



Course ISO 13485:2004/ISI 19011 Lead Auditor

About ISO 13485 series

ISO 13485:2003 (Medical devices - Quality management systems - Requirements for regulatory purposes) is essentially ISO 9001 adapted to meet the requirements of the medical device industry and it addresses most FDA requirements (21CFR820). The main difference between ISO 9001 and ISO 13485 is that ISO 13485 is more focused towards ensuring medical device safety and efficacy rather than enhancing customer satisfaction and continual improvement. Once you implement processes and procedures that comply with the requirements listed in ISO 13485:2003, you can be audited by a third party organization called Registrar such as TUV or UL who will certify your organization to this standard. It will also meet most of the FDA requirements to have a Quality System in compliance with the QSRs set forth by 21CFR820. To achieve compliance, you can train employees who will drive the implementation internally, and/or use a consulting firm that can assist in the training and implementation. Providing training on the basis of the standard and the FDA's current Good manufacturing Practice (cGMP) for key players (QC personnel, QA personnel, RA personnel, engineering staff, p[roduction personnel) in your organization so that they can understand what it entails, is a good starting point.

Online ISO 13485:2004/ISO 19011 Auditor class

- Can be taken from home or at work through the Internet.
- Have "save and exit" features so that you can do it at your own pace
- After registration, there are no time limits, and you have complete flexibility in taking the course around your schedule.
- Use quizzes and case studies that give very good exposure on various types and classes of medical devices.
- Provides excerpts of the International Standard ANSI/ISO/ASQ Q9001-2000 and uses ANSI/ISO/ASQ ISO 19011 to give guidance on auditing quality systems. Both standards are reprinted with permission of the American Society for Quality and ANSI. All the theoretical aspect of auditing is covered according to the guidelines of RAB (Registrar Accreditation Board). Practical training with trained auditors, such as participation in an audit is necessary before you can audit effectively after taking this class.
- Use a continuous evaluation method with on-going quizzes to facilitate the information retention. If your final average is equal or greater to 70% you will be issued a **training certificate**. If your final average evaluation is

less than 70%, you will have to take a final exam and score above 70% to be issued the training certificate.