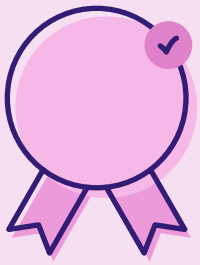
Qualio



ISO 13485 compliance checklist

© Qualio — QMS for Life Sciences

ISO 13485 lays out the broad quality requirements for the modern medical device quality management system. Use this checklist to ensure compliance with the particular and unique areas of the standard: Clauses 4 to 8.

4. Quality management system

Item number	Requirement	Complete?
4.1	**General requirements**	
	Does the organization ensure the control of any outsourced processes, which affect product conformity with requirements and is the control of such outsourced processes identifiable within the QM system?	☐
	Does the organization document a quality management system and maintain its effectiveness in accordance with the requirements of this international standard and applicable regulatory requirements?	☐
	Does the organization establish, implement and maintain any requirement, procedure, activity or arrangement required to be documented by this international standard or applicable regulatory requirements?	☐
	Does the organization document the role(s) undertaken by the organization under the applicable regulatory requirements?	☐
	Does the organization...	
	a) determine 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?	☐
	b) apply a risk-based approach to the control of the appropriate processes needed for the quality management system?	☐
	c) determine the sequence and interaction of these processes?	☐
	Does the organization...	☐
	a) determine criteria and methods needed to ensure that both the operation and control of these processes are effective...	☐
	b) ensure the availability of resources and information necessary to support the operation and monitoring of these processes...	☐

c) implement actions necessary to achieve planned results and maintain the effectiveness of these processes...	☐
d) monitor, measure as appropriate, and analyze these processes...	☐
e) establish and maintain records needed to demonstrate conformance to this international standard and compliance with applicable regulatory requirements for each quality management system process?	☐
The organization manages these quality management system processes in accordance with the requirements of this international standard and applicable regulatory requirements. Are the following changes to these processes:	
a) evaluated for their impact on the quality management system?	☐
b) evaluated for their impact on the medical devices produced under this quality management system?	☐
c) controlled in accordance with the requirements of this international standard and applicable regulatory requirements?	☐
Does the organization monitor and ensure control to any outsourced processes that affects product conformity to requirements?	☐
Does the organization retain responsibility of conformity to this international Standard and to customer and applicable regulatory requirements for outsourced processes?	☐
Are the controls proportionate to the risk involved and the ability of the external party to meet the requirements in accordance with 7.4?	☐
Do the controls include written quality agreements?	☐
Does the organization document procedures for the validation of the application of computer software used in the quality management system?	☐
Are such software applications validated prior to initial use and, as appropriate, after changes to such software or its application?	☐
Are the specific approach and activities associated with software validation and revalidation proportionate to the risk associated with the use of the software?	☐
Are records of such activities maintained (see 4.2.5)?	☐

4.2	**Documentation requirements**	
4.2.1	**General**	
	Does the quality management system documentation (see 4.2.4) include:	
	a) documented statements of a quality policy and quality objectives?	☐
	b) a quality manual?	☐
	c) documented procedures and records required by this international standard?	☐
	d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation, and control of its processes?	☐
	e) other documentation specified by applicable regulatory requirements?	☐
	Are files available, containing all products specifications and quality assurance specifications, or is the location of those documents described exactly?	☐
	Is this information available and comprehensible for each type or each model of the medical device?	☐
4.2.2	**Quality manual**	
	Does the organization document a quality manual that includes:	
	a) the scope of the quality management system, including details of and justification for any exclusion or non-application?	☐
	b) the documented procedures for the quality management system, or reference to them?	☐
	c) a description of the interaction between the processes of the quality management system?	☐
	Does the quality manual outline the structure of the documentation used in the quality management system?	☐
4.2.3	**Medical device file**	
	Does the organization establish and maintain for each medical device type or medical device family, one or more files either containing or referencing documents generated to demonstrate conformity to the requirement of this international standard and compliance with applicable regulatory requirements?	☐

	Does the content of the file(s) include (but is not limited to):	
	a) general description of the medical device, intended use/purpose, and labeling, including any instructions for use?	☐
	b) specifications for product?	☐
	c) specifications or procedures for manufacturing, packaging, storage, handling and distribution?	☐
	d) procedures for measuring and monitoring?	☐
	e) as appropriate, requirements for installation?	☐
	f) as appropriate, procedures for servicing?	☐
4.2.4	**Control of documents**	
	Are documents controlled required by the quality management system?	☐
	Records are a special type of document. Are they controlled according to the requirements given in 4.2.5?	☐
	Does a documented procedure define the controls needed to:	
	a) review and approve documents for adequacy prior to issue?	☐
	b) review, update as necessary and re-approve documents?	☐
	c) ensure that the current revision status of and changes to documents are identified?	☐
	d) ensure that relevant versions of applicable documents are available at points of use?	☐
	e) ensure that documents remain legible and readily identifiable?	☐
	f) ensure that documents of external origin, determined by the organization to be necessary for the planning and operation of the quality management system, are identified and their distribution controlled?	☐
	g) prevent deterioration or loss of documents?	☐
	h) prevent the unintended use of obsolete documents and apply suitable identification to them?	☐
4.2.5	**Control of records**	
	Are records maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system?	☐
	Does the organization documents procedures to define the controls needed for the identification, storage, security and integrity, retrieval, retention time and disposition of records?	☐

