MDTI

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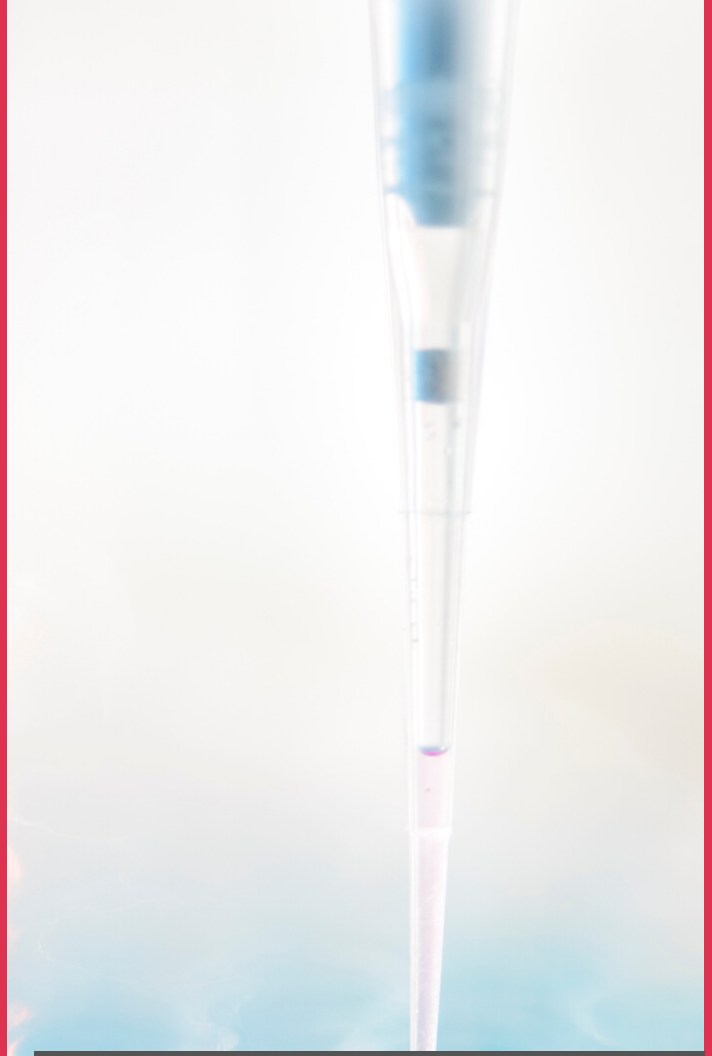
Fundamentals of EU Regulations for Medical Devices

5-week Online Academy

Starts 18 May 2020



MEET THE TRAINER

ANNE JURY

Anne has her own consulting company, advising on regulatory affairs and quality assurance to medical technology industries.

Anne previously worked for BSI Product Certification as a medical devices notified body Certification Manager, managing BSI's regulatory compliance for CE marking to the Active Implantable Medical Devices Directive 90/385/EEC and Medical Device Directive 93/42/ECC. In addition, Anne worked worked for TUV, where she was responsible for the development of the Medical-Health-Sports (MHS) Business Uni.

Agenda

Module 1: Introduction to Medical Devices and the New MDR and IVDR

- Definitions
- Competent Authorities and Notified Bodies
- Placing on the market and enforcement
- Introduction to the MDR & IVDR and reasons behind their development
- Chief differences of MDR with MDD
- Economic operators - obligations of manufacturers, distributors, importers and authorised representatives

Module 2: Borderlines & Classifications

- Borderline determination
- Principles of classification – MDR and IVDR
- Risk classes and practical examples
- Annex XVI devices

Module 3: General safety and performance requirements

- GSPRs - technical requirements - role of standards in demonstrating compliance with GSPRs
- Chief differences with MDD
- Labelling requirements – impact of Unique Device Identification and registration on EUDAMED

Agenda

Module 4: Clinical Evaluations & Investigations

- Overview of the specific regulations and guidance
- Definitions of clinical evaluation, clinical data and clinical investigation
- Overview of Clinical Investigation requirements under Standard ISO 14155

Module 5: Risk Assessment & Management

- Risk Management concept and ISO 14971:2012
- Risk Management process and linkage of clinical evaluation with risk conclusions.
- Key output documents
  - Risk Management Plan
  - Risk Benefit Analysis
  - Risk Management Report

Module 6: Technical documentation

- Annex II of MDR - Technical file format
- Inclusion of regulatory processes in the Quality Management System
- Annex III - Post-Market Surveillance
- Good documentation practice

Agenda

Module 7: Quality Management System

- Structure of documentation required by ISO13485:2016
- Best practice for document control and record keeping
- Inclusion of regulatory processes with the QMS
- Role of QMS in conformity assessment by notified bodies
- Requirements for person responsible for regulatory compliance

Module 8: Conformity Assessment Routes

- Examination of the possible conformity assessment routes
- Analysis of the routes defined by the MDR and IVDR documents
- Presentation of data for conformity assessment

Module 9: PMS & Vigilance

- Post-market surveillance requirements & key output documents
  - PMS Plan
  - PMS Report
  - Periodic Safety Update Report
- Vigilance (reporting and follow up of serious incidents)
- Market Surveillance by Competent Authorities

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For information or to book a course please contact our Training Consultants

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