



WORLD MEDICAL DEVICE ORGANIZATION

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Online Training for Medical Device Professionals

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**Course Title:**

## **Centralized vs. Onsite Monitoring Applying FDA's Risk-Based Approach**

Product ID: N190

Duration: 50 mins

SME: Danielle Giroud

**Course Description:**

The course provides an overview of onsite monitoring and discusses the regulations and standards that currently govern the monitoring practice. It also examines the FDA guidance on risk-based monitoring, discusses real-world applications of the guidance, and looks at the current monitoring climate.

**Watch the Course Trailer:**

**Learning Objectives:**

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

- Define risk-based monitoring
- Implement risk-based monitoring approaches to clinical trial oversights
- Understand the FDA guidance "Oversight of Clinical Investigations: A Risk-Based Approach to Monitoring"

**Who Should Enroll:**

Clinical research professionals 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:** €114.00.- **Basic:** €152.00.-

**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.