The ISO 13485:2016 Internal Audit Checklist

This checklist is based on the information provided in the 2016-03-01 release of the ISO 13485:2016 international standard. The checklist is best used by trained and practicing auditors to evaluate or assess Quality Management Systems requirements based on the standard. You will see questions on the checklist that refer to the standard, and for each clause, provisions are made for additional questions.

The auditors are expected to keep in mind that the standard requires six (6) mandatory procedures, such as with clauses 4.2.4, 4.2.5, 8.2.4, 8.3, 8.5.2, and 8.5.3. For other 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

4 QUALITY MANAGEMENT SYSTEM

	REQUIREMENTS	OBSERVATIONS / COMMENTS / DOCUMENTS REVIEWED	RESULT
4.1	**General Requirements**		
4.1.1	Is there a Quality Management System in place that has been established and documented to meet the requirements of the ISO 13485:2016 Standard and the applicable regulatory requirements?		
	Are the role(s) undertaken by your company under the regulatory requirements (*as a manufacturer, a distributor, an authorized representative, or an importer*) documented?		
4.1.2	For the undertaken role(s), are the processes needed for the QMS applied throughout the company?		
	Is a risk-based approach to the control of processes applied?		
	Are the sequence and interaction of the processes determined?		
4.1.3	Is the system maintained and is there evidence that its effectiveness is maintained?		
	• Look for methods and criteria needed to ensure that operation and control of the processes are effective.		
	• Look for the resources and information needed to support the operation and monitoring of the QMS processes.		

	Are records maintained?		
	Additional Questions		
4.2	**Documentation Requirements**		
4.2.1	**General**		
	Does your quality system documentation include the documentation required by ISO 13485:2016?		
	Does it include:		
	• Documented statements of the Quality Policy and Quality Objectives?		
	• A Quality Manual?		
	• Documented procedures (6) required by the standard?		
	• Documents required to ensure the effective planning, operation and control of your processes?		
	• A list or other means of identifying the documentation required by your QMS?		
	• Availability of the required documents?		
	• Records required by the standard?		
	• Other documentation required by national or regional regulations?		

	When the standard specifies that a requirement, a procedure, an activity or arrangement be “documented”, is it implemented and maintained?		
	Additional Questions		
4.2.2	**Quality Manual**		
	Review the Quality Manual (if available).		
	Does the manual include:		
	• The scope of your QMS including the details of and justification for any exclusion and/or non-application in clauses 6, 7 or 8?		
	• The documented procedures (6) established for the QMS, or reference to them?		
	• A description or illustration of the interrelation of the processes of the QMS?		
	Does the Quality Manual outline the structure for the documentation used in the QMS?		
	Additional Questions		
4.2.3	**Medical Device File**		
	Is a medical device file maintained for each medical device type or medical device family?		

	• Determining causes?		
	• Evaluate need and identify action to prevent reoccurrence?		
	• Planning, documenting and implementing action needed, including, if appropriate, updating of the documentation?		
	• Verifying that action taken does not adversely affect the ability to meet regulatory requirements and the safety and performance of the medical device?		
	• Recording of the results of any investigation and of action taken?		
	• Reviewing the corrective action taken and its effectiveness?		
	Additional Questions		
8.5.3	**Preventive Action**		
	Has your company established a procedure to eliminate the cause of potential nonconformities?		
	Does the procedure include items required by the standard for:		
	• Determining potential nonconformities and their causes?		
	• Evaluating the need for action?		