PathWise

Medical Device Audit Checklist Example

ISO 13485:2016 and 21 CFR 820

Standard Reference	Requirement	Complies? (Y/N/NA)	Notes and Evidence
Quality Management System			
4.1.1 §820.5	Is the quality management system (QMS) documented, implemented, and maintained?		
4.1.2 4.1.3	Are the QMS processes monitored and measured? Are there adequate resources to support the processes? Are the processes controlled using a risk-based approach?		
4.1.4	Are changes to QMS processes evaluated for impact on the QMS and devices? Are changes controlled?		
4.1.5	Are outsourced processes adequately controlled?		
4.1.6	Is software used in the QMS system properly monitored and controlled, including validations and revalidations based on risk and in writing?		
Documentation requirements			
4.2.1	Does the quality management system (QMS) documentation include quality policy, quality objectives, procedures, and records?		
4.2.2 §820.20(e)	Is the Quality Manual properly documented, including procedures or references to them? Does it include details of and justification for any exclusion or non-application? Does it address all relevant requirements of ISO 13485 and 21 CFR 820?		
4.2.2	Is the interaction between the processes of the quality system documented (process map, flowcharts, etc.)?		
4.2.2	Is the structure of the quality system documentation outlined in the manual?		

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Standard Reference	Requirement	Complies? (Y/N/NA)	Notes and Evidence
4.2.3 §820.181	Is there a Medical Device File (ISO) for each medical device type or medical device family, and/or Device Master Record (FDA) including: • description of the device, intended use/purpose, packaging, labeling, instructions for use; • product specifications; • production process specifications; • procedures for measuring and monitoring / quality assurance; and, • as appropriate: requirements for installation, maintenance and service?		
Control of Documents			
4.2.4 §820.40(a)	Is there a written procedure defining the controls needed to: ● Review and approve documents prior to issue, ● Review, update and re-approve documents, ● Identify changes and current revisions of documents ● Make relevant versions of applicable documents available at points of use ● Ensure that documents are legible and identifiable, ● Identify and control the distribution of documents of external origin, and ● Prevent deterioration or loss of documents ● Identify retained obsolete documents and prevent their unintended use Is there evidence of implementation of the procedure?		

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Standard Reference	Requirement	Complies? (Y/N/NA)	Notes and Evidence
4.2.4 §820.180	Is the period for retention of obsolete controlled documents defined? Is the retention period at least equal to the lifetime of the device?		
4.2.4 §820.40(b)	Are document changes reviewed and approved by the same function that performed the original review and approval (unless specifically designated otherwise)? Are change records maintained, including description of the change, identification of the affected documents, approval signatures and date, and when the change becomes effective?		
Control of Records			
4.2.5	Are quality records maintained?		
4.2.5 §820.184	Do procedures define the control for identity, storage, security, retrieval, retention, and disposition of records?		
4.2.5 §820.186	Is confidential health information protected?		
4.2.5 §820.180	Are retention periods for records defined? Are records retained for at least the period of time equivalent to the expected life of the device, and no less than 2 years?		
4.2.5 §820.180	Are records organized and maintained to ensure that they remain legible, readily identifiable and retrievable, and to prevent deterioration and loss? Are records accessible to the regulatory inspections? Are electronic records backed up?		
4.2.5	Are records maintained to enable changes to records to remain identifiable?		

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Management Responsibility			
5.1 §820.20	Is the top management ● communicating to the organization the importance of meeting customer and other applicable requirements, ● establishing the quality policy, ● establishing quality objectives, ● conducting management reviews, and ● ensuring availability of resources?		
5.2	Is the top management ensuring that customer requirements are determined and are met?		
5.3 §820.20	Is there a documented quality policy; and ● Is it appropriate to the purpose of the organization? ● Does it include a commitment to comply with requirements and to maintain the effectiveness of the quality management system? ● Does it provide a framework for establishing the quality objectives? ● Is it communicated and understood throughout the organization? ● Is it periodically reviewed for continuing suitability?		
5.4.1	Are quality objectives, including those needed to meet applicable regulatory/ product requirements, established within the organization? Are they consistent with the quality policy?		
5.4.1	Are the quality objectives measurable?		
5.4.2 §820.20	Is quality management system planning carried out to ensure quality objectives are met and the QMS integrity remains when changes are		

