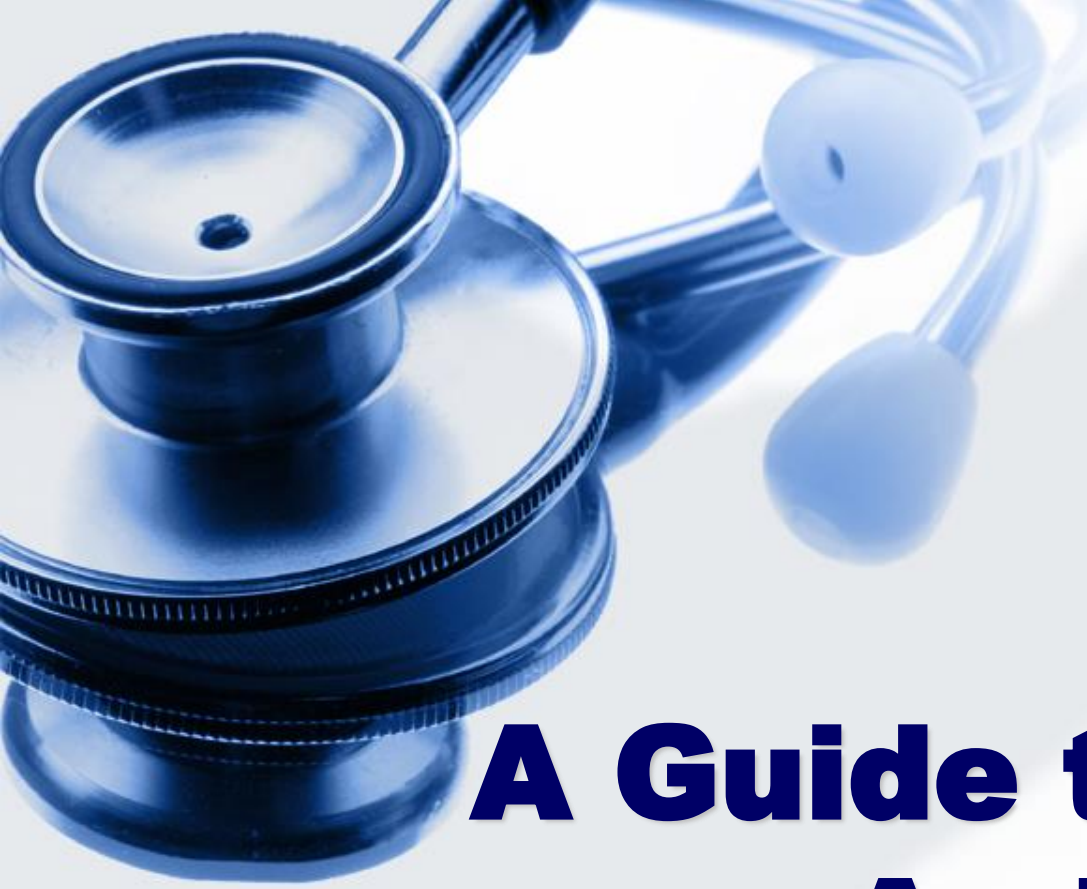

A Guide to Internal Auditing

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.

INSERT YOUR COMPANY NAME HERE

ISO 9001:2015 – with – ISO 13485:2016 - Quality Management Systems - Internal Audit Checklist

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This checklist helps audit a Quality Management System against both ISO 9001:2015 and ISO 13485:2016. The checklist is best used by trained and practicing auditors to evaluate or assess Quality Management Systems requirements. You will see questions on the checklist that refer to the standards and for each clause provisions are made for additional questions.

While the editions of the standards do not line up when comparing the contents and requirements, the ISO 13485:2016 requirements over ISO 9001:2015 are highlighted in yellow and the relevant ISO 13485:2016 clause number appears with the audit question. The auditors are expected to keep in mind that while ISO 13485:2016 requires specific procedures for some QMS processes, the ISO 9001 standard does not require such mandatory procedures; however, the auditors will expect documented information to be available because in the clauses of the standard, the phrase such as 'documented procedures' is used to specify that a process, a method, a system, a work instruction, or an arrangement be documented.

The auditors must use a great deal of discretion and therefore must be careful and thoughtful prior to establishing a deficiency against a requirement. Evidence for visible top management leadership, commitment and quality management action must be looked for.

The **bold** numbers and tittles used in the first two columns of the checklist indicate the "Requirements" and may be referred to on nonconformity reports prepared by the auditor.

During assessment of each requirement, auditors record the status of the evaluation by indicating in the right-hand column a

Yes - for Acceptable Condition or **No -** for Deficient Condition

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	• Available to relevant interested parties?		
	Additional Questions		
5.3	**Organizational roles, responsibilities, and authorities**		
	Does the top management ensure that the responsibilities and authorities for relevant roles are assigned, communicated, and understood within the company?		
	5.5.1 Have you document the interrelation of personnel whose work affect quality?		
	Does top management assign the responsibility and authority for:		
	• Ensuring that the QMS conforms to the requirements of ISO 9001:2015 standard?		
	• Ensuring that the processes are delivering their intended outputs?		
	• Reporting on the performance of the QMS on opportunities for improvement and for reporting to top management?		
	• Ensuring the promotion of customer focus throughout your company?		

	• Ensuring that the integrity of the QMS is maintained when changes to the QMS are planned and implemented?		
	5.5.2 Has top management appointed a management representative with responsibility and authority for:		
	• Ensuring that QMS processes are documented?		
	• Reporting to top management on the performance of the QMS and the need for improvement?		
	• Ensuring the promotion of awareness of regulatory and QMS requirements?		
	• Maintaining the integrity of the QMS when changes are planned and implemented?		
	Additional Questions		
6	**PLANNING**		
6.1	**Actions to address risks and opportunities**		
6.1.1	When planning for the QMS, does your company consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed?		
	5.4.2 a) Does top management ensure the planning is		

	carried out to meet the requirements? 5.4.2 b) Is the integrity of the QMS maintained when changes are planned and implemented		
	Is this performed to:		
	• Give assurance that the QMS can achieve its intended results?		
	• Enhance desirable effects?		
	• Prevent, or reduce undesired effects?		
	• Achieve improvement?		
6.1.2	Does the company plan:		
	• Actions to address these risks and opportunities?		
	• How to integrate, implement the actions into the QMS processes and evaluate their effectiveness?		
	Do you take actions to address risks and opportunities that are proportionate to the potential impact on the conformity of products and services?		
	7.1 Have you document one or more processes for risk management and do you maintain records?		
	Additional Questions		