



NewGrange

TRAINING & SERVICES LTD

Better People, Better Business®



ISO 13485 Internal Auditor

A one day in-house training course which provides an insight into the requirements of a ISO 13485 medical device management system for device manufacturers.

- Course Location:** On-Site at your premises
- Course Duration:** One Full Day, 9.30am - 4.30pm (date to suit you)
- No. of Delegates:** 10 delegates max

Who should attend?

Senior Managers, Quality Managers, Regulatory Affairs Managers, Internal Auditors, anyone involved with the management/implementation of the standard.

Course Prerequisites?

There are no prerequisites for this course, but delegates will benefit from a basic working knowledge of the quality management system ISO 9001:2015 or ISO 13485:2016

Course Content:

This course includes the following (and will be tailored to your organisation):

- ISO 13485 auditing terminology
- Implementation tasks
- Reviewing the management system - continual improvement
- Interpreting the requirements of the ISO 13485 standard
- Defining your Medical Devices policy and objectives
- Defining your processes
- Key do's and don'ts's
- The internal audit process
- Audit planning and scheduling

Delegates Receive:

Comprehensive Course Notes, Course Materials & Certificate of Training

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