

ISO 13485: 2003 Internal Audit Refresher Course

L. Buck Consulting

“our success is measured by our clients’ successes”

ISO 13485: 2003 1-Day Internal Audit Refresher Course

train up to 9 people
at your facility
\$2,900 complete

This **one-day** workshop is designed to sharpen the fundamental audit skills of **experienced Internal Auditors** and to enhance their understanding and application of the requirements of the ISO 13485: 2003 Standards.

Participants will gain an increased knowledge of the ISO13485: 2003 Standards and the practice of systematically applying the requirements of the Standard to various audit situations, determining if there are any nonconformances, and the proper preparation of nonconformance reports.

COURSE CONTENT

- **Quality Vocabulary** - Review of the definitions from ISO 9000:2005, *Quality management systems—Fundamentals and vocabulary*.
- **ISO 13485: 2003** – *Quality management system standard*. Exercises used to review of the requirements of the standard, with a focus on “Objective Evidence” of compliance. **Materials have been updated to include the ISO 13485: 2003 requirements.**
- **Audits-Auditing-Auditors** - Participants will review the various types of audits that are performed and the various stages of an audit, including; information gathering, checklist preparation and use, auditing and reporting.
- **Nonconformance Reports** - Participants will review the proper method of clearly writing nonconformance reports. The use of case studies and exercises will challenge the participants to evaluate a number of audit situations and, based on the ‘facts’ presented determine if there are nonconformances. The exercise will involve both the application of the Standard, and the ability to write clear, concise and factual nonconformances.
- **Follow Up Audits** - Participants will review the audit cycle to ensure that the practice of ‘follow up audits to verify corrective action is understood.

WHO SHOULD ATTEND

Previously trained auditors who wish to enhance their audit skills and become familiar with the ISO 13485:2003 Standards..

The TC 176 committee says “....auditors will need to demonstrate new competence based on the ISO 13485: 2003 Quality management system – Requirements.”

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Offering Quality training through **Batalas Limited** which have international offices in

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