

Understanding ISO13485 requirements

GOALS

- Understanding and implementing the requirements for successful ISO 13485 certification.

PROGRAMME

- Regulatory and normative context of medical devices
- Structure of ISO 13485
- Vocabulary
- Quality management system - Chapter 4
- Management responsibility - Chapter 5
- Resource management - Chapter 6
- Product realisation - Chapter 7
- Measurement, analysis and improvement - Chapter 8
- Methodology for implementing a QMS

PREREQUISITES

- None

PUBLIC CONCERNED

- Any professional involved in the planning, implementation or maintenance of the ISO 13485 QMS.

Please contact us for any enquiries regarding facilities and access for disabilities people.

DURATION

2 jours (14 heures)

PRICES

INTER training: 1 550,00 € HT/participant (minimum of 3 participants)

INTRA training: please contact us

TERMS AND CONDITIONS OF ACCESS

INTER: registration is open until two weeks before the training date.

INTRA: training can be provided one month after acceptance of the quote (as a guide).

METHODS EMPLOYED

The training course combines theory, games, examples and/or practical case studies.

Trainees must bring a laptop computer. A file is given to participants at the end of the session
(containing the theoretical principles covered during the training course and exercise materials).

ASSESSMENT METHODS

Trainees' knowledge acquisition is generally validated by a quiz.

It may also be assessed using other methods *(at the discretion of the trainer and/or in agreement with the Client).*

At the end of the training course, a certificate is issued based on the results of the assessments.

