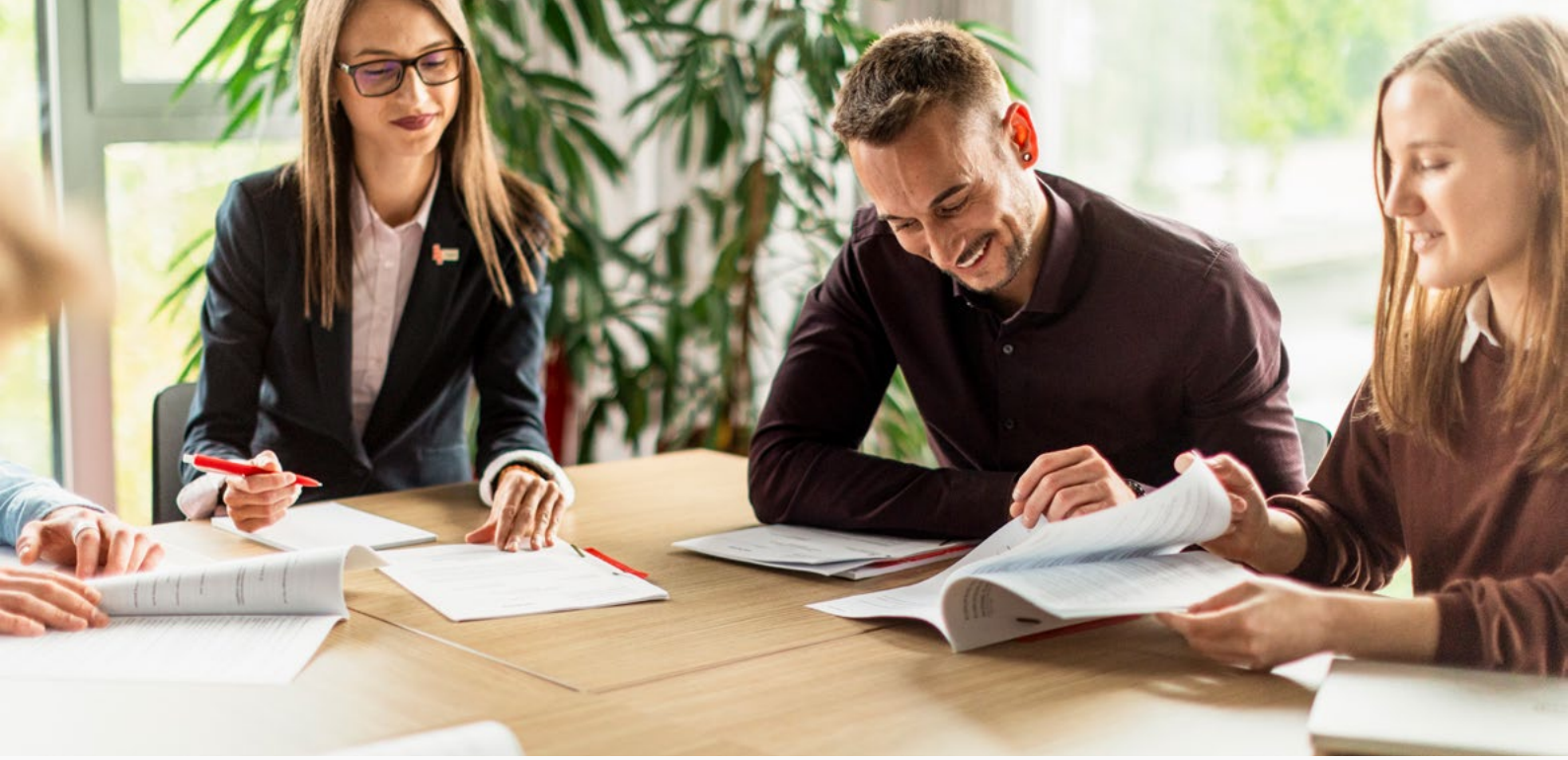

Johner Institute

SEMINAR AI ACT FOR MEDICAL DEVICE AND IVD MANUFACTURERS

AI Act meets MDR/IVDR: Implementing regulatory requirements in a legally compliant and efficient manner

This intensive seminar provides you with the necessary know-how to apply the AI Act (not only) for your medical and IVD medical devices in a legally compliant manner and to integrate it efficiently into your existing regulatory processes (MDR/IVDR) – from classification to practical implementation.

What Characterizes the Seminar

- Learn directly from the most renowned expert in the medical technology industry and author of the AI Act Starter Kit and AI Act e-learning course.
- The seminar clearly outlines when the AI Act applies to your devices and how it interacts with MDR/IVDR. You will learn how to meet the requirements of all EU regulations simultaneously, avoid redundant documentation, and achieve regulatory safety through lean, maintainable documentation.
- During the seminar, you will conduct a gap analysis yourself and work directly with the AI guideline of the notified bodies. As a result, you will not only know the theory but will also have developed concrete solutions for your company and be optimally prepared for upcoming audits.
- The seminar provides you with concrete tools for project planning and implementation. You will then know precisely what resources you need and how to budget your implementation project. The certificate also documents your AI competence in accordance with the requirements of the AI Act.

