

L. Buck Consulting

ISO 13485: 2003 Medical Device Internal Audit Course

"our success is measured by our client's successes"

This **two-day** workshop provides all the necessary information, skills and methods for auditing quality systems to the requirements of the ISO 13485: 2003 International Standard.

Participants will gain the knowledge and skills required to compare existing systems and documentation with ISO 13485: 2003 requirements and to assist their company plan and perform the periodic audits required by the standard.

ISO 13485: 2003 2-Day Internal Audit Course

COURSE CONTENT

Principles and Concepts of Auditing - Participants will learn a common, ISO 9000: 2000 compatible definition of auditing.

Types of Audits - Participants will learn the different types and levels of audits.

Familiarization - Participants will become familiar with the requirements of the ISO 13485: 2003 Standard.

Preparing the Audit - Participants will learn how to prepare and structure an audit.

Conducting the Audit - Participants will learn interviewing techniques, listening skills and note taking techniques.

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 nonconformance's. The exercise will involve both the application of the Standard, and the ability to write clear, concise and factual nonconformance's.

WHO SHOULD ATTEND

Project Leaders and Team Leaders who must schedule and plan an audit program in compliance with ISO 13485: 2003.

Personnel responsible for performing periodic audits in compliance with ISO 13485: 2003 and/or other quality systems.

up to 9 students
at your facility
\$4,900 complete

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

* USA * UK * Brazil * Belgium * Taiwan * Netherlands * Finland * Hong Kong * Hungary * Turkey * Malaysia