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EN 62304 - Software Lifecycle

Duration: 1 day

Training objectives:

- Understand the key concepts related to the development of software for a medical device.
- Understand the necessary modifications in the Quality Management System in order to sustain a software development process compliant to IEC 62304.
- Be able to develop a documentation structure and content to be included in a Medical Device Technical Documentation prepared for regulatory submission.

Training content:

- Regulatory context and considerations (EU and US regulations and state of the art)
- Key concepts:
  - Good Documentation Practices
  - Usability
  - Risk management & Safety classification
  - Life Cycle Model
  - SOUP
  - Verification and Validation
  - Requirements Traceability
  - Cybersecurity
- Quality System Documentation (Software development procedure, Change management, Software configuration)
- Technical File Documentation (Software Development Plan, Software Requirements Specification, Software Architecture Specification, Software Design Specification, Risk Management, V&V, …)
- The IEC 62304 Compliance Matrix

The training is delivered by Dr. William Enns-Bray, Project Associate at Medidee Services.

Price: CHF 750.-
Location: Medidee Services SA | Chemin de Rovéréaz 5 | 1012 Lausanne | Switzerland

Contact & registration: training@medidee.com