



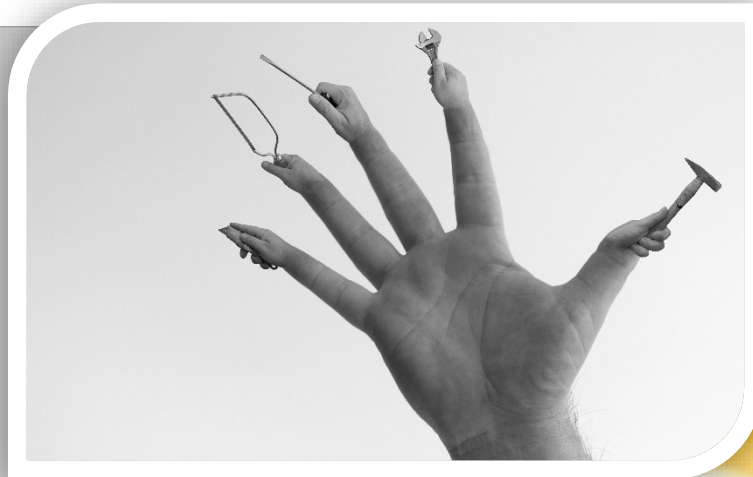
Medical Device & Pharma Courses

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Webinar & Trainings

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



LIVE WEBINAR – TECHNICAL FILE STRUCTURE ACCORDING TO THE NEW MEDICAL DEVICE REGULATION

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Description:

The course is aimed at Quality Assurance personnel, Regulatory and Research and Development of biomedical companies, medical device manufacturers of any class, agents and distributors. The course describes the structure and content of a technical file and its main attachments for the CE marking of a medical device.

LEVEL: INTERMEDIATE (requires understanding of the current regulation)

Technical File (TF) is required to obtain CE mark and normally contains the following information:

- General Information / Product Description / EC Authorized Representative
- Classification Determination (Annex IX, Rule)
- Essential Requirements (Annex I)
- Risk Analysis
- Labeling
- Product Specifications
- Design Control
- Clinical Evaluation (Annex X; literature review, et al.)
- System Test Reports
 - Functional Bench Testing
 - Lab Testing (cytotox, hemolysis, sensitization, carcinogenicity, other biocompatibility testing)
 - Sterilization validation (or AAMI TIR 28 Analysis)
- Packaging Qualifications
- Manufacturing
- Sterilization
- Conclusion
- Declaration of Conformity (Annex II, V, VII)
- Appendix (further supporting information / details on the above).

A clear understanding of the structure and arrangement of Tech File documentation is required in order to fulfil the regulations and experience a smooth and fast commercialization of a new medical device.

Early bird booking Promotion:

Register now and get 25% Off!! Send email to info@mdpharmacourses.com to get the discount code.

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:

- 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