Medical Device & Pharma Courses

Because Competence is the Key

MDPHARMACOURSES.com

Is the platform that strengthens your preparation and skills in the life science field.

Regulatory, Quality and Compliance are very challenging fields where continuous improvement of competence knowledges and skills makes the difference.

- FDA & EU Regulations
- Quality System
- Process Validation
- Design Control
- R&D and Technical

Webinar & Trainings

By highly experienced Subject Matter Experts (SMEs) from Pharma and Medical Device industry.

CLINICAL EVALUATION OF MEDICAL DEVICE

GO TO THE COURSE

Course Description:

This Webinar course provides a guideline on how to prepare a clinical evaluation for a Medical Device, considering the applicable laws and standard, providing example and also a guideline in setting up a SOP for the conduction of clinical evaluation. An overview of discussed topic is here reported:

- Applicable Laws
- Annex X
- EN ISO 14155:2011 Clinical investigation of medical devices for human subjects
- Applicable Guidelines
- Meddev 2.7/1 Clinical Evaluation: A Guide for Manufacturers and Notified Bodies
- Meddev 2.7/4 Guidelines on Clinical Investigation
- Explanation of Essential Requirement related to Clinical Evaluation
- Helsinki Declaration
- Guideline on how to prepare a SOP for correct performing of Clinical Evaluation
- Content and Team
- Evaluation process
- Endpoints and Checklist
- Evaluation Report
- Post Market Surveillance and follow-up
- European Community Medical Devices directive

Availability: Right Now (Recorded Presentation)
Duration: 70 min. (the average time to complete the training program).

Who Will Benefit:

- *Regulatory Affairs specialist*
- *Medical Affairs specialist*
- *Clinical Affair specialist*
- *R&D Engineers*
- *Quality Engineers*
- *Marketing*

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Why Should You Attend:

Creating and reviewing the Clinical Evaluation of a Medical Device is a very important and critical step for the development and registration of a new Medical Device.

Regulators around the world are increasing expectations for clinical evaluation of medical devices for all devices with tougher requirements for higher risk devices and especially implantables.

This webinar will explore the key points related to **Clinical Evaluation** and will give guidance into this key process.

Certification Requirements:
Students must view the entire program and successfully pass an online, multiple choice final assessment with >80% passing grade.

Certificate will be printable in PDF format immediately after satisfying requirements.

Online Training Programs Include:

- 90 days of 24/7 access to individual eLearning courses.
- Answer to questions submitted during the Webinar.
- An online final assessment with multiple-choice questions.
- A Certificate of Completion.

Course Presented and Commented by: Ing. A. Ravizza

Alice Ravizza *is a Biomedical Engineer, graduated at Politecnico di Milano. She has great and extensive experience in R&D and QA / RA in the biomedical field. She is specialized in supporting Medical Device companies in building up and improve Quality System Management and assure Compliance through all the internal processs. She assist companies during the registration process for CE Mark making sure all the technical documentation is compliant to applicable standards and regulations. She is aswell an experienced Trainer and Lecturer.*