Q#	ISO 9001:2000 and/or ISO 13485:2003 Clause Text	Sample Audit Question	Evidence
	4 Quality management system		
	4.1 General requirements		
4.1q1	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)	
4.1q2a	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)	
4.1q2b	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)	
4.1q2c	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?	
4.1q2d	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)	
4.1q2e	The organization shall e) monitor, measure and analyse these processes, and	How does Organization monitor, measure and analyze QMS processes? (See section 8)	
4.1q2f	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?	
4.1q3	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?	
4.1q4	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)	
4.1q5	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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