	Does the organization define and implement methods for protecting confidential health information contained in records in accordance with the applicable regulatory requirements?	☐
	Do records remain legible, readily identifiable and retrievable? Do changes to a record remain identifiable?	☐
	Does the organization retain the records for at least the lifetime of the medical device as defined by the organization, or as specified by applicable regulatory requirements, but not less than two years from the medical device release by the organization?	☐
	Does the manufacturer keep the records for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last product has been manufactured?	☐

5. Management responsibility

Item number	Requirement	Complete?
5.1	**Management commitment**	
	Does top management provides evidence of its commitment to the development and implementation of the quality management system and maintenance of its effectiveness by:	
	a) communicating to the organization the importance of meeting customer as well as applicable regulatory requirements?	☐
	b) establishing the quality policy?	☐
	c) ensuring that quality objectives are established?	☐
	d) conducting management reviews?	☐
	e) ensuring the availability of resources?	☐
5.2	**Customer focus**	
	Does top management ensure that customer requirements and applicable regulatory requirements are determined and met?	☐
5.3	**Quality policy**	
	Does top management ensure that the quality policy:	

	a) is applicable to the purpose of the organization?	☐
	b) includes a commitment to comply with requirements and to maintain the effectiveness of the quality management system?	☐
	c) provides a framework for establishing and reviewing quality objectives?	☐
	d) is communicated and understood within the organization?	☐
	e) is reviewed for continuing suitability?	☐
5.4	**Planning**	
5.4.1	**Quality objectives**	
	Are quality objectives (preferably measurable) established at relevant functions and levels within the organization? Are the quality objectives measurable and consistent with the quality policy?	☐
	Are there objectives needed to meet the requirements for products?	☐
	Does top management ensures that quality objectives, including those needed to meet applicable regulatory requirements and requirements for product, are established at relevant functions and levels within the organization?	☐
	Does the quality manual outline the structure of the documentation used in the quality management system?	☐
	Are the quality objectives measurable and consistent with the quality policy?	☐
5.4.2	**Quality management system planning**	
	Does top management ensure that:	
	a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives?	☐
	b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented?	☐
5.5	**Responsibility, authority & communication**	
5.5.1	**Responsibility & authority**	
	Does the top management ensures that the responsibilities and authorities are defined, communicated and documented within the organization?	☐

	Is the necessary independence and authority to perform these tasks ensured and is particular attention paid to the nomination of specific persons responsible for activities related to product monitoring from the post-production stage and reporting adverse events?	☐
	Does top management document the interrelation of all personnel who manage, perform and verify work affecting quality and ensures the independence and authority necessary to perform these tasks?	☐
	Are documents controlled required by the quality management system?	☐
5.5.2	**Management representative**	
	Has the top management appointed a member of the organization's management, who irrespective of other responsibilities, has responsibility and authority that includes...	☐
	a) ensuring that processes needed for the quality management system are documented?	☐
	b) reporting to top management on the effectiveness of the quality management system and any need for improvement?	☐
	c) ensuring the promotion of awareness of applicable regulatory requirements and quality management system requirements throughout the organization?	☐
5.5.3	**Internal communication**	
	Does top management ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system?	☐
5.6	**Management review**	
5.6.1	**General**	
	Does the organization document procedures for management review? Top management reviews the organization's quality management system at documented planned intervals to ensure its continuing suitability, adequacy and effectiveness?	☐
	Does the review include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives?	☐

	Are records from management reviews maintained (see 4.2.5)?	☐
5.6.2	**Review input**	
	Does the input to management review include, but is not limited to, information arising from:	
	a) feedback?	☐
	b) complaint handling?	☐
	c) reporting to regulatory authorities?	☐
	d) audits?	☐
	e) monitoring and measurement of processes?	☐
	f) monitoring and measurement of product?	☐
	g) corrective action?	☐
	h) preventive action?	☐
	i) follow-up actions from previous management reviews?	☐
	j) changes that could affect the quality management system?	☐
	k) recommendations for improvement?	☐
	l) applicable new or revised regulatory requirements?	☐
5.6.3	**Review output**	
	Does the output from management review be recorded (see 4.2.5) and include the input reviewed and any decisions and actions related to:	
	a) improvement needed to maintain the suitability, adequacy, and effectiveness of the quality management system and its processes?	☐
	b) improvement of product related to customer requirements?	☐
	c) resource needs?	☐
	d) changes needed to respond to applicable new or revised regulatory requirements?	☐

6. Resource management

Item number	Requirement	Complete?
6.1	**Provision of resources**	
	Does the organization determine and provide the resources needed to:	
	Implement the quality management system and to maintain its effectiveness?	☐

