Johner Institute

IT SECURITY FOR MEDICAL DEVICES AND IEC 81001-5-1 (2 DAYS)

Get a head start in knowledge and reduce the risk of IT security incidents to a minimum

In this seminar, as a manufacturer of medical devices, you will learn about the regulatory requirements for IT security and data protection for medical devices and how to implement them professionally in your company.

What characterizes the seminar

- Concepts are explained in detail so that even beginners can easily follow the topic.
- The course material fully covers the entire security lifecycle of medical devices.
- The course material includes references to other practical sources of information and tools to expand knowledge and provide guidance on practical implementation.
- The trainer has more than 25 years of experience in the regulated medical device environment, including 13 years in software development.

Certificate

There is a voluntary online exam at the end of the seminar (duration: approx. 20 min). By passing this exam, you will receive a certificate proving your newly acquired knowledge and skills in addition to your attendance confirmation.

Learning Content

- Relevant regulatory requirements related to IT security
- Distinction between data protection and IT security
- Data protection requirements in the context of a medical device
- Relevant terms and concepts
- Implementation of IT security in the life cycle process of a medical device (IEC 81001-5-1)
- Systematic identification and minimization of IT security risks
- Derivation and formulation of safety-specific product requirements
- Relevant architecture and implementation specifications
- Specific test methods for IT security
- Handling of already approved devices that have not been developed according to current specifications

Learning Objectives

After the seminar you will be able to:

- deal professionally with the most important terms and concepts of IT security in everyday business.
- develop regulatory-compliant standard operating procedures and document templates.
- create a complete and compliant product file for IT security.
- implement the IT security life cycle process in a compliant manner, including market surveillance.

Target Group

This seminar is designed for people in the field of:

- Software Development and Architecture
- Quality Management
- Regulatory Affairs
- Management
- Internal Audits, Supplier Audits
- Authorities and Notified Bodies

Requirements for participation

Participants can follow this seminar well even without any special prior knowledge. An understanding of their own medical devices is helpful.

Schedule (Agenda) Day 1

TIME	CONTENT
09:00 am - 09:30 am	Welcoming and clarifying expectations
09:30 am - 10:00 am	Introduction
10:00 am - 10:30 am	Regulatory framework
15 min break	
10:45 am - 11:30 am	Shared responsibility
11:30 am - 12:30 am	Data protection
60 min lunch break	
01:30 pm - 02:15 pm	Life cycle process, basic considerations of IEC 81001-5-1
02:15 pm - 03:00 pm	Risk management
15 min break	
03:15 pm - 04:00 pm	Risk management
04:00 pm - 04:30 pm	Planning
04:30 pm - 05:00 pm	Questions and answers, summary, and closing

Schedule (Agenda) Day 2

TIME	CONTENT
09:00 am - 09:30 am	Summary and recap of day 1
09:30 am - 10:00 am	Requirements management
10:00 am - 10:30 am	Architecture
15 min break	
10:45 am - 11:30 am	Design and implementation
11:30 am - 12:30 pm	Testing
60 min lunch break	
01:30 pm - 02:15 pm	Release
02:15 pm - 03:00 pm	Post-market activities
15 min break	
03:15 pm - 04:00 pm	Legacy devices
04:00 pm - 04:30 pm	Discussions and practical implications
04:30 pm - 05:00 pm	Questions and answers, summary, and closing

Further information and the registration form can be found **HERE**

Trainer

Christian Rosenzweig

As an engineer for biomedical technology, Christian Rosenzweig was responsible for basic and software development for complex active medical devices for many years. As the person responsible for carrying out and guiding conformity assessment procedures in the EU and USA, he gained experience with all forms of audits and various markets (in particular, FDA and MDSAP). He was also an ISO 13485 quality management representative in a large corporation. As a sought-after expert, he assists our customers with strategy issues and the implementation of quality or regulatory affairs management. His focus is on the safety of medical devices, risk management, and IT security.

Feedback

"The concepts were explained with clarity, and the recommendations are very useful to implement the IT security process."

"I appreciated the teacher's clarity and preparation. The provided materials (slides and exercises) were sufficient to follow the seminar."