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

In this seminar, you will learn how to develop and operate your AI-based medical and IVD medical devices as well as other systems in compliance with the law:

- **Determine the scope of application:** Check whether your devices and systems fall under the AI Act
- **Basics and classification:** Correctly classify AI systems according to risk classes
- **Manufacturer requirements:** Know and fulfill additional requirements for technical documentation and QMS for MDR/IVDR
- **Risk management:** Identify and control AI-specific risks, including fundamental rights risks
- **Operator responsibility:** Operate AI systems such as medical devices and tools such as ChatGPT in a legally compliant manner in a corporate context
- **Practical implementation:** Supplement standard operating procedures and work instructions and perform gap analyses
- **Time planning:** Plan projects and implementation, taking into account transition periods
- **Team qualification:** Determine competence requirements and training needs

Learning Objectives

By attending the seminar, participants will achieve the following objectives:

- They can decide whether their medical or IVD medical devices fall under the AI Act (qualification). If so, they can determine the risk class for their devices (classification). Participants can work with the „Commission Guideline“ on qualifying AI systems in this context.
- They are familiar with other typical areas of application for AI in their companies and can assess their use from a regulatory perspective, for example, which legal requirements they fall under (e.g., AI Act, MDR, ISO 13485, ISO 14971), and can carry out qualification and classification for them.
- The participants are familiar with the structure of the AI Act, know its classifications, and can navigate the legislation confidently and identify relevant requirements. For example, they can assess when the requirements for „GPAI“ and for the special AI systems in accordance with Article 50 must be considered.
- As a result, they are familiar with the different requirements of the AI Act for manufacturers and operators of AI systems that must be considered in the various life cycle phases (research, development, conformity assessment, sale, and post-market surveillance).
- They can identify where and how the requirements of the AI Act go beyond the requirements for medical and IVD medical devices, where they complement each other, and where they contradict each other.
- They know which specification documents, such as standard operating procedures, templates, and checklists, they need to create or adapt and how much effort this will require.
- They can perform gap analyses and identify non-conformities, in particular gaps and inconsistencies in their technical documentation and their QM system, and apply the guidelines of the notified bodies.
- They can expand the risk management file to include fundamental rights risks.

Target Group

This seminar is designed for employees of medical device and IVD manufacturers who develop AI-based devices or use AI in their company, for example in development or other regulatory-relevant processes.

These individuals are typically employed in the following areas:

- Regulatory Affairs
- Development, including Data Science
- Risk and Quality Management
- Product Management, Clinical Affairs, and Post-Market Surveillance
- IT
- Legal & Compliance

Requirements for Participation

You will benefit most from this seminar if you meet the following requirements:

- Knowledge of MDR and IVDR
- Basic understanding of risk management according to ISO 14971
- Knowledge of AI is optional
- Knowledge of the AI Act is optional

Schedule (Agenda)

TIME	CONTENT
09:00 am - 09:30 am	• Introduction • Definitions • AI-specific risks in medical and IVD medical devices
09:30 am - 10:00 am	• The regulatory framework • Structure and scope of the AI Act • Risk classification
10:00 am - 10:45 am	Exercise: Qualification and classification in accordance with the AI Act
35 min break	
11:20 am - 12:00 pm	The AI Act's requirements for manufacturers: • Technical documentation • QM system • Risk management • Development • Post-market surveillance
60 min lunch break	
01:00 pm - 02:30 pm	Implementation of these requirements: • Standard operating procedures and work instructions • Templates and checklists Exercise: Gap analysis with the AI guideline
20 min break	
02:50 pm - 03:15 pm	The AI Act's requirements for (manufacturers as) operators: • Classification of AI-based systems such as ChatGPT & Co. • Use of AI, e.g., in complaint handling • Customer communication
03:15 pm - 03:45 pm	The strategy map for implementation: • Project plan (effort, duration, roles to be involved, work packages) • Roadmap for qualification, budgeting
03:45 pm - 04:00 pm	Closing: Summary, Q&A, feedback

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

Trainer

Prof. Dr. Christian Johner

Prof. Dr. Christian Johner is the owner of the Johner Institute and an expert in the development and approval of medical devices that contain or are software. As an auditor, member of a standards committee, trainer for notified bodies, and author of several books and guidelines, he contributes to the further development of the regulatory landscape. His work includes guidelines developed for the WHO and notified bodies. He is also one of the most important contacts for the medical technology industry on AI. He has already created the AI Act Starter Kit and the AI Act E-Learning Course. Christian Johner has taught at several universities, including the University of Applied Sciences in Konstanz, the University of St. Gallen, the University of Würzburg, and Stanford University, where he focused primarily on software architecture, software quality assurance, and medical informatics.