Udo Consultancy

kwaliteitsmanagement als basis voor duurzame verbeteringen

IMPLEMENTATION CHECKLIST

ISO 13485:2003

Quality Management Systems – Requirements for regulatory purposes

Company	Auditor	Date of Review

ISO13485	Paragraph & check point(s)	Objective evidence
4	***Quality Management System***	
4.1	***General requirements***	
1.1	*How does the organization,*	
a)	*identify the processes needed for the QMS (see section 7:Customer related processes, Design and development, Purchasing, Production and service provision);*	
b)	*determine the sequence and interaction of these processes (e.g. by use of algorithms, flow charts, process mappings, descriptions);*	
c)	*determine criteria and methods required to ensure the operation and control of these processes are effective;*	
d)	*ensure the availability of resources and information necessary to support the operation and monitoring of these processes;*	
e)	*measure, monitor and analyze these processes;*	
f)	*implement action necessary to achieve planned results and maintain the effectiveness of these processes;*	
1.2	*How does the organization can maintain the effectiveness of its established QMS (i.e. internal audits, management review, corrective and preventive actions, and independent external assessments).*	
1.3	*What evidence is available that outsourced processes that affect product conformity with requirements are controlled by the organization (see section 8.5.1)?*	

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	9.3	*What evidence is available those quality objectives are communicated (6.2.2) to relevant personnel, and are deployed through internal communications (5.5.3)?*	
5.4.2		***Quality Management System planning***	
	10.1	*How does top management ensure that the planning of the QMS meets the requirements of clause 4.1 (i.e. quality manual and supporting documentation, gap analyses, action plans and their results)?*	
	10.2	*How does the organization plan their QMS to meet its quality objectives?*	
	10.3	*How does the organizations planning process ensure that the integrity of the QMS is maintained during time of change (e.g. restructuring, acquisitions, outsourcing, product and process development, introduction of a new technology, etc)?*	
5.5		***Responsibility, authority and communication***	
5.5.1		***Responsibility and authority***	
	11.1	How does the quality manual, the supporting procedures or other documentation (e.g. job descriptions) clearly define the personnel, their responsibilities, and their limits of authority?	
	11.2	Interview personnel at appropriate levels in the organization to ensure that responsibilities and authorities are communicated and understood.	
	11.3	How has top management ensure the independence and authority necessary for personnel who manage, perform and verify work affecting quality?	
5.5.2		***Management representative***	
	12.1	*Which member of management has been appointed as the quality management representative?*	
	12.2	*Verify that the management representative has defined responsibility and authority that includes,*	
		a) ensuring that processes needed for the QMS are established, implemented and maintained;	
		b) reporting on the performance of the QMS to top management, including needs for improvement;	
		c) ensuring the promotion of awareness of regulatory and customer requirements throughout the organization;	

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6.3	***Infrastructure***	
	20.1 How does the organization identify, provide and maintain,	
	a) buildings, workspace and associated utilities (storage areas, handling facilities, laboratory, test buildings, office space);	
	b) process equipment (both hardware and software, planned maintenance, cleaning systems);	
	c) supporting services (such as transport or communication, emergency services, back-up facilities, disaster recovery plans);	
	to achieve the conformity to product requirements?	
	20.2 Verify that documented procedures are available for the maintenance, cleaning and checking of all equipment used in production, and for the control of the work environment.	
	20.3 Verify that the necessary adjustments and maintenance intervals are established.	
	20.4 Verify that the documented requirements for maintenance activities include a frequency.	
6.4	***Work environment***	
	21.1 How does the organization determine the needs for the work environment to achieve conformity to product requirements?	
	21.2 Verify that requirements for health, cleanliness and clothing of personnel in contact with the product are lived up.	
	21.3 Verify that, where applicable, the organization has identified critical work environment requirements (temperature, humidity, light, noise, air cleanliness, electrostatic discharges, work garments, hygiene and contamination control).	
	21.4 Verify that personnel who are required to work temporarily under special environmental conditions are appropriately trained or supervised by a trained person.	
	21.5 Verify that special arrangements are established for the control of (potential) contaminated product to prevent contamination of other product, the work environment or personnel.	
	21.6 Does the environment appear safe? Is it clean, given the processes being undertaken?	
	21.7 What evidence is available that the organization pays attention to the requirements of this element?	
	21.8 What type of approaches does the organization use to gain team involvement for issues like safety, housekeeping, awards and recognition?	

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	27.9 Verify that the content of labels complies with regulatory requirements, general standards and medical device standards.	
	27.10 Verify how label translations are checked if the medical device is to be supplied to countries with different languages, and the language to be used on the labels has been specified.	
7.3.3	***Design and development outputs***	
	28.1 Verify that outputs of the design are documented in a manner that enables verification against the design inputs.	
	*28.2 What is the evidence that design output documents are approved prior to release?*	
	28.3 Verify that design and development output,	
	a) meet the design input requirements;	
	b) provide appropriate information for purchasing, production and for service provision;	
	c) contain or reference product acceptance criteria;	
	d) specify the characteristics of the product that are essential to its safe and proper use;	
	28.4 What is the evidence that records of design outputs are maintained?	
7.3.4	***Design and development review***	
	29.1 What is the evidence that design reviews are conducted, at suitable stages, in accordance with planned arrangements to,	
	a) evaluate the ability of the results of design to meet requirements;	
	b) identify problems and propose necessary actions;	
	29.2 Verify that design reviews include representatives of functions concerned with the design stage being reviewed.	
	*29.3 What is the evidence that records of design reviews and subsequent follow-up actions are maintained?*	
7.3.5	***Design and development verification***	
	30.1 What evidence is available that design verification is performed to ensure that design output meets design input requirements?	
	*30.2 What is the evidence that records of design verification and subsequent follow-up actions are maintained?*	

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	54.19	*Verify that positive recall procedures are adopted where product is released prior to completion of in-process inspection.*	
8.2.4.2		***Particular requirement for active implantable medical devices and implantable medical devices***	
	55.1	Verify that inspection and test records shows the identity of personnel performing any inspection or testing.	
8.3		***Control of nonconforming product***	
	56.1	*Verify that the procedure defines the controls and related responsibilities and authorities for dealing with nonconforming product;*	
	56.2	*How does the organization ensure that product which does not conform to requirements is identified and controlled to prevent unintended use or delivery?*	
	56.3	How does the organization ensure that nonconforming product is only accepted by concession if regulatory requirements are met?	
	56.4	Verify that the controls and related responsibilities and authorities for dealing with nonconforming product are defined.	
	56.5	Verify that records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, are maintained.	
	56.6	Verify that records identify the person(s) authorizing the concessions.	
	56.7	*Verify that corrected product is subject to re-verification to demonstrate conformity to requirements.*	
	56.8	How does the organization ensure appropriate action regarding the consequences of the nonconformity when nonconforming product is detected after delivery or use has started?	
	56.9	Verify prior to authorization and approval of the (re)work instruction, a determination of any adverse effect of the rework upon product was made and documented (see 4.2.3 and 7.5.1).	
	56.10	*Is product held until required inspection and tests have been completed or necessary reports received and verified?*	
	56.11	*How is nonconforming product (clearly) defined?*	
	56.12	*Verify that the type of identification used for nonconforming product is conspicuous and suitable?*	
	56.13	*Where are repair, rework or concessions on nonconforming material and parts recorded?*	