	Meet applicable regulatory and customer requirements?	☐
6.2	**Human resources**	
	Are personnel performing work affecting product quality competent on the basis of appropriate education, training, skills and experience?	☐
	Does the organization document the process(es) for establishing competence, providing needed training, and ensuring awareness of personnel?	☐
	Does the organization:	
	a) determine the necessary competence for personnel performing work affecting product quality?	☐
	b) provide training or take other actions to achieve or maintain the necessary competence?	☐
	c) evaluate the effectiveness of the actions taken?	☐
	d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives?	☐
	e) maintain appropriate records of education, training, skills and experience (see 4.2.5)?	☐
6.3	**Infrastructure**	
	Does the organization document the requirements for the infrastructure needed to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product?	☐
	Infrastructure includes, as appropriate:	
	a) buildings, workspace and associated utilities;	☐
	b) process equipment (both hardware and software);	☐
	c) supporting services (such as transport, communication, or information systems)	☐
	Does the organization document requirements for the maintenance activities, including the interval of performing the maintenance activities, when such maintenance activities, or lack thereof, can affect product quality?	☐
	Do, as appropriate, the requirements apply to equipment used in production, the control of the work environment and monitoring and measurement?	☐

	Are records of such maintenance maintained (see 4.2.5)?	☐
6.4	**Work environment and contamination control**	
6.4.1	**Work environment**	
	Does the organization document the requirements for the work environment needed to achieve conformity to product requirements?	☐
	If the conditions for the work environment can have an adverse effect on product quality, does the organization document the requirements for the work environment and the procedures to monitor and control the work environment?	☐
	Does the organization:	
	a) document requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could affect medical device safety or performance?	☐
	b) ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are competent or supervised by a competent person?	☐
6.4.2	**Contamination control**	
	Does, as appropriate, the organization plan and document arrangements for the control of contaminated or potentially contaminated product in order to prevent contamination of the work environment, personnel, or product?	☐
	Does the organization, for sterile medical devices, document requirements for control of contamination with micro-organisms or particulate matter and maintain the required cleanliness during assembly or packaging processes?	☐

7. Product realization

Item number	Requirement	Complete?
7.1	**Planning of product realization**	
	Does the organization plan and develop the processes needed for product realization? Is the planning of product realization consistent with the requirements of the other processes of the QM system?	☐
	Does the organization document one or more processes for risk management in product realization?	☐
	Are records of risk management activities maintained (see 4.2.5)?	☐
	Does the organization determine the following, as appropriate, in planning product realization...	
	Quality objectives and requirements for the product?	☐
	Required verification, validation, monitoring, measurement, inspection and test activities storage, distribution and traceability specific to the product together with the and the criteria for product acceptance?	☐
	Records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.5)?	☐
	Is the output of this planning in a suitable form for the organization's method of operations documented?	☐
	Has the organization established the documented requirements for risk management throughout product realization?	☐
	Are records arising from risk management including the results getting maintained? (See for example EN ISO 14971)	☐
7.2	**Customer-related processes**	
7.2.1	**Determination of requirements related to the product**	
	Does the organization determine...	
	Requirements specified by the customer, including the requirements for delivery and post-delivery activities?	☐

	Requirements not stated by the customer but necessary for specified or intended use, where known?	☐
	Applicable regulatory requirements related to the product?	☐
	Any user training needed to ensure specified performance and safe use of the medical device?	☐
	Any additional requirements determined by the organization?	☐
7.2.2	**Review of requirements related to the product**	
	Does the organization review the requirements related to the product? Is this review conducted prior to the organization's commitment to supply a product to the customer (for example: Submission of tenders, acceptance of contracts or orders, acceptance of a contract or orders, acceptance of changes to contracts or orders)	☐
	Does this review ensure that...	
	a) product requirements are defined and the organization has the ability to meet the defined requirements?	☐
	b) contract or order requirements differing from those previously expressed are resolved?	☐
	c) applicable regulatory requirements are met?	☐
	d) any user training identified in accordance with 7.2.1 is available or planned to be available?	☐
	e) the organization has the ability to meet the defined requirements?	☐
	Are the records of the results of the review and actions arising from the review maintained and stored (see 4.2.5)?	☐
	Does the organization confirm the customer requirements before acceptance, where the customer provides no documented statement of requirement?	☐
	Does the organization ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements?	☐
7.2.3	**Communication**	
	Does the organization plan and document arrangements for communicating with customers in relation to:	

	a) product information? b) enquiries, contracts or order handling, including amendments? c) customer feedback, including complaints? d) advisory notices?	☐ ☐ ☐ ☐
	Does the organization communicate with regulatory authorities in accordance with applicable regulatory requirements?	☐
7.3	**Design and development**	
7.3.1	**General**	
	Does the organization document procedures for design and development?	☐
7.3.2	**Design and development planning**	
	Does the organization plan and control the design and development of product?	☐
	As appropriate, are design and development planning documents maintained and updated as the design and development progresses?	☐
	During design and development planning, does the organization document:	
	a) the design and development stages? b) the review(s) needed at each design and development stage? c) the verification, validation, and design transfer activities that are appropriate at each design and development stage? d) the responsibilities and authorities for design and development? e) the methods to ensure traceability of design and development outputs to design and development inputs? f) the resources needed, including necessary competence of personnel?	☐ ☐ ☐ ☐ ☐ ☐
7.3.3	**Design and development inputs**	
	Are inputs related to product requirements determined and records maintained (see 4.2.5)?	☐
	Do these inputs include ...	
	Functional, performance usability and safety requirements according to the intended use?	☐

