



***A Guide to Internal  
Auditing  
ISO 13485***

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## *Introduction: Why are you here?*

- To learn more about ISO 13485
- 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

# *Types of Audits*

**There are three kinds of audits that can be conducted in your organization:**

- 1. *First party audit*** or an **Internal audit** that is the topic of this presentation.
- 2. *Second party audit***, carried out by a customer or a customer's representative, usually to ensure that you comply with contractual requirements.
- 3. *Third party audit***, carried out by a Registrar, usually to certify that your quality management system is in compliance to the ISO 13485 standard.

# *Why Audit?*

**The Internal Audit process is one of the most important Requirements in an ISO-Based standard .**

ISO Standards require that audit procedures be established, implemented, and maintained.

- ISO 9001, Par. 8.2.2
- ISO 13485, Par. 8.2.2
- ISO 14001, Par. 4.5.5
- Etc.

Failure to perform Internal Audits becomes a significant  
**“Road-Block to Registration”.**





# *Performing an Internal Audit*

## **»Overview**

### **Internal Auditor training covers:**

- The purpose and scope for auditing the QMS to the ISO Standard
- The requirements for planning and scheduling internal audits
- The practices followed during the internal audit
  - including opening and closing meetings
- How to develop check lists and questions for the various audits
- How to interview and what to look for when asking questions
- Reporting on the internal audit and follow-up activities.

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# *Performing an Internal Audit*

## *»Techniques*

### **What sort of questions are asked?**

There are two types of audit questioning:

- 1. System audits** where the auditor confirms that the procedures and instructions are understood and implemented.
- 2. Process audits** where the auditor follows processes from the beginning to the end to confirm all requirements and records are in place.