ISO 13485:2016 Internal Audit Checklist

Medical devices – Quality management systems – Requirements for regulatory purposes

Organisation		**Audit reference no.**	
Site / department(s)		**Audit date(s)**	
Audit scope		**Lead auditor**	
Audit criteria	ISO 13485:2016, applicable regulations, internal procedures	**Auditor(s) / auditee(s)**	

How to use this checklist: Select the clauses in scope from the audit programme. For each clause, verify the listed requirements through interviews, observation and records. Mark the result: C = