



Quality Audits according to ISO 19011

REF. MQ05 - INTRA/INTER

QUALITY SYSTEM

COURSE DESCRIPTION

This course will allow you to acquire practical knowledge to prepare, conduct and document an internal audit or supplier audit based on the principles set out in ISO 19011:2018.

DURATION

1 day/7 hours



IN-PERSON



VIRTUAL CLASSROOM

OBJECTIVES

- Become familiar with audit principles
- Learn techniques on how to communicate with audited entities
- Draft an audit plan
- Know how to draw up observations and the audit report

TARGET TRAINEES

- Medical Device manufacturers
- Quality Managers
- Auditors

PREREQUISITES

- Familiarity with the requirements applicable to quality management systems (ISO 9001, ISO 13485)

TRAINING RESOURCES

- PowerPoint presentation handed out at the end of training
- Examples tailored to the company's products
- ISO 19011
- Quizzes

COURSE CONTENT

Participants welcomed and presented/Course objectives/ Presentation of the course content

1. Requirements of the Quality Management System standards (ISO 9001, ISO 13485): a review
2. ISO 19011:2018
 - a. Scope - terms and definitions
 - b. Organize the audit - collect information
 - c. Prepare the audit plan and audit
 - d. Conduct the audit: initial meeting and collection of information; communication with the audited entities
 - e. Draw up audit observations
 - f. Lead the audit closure meeting - communicate the results and audit conclusions
 - g. Draw up the audit report
3. Summary/Q&A
4. Course evaluation and conclusion

EVALUATION METHODS

Course evaluation quiz
Satisfaction survey
Attendance certificate

This training is assessed based on an evaluation of each individual's acquisition of knowledge via quizzes during and at the end of the program (*success criteria* $\geq 75\%$).



Do you have a question? Contact us!

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