COBBLESTONE

COURSE ID 2966

NEW!

# Combination Product Risk Management Principles, Part 2

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
- Quality Agreements
- Risk-based Deviations and CAPA
- FDA CAPA Expectations
- Risk-based Change Control and Validations
- ISPE Change Management and Initiatives

## 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 second of two 90-minute accredited training courses will define and apply recognized risk management principles in developing effective and compliant Quality Agreements, tiered supplier monitoring, CAPA, validation and Change Control systems. It is recommended that participants attend Part I of this course.

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.

2965: Combination Product Risk Management Principles: Part 1 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:**

- Create effective and unambiguous Quality Agreements that comply with FDA Guidance's
- Develop effective supplier and internal CAPA processes utilizing risk management principles
- Develop effective supplier and internal Change Control processes utilizing risk management principles
- Apply risk-based principles to commissioning and validating equipment and systems
- Categorize significant changes from minor changes
- List the elements of ISPEs drug shortage initiative

## course outline

**Review of Learning Objectives**

**Module 1: Quality Agreements**

- Definition of Combination Product
- Quality Agreement format
- Suggestions for defining clear-cut responsibilities
- Complying with the FDA Quality Agreement Guidance

**Module 2: Deviations and CAPA's**

- Most common FDA 483's for Drugs and Devices
- Tiered, risk-based supplier monitoring
- Supplier Corrective Action Requests (SCAR)
- Risk-based steps from Deviation to CAPA to Change Control
- FDA CAPA expectations

**Module 3: Change Controls**

- ISPE Change Management Definitions
- Are Good Engineering Practices regulated activities?
- Using risk management principles to determine significance of changes
- Applying risk management principles to improve efficiency of Change Controls
- Risk-based commissioning and validations
- ISPE Drug Shortage Initiative
- Supplier Management Cycle

**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