

Lausanne, 5.11.2024

Course name: ISO 13485 Quality Magement System - EN ISO 13485:2016 /
A11:2021 QMS Architecture and Content

Date (DD.MM.YYYY): 5-7.11.2024

Instructor: Dr Lydie Moreau

Topics:

- Introduction to ISO 13485:2016: why implementing a QMS, QMS goals and benefits, the certification process
- Implementation Phases of the standard
- Visit of the architecture of a QMS
- Deep dive into the requirements of key processes (such as Management Responsibilities, Resource Management, Design and Development, Manufacturing, CAPA, etc), during dedicated sections
- Review of concrete examples of key QMS documents (quality manual, key standard operating procedures...)

Training Format:

- Presentation with interactive discussions
- Exercises during the training
- End of training assessment (participants will receive a training certificate)
