and auditing will be presented.

In addition, the course examines how best practices of project management can transform an outsourcing schedule into a true project plan.

The course includes hands-on workshops in which mini teams analyze case studies and present their findings.

Since this training is highly interactive, you must have a webcam on your computer equipped with a microphone and speakers/headset to fully participate.

## who should attend

This course has been designed for those who need to select, implement, improve, and/or manage Contract Manufacturing Organizations in the pharmaceutical industry as well as the biological, device, diagnostics and cosmetics industries. It will be of particular interest to individuals in:

- Corporate & Operations Management of "Virtual" Organizations
- Managers of CMO's, Contract Development & Manufacturing (CDMO's), and Contract Research Organizations (CRO's) including Combination Products
- Supply Chain Management/Project Management
- QA/QC
- Manufacturing
- Engineering/Process Development
- Regulatory Affairs
- Packaging
- Purchasing

Individuals within R&D who outsource any of their functions and face many of the same challenges with Contractors would additionally benefit from this course.

## learning objectives

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

- Implement effective methods to evaluate potential CMO's and other critical suppliers
- Compare and contrast the multitude of regulatory requirements in outsourcing pharmaceutical operations
- Organize and implement an effective supplier/CMO qualification program based on risk management principles
- Implement project management "Best Practices" in outsourcing
- Recognize, determine the root cause, and improve common contractor/client relationship conflicts
- Apply Risk Management techniques to identify, prioritize, avoid and mitigate contractor risks

## course outline

**Introductions and Review of Learning Objectives**

- Review & Discussion of Attendees' CMO & Supplier Issues

**Risk Management**

- Risk Management Principals & Process
- ICH References
- Risk Matrix

**Outsourcing Strategies**

- When & Why you outsource
- Direction of Industry
- Strategy Development
- Outsourcing Strategy Overview
- Single Sourcing vs. Secondary Supplier Strategies

**Regulatory Considerations**

- Differences/Similarities of Applicable Regulations
- FDA Guidance for Industry
- IPEC
- The Rules Governing Medicinal Products in the European Union
- US Medical Device GMP's (QSR's) and ISO

**Finding the Right Contractor/Supplier**

- Resources – Incentives-Culture
- Lowest Total Cost Strategy
- Initiating & Maintaining Relationships
- Strategic Alliance Communication
- Communication & the Value of a Point Person
- Managing the Long-Term Relationship

**CMO/Supplier & Material Qualification**

- Difference in Scope of Supplier and Material Qualification
- Supplier Qualification
- Supplier Quality Team (SQT)
- Tiered, Risk-Based Approach
- Material Qualification
- Transitioning to a More Comprehensive System

**Supplier Monitoring**

- Supplier Monitoring – A Tiered Approach
- Issues in Measuring Performance
- Periodic Surveys & Audits
- ISO Certification Review
- Supplier Corrective Action Reports (SCAR)
- Supplier Probation/Disqualification
- Supplier Performance Reports

**Contracts, & Agreements, RFP's**

- Request for Proposal/Quotes (RFP, RFQ's)
- Master Service Contracts
- Quality Agreements

**Supplier Auditing Overview**

- Types of Auditing
- FDA Requirements
- Use of "Risk Management" Techniques
- Systems vs. Performance Audits
- Auditing Operations
- Auditing Interviews & Reports
- Audit Priorities

**Current Outsourcing Issues**

- Quality by Design
- Supply Chain Security
- Serialization – Drug Supply Chain Security Act
- Data Integrity
- Class Project Introduction

**Outsourcing Project Planning**

- The Most Common Project Planning Problems
- Scope – Schedule – Resources
- Project Plans for Outsourcing
- Project Risks – Avoidance and Mitigation
- Project Best Practices
- Scaling Up – One size does not fit all

**Class Project and Presentations**

**Wrap Up and Question/Answers**

**Assessment Opportunity**

## course instructor

**Frank Carroll** is currently an independent pharmaceutical operations/supply chain consultant and Principal of Carroll Pharma Consulting, LLC. He has over 30 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, including Principal Supply Chain Consultant, and Compliance Architects, as well as senior management positions at Zosano Pharma, Genitope Corp., Alpha Therapeutics, McGhan/Inamed Corp., Collagen Corp., and Bayer AG.

In 2019, he was a contributor to Good Distribution Practice-A Handbook for Healthcare Manufacturers and Suppliers-Volume 1, Siegfried Schmitt, Editor, PDA, Bethesda, MD USA
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 12 contact hours, or 1.2 CEUs. For further information, visit www.iacet.org