medídee®

EN 62304: Software Lifecycle Training

Date: **22. June 2017**
Duration: **1 day**
Place: **Medical Valley; Henkestraße 91, 91052 Erlangen**
Cost: **€ 450.-**
Subscription: training@medidee.com

Training objectives:

- Understand the key concepts related to the development of software for a medical device.
- Learn to implement the necessary modifications in the Quality Management System to sustain a software development process compliant with IEC 62304.
- Familiarize with a documentation structure and content to be included in a Medical Device Technical Documentation prepared for regulatory submissions.

Training contents:

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

Trainer:

Kim Rochat is an Expert for software compliance projects in medical devices, active implants and IVDs. His expertise includes software product validation and clinical verification & validation. Kim is performing pre-submission scrutiny reviews for stand-alone software including mobile apps and software as part of medical devices for EU and US-FDA regulatory environments. Mr Rochat manages compliance of software validation for GMP purposes including Quality System supporting software and ERP systems.

Kim holds a MBA in IS Security, a CAS in Project Management and a CAS in Medtech Ventures Management, a CAS in Medical Informatics and he is certified Data Protection Officer. Kim combines medical device experience with a proven expertise in Supply Chain Optimization and implementation of good practices.