

Certified ISO 13485 Lead Auditor Course

Learning content

- Learning and interpreting the requirements of EN ISO 1348
- Definition of the relevant terms in EN ISO 19011:2018
- Described audit principles in EN ISO 19011:2018
- Formal requirements for audits and audit programs, including audit types, criteria, objectives and roles
- Phases of conducting an audit in accordance with EN ISO 19011:2018
- Formalities for opening and closing audits
- Content of an audit plan and audit report
- Concept of conformity and non-conformity
- Optimal creation of audit plans
- Planning and preparation of individual audit sessions
- Benefit from company-specific data when planning individual audit sessions
- Conducting opening and closing meetings
- Collection of evidence of (non-)compliance
- Methods of interviewing, observing, and evaluating documentation
- Efficient and professional communication with the auditee

Information on the schedule

The course takes place **daily from 09:00 am to 05:00 pm** in the specified period.

There will be a one-hour lunch break every day and short breaks in between as required.

The individual contents are taught in a flexible and situation-specific manner. Therefore, no standardized schedule can be provided here.

The **examination** takes place **on the last day** of the course.

You can find more information and the registration option [here](#)