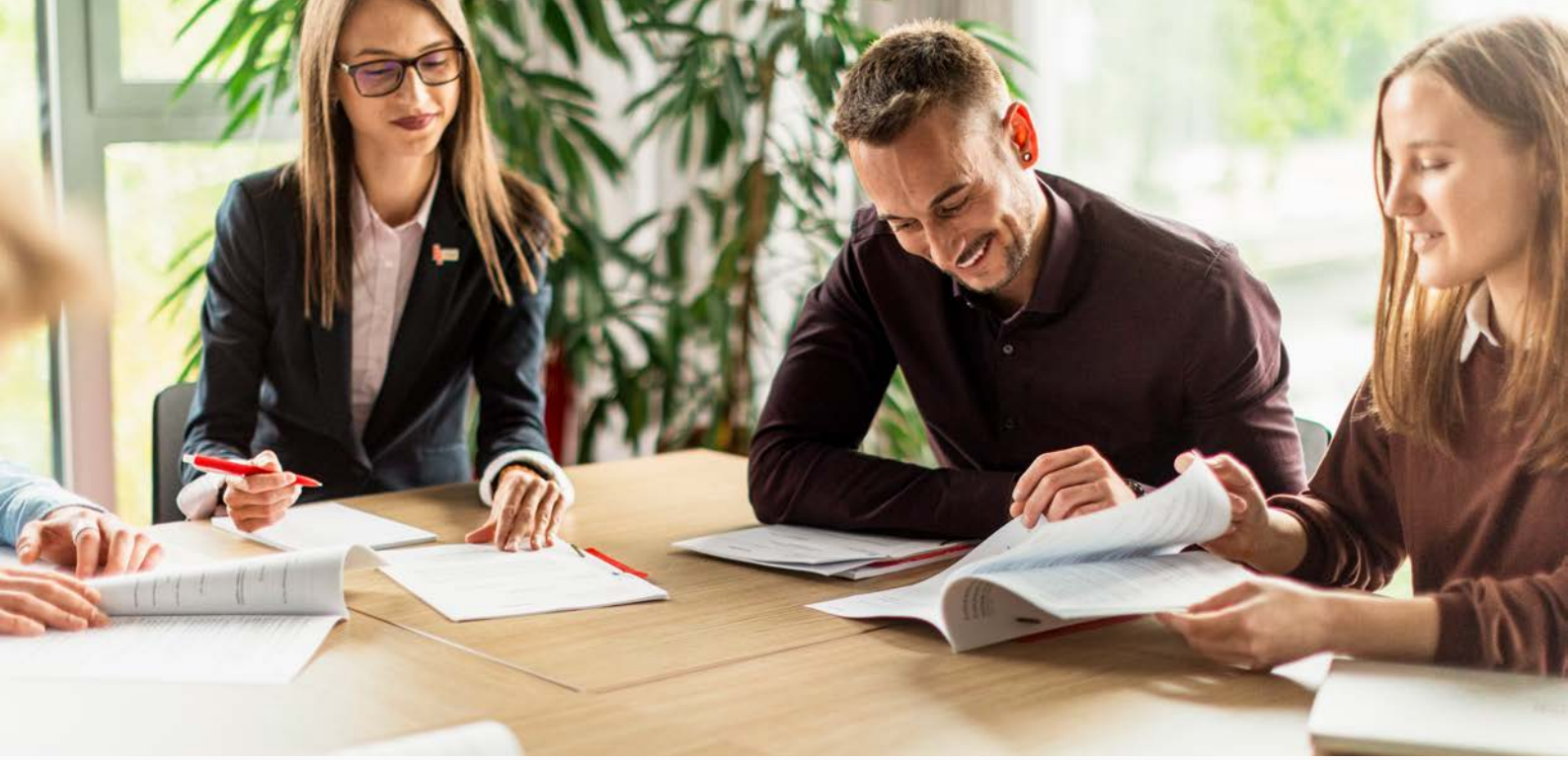

Johner Institute

SEMINAR RISK MANAGEMENT AND ISO 14971 (2 DAYS)

Create an ISO 14971-compliant and audit-proof risk management file without stress

This seminar provides you with comprehensive knowledge of risk management and the competence to coordinate all your company's risk management activities and create compliant risk management files for your medical devices.