	Applicable statutory and regulatory requirements, as well as the results from the risk management and standards?	☐
	Where applicable, information derived from previous similar designs and other requirements essential for design and development?	☐
	Applicable output(s) of risk management?	☐
	As appropriate, information derived from previous similar designs?	☐
	Other requirements essential for design and development of the product and processes?	☐
	Are these inputs reviewed for adequacy and approved?	☐
	Are these requirements complete, unambiguous, able to be verified or validated and not in conflict with each other?	☐
	Is the requirement related to the management of the interfaces between different groups involved in design and development eliminated?	☐
7.3.4	**Design and development outputs**	
	Are the outputs of the design and development in a form suitable for verification against the design and development input and are approved prior to release?	☐
	Do design and development outputs...	
	a) meet the input requirements for design and development? b) contain or reference product acceptance criteria? c) provide appropriate information for purchasing, production and service provision? d) specify the characteristics of the product that are essential for its safe and proper use?	☐ ☐ ☐ ☐
	Are records of the design and development outputs maintained (see 4.2.5)?	☐
7.3.5	**Design and development review**	
	At suitable stages, are systematic reviews of design and development performed in accordance with planned and documented arrangements to:	

	a) evaluate the ability of the results of design and development to meet requirements? b) identify and propose necessary actions?	☐ ☐
	Do participants in such reviews include representatives of functions concerned with the design and development stage being reviewed, as well as other specialist personnel?	☐
	Are Records of the results of the reviews and any necessary actions maintained and include the identification of the design under review, the participants involved and the date of the review (see 4.2.5)?	☐
7.3.6	**Design and development verification**	
	Are design and development verification performed in accordance with planned and documented arrangements to ensure that the design and development outputs have met the design and development input requirements?	☐
	Does the organization document verification plans that include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size?	☐
	If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), does verification include confirmation that the design outputs meet design inputs when so connected or interfaced?	☐
	Are records of the results and conclusions of the verification and necessary actions maintained (see 4.2.4 and 4.2.5)?	☐
7.3.7	**Design and development validation**	
	Are design and development validation performed in accordance with planned and documented arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use?	☐
	Does the organization document validation plans that include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size?	☐
	Are design validation conducted on representative product? Representative product includes initial production units, batches or their equivalents.	☐

	Is the rationale for the choice of product used for validation recorded (see 4.2.5)?	☐
	As part of design and development validation, does the organization perform clinical evaluations or performance evaluations of the medical device in accordance with applicable regulatory requirements? A medical device used for clinical evaluation or performance evaluation is not considered to be released for use to the customer.	☐
	If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), does validation include confirmation that the requirements for the specified application or intended use have been met when so connected or interfaced?	☐
	Are validation completed prior to release for use of the product to the customer?	☐
	Are records of the results and conclusion of validation and necessary actions maintained (see 4.2.4 and 4.2.5)?	☐
7.3.8	**Design and development transfer**	
	Does the organization document procedures for transfer of design and development outputs to manufacturing?	☐
	Are these procedures ensure that design and development outputs are verified as suitable for manufacturing before becoming final production specifications and that production capability can meet product requirements?	☐
	Are results and conclusions of the transfer recorded (see 4.2.5)?	☐
7.3.9	**Control of design and development changes**	
	Does the organization document procedures to control design and development changes?	☐
	Does the organization determine the significance of the change to function, performance, usability, safety and applicable regulatory requirements for the medical device and its intended use?	☐
	Are design and development changes identified and records maintained and reviewed, verified and validated, as appropriate? Are design and development changes approved before implementation?	☐

	Does the review of design and development changes include evaluation of the effect of the changes on constituent parts and product in process or already delivered or outputs of risk management and product realization processes?	☐
	Are records of the results of the review of changes and any necessary actions maintained? (see 4.2.5).	☐
	Which procedures guarantees that the DQS is informed when substantial modifications are done to the products?	☐
7.3.10	**Design and development files**	
	Does the organization maintain a design and development file for each medical device type or medical device family?	☐
	Does this file include or reference records generated to demonstrate conformity to the requirements for design and development and records for design and development changes?	☐
7.4	**Purchasing**	
7.4.1	**Purchasing process**	
	Does the organization document procedures (see 4.2.4) to ensure that purchased product conforms to specified purchasing information?	☐
	Does the organization establish criteria for the evaluation and selection of suppliers? Are the criteria:	
	a) based on the supplier's ability to provide product that meets the organization's requirements?	☐
	b) based on the performance of the supplier?	☐
	c) based on the effect of the purchased product on the quality of the medical device	☐
	d) proportionate to the risk associated with the medical device?	☐
	Does the organization plan the monitoring and re-evaluation of suppliers?	☐
	Is supplier performance in meeting requirements for the purchased product monitored?	☐
	Does the results of the monitoring provide an input into the supplier re-evaluation process?	☐

