ISO 13485:2016 Master Internal Audit Checklist

Quick links: Process List | Recommendations | Root-cause List | Result List | Errors

Before you begin auditing, review and edit the process name list in Cell C406. This will populate the drop-down menus in Column G and various axes within the audit result charts. Use the drop-down menu in Column H to select one of four audit findings defined by the audit criteria. Column I will automatically display a recommendation based on the audit finding. The response is then automatically represented as an 'x' in either Column J, K, L, or M. These columns are hidden. The indicator in Column N will update according to the perceived level of risk, e.g., minor or major. (Ref. Clause 6.4.8, ISO 19011:2018). Use the drop-down menus in Col O to select an appropriate root-cause. You can change this list by editing the root-cause list in Cell N406. Describe how to correct a nonconformance or adopt an opportunity in Col P. Record audit evidence, such as document numbers and revisions in Col Q.

							Audit Findings & Actions					
Main Clause	**Main Clause Title**	**Sub-clause**	**Sub-clause Title**	**Q-No**	**Requirements/Questions**	**Process Name**	**Audit Result**	**Recommendations**	**Score**	**Possible Root-cause**	**Action Plan**	**Audit Evidence & Notes**
4.1	Quality Management System	4.1.1	General requirements	1	Has your organization documented its quality management system and maintained its effectiveness in accordance with the requirements of ISO 13485:2016 and applicable regulatory requirements?	Management System	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.1	Quality Management System	4.1.1	General requirements	2	Has your organization established, implemented and maintained any requirement, procedure, activity or arrangement required to be documented by ISO 13485:2016 or applicable regulatory requirements?	Management System	Minor NC	Identify and discuss the root-cause within 4 weeks and correct.	75	Process - Procedures or work-instructions were inadequate/non-existent	Review and rewrite WI	
4.1	Quality Management System	4.1.1	General requirements	3	Has your organization documented the role(s) undertaken by the organization under the applicable regulatory requirements?	Management System	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.1	Quality Management System	4.1.2a	General requirements	4	Has your organization determined the processes needed for the quality management system and the application of these processes throughout the organization taking into account the roles undertaken by the organization?	Management System	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.1	Quality Management System	4.1.2b	General requirements	5	Has your organization applied a risk based approach to the control of the appropriate processes needed for the quality management system?	Management System	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.1	Quality Management System	4.1.2c	General requirements	6	Has your organization determined the sequence and interaction of these processes?	Management System	Major NC	Contain the problem immediately. Identify the root-cause within one week and correct.	25	Human - Inadequate management involvement	Reinforce training	
4.1	Quality Management System	4.1.3a	General requirements	7	For each quality management system process, has your organization determined the criteria and methods needed to ensure that both the operation and control of these processes are effective?	Management System	Major NC	Contain the problem immediately. Identify the root-cause within one week and correct.	25	Human - Inadequate management involvement	Reinforce training	
4.1	Quality Management System	4.1.3b	General requirements	8	For each quality management system process, has your organization ensured the availability of resources and information necessary to support the operation and monitoring of these processes?	Management System	Major NC	Contain the problem immediately. Identify the root-cause within one week and correct.	25	Human - Inadequate management involvement	Reinforce training	
4.1	Quality Management System	4.1.3c	General requirements	9	For each quality management system process, has your organization implemented the actions necessary to achieve planned results and maintain the effectiveness of these processes?	Management System	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.1	Quality Management System	4.1.3d	General requirements	10	For each quality management system process, does your organization monitor, measure as appropriate, and analyze these processes?	Management System	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.1	Quality Management System	4.1.3e	General requirements	11	For each quality management system process, has your organization established and maintained the records needed to demonstrate conformance to ISO 13485:2016 and compliance with applicable regulatory requirements (see 4.2.5)?	Management System	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.1	Quality Management System	4.1.4	General requirements	12	Does your organization manage these quality management system processes in accordance with the requirements of ISO 13485:2016 and applicable regulatory requirements?	Management System	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.1	Quality Management System	4.1.4a	General requirements	13	When changes are to be made to these processes, are they evaluated for their impact on the quality management system?	Management System	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.1	Quality Management System	4.1.4b	General requirements	14	When changes are to be made to these processes, are they evaluated for their impact on the medical devices produced under this quality management system?	Management System	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.1	Quality Management System	4.1.4c	General requirements	15	When changes are to be made to these processes, are they controlled in accordance with the requirements of ISO 13845:2016 and applicable regulatory requirements?	Management System	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.1	Quality Management System	4.1.5	General requirements	16	When your organization chooses to outsource any process that affects product conformity to requirements, does it monitor and ensure control over such processes?	