COBBLESTONE

COURSE ID 2965

NEW!

Combination Product Risk Management Principles, Part 1

An Engineering and QA Perspective

DIRECTED BY

Frank Carroll — Principal of Carroll Pharma Consulting, LLC

90 MINUTE

ACCREDITED COURSE

Course Topics Include:

- FDA Combination Product Definitions
- ICH Q9 Risk Management Process/Principles
- Risk-based Supplier and Material Qualification
- Supplier Agreements
- Request for Proposals/Quotes (RFP/RFQ)

about the course

Managing the complex lifecycle of combination products requires the efficient utilization of resources of a pharma/device company regardless if the company is vertically integrated, utilizes both in-house and contract manufacturing, or is a truly virtual company.

This first of two 90-minute accredited training courses will define and apply recognized risk management principles in identification of required GMP's and Quality Systems Regulations, developing a risk-based, tiered supplier and material qualification system, and developing effective Master Supply Agreements and Requests for Quotations (RFQ's).

The course is appropriate for all operations, quality, development, and project management functional areas but will emphasize the perspective of Engineering and Good Engineering Practices where applicable.

For maximum training benefit, participants are encouraged to attend the complete 2-part series.

2966: Combination Product Risk Management Principles: Part II An Engineering and QA Perspective

who should attend

This course is intended for professionals involved in the Pharmaceutical, Medical Device, Biopharma and Biologics industries. Managers, Directors and Specialists working in Engineering, Supply Chain, Manufacturing, Packaging, QA/QC and Project Management will benefit greatly by attending this training.

All operations, quality, development, and project management personnel who are involved in ensuring Good Engineering Practices should attend.

learning objectives

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

- Identify and understand the FDA classification of combination products
- Compare and contrast the use of risk management requirements from ICH, FDA, and professional engineering societies
- Identify the minimum GMP and QSR requirements for combination products
- Implement a risk-based supplier and material qualification process
- Implement best practices for developing Master Service Agreements and Requests for Proposals/Request for Quote

course outline

Review of Learning Objectives
Module 1: Risk Management

- Definition of Combination Products
- ICH Q9: General Risk Management Process
- Risk Analysis Tools
- Application of Risk Management Principles

Module 2: Application of GMPs and QSRs in Combination Products

- Minimum FDA requirements of GMPs and QSRs in Combination Products
- A Risk-based Supplier Qualification System
- Responsibilities of a Supplier Quality Team (SQT)
- Supplier Qualification SOP's
- Material Qualification

Module 3: Contractual Agreements

- Supply vs Quality Agreements
- Master Supply Agreement (MSA) Elements
- Recommendations for MSA's
- Development of Effective Requests for Quotations (RFQ's)

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 1.5 contact hours, or .2 CEUs. For further information, visit www.iacet.org