

Course Title:

Introduction to Combination Products in the US

Product ID: 213

Duration: 62 mins

SME: Lee Leichter

First Released On: 07/07/2011

Course Description:

This course examines the historical and legislative perspectives that led to the definition and regulation of combination products in the US, including the establishment of the Office of Combination Products (OCP).

Watch the Course Trailer:

Learning Objectives:

Upon successfully completing this course, learners will be able to:

- Comprehend the evolution and organization of the regulation of combination products in the US
- Understand the definitions and classifications of US combination products
- Recognize the legislative authority of the OCP and its role

Who Should Enroll:

Regulatory Affairs Associate, Regulatory Affairs Manager, Quality Assurance Associate, Quality Assurance Manager, Quality Assurance Engineer, Manufacturing Engineer, Supply Manager, Purchasing Manager, Design Engineer, Validation Engineer, Electrical Safety Engineer, Internal Auditor, Lead auditor, Pre-Clinical Study Manager, Export Manager, Clinical Affairs Director, and R&D Engineer are all welcome to participate in this course.

Related Resources: Yes

Prerequisite Knowledge

Individuals taking this course should have a basic understanding of US Food and Drug legislation and regulation.

The following pre-requisite knowledge is required:

- Introduction to the US FDA (ID 76)

Price:

Premium: €182.00.- **Basic:** €242.00.-

Course Format:

All WMDO professional online training courses are fully interactive and contain audio, video, graphic animation, online quizzes and include all necessary course materials. Trainees receive a minimum of 60 days of unlimited access in which to complete each course depending on course length and complexity. (See individual course descriptions for details). Courses include handouts, case studies, working documents and other useful links. After successful completion of your course, you will be able to download your WMDO Certificate of Completion for your training records.

Online courses are cross-browser compatible and require internet connection (minimum 300kbs) and Adobe Flash Player installed (Free download available at: <http://www.adobe.com/products/flashplayer>).

Premium Account Holders:

Premium account holders enrolling in this course will receive complimentary email access to subject matter experts for any questions, clarifications or feedback they may have concerning this course and its contents, including free automatic course updates for 1 full year.