What characterizes the seminar

- Our trainer does not just point out mistakes like an inspector but uses his own daily work to teach you the best practices that you can use to create precise and compliant risk management files quickly and thus pass audits and reviews successfully.
- Instead of a theory lecture with tasks that are difficult to transfer to your devices, our trainer, who creates risk management files daily, helps you directly transfer what you have learned into your everyday work and for your devices with practical exercises and sample documents.
- Concrete guidance and precise answers spare you the constant refrain: „You can't say that in general terms."
- Instead of clinging to rigid plans and outdated examples of little practical relevance, our trainer explains the topic using current and real devices and addresses your specific case.

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

- Regulatory framework in Europe with embedding of risk management
- Definitions according to ISO 14971 (with practical exercise)
- Risk policy and evaluation (with practical exercise)
- Risk analysis according to PHA (Preliminary Hazard Analysis)
- Risk analysis according to FMEA (Failure Mode and Effect Analysis)
- Risk analysis according to FTA (Fault Tree Analysis)
- Software-specific procedures
- Probabilities of technical faults and harm to people
- Practical exercise for risk analysis in small groups
- Risk control
- Risk management in the post-production phase
- Risk management files and the ISO 14971 standard itself
- Linking risk management with other processes (clinical evaluation and cybersecurity risk management)

Learning Objectives

After the seminar you will be able to:

- define comprehensible risk acceptance criteria.
- systematically identify hazards and assess risks.
- define suitable measures for risk control.
- create risk management files and check them for conformity.
- set requirements for post-market surveillance (PMS) and evaluate PMS data.

Target Group

This seminar is designed for people who will (in the future) take on one or more of the following roles:

- Risk Manager
- Quality and Regulatory Affairs Manager
- Product Manager and Product Owner
- Employee in medical device development (software, electronics, mechanics)
- Person responsible for the production
- Employee of notified bodies and authorities
- Person Responsible for Regulatory Compliance (in accordance with Article 15 of the MDR or IVDR)

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	Regulatory framework in Europe with embedding of risk management
10:00 am - 10:30 am	Definitions according to ISO 14971
15 min break	
10:45 am - 11:30 am	Joint exercises on definitions of terms
60 min lunch break	
01:30 pm - 03:00 pm	Practical exercise on risk policy in small groups
15 min break	
03:15 pm - 04:00 pm	Risk analysis according to PHA (Preliminary Hazard Analysis)
04:00 pm - 04:30 pm	Risk analysis according to FMEA (Failure Mode and Effect Analysis)
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	Risk analysis according to FTA (Fault Tree Analysis)
10:00 am - 10:30 am	Software-specific procedures
15 min break	
10:45 am - 11:30 am	Probabilities of technical faults and harm to people
11:30 am - 12:30 pm	Practical exercise for risk analysis in small groups
60 min lunch break	
01:30 pm - 02:15 pm	Risk control
02:15 pm - 03:00 pm	Risk management in the post-production phase
15 min break	
03:15 pm - 04:00 pm	Risk management files and the ISO 14971 standard itself
04:00 pm - 04:30 pm	Linking risk management with other processes (clinical evaluation and cybersecurity risk management)
04:30 pm - 05:00 pm	Proof of effectiveness of the training (final examination) 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

Previous participants particularly appreciated that the seminar successfully combined theory and practice, enabling them to apply their new knowledge competently. The following points reflect the feedback and appreciation:

- **Interactive exchange** promotes learning and knowledge sharing.
- **Direct answers** to questions deepen understanding.
- **Practical examples and exercises** make complex content tangible.
- **A friendly atmosphere** creates a pleasant learning environment.
- **The trainer's personal experience** enriches the course.
- **Structured content** leads to efficient learning.
- **Active participation** by everyone ensures dynamic discussions.
- **Regular breaks** increase concentration and receptivity.
- **Helpful information** provides a solid introduction to risk management.

„An incomparable experience - the seminar not only gave me knowledge but also opened up new perspectives. Absolutely recommendable!“

„The seminar was very informative and also very interactive. Many good examples and well-prepared exercise materials really contributed to a better understanding. I learned a lot and had fun. It was great! Thank you very much!“

„The trainer‘s professional qualifications and practical experience are important and clearly visible. The training was not purely theoretical.“

„You get a good overview of the requirements of ISO 14971. Mr. Rosenzweig is a very nice trainer who has a pleasant manner and a lot of specialist knowledge. He was also able to answer all questions relating to risk management for medical devices in detail and gave us very helpful tips for implementation in our companies.“

„The seminar was excellently structured and covered all relevant aspects of risk management and ISO 14971 in a way that was both thorough and easy to understand. Although the topic can be complex, the issues were explained in a clear and practical way, and the reference to the MDR was also well illustrated.“