

TRAINING COURSES

ISO 13485 Internal Auditors Course



This 2-day course is designed for people who are familiar with ISO 13485 Quality Management Systems but would like to perform internal audits or enhance their audit skills.

It complies with the latest guidance on auditing of QMS management systems (ISO 19011:2018) and uses practical examples to allow delegates to learn the necessary skills.

The course includes:

- An overview of QMS requirements and ISO 13485, including the Plan, Do, Check, Act Cycle and the Process Approach
- Introduction to the audit life cycle
- Audit planning and preparation considerations
- Techniques to make the most of the audit time allocated, when collecting evidence, including sampling and adoption of a risk-based approach
- Audit Interview skills to create a robust audit trail
- Evaluation practise, ensuring findings are objective and made against the audit criteria
- Guidance for writing non-conformity reports that avoid ambiguity and challenges
- Appreciation of the need to follow-up and close out audit findings to improve the QMS

The course comprises of a series of role play, written and verbal activities to reinforce learning objectives.

The course is delivered by our Director of Quality and Regulatory Affairs, Dr Edward Staunton, an IRCA Certified Lead Auditor who has trained numerous internal auditors, notified body auditors and lead auditors.

Personalised feedback is available for evaluation of training effectiveness if requested.

This course is available at your offices/facilities by arrangement.

For further details or to arrange a quote for training contact:

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