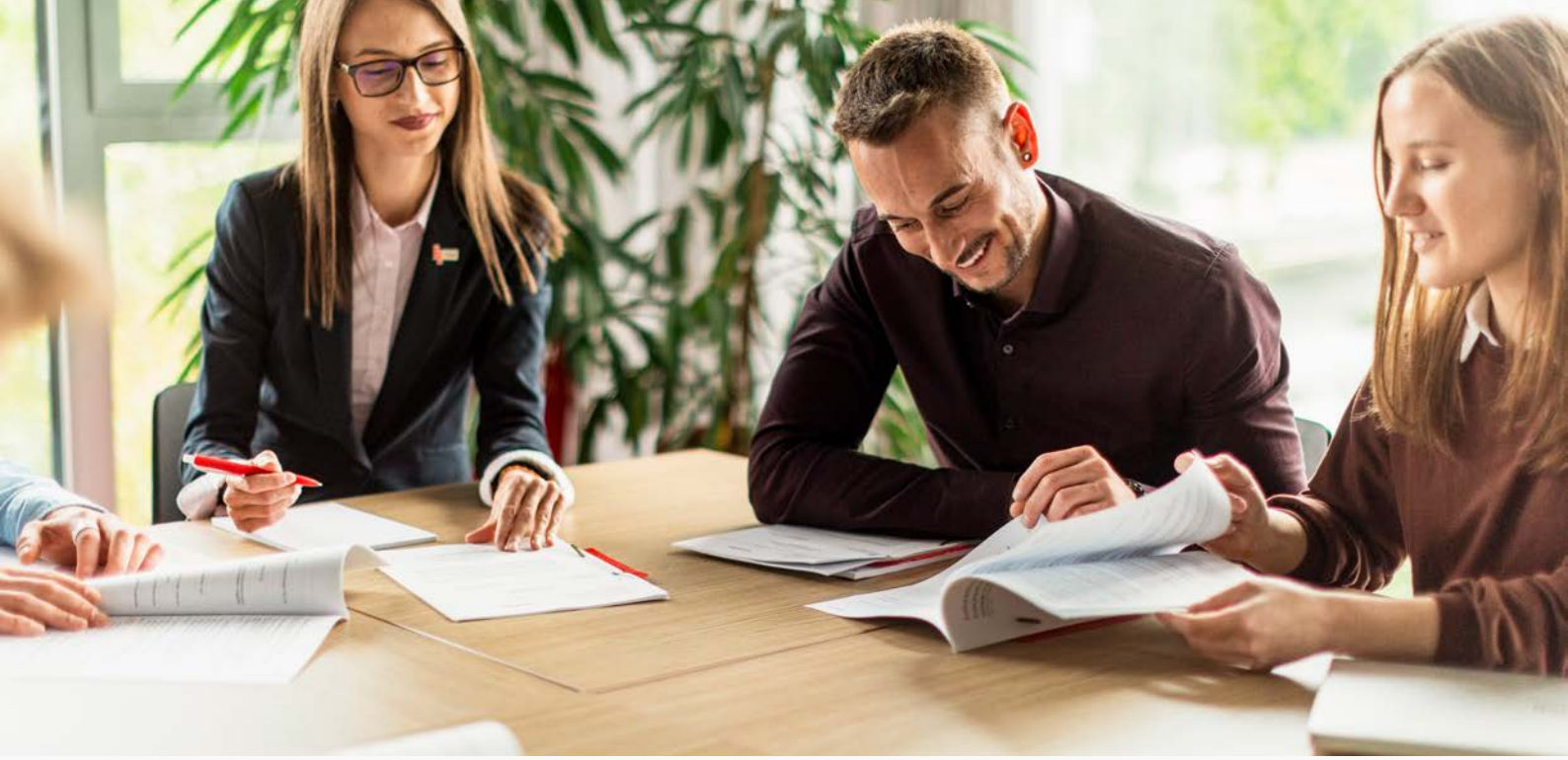


Johner Institute

SEMINAR FDA'S QUALITY MANAGEMENT SYSTEM REGULATION

Learn about the new regulation in detail to optimally prepare your quality management system

This seminar will help you to understand the FDA's new requirements for your quality management system (QMS). You will learn what changes there are with regard to harmonization with ISO 13485:2016 and how to implement them in your company successfully.

