

Internal Quality Management System Audit Checklist (ISO 13485:2003/ISO 9001:2000)

Q#	ISO 9001:2000 and/or ISO 13485:2003 Clause Text	Sample Audit Question	Evidence
4 Quality management system			
4.1 General requirements			
4.1a	The organization shall establish, document, implement and maintain a quality management system and maintain (continually improve) its effectiveness in accordance with the requirements of this International Standard.	Has Organization established, documented, implemented and maintained a QMS and maintained (continually improved) its effectiveness in accordance with ISO 9001/13485? (Questions in section 4.1 are verified throughout the audit)	
4.1a1	The organization shall a) identify the processes needed for the quality management system and their application throughout the organization (see 1.2).	Where has Organization identified the processes needed for the QMS and their application throughout the organization? (See 4.2.2)	
4.1a2	The organization shall b) determine the sequence and interaction of these processes.	Where has Organization determined the sequence and interaction of QMS processes? (See 4.2.2)	
4.1a3	The organization shall c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective.	What are the criteria and methods Organization uses to ensure that the operation and control of QMS processes are effective?	
4.1a4	The organization shall d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes.	Has Organization provided resources and information needed to support the operation and monitoring of QMS processes? (See section 6)	
4.1a5	The organization shall e) monitor, measure and analyze these processes, and	How does Organization monitor, measure and analyze QMS processes? (See section 8)	
4.1a6	The organization shall f) implement actions necessary to achieve planned results and maintain the effectiveness (continual improvement) of these processes.	How has Organization implemented actions necessary to achieve planned results and maintain the effectiveness (continual improvement) of processes needed for the QMS?	
4.1a7	These processes shall be managed by the organization in accordance with the requirements of this International Standard.	Are processes needed for the QMS managed by the organization in accordance with the requirements of ISO 9001:2000?	
4.1a8	Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes.	When Organization outsources any process that affects product conformity with requirements, how is control ensured over such processes? (See 7.4)	
4.1a9	Control of such outsourced processes shall be identified within the quality management system (see 8.5.1).	Where is the control of outsourced processes that affect product conformity with requirements identified within the QMS? (See 7.4)	
NOTE: Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.			

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Lei Shi



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