



WORLD MEDICAL DEVICE ORGANIZATION

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Online Training for Medical Device Professionals

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**Course Title:**

## US FDA Investigational Device Exemption (IDE) Overview

Product ID: 121

Duration: 125 mins

SME: Carole Stamp

First Released On: 07/09/2010

**Course Description:**

This four-part course, created by US regulatory expert Carole Stamp, outlines the FDA regulations concerning US clinical studies for medical devices. It provides a comprehensive and clear look at the Investigational Device Exemption (IDE) application process, significant and non-significant risk studies, common problems that can arise during studies, and an overview of FDA inspection procedures and requirements.

Based on certain risk factors surrounding investigational devices, IDEs are now required by the FDA in order for investigational devices to be used in the following circumstances:

- Procuring clinical studies
- Collecting safety and effectiveness data in support of PMA applications
- Writing 510(k) submissions (applicable only in certain cases)

### Watch the Course Trailer:

**Learning Objectives:**

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

- Comprehend the FDA regulations concerning US clinical studies for both medical devices and the IDE process
- Recognize the differences and implications involved in both significant and non-significant risk studies
- Identify and address common problems that can occur during clinical studies and that can directly affect IDEs
- Define FDA inspection procedures and requirements relevant to the IDE approval process

**Who Should Enroll:**

Professionals who participate in IDE study teams are encouraged to enroll in this course.

**Related Resources:** Yes

**Prerequisite Knowledge**

There is no prerequisite knowledge required for this course; all areas of expertise are welcome.

**Price:**

**Premium:** €286.00.- **Basic:** €381.00.-

**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.