What characterizes the seminar

This seminar will provide you with a pragmatic approach for implementing the QMSR requirements in your company on time.

During the seminar, you will always have the opportunity to ask questions.

Through exercises and discussions, we can tailor the content to address company-specific scenarios according to your requirements.

Learning Content

- Historic background
- Scope of the QMSR
- Overview of the structure of the QMSR
- Understanding and implementing contents and requirements of the QMSR
- Differences between the QSR and QMSR

Learning Objectives

After the seminar, you will know:

- the scope of the QMSR.
- the contents of the QMSR (Note: Since ISO 13485 makes up a large part of the QMSR, the discussion of the standard requirements takes up the main part of the time).
- the transition period.
- strategies for interpreting and implementing the contents of the QMSR.
- the differences between QMSR (Quality Management System Regulation) and QSR (Quality System Regulation).

Target Group

This seminar is designed for people who have/will take on one or more of the following roles:

- Quality Managers
- Management Representatives (“QMR”)
- Regulatory Affairs Managers
- Others, e.g., Top Management of small companies

Requirements for participation

The seminar is aimed at people with little or no knowledge of ISO 13485. Therefore, participants can easily follow this seminar without any special previous knowledge.

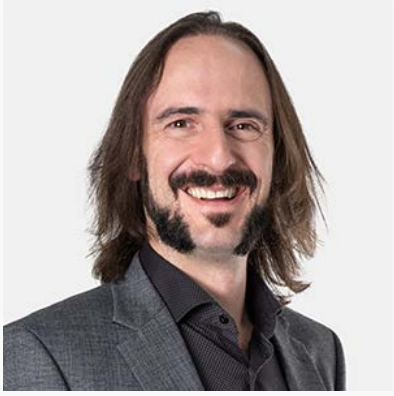
Schedule (Agenda)

TIME	CONTENT
9:00 am – 09:30 am	Introduction and expectations
9:30 am – 09:45 am	Historic background
9:45 am – 10:00 am	Scope
10:00 am – 10:30 am	Overview of the structure
10:30 am – 12:00 pm	Understand and implement content and requirements of the QMSR
60 min lunch break	
01:00 pm – 04:15 pm	Understand and implement content and requirements of the QMSR
04:15 pm – 04:30 pm	Differences between the QSR and QMSR
04:30 pm – 05:00 pm	Questions and feedback

Short breaks in between as needed

You can find more information and the registration option **HERE**

Trainer



Andreas Kalchschmid-Lehmann

M.Sc. Stem Cells and Regeneration

Andreas Kalchschmid-Lehmann is an expert in in-vitro diagnostic medical devices with more than 17 years of practical experience in molecular diagnostics. He is the author of the German book “ISO 13485 - Opportunity instead of a Hurdle” and has extensive experience in other QM systems, including ISO 17025, ISO 15189, and MDSAP. As a laboratory manager, he gained detailed knowledge of processes in a routine diagnostic laboratory. As a former quality manager, he knows how to successfully set up and maintain a QMS for IVDs. He also worked as a product specialist and lead auditor at a major notified body, where he evaluated technical documentation for IVDs and QM systems.

Claudia Volk

M.Sc. Agricultural and Food Economics (focus on QM)

Claudia Volk has several years of experience as a quality and regulatory affairs manager in regulated environments, initially in food production and later as a management representative and PRRC for manufacturers of in-vitro diagnostic medical devices. In this role, she has set up, developed, and audited QM systems and implemented digital QM tools. At the Johner Institute, she supports our customers in setting up and developing their QM systems and training their employees.