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	planned and implemented? Has the manufacturer established how the requirements for quality will be met?		
5.5.1 §820.20	Is top management ensuring that responsibilities and authorities are defined, documented, and communicated within the organization?		
5.5.1 §820.20	Is an outline of the interrelation of all personnel who manage, perform, and verify work affecting quality documented?		
5.5.1	Is top management ensuring the independence and authority necessary to perform tasks and work affecting quality?		
5.5.2 §820.20	Is there an appointed member of management (Management Representative) whose responsibility and authority includes the following? ● Ensuring processes needed for the QMS are documented ● Reporting to top management on the effectiveness of the QMS and any need for improvement ● Ensuring the promotion of awareness of applicable regulatory requirements and quality management system requirements throughout the organization		
5.5.3	Are appropriate communication processes established within the organization? Does top management ensure that communication takes place regarding the effectiveness of the QMS?		
5.6.1 §820.20	Does the organization have documented procedures for Management Review? Does top management review the organization's quality management system at documented planned intervals to ensure continuing suitability, adequacy, and effectiveness? Are records of reviews maintained?		

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5.6.2	Does input to management reviews cover the appropriate topics, including the following? • Customer feedback • Complaint Handling • Reports to regulatory authorities • Audits • Monitoring/ measurement of processes • Monitoring/ measurement of products • Corrective Actions • Preventive Actions • Follow-up actions from previous Management Reviews • Changes affecting the QMS • Assessment of opportunities for improvement and need for changes to the QMS • Applicable new or revised regulatory requirements		
5.6.3	Is output from management review recorded, including recording the input reviewed and any decisions and actions related to improvements to QMS or product, any resource needs, and changes needed to respond to new or revised regulatory requirements?		
Resource Management			
6.1 §820.25	Has the organization determined and provided sufficient resources to implement and maintain the QMS and meet regulatory and customer requirements?		
6.2 §820.25	Are personnel performing work affecting product quality competent on the basis of appropriate education, training, skills, and experience? Are records of competence maintained?		

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6.2	Is there a documented process for establishing competence, providing needed training, and ensuring awareness of personnel?		
6.2 §820.25	Does the organization provide training or take other action to achieve or maintain the necessary competence?		
6.2	Is the effectiveness of the training or other actions evaluated? Is the evaluation method proportionate to the risk associated with the functions?		
6.2 §820.25	Are personnel aware of the effects of their activities and how they contribute to the quality objectives?		
6.3 §820.70	Are there adequate buildings, workspace, and utilities present to achieve compliance to product requirements?		
6.3 §820.70	Does the organization have documented requirements for the maintenance activities, including the interval of performance of maintenance activities that can affect product quality?		
6.3 §820.70	Are records of maintenance maintained?		
6.4.1 §820.70	Does the organization have documented requirements for the work environment needed to achieve conformity to product requirements? Does the organization have procedures to monitor and control the work environment?		
6.4.1 §820.70	Are requirements documented for health, cleanliness, and clothing of personnel where contact could affect medical device safety or performance?		

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Standard Reference	Requirement	Complies? (Y/N/NA)	Notes and Evidence
6.4.1 §820.70	Are temporary personnel adequately trained or supervised within special environmental conditions within the work environment?		
6.4.2 §820.70	Does the organization plan and document arrangements for the control of contaminated or potentially contaminated products in order to prevent further contamination of the work environment, personnel, or product?		
6.4.2	For sterile medical devices, are requirements for control of contamination and micro-organisms documented? Does the organization maintain the required cleanliness during assembly or packaging processes?		
Product Realization			
7.1	Is there a procedure for product realization?		
7.1	Is there a process for risk management? Are records of risk management documented?		
7.1 §820.80	Is there evidence of the following? • Objectives/ requirements for the product? • Process documents and resources available? • Requirements for validation, verification, monitoring, measurement, inspection, handling, storage, distribution and product acceptance? • Documentation that the product and design control processes meet the requirements?		
7.2.1	Are delivery and post-delivery requirements defined?		
7.2.1	Are requirements necessary for specified intended use defined? (Both specified and not specified by the customer)		

