

ISO 13485 Audit Checklist Sample Report

ISO 13485 Audit Checklist		1. Issues, 10/10/2023
Management Controls		
Quality Manual defines scope of QMS, procedures (or reference to) within QMS, and description of the interaction of processes within QMS? (ISO 13485:2016: 4.1, 4.2.2)	Yes	
Criteria and methods are in place to monitor and control processes for effectiveness? (ISO 13485:2016: 4.1.3(a), 4.2.1(d), 8.4)	Yes	
Firm has established and conducts Management Reviews, at least annually? (ISO 13485:2016: 5.1(d), 5.6)	Yes	
Management reviews examine suitability and effectiveness of quality systems, improvements needed because of customer requirements, and resource needs? (ISO 13485:2016: 4.1.3(c), 5.6.1, 5.6.3, 6.1, 8.4)	Yes	
Management review addresses audit results, customer feedback, process performance, Corrective and Preventive Actions (CAPAs), previous management reviews, changes to QMS, recommendations for improvement, and new or revised regulatory requirements? (ISO 13485:2016: 5.6.2)	Yes	
I think we can improve on this moving forward not that we have utilized our digital audit tool. We previously depended on paper checklists for audits and we just found we missed audits in the past.		
Firm has established a Quality Manual and Quality System Procedures and Instructions that are appropriate? (ISO 13485:2016: 4.1.2(a), 4.2.1(b), (c))	Yes	
Firm has established Quality Plan? (ISO 13485:2016: 4.2.1(d), 5.4)	Yes	
Quality Planning addresses QMS needs and Quality Objectives? (ISO 13485:2016: 5.4.2)	Yes	
Firm has implemented Quality Policy and Quality Objectives? (ISO 13485:2016: 4.2.1(a), 5.1(b), (c), 5.3, 5.4.1)	Yes	
Firm has established Quality Audit procedures and conducts audits? (ISO 13485:2016: 4.2, 8.2.4)	Yes	
Will meet with head auditor to check on the new tool we have.		
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Update on digital audits		
Quality audits examine compliance and effectiveness? (ISO	Yes	

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Christian Drosten

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