Management System	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.1	Quality Management System	4.1.5	General requirements	17	Does your organization retain responsibility of conformity to ISO 13485:2016 and to customer and applicable regulatory requirements for outsourced processes?	Management System	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.1	Quality Management System	4.1.5	General requirements	18	Are the controls applied proportionate to the risk involved and the ability of the external party to meet the requirements in accordance with 7.4?	Management System	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.1	Quality Management System	4.1.5	General requirements	19	Are the controls included in written quality agreements?	Management System	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.1	Quality Management System	4.1.6	General requirements	20	Does your organization document procedures for the validation of the application of computer software used in the quality management system?	Management System	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.1	Quality Management System	4.1.6	General requirements	21	Are software applications that are used in the quality management system validated prior to initial use and, as appropriate, after changes to such software or its application?	Management System	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.1	Quality Management System	4.1.6	General requirements	22	Is the specific approach and activities associated with software validation and revalidation proportionate to the risk associated with the use of the software?	Management System	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.1	Quality Management System	4.1.6	General requirements	23	Does your organization maintain records of such activities (see 4.2.5)?	I.T. & Doc Control	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.2	Documentation Requirements	4.2.1a	General	24	Does your organization's quality management system documentation (see 4.2.4) include documented statements of a quality policy and quality objectives?	Business Planning	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.2	Documentation Requirements	4.2.1b	General	25	Does your organization's quality management system documentation (see 4.2.4) include a quality manual?	Business Planning	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.2	Documentation Requirements	4.2.1c	General	26	Does your organization's quality management system documentation (see 4.2.4) include the documented procedures and records required by ISO 13485:2016?	Business Planning	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.2	Documentation Requirements	4.2.1d	General	27	Does your organization's quality management system documentation (see 4.2.4) include the documents, including records, determined by your organization to be necessary to ensure the effective planning, operation, and control of its processes?	Business Planning	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.2	Documentation Requirements	4.2.1e	General	28	Does your organization's quality management system documentation (see 4.2.4) include other documentation specified by applicable regulatory requirements?	Business Planning	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.2	Documentation Requirements	4.2.2	Quality Manual	29	Has your organization documented a quality manual that includes the scope of the quality management system, including details of and justification for any exclusion or non-application?	Business Planning	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.2	Documentation Requirements	4.2.2a	Quality Manual	30	Has your organization documented a quality manual that includes the documented procedures for the quality management system, or reference to them?	Business Planning	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.2	Documentation Requirements	4.2.2b	Quality Manual	31	Has your organization documented a quality manual that includes a description of the interaction between the processes of the quality management system?	Business Planning	Minor NC	Identify and discuss the root-cause within 4 weeks and correct.	75	Human - Poor employee involvement	Reinforce training	
4.2	Documentation Requirements	4.2.2c	Quality Manual	32	Does the quality manual outline the structure of the documentation used in the quality management system?	Business Planning	Major NC	Contain the problem immediately. Identify the root-cause within one week and correct.	25	Human - Poor employee involvement	Reinforce training	
4.2	Documentation Requirements	4.2.3	Medical Device File	33	For each medical device type or medical device family, does your organization establish and maintain one or more files either containing or referencing documents generated to demonstrate conformity to the requirement of ISO 13845:2016 and compliance with applicable regulatory requirements?	Business Planning	Opportunity	Review and implement actions to deploy the opportunity to improve the process(s).	100	Opportunity for improvement	Job descriptions to be signed off	
4.2	Documentation Requirements	4.2.3a	Medical Device File	34	Does the content of the file(s) include, but is not limited to a general description of the medical device, intended use/purpose, and labelling, including any instructions for use?	Business Planning	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.2	Documentation Requirements	4.2.3b	Medical Device File	35	Does the content of the file(s) include, but is not limited to specifications for the product?	Business Planning	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.2	Documentation Requirements	4.2.3c	Medical Device File	36	Does the content of the file(s) include, but is not limited to specifications or procedures for manufacturing, packaging, storage, handling and distribution?	Business Planning	Opportunity	Review and implement actions to deploy the opportunity to improve the process(s).	100	Opportunity for improvement	Job descriptions to be signed off	
4.2	Documentation Requirements	4.2.3d	Medical Device File	37	Does the content of the file(s) include, but is not limited to procedures for measuring and monitoring?	Business Planning	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			
4.2	Documentation Requirements	4.2.3e	Medical Device File	38	Does the content of the file(s) include, but is not limited to as appropriate, requirements for installation?	Business Planning	Conforms	Continue to monitor trends and indicators to determine ongoing stability.	100			