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Standard Reference	Requirement	Complies? (Y/N/NA)	Notes and Evidence
7.2.1	Are regulatory requirements defined and met?		
7.2.1	Is necessary user training for the safe use of the device identified?		
7.2.2	Are product requirements defined and documented?		
7.2.2	Are contract and order requirements resolved?		
7.2.2	Is the organization able to meet the defined requirements?		
7.2.2	Are relevant documents amended when product requirements change?		
7.2.2	Are records of product requirement reviews retained?		
7.2.3	Are there documented arrangements for communications with the customer for product information, customer feedback (complaints), advisory notices, and contracts/ amendments to contracts?		
7.3.1 §820.30	Are there documented Design and Development Procedures?		
7.3.2 §820.30	Are the following subjects documented? • Design/ development stages • Reviews needed for each stage • Verification, validation, and design transfer activities • Methods to ensure traceability of design outputs to design inputs • Resources needed, including competent personnel		
7.3.3 §820.30	Are the following covered by design inputs? • Regulatory requirements and standards • Functional performance, usability, and safety requirements per intended use • Output risk management		

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Standard Reference	Requirement	Complies? (Y/N/NA)	Notes and Evidence
	• Information derived from similar designs • Other requirements needed for the development of the product • Are the inputs reviewed, approved, and documented		
7.3.4 §820.30	Are design outputs verifiable against the design inputs?		
7.3.4 §820.30	Do design outputs provide appropriate and adequate information for purchasing, production, and servicing?		
7.3.4 §820.30	Do design outputs reference product acceptance criteria?		
7.3.4 §820.30	Are the essential characteristics for safe and proper use specified in the design outputs?		
7.3.4 §820.30	Are design outputs approved prior to release?		
7.3.5 §820.30	Are systematic reviews of the design performed at the appropriate stages?		
7.3.5 §820.30	Do design reviews evaluate whether the design results meet the requirements? Do they include identification and proposal of necessary actions?		
7.3.6 §820.30	Is design verification performed for each documented process to verify that the design outputs meet the design inputs?		
7.3.6 §820.30	Does design verification specify the method, acceptance criteria, statistical techniques, and rationale for sample size?		
7.3.6 §820.30	If a device is required to interface with another device, does the verification confirm that design outputs meet design inputs when the devices are interfaced?		

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Standard Reference	Requirement	Complies? (Y/N/NA)	Notes and Evidence
7.3.6 §820.30	Are records of results and conclusions of design verification maintained?		
7.3.7 §820.30	Is design validation performed for each documented process to verify that the design can meet the requirements for the intended use?		
7.3.7 §820.30	Does design validation specify the method, acceptance criteria, statistical techniques, and rationale for sample size?		
7.3.7	Is design validation conducted on representative product?		
7.3.7	Does design validation include clinical evaluation?		
7.3.7 §820.30	If a device is required to interface with another device, does the validation confirm that design requirements have been met when the devices are interfaced?		
7.3.7 §820.30	Are records of results and conclusions of design validations maintained?		
7.3.8 §820.30	Are design transfer processes documented? Do the processes ensure design outputs are verified to be suitable for manufacturing?		
7.3.8	Does production capability meet product requirements?		
7.3.9 §820.30	Are changes to design and development reviewed, verified, validated (when needed), and approved? Are changes evaluated for the impact to the component or device?		
7.3.10 §820.30	Is there a design and development file or Design History File (DHF) for each device or device family?		
7.3.10 §820.30	Does the design and development file contain references to records that demonstrate conformance to the device requirements and design changes?		

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Standard Reference	Requirement	Complies? (Y/N/NA)	Notes and Evidence
7.4.1 §820.50	Is there a procedure defining the purchasing process and ensuring that purchased product conforms to the purchasing information?		
7.4.1 §820.50	Are there criteria for selection and approval of suppliers, proportional to the risk related to the device? Are criteria based on the following? • Suppliers' ability to provide product that meets the component/service requirements • Supplier's performance • Effect of the product of the quality of the device		
7.4.1 §820.50	Are suppliers monitored and reevaluated? Does reevaluation consider supplier performance?		
7.4.1	Are supplier nonconformances addressed in proportion to the risk associated with the purchased product and compliance to regulatory requirements?		
7.4.1 §820.50	Are results of supplier selection, evaluation, re-evaluation, performance, and actions arising from these activities documented?		
7.4.2	As appropriate, is the following purchasing information provided? • Product specifications • Product acceptance, processes, and equipment requirements • Qualifications of supplier personnel • QMS requirements • Purchase order review and approval • Change notification on file • Records of purchased materials maintained		
7.4.3	Are verification processes established to confirm purchased product meet requirements?		

