

Internal Auditor ISO 13485:2016



Code: AUI
Type: Workshop
Time: 16 Hours

Objective:

- By attending this course, participants will be able to plan, execute and report internal quality audits in accordance with the ISO 19011 standard to assess conformity of the quality system with ISO 13485: 2016 and international regulations.

Audience:

- Quality managers, engineers and technicians
- Lead auditors, internal auditors, supplier auditors
- People responsible for internal and supplier audit programs
- People who require to have knowledge of ISO 13485:2016 standard

Contents:

- Definitions and key terms
- Requirements of ISO 13485:2016 standard
- ISO 19011:2018 standard
- Audit initiation
- Audit preparation
- Audit conduction
- Nonconformity writing
- Audit report
- Audit closing
- Audit follow up

Mode:

- Face-to-face or virtual

Methodology:

- The course is a combination of keynote presentations, individual and group exercises and application examples

Equipment and materials

- Computer with MS Office, MS Teams and Internet for virtual mode
- Copy of ISO 13485:2016 standard



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