



A Guide to Internal Auditing

ISO 13485:2016

Introduction: Why are you here?



- To learn more about ISO 13485:2016
- To be able to evaluate you own area and make improvements.
- To understand the audit process.
- To be able to participate in the audit process.

Performing an Internal Audit

»Techniques

More about audits and auditing techniques

- Auditees must be made comfortable during interviews and there are techniques that are used by auditors to make it easier.
- Experienced auditors learn to read body language and other non-verbal clues.
- The auditor will question the auditee, listen to the answers, and anticipate the answer to the question.
- It is necessary to listen critically, analyze the answer, record the information and at the same time prepare the next question.



Internal Audits: Conclusion



The Internal Audit process is one of the most important in ISO 13485 or any ISO based standard.

Conduct internal audits to determine if the QMS:

- Conforms to planned arrangements for quality management .. this includes both the requirements of the ISO standard and your own operational requirements.
- Has been properly implemented and is maintained.
- Provide information on results of audits to the management group.