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Standard Reference	Requirement	Complies? (Y/N/NA)	Notes and Evidence
7.4.3	Are changes to the purchased product evaluated for impact on the finished medical device?		
7.4.3	If source inspection is performed, are verification activities and product release requirements defined on the purchase order?		
7.5.1	Are there procedures in place for the control of production?		
7.5.1	Is the infrastructure qualified?		
7.5.1	Are process parameters monitored and measured? Is equipment available for monitoring and measurement?		
7.5.1	Are defined operations for labeling and packaging implemented?		
7.5.1	Are release, delivery, and post-delivery instructions implemented?		
7.5.1 §820.65	Are traceability requirements recorded on the manufacturing records?		
7.5.2	Is cleanliness or contamination abatement of the product defined?		
7.5.3 §820.170	Where installation is applicable, are acceptance criteria and verification of installation documented? Are records maintained?		
7.5.4 §820.200	Are servicing procedures documented?		
7.5.4 §820.200	Are service records analyzed to determine if they are to be handled as a complaint? Are service records used as an input for the improvement process?		
7.5.4 §820.200	Are servicing records maintained?		
7.5.5	For sterile medical devices: Are sterilization process parameters for each lot/batch of devices maintained?		

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Standard Reference	Requirement	Complies? (Y/N/NA)	Notes and Evidence
7.5.5	For sterile medical devices: Are sterilization records traceable to each lot/batch?		
7.5.6 §820.140	Where outputs are not verified or measurable, are they validated? Does the validated process include the following? • Criteria for review/approval of the process • Equipment and personnel qualification • Methods, procedures, and acceptance criteria		
7.5.7	Is there a procedure outlining the requirements for sterilization validation and sterile barriers?		
7.5.7	Has sterilization been validated prior to implementation? Have any process changes been validated, as appropriate?		
7.5.8 §820.60	Is there a procedure defining identification of the product?		
7.5.8 §820.60	Is product status maintained throughout the manufacturing, storage, installation, and servicing process?		
7.5.9 §820.65	Is there a procedure defining traceability?		
7.5.9 §820.65	Are records of traceability maintained?		
7.5.9 §820.65	For implantable devices: • Are requirements that could affect performance or safety of the device defined (materials, components, environmental conditions, etc.)? • Do distributors keep records of distribution? • Are consignee names and addresses maintained?		

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7.5.10	Is customer property for use in the manufacture of the device identified and protected while in the manufacturer's possession?		
7.5.10	Are records of damage, loss, and unsuitability conveyed to the customer? Are the records maintained?		
7.5.11 §820.140 §820.150 §820.160	Is there a procedure providing for the preservation of conformity of the product during all phases of manufacturing, handling, storage and distribution?		
7.5.11 §820.130	Are the packaging/ shipping procedures suitably designed to protect the product and prevent contamination?		
7.5.11	Where special conditions are required, are they controlled and documented?		
7.6	Are there procedures ensuring that monitoring and measurement can be carried out consistent with the requirements?		
7.6	Is equipment calibrated at specified intervals using recognized national/international standards? Are any adjustments documented?		
7.6 §820.72	Is equipment identified to determine its calibration status?		
7.6 §820.72	Is equipment safeguarded from adjustments that would invalidate measurement results? Is it protected from damage during handling, storage, and maintenance?		
7.6 §820.72	Are calibration and verification records maintained?		

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Standard Reference	Requirement	Complies? (Y/N/NA)	Notes and Evidence
7.6	Does the organization review the validity of prior measurements if the equipment is found to be out of tolerance? Is appropriate action taken?		
7.6 §820.70	Is software used in measuring equipment validated in accordance with risk? Is there a software validation procedure?		
Measurement, Analysis, Improvement			
8.1	Does the organization implement monitoring, measurement, analysis, and improvement to confirm the following? • Conformity of the product • Conformity to the QMS • Effectiveness of the QMS Are statistical techniques used defined?		
8.2.1	Is the process for manufacturing and postproduction feedback documented? Does the process cover regulatory requirements?		
8.2.1	Does postproduction feedback feed into risk management and the product improvement process?		
8.2.2 §820.198	Is there a complaint handling procedure that contains covers the following? • Receipt and recording of information • Determination of complaint status • Investigation of complaints • Determining regulatory reporting requirements • Handling complaint product • Determining the need for correction and corrective actions		
8.2.2	Are complaint records maintained?		

