



# NewGrange

TRAINING & SERVICES LTD

Better People, Better Business®



## ISO 13485 Training/Workshop

**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 9001:2008 or ISO 13485:2003.

### 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

Tel: +44(0) 1562 632143

Fax: +44(0) 1562 632584

email: [info@newgrangetraining.co.uk](mailto:info@newgrangetraining.co.uk)

[www.newgrangetraining.co.uk](http://www.newgrangetraining.co.uk)