



TRAINING

Software Life Cycle Processes (IEC 62304)

Duration: **8 hours** | 2 x 1:00 – 5:00 PM CEST | 2 x 7:00 – 11:00 AM EDT

Date: **May 30-31st, Online**

Speaker: **Dr Niels Burzan**

Training objectives: This training consists of 2 modules of 4 hours each. The objective of this training is to provide an overview of the IEC 62304 standard that is applicable for medical device software and software as medical device. It covers the software life cycle but also reaches the related field of quality management systems for medical devices (ISO 13485). The training is aimed at software developers and regulatory employees of medical device manufacturers who seek to understand the requirements of documentation as per IEC 62304 for their software product that falls under the definition as medical device (under Medical Device Regulation [MDR] 2017/745 in Europe or according to FDA definitions and/or guidance).

Training content: This training outlines the requirements of the IEC 62304 standard “Medical device software – Software Life Cycle Processes” that is applicable for a growing number of medical devices that include software components but also SaMD: Software as medical device. By attending this training, you will receive in-depth knowledge on the following topics:

- Regulatory context & key concepts of software development for medical devices
- Software in medical devices: Characteristics and examples of software as medical device and software used in medical devices
- Software classification
- General requirements and key concepts
- Key concepts associated with IEC 62304
 - Human Factors Engineering / Usability Engineering
 - Risk Management
 - Software Safety Classification
 - Software Design Life Cycle (SDLC), Development Workflow and useful Software Development Tools
 - Software of Unknown Provenance (SOUPs) / Off-The-Shelve (OTS) Software
 - Quality Management System
- Medical device software – Software Life Cycle Processes (IEC 62304)
 - Chapter by Chapter, including:
 - Scope, terms and definitions
 - General requirements
 - Software development process & the V-model, including:
 - Software Architecture

- Software Integration
- Software Verification & Validation
- Software Release
- Software Maintenance Process
- Software Risk Management Process
- Software Configuration Management Process
- Software Problem Resolution Process
- Typical documentation architecture
 - Software development tool examples for the documentation throughout the software development process
- Intersection of IEC 62304 with ISO 13485

Training format:

- Presentations with interactive discussions
- Group and individual exercises
- End of training assessment

Price:

EUR 775 incl. course material and certificate

Registration: education-veranex.talentlms.com

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