

Course Title:

Medical Device Clinical Investigation in Germany – Requirements of the Radiation Ordinances

Product ID: N159

Level: CMDP

Duration: 50 mins

SME: Danielle Giroud

Course Description:

This course provides a comprehensive overview of the German regulatory requirements for the use of diagnostic or therapeutic ionizing radiation during clinical investigations.

It covers the following topics:

- How the Medical Devices Act (MPG) is linked to the StrlSchV and RöV radiation protection ordinances
- Scope of the radiation protection ordinances related to clinical trials
- Clarification of applicable definitions
- Conditions and context of use (medical or research)
- Pathways to obtain authorization
- Use of radiation as an accompanying diagnostic (Begleitdiagnostik)
- Summary of key points

Watch the Course Trailer:

Learning Objectives:

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

- Compile clinical investigation notifications to Germany for studies involving x-ray diagnostics, scintigraphy, and more
- Apply for an authorization for the use of radiation-based diagnostics or therapy within the framework of Bundesamt für Strahlenschutz (BFS) clinical investigations
- Incorporate the radiation approval process to clinical investigation timelines

Who Should Enroll:

Investigators in Germany, study coordinators, hospital staff responsible for radiation protection and involved in clinical investigations, regulatory managers, and clinical research project managers and associates involved in submissions and conduct of clinical investigations in Germany are all welcome to enroll in this course.

Related Resources: Yes

Prerequisite Knowledge

The following course is required:

- Conducting Medical Device Clinical Investigations in Germany (ID N157)

Price:

Premium: €150.00.- **Basic:** €200.00.-

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>).



WORLD MEDICAL DEVICE ORGANIZATION

WMDO SA
Route de Denges 28E
1027 Lonay
Switzerland
Tel. +41 21 349 96 36
Fax +41 21 349 96 37
contact@wmdo.org

WMDO USA
3565 IDS Center 80
South 8th Street, Minneapolis
MN 55402, USA

Online Training for Medical Device Professionals

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.