	Are non-fulfillment of purchasing requirements addressed with the supplier proportionate to the risk associated with the purchased product and compliance with applicable regulatory requirements?	☐
	Are records of the results of evaluation, selection, monitoring and re evaluation of supplier capability or performance and any necessary actions arising from these activities maintained (see 4.2.5)?	☐
7.4.2	**Purchasing information**	
	Does the purchasing information describe the product to be purchased?	☐
	Does the information include, where appropriate ...	
	a) product specifications?	☐
	b) requirements for (approval of) product acceptance, procedures, processes and equipment?	☐
	c) requirements for qualification of personnel? d) quality management system requirements?	☐
	Is the adequacy of specified purchase requirements ensured, prior to their communication to the supplier?	☐
	Does purchasing information include, as applicable, a written agreement that the supplier notify the organization of changes in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified purchase requirements?	☐
	To the extent required for traceability given in 7.5.9, does the organization maintain relevant purchasing information in the form of documents (see 4.2.4) and records (see 4.2.5)?	☐
7.4.3	**Verification of purchased product**	
	Does the organization establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements?	☐
	Is the extent of verification activities based on the supplier evaluation results and proportionate to the risks associated with the purchased product?	☐
	When the organization becomes aware of any changes to the purchased product, does the organization determine whether these changes affect the product realization process or the medical device?	☐

	Where the organization or its customer intends to perform verification at the supplier's premises: are the intended verification activities (arrangements) and method of product release stated in the purchasing information?	☐
	Are records of the verification maintained (see 4.2.5)?	☐
7.5	**Production and service provision**	
7.5.1	**Control of production and service provision**	
	Are production and service provision planned, carried out, monitored and controlled to ensure that product conforms to specification?	☐
	As appropriate, does production controls include but are not limited to:	
	a) documentation of procedures and methods for the control of production (see 4.2.4)?	☐
	b) qualification of infrastructure?	☐
	c) implementation of monitoring and measurement of process parameters and product characteristics?	☐
	d) availability and use of monitoring and measuring equipment?	☐
	e) implementation of defined operations for labeling and packaging?	☐
	f) implementation of product release, delivery and post-delivery activities?	☐
	Does the organization establish and maintain a record (see 4.2.5) for each medical device or batch of medical devices that provides traceability to the extent specified in 7.5.9 and identifies the amount manufactured and amount approved for distribution?	☐
	Is the record verified and approved?	☐
7.5.2	**Cleanliness of product**	
	Does the organization document requirements for cleanliness of product or contamination control of product if:	
	a) product is cleaned by the organization prior to sterilization or its use?	☐
	b) product is supplied nonsterile and is to be subjected to a cleaning process prior to sterilization or its use?	☐
	c) product cannot be cleaned prior to sterilization or its use, and its cleanliness is of significance in use?	☐
	d) product is supplied to be used nonsterile, and its cleanliness is of significance in use?	☐

	e) process agents are to be removed from product during manufacture?	☐
	Was the product cleaned in accordance with a) or b) above? (The requirements contained in 6.4.1 do not apply prior to the cleaning process)	☐
7.5.3	**Installation activities**	
	Does the organization document requirements for medical device installation and acceptance criteria for verification of installation, as appropriate?	☐
	If the agreed customer requirements allow installation of the medical device to be performed by an external party other than the organization or its supplier, does the organization provide documented requirements for medical device installation and verification of installation?	☐
	Are records of medical device installation and verification of installation performed by the organization or its supplier maintained (see 4.2.5)?	☐
7.5.4	**Servicing activities**	
	If servicing of the medical device is a specified requirement, does the organization document servicing procedures, reference materials, and reference measurements, as necessary, for performing servicing activities and verifying that product requirements are met?	☐
	Does the organization analyses records of servicing activities carried out by the organization or its supplier:	
	a) to determine if the information is to be handled as a complaint? b) as appropriate, for input to the improvement process?	☐ ☐
	Are records of servicing activities carried out by the organization or its supplier maintained (see 4.2.5)?	☐
7.5.5	**Particular requirements for sterile medical devices**	
	Does the organization maintain records of the sterilization process parameters used for each sterilization batch (see 4.2.5)?	☐
	Are sterilization records traceable to each production batch of medical devices?	☐
7.5.6	**Validation of processes for production and service provision**	

	Does the organization validate any processes for production and service provision where the resulting output cannot be or is not verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered?	☐
	Does validation demonstrate the ability of these processes to achieve planned results consistently?	☐
	Does the organization document procedures for validation of processes, including:	
	a) defined criteria for review and approval of the processes?	☐
	b) equipment qualification and qualification of personnel?	☐
	c) use of specific methods, procedures and acceptance criteria?	☐
	d) as appropriate, statistical techniques with rationale for sample sizes?	☐
	e) requirements for records (see 4.2.5)?	☐
	f) re-validation, including criteria for re-validation?	☐
	g) approval of changes to the processes?	☐
	Does the organization document procedures for the validation of the application of computer software used in production and service provision?	☐
	Are such software applications validated prior to initial use and, as appropriate, after changes to such software or its application?	☐
	Are the specific approach and activities associated with software validation and revalidation proportionate to the risk associated with the use of the software, including the effect on the ability of the product to conform to specifications?	☐
	Are records of the results and conclusion of validation and necessary actions from the validation maintained (see 4.2.4 and 4.2.5)?	☐
7.5.7	**Particular requirements for validation of processes for sterilization and sterile barrier systems**	
	Does the organization document procedures (see 4.2.4) for the validation of processes for sterilization and sterile barrier systems?	☐
	Are processes for sterilization and sterile barrier systems validated prior to implementation and following product or process changes, as appropriate?	☐
	Are records of the results and, conclusion of validation and necessary actions from the validation maintained (see 4.2.4 and 4.2.5)?	☐

