Johner Institute

# PRACTICAL WORKSHOP AI POWER FOR MEDICAL DEVICE DEVELOPMENT

## Faster to market with LLMs: From skeptic to accelerator in just one day

Learn in just one day how to use large language models (LLMs) specifically in developing medical devices – from the initial idea to post-market surveillance.

This practical workshop with product expert Mario Klessascheck and regulatory and AI expert Prof. Johner will teach you specific methods for drastically reducing your development time while remaining MDR-compliant.

## What Characterizes the Workshop

- Practical relevance and easy understanding thanks to consistent example
- Consideration of the entire life cycle and the respective benefits
- Specificity for medical device manufacturers
- Practical skills through hands-on exercises
- Tips for transforming your own company into an “AI-first company”

## Learning Content

The workshop covers the following topics:

- AI models
  - Types of generative AI models
  - Tools, providers
  - How they work “in a nutshell”
- Working with LLMs
  - Customization options: prompting, RAG, fine-tuning
  - Adapting model parameters
  - Optimizing prompts
- Application of LLMs in product development
  - Generating product ideas
  - Identifying customer requirements
  - Identifying, checking, and supplementing product requirements
  - Identification of hazards, risk analysis
  - Design and review of a system architecture
  - Software development (vibe coding)
  - Deriving software, component, integration, and system tests
- AI technologies
  - Agents and agentic workflows
  - MCP
  - Company-owned AI
- Regulatory requirements for the use of AI in product development
- The path to an AI strategy map and an AI-first company

## Learning Objectives

By attending the workshop, participants will achieve the following objectives

- Be able to assess which activities in the development process or product life cycle LLMs can help with and in what way
- Know the prerequisites (e.g., competencies) and limitations of AI
- Be able to write effective prompts
- Decide when to use prompts, system prompts, custom GPTs, RAG, and fine-tuning
- Assess your AI maturity level, identify gaps and areas for action, and name the characteristics of an AI-first company
- Know how to operate AI securely (IP protection)
- Be able to demonstrate to a notified body/authority that AI is being used in accordance with the law

## Target Group

This workshop is designed for employees of medical and IVD medical device manufacturers who are responsible for the development of devices.

These include, for example:

- Development Managers
- Developers
- Product Managers
- Managing Directors, Board Members, Division Managers, CEOs

## Requirements for Participation

Participants should have basic AI skills and a general understanding of medical device development processes and the product life cycle.

Ideally, participants will already have experience working with technologies and be open to integrating new, innovative AI-based solutions into their everyday work.

## Schedule (Agenda)

| TIME | CONTENT |
|---|---|
| 09:00 am - 09:20 am | • Introduction<br>• Context: Regulation, technology (general and AI), competition |
| 09:20 am - 09:30 am | Product life cycle and associated artifacts |
| 09:30 am - 10:20 am | • Overview of generative models<br>• Use of generative models (e.g., prompt techniques, RAG, parameterization, fine-tuning) |
| 20 min break | |
| 10:40 am - 12:00 pm | Application of LLMs in the product life cycle (guided exercise) (part 1)<br>• Generation of product ideas<br>• Identification of customer requirements<br>• Identification, verification, and supplementation of product requirements<br>• Identification of hazards, risk analysis<br>• Design and review of system architectures<br>• Software development<br>• Derivation of test cases<br>• Document generation and review |
| 60 min lunch break | |
| 01:00 pm - 02:00 pm | • Application of LLMs in the product life cycle (guided exercise) (part 2)<br>• Applying LLMs in your own company |
| 02:00 pm - 02:30 pm | • AI technologies, agents and agentic workflows, MCP<br>• Operation of a company-owned AI |
| 20 min break | |
| 02:50 pm - 03:20 pm | Regulatory requirements for the use of AI in QM processes |
| 03:20 pm - 03:50 pm | The path to an AI strategy map and an AI-first company |
| 03:50 pm - 04:00 pm | Closing: Summary, Q&A, feedback |

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

# Trainers

## 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.

## Mario Klessascheck

Mario Klessascheck is an electrical engineer (TU) with over 25 years of experience as an embedded developer for active medical devices. As CEO of Johner Institut Schweiz GmbH, he supports companies in the development and approval of safe, standard-compliant medical devices. He is an author, member of standards committees, lecturer, and trainer, and is valued for his comprehensive expertise and practical consultancy in the medical technology industry. Another focus of his work is integrating artificial intelligence into the development processes of medical systems. His expertise includes medical systems engineering and functional safety.