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Standard Reference	Requirement	Complies? (Y/N/NA)	Notes and Evidence
§820.198			
8.2.3 §820.198	Are there procedures in place to direct documenting reporting of complaints to regulatory authorities when needed (i.e. advisory notices, adverse events)?		
8.2.3 §820.198	Are reports to regulatory authorities maintained?		
8.2.4	Are internal audits performed at planned intervals?		
8.2.4 §820.22	Does the internal audit process ensure conformance to documentation and to regulatory requirements?		
8.2.4 §820.22	Do internal audits include the following? • Evaluation of the effectiveness of the implementation and maintenance of the Quality System • Review of prior audit results • Defined audit scopes, methods, and intervals		
8.2.4 §820.22	Are auditors qualified and objective?		
8.2.4 §820.22	Does management ensure that corrective actions are implemented and effective?		
8.2.5	Are measurements and methods appropriate to ensure the processes can achieve planned results? Have corrective actions been implemented when required?		
8.2.6	Are monitoring and measurement activities carried out at applicable stages during product realization?		
8.2.6 §820.86	Is evidence of conformity to the acceptance criteria maintained?		

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Standard Reference	Requirement	Complies? (Y/N/NA)	Notes and Evidence
8.2.6 §820.80	Is the test equipment used to perform acceptance identified on the measurement?		
8.2.6 §820.80	Is the person performing inspections/ tests recorded?		
8.3.1 §820.90	Is there a procedure documenting controls, roles, and responsibilities to identify, segregate, evaluate, and disposition nonconforming product? Does the process determine the need for an investigation and notification to external sources responsible for the nonconformity?		
8.3.1 §820.90	Is nonconforming product identified and segregated?		
8.3.1 §820.90	Are records regarding nonconformances and subsequent actions maintained?		
8.3.2 §820.90	When a nonconformance is detected before delivery, are one or more of the following actions prescribed/taken? • Eliminate nonconformity • Preclude its original intended use • Authorize use/ acceptance under concession		
8.3.3 §820.90	When nonconformities are detected post-delivery: • Does the organization base actions on the effects or potential effects of the nonconformity? Are the actions maintained? • Is there a procedure for submitting advisory notices? Are records of advisory notices maintained?		
8.3.4 §820.90	Is there a procedure for rework? Does it have the same level of approval as the original procedure?		

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8.3.4 §820.90	Has the rework been verified to conform to the acceptance criteria and regulatory requirements?		
8.3.4 §820.90	Are records of rework maintained?		
8.4	Is there a procedure that defines the collection and analysis of data to determine the adequacy and effectiveness of the QMS (methods, statistical techniques, and extent of use)? Does data include • Feedback? • Conformity to product requirements? • Trends and opportunities for improvement? • Supplier data? • Audit data? • Service reports (if required)?		
8.4	Are records for data analysis maintained?		
8.5.1	Does the organization use audit results, quality objectives, market surveillance, corrective and preventive actions, and analysis of data to improve the QMS and device safety and performance?		
8.5.2 §820.100	Is there a corrective action procedure to address issues including complaints and nonconforming product?		
8.5.2 §820.100	Does the corrective action process include the following? • Determination of the root cause of the issue • Evaluating need for action to ensure non-recurrence • Documenting completed corrective action e.g. document change • Assessment of corrections on impact of the ability of the device to meet requirements • Effectiveness checks		

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Standard Reference	Requirement	Complies? (Y/N/NA)	Notes and Evidence
	• Maintaining records		
8.5.3 §820.90 §820.100	Is there a procedure for identifying potential nonconformities and their causes?		
8.5.3 §820.100	Does the preventive action process include the following? • Evaluating the need for corrective action • Documenting actions taken and the ability to meet the device safety and device performance requirements • Verification that actions taken do not adversely affect the device performance, safety, or conformance with regulatory requirements • Verification of the effectiveness of actions taken		
8.5.3 §820.100	Are records of preventive actions maintained?		

Please note: The above Checklist is provided as an example only. Please reference the applicable standard / regulation for additional details.

Additional Notes:

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