7.5.8	**Identification**	
	Does the organization document procedures for product identification and identify product by suitable means throughout product realization?	☐
	Does the organization identify product status with respect to monitoring and measurement requirements throughout product realization?	☐
	Is identification of product status maintained throughout production, storage, installation and servicing of product to ensure that only product that has passed the required inspections and tests or released under an authorized concession is dispatched, used or installed?	☐
	If required by applicable regulatory requirements, does the organization document a system to assign unique device identification to the medical device?	☐
	Does the organization document procedures to ensure that medical devices returned to the organization are identified and distinguished from conforming products?	☐
7.5.9	**Traceability**	
7.5.9.1	**General**	
	Does the organization document procedures for traceability?	☐
	Do these procedures define the extent of traceability in accordance with applicable regulatory requirements and the records to be maintained (see 4.2.5)?	☐
7.5.9.2	**Particular requirements for implantable medical devices**	
	Do the records required for traceability include records of components, materials, and conditions for the work environment used, if these could cause the medical device not to satisfy its specified safety and performance requirements?	☐
	Does the organization require that suppliers of distribution services or distributors maintain records of the distribution of medical devices to allow traceability and that these records are available for inspection?	☐
	Are records of the name and address of the shipping package consignee maintained (see 4.2.5)?	☐

7.5.10	**Customer property**	
	Does the organization identify, verify, protect, and safeguard customer property provided for use or incorporation into the product while it is under the organization's control or being used by the organization?	☐
	If any customer property is lost, damaged or otherwise found to be unsuitable for use, does the organization report this to the customer and maintain records (see 4.2.5)?	☐
7.5.11	**Preservation of product**	
	Does the organization document procedures for preserving the conformity of product to requirements during processing, storage, handling, and distribution?	☐
	Does preservation apply to the constituent parts of a medical device?	☐
	Does the organization protect product from alteration, contamination or damage when exposed to expected conditions and hazards during processing, storage, handling, and distribution by:	
	a) designing and constructing suitable packaging and shipping containers? b) documenting requirements for special conditions needed if packaging alone cannot provide preservation?	☐ ☐
	If special conditions are required, are they controlled and recorded (see 4.2.5)?	☐
7.6	**Control and monitoring of measuring equipment**	
	Does the organization determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements?	☐
	Does the organization document procedures to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements?	☐
	Is the measuring equipment necessary to ensure valid results...	
	Be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards?	☐

Is the basis used for calibration or verification recorded, where no such standards exist?	☐
Be safeguarded from adjustments that would invalidate the measurement result?	☐
Be protected from damage and deterioration during handling, maintenance and storage?	☐
Does the organization perform calibration or verification in accordance with documented procedures?	☐
Is the validity of previous measuring results assessed and recorded, when the measuring equipment is found not to conform to requirements? Does the organization take appropriate action on the measuring equipment and any product affected?	☐
Are records of the results of calibration and verification maintained (see 4.2.5)?	☐
Does the organization document procedures for the validation of the application of computer software used for the monitoring and measurement of requirements?	☐
Are such software applications validated prior to initial use and, as appropriate, after changes to such software or its application?	☐
Are the specific approach and activities associated with software validation and revalidation proportionate to the risk associated with the use of the software, including the effect on the ability of the product to conform to specifications?	☐
Are records of the results and conclusion of validation and necessary actions from the validation maintained (see 4.2.4 and 4.2.5)?	☐

8. Measurement, analysis and improvement

Item number	Requirement	Complete?
8.1	**General**	
	Does the organization plan and implement the monitoring, measurement, analysis and improvement processes needed to...	☐
	Demonstrate conformity of the product?	☐
	Ensure conformity of the QMS and to maintain the effectiveness of the QMS?	☐
	Continually improve the effectiveness of the QMS?	☐
	Does this include determination of applicable methods, including statistical techniques, and the extent of their use?	☐
8.2	**Monitoring and measurement**	
8.2.1	**Feedback**	
	As one of the measurements of the effectiveness of the quality management system, does the organization gather and monitor information relating to whether the organization has met customer requirements?	☐
	Are the methods for obtaining and using this information documented? Does the organization document procedures for the feedback process?	☐
	Does this feedback process include provisions to gather data from production as well as post-production activities?	☐
	Does the information gathered in the feedback process serve as potential input into risk management for monitoring and maintaining the product requirements as well as the product realization or improvement processes?	☐
	If applicable regulatory requirements require the organization to gain specific experience from post-production activities, does the review of this experience form part of the feedback process?	☐

8.2.2	**Complaint handling**	
	Does the organization document procedures for timely complaint handling in accordance with applicable regulatory requirements?	☐
	Do these procedures include at a minimum requirements and responsibilities for:	
	a) receiving and recording information?	☐
	b) evaluating information to determine if the feedback constitutes a complaint?	☐
	c) investigating complaints?	☐
	d) determining the need to report the information to the appropriate regulatory authorities?	☐
	e) handling of complaint-related product?	☐
	f) determining the need to initiate corrections or corrective actions?	☐
	If any complaint is not investigated, is justification documented?	☐
	Is any correction or corrective action resulting from the complaint handling process documented?	☐
	If an investigation determines activities outside the organization contributed to the complaint, are relevant information exchanged between the organization and the external party involved?	☐
	Are complaint handling records maintained (see 4.2.5)?	☐
8.2.3	**Reporting to regulatory authorities**	
	If applicable regulatory requirements require notification of complaints that meet specified reporting criteria of adverse events or issuance of advisory notices, does the organization document procedures for providing notification to the appropriate regulatory authorities?	☐
	Are records of reporting to regulatory authorities maintained (see 4.2.5)?	☐
8.2.4	**Internal audit**	
	Does the organization conduct internal audits at planned intervals to determine whether the quality management system:	

	a) conforms to planned and documented arrangements, requirements of this international standard, quality management system requirements established by the organization, and applicable regulatory requirements?	☐
	b) is effectively implemented and maintained?	☐
	Does the organization document a procedure to describe the responsibilities and requirements for planning and conducting audits and recording and reporting audit results?	☐
	Is an audit program planned, taking into consideration the status and importance of the processes and area to be audited, as well as the results of previous audits?	☐
	Are the audit criteria, scope, interval and methods defined and recorded (see 4.2.5)?	☐
	Does the selection of auditors and conduct of audits ensure objectivity and impartiality of the audit process?	☐
	Do auditors not audit their own work?	☐
	Are records of the audits and their results, including identification of the processes and areas audited and the conclusions, maintained (see 4.2.5)?	☐
	Does the management responsible for the area being audited ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes?	☐
	Do follow-up activities include the verification of the actions taken and the reporting of verification results?	☐
8.2.5	**Monitoring and measurement of processes**	
	Does the organization apply suitable methods for monitoring and, as appropriate, measurement of the quality management system processes?	☐
	Do these methods demonstrate the ability of the processes to achieve planned results?	☐
	When planned results are not achieved, are correction and corrective action taken, as appropriate?	☐
8.2.6	**Monitoring and measurement of product**	

	Does the organization monitor and measure the characteristics of the product to verify that product requirements have been met?	☐
	Is this carried out at applicable stages of the product realization process in accordance with the planned and documented arrangements and documented procedures?	☐
	Is evidence of conformity to the acceptance criteria maintained?	☐
	Is the identity of the person authorizing release of product recorded (see 4.2.5)?	☐
	As appropriate, do records identify the test equipment used to perform measurement activities?	☐
	Does product release and service delivery not proceed until the planned and documented arrangements have been satisfactorily completed?	☐
	For implantable medical devices, does the organization record the identity of personnel performing any inspection or testing?	☐
8.3	**Control of nonconforming product**	
	Does the organization ensure that products which does not conform to product requirements are identified and controlled to prevent is unintended use or delivery?	☐
	Is there a documented procedure established to define the controls and related responsibilities and authorities for dealing with non-conforming product?	☐
	Does the evaluation of nonconformity include a determination of the need for an investigation and notification of any external party responsible for the nonconformity?	☐
	Are records of the nature of nonconformities and any subsequent actions taken, including the evaluation, any investigation and the ration ale for decisions concessions obtained maintained? (see 4.2.5)	☐
8.3.2	**Actions in response to nonconforming product detected before delivery**	
	Does the organization deal with nonconforming product by one or more of the following ways:	

	a) taking action to eliminate the detected nonconformity? b) taking action to preclude its original intended use or application? c) authorizing its use, release or acceptance under concession?	☐ ☐ ☐
	Does the organization ensure that nonconforming product is accepted by concession only if the justification is provided, approval is obtained and applicable regulatory requirements are met?	☐
	Are records of the acceptance by concession and the identity of the person authorizing the concession maintained (see 4.2.5)?	☐
8.3.3	**Actions in response to nonconforming product detected after delivery**	
	When nonconforming products are detected after delivery or use has started, does the organization take action appropriate to the effects, or potential effects, of the nonconformity. Are records of actions taken maintained (see 4.2.5)?	☐
	Does the organization document procedures for issuing advisory notices in accordance with applicable regulatory requirements?	☐
	Are these procedures capable of being put into effect at any time?	☐
	Are records of actions relating to the issuance of advisory notices maintained (see 4.2.5)?	☐
8.3.4	**Rework**	
	Does the organization perform rework in accordance with documented procedures that takes into account the potential adverse effect of the rework on the product?	☐
	Do these procedures undergo the same review and approval as the original procedure?	☐
	After the completion of rework, is product verified to ensure that it meets applicable acceptance criteria and regulatory requirements?	☐
	Are records of rework maintained (see 4.2.5)?	☐
8.4	**8.4 Analysis of data**	
	Does the organization determine, collect and analyses appropriate data to demonstrate the suitability and effectiveness of the QM system (and to assess and evaluate where improvement of the effectiveness of the quality management system can be made)?	☐

	Do the procedures include determination of appropriate methods, including statistical techniques and the extent of their use?	☐
	Does the analysis of data include data generated as a result of monitoring and measurement and from other relevant sources and include, at a minimum, input from:	
	a) feedback?	☐
	b) conformity to product requirements?	☐
	c) characteristics and trends of processes and product, including opportunities for improvement?	☐
	d) suppliers?	☐
	e) audits?	☐
	f) service reports, as appropriate?	☐
	If the analysis of data shows that the quality management system is not suitable, adequate or effective, does the organization use this analysis as input for improvement as required in 8.5?	☐
	Are records of the results of analyses maintained (see 4.2.5)?	☐
8.5	**Improvement**	
8.5.1	**General**	
	Does the organization identify and implement any changes necessary to ensure and maintain the continued suitability, adequacy and effectiveness of the quality management system as well as medical device safety and performance with the use of the quality policy, quality objectives, audit results, post-market surveillance, analysis of data, corrective actions, preventive actions and management review?	☐
8.5.2	**Corrective action**	
	Does the organization take action to eliminate the causes of non-conformities in order to prevent recurrence?	☐
	Are corrective actions appropriate to the effects of the nonconformities encountered?	☐
	Is a documented procedure established to define requirements for...	
	Reviewing nonconformities (including customer complaints)?	☐

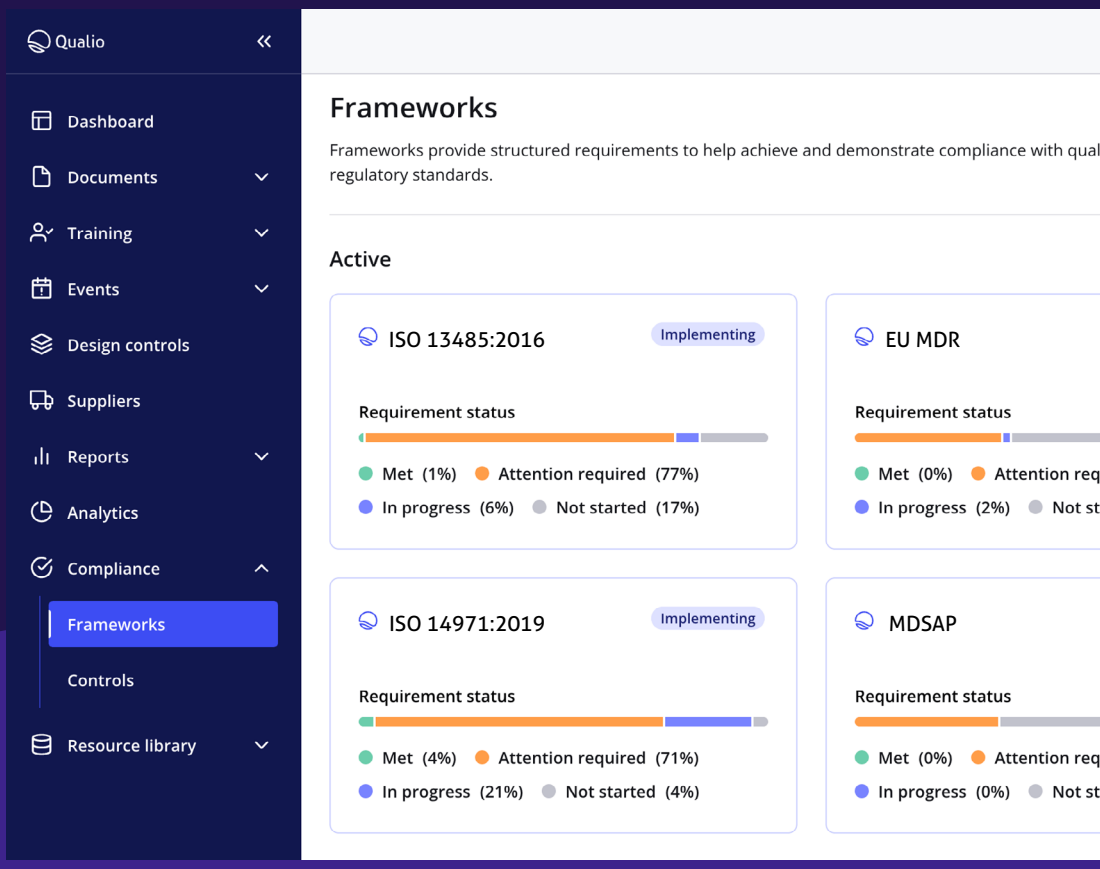
	Determining the causes of nonconformity?	☐
	Evaluating the need for action to ensure that nonconformities do not recur?	☐
	Determining and implementing planning and documenting action needed, including, if appropriate, updating documentation (see 4.2)?	☐
	Verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device?	☐
	Recording of the results of any investigation and of action taken? Reviewing the corrective action taken and its effectiveness?	☐
	Are records of the results of any investigation and of action taken maintained (see 4.2.5)?	☐
8.5.3	**Preventive action**	
	Does the organization determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence?	☐
	Are preventive actions appropriate to the effects of the potential problems?	☐
	Is a documented procedure established to define requirements for...	
	Determining potential nonconformities and their causes?	☐
	Evaluating the need for action to prevent occurrence of nonconformities?	☐
	Planning and documenting action needed and implementing such action, including, as appropriate, updating documentation?	☐
	Verifying that the action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device?	☐
	Reviewing the effectiveness of the preventive action taken, as appropriate?	☐
	Are records of the results of any investigations and of action taken maintained (see 4.2.5)?	☐

Qualio

Master every ISO 13485 requirement

Our quality and compliance management software gives you everything you need for complete ISO 13485 compliance — from a holistic, digital medtech QMS to AI-powered compliance gap analysis.

Learn more



Call us today

1.855.203.2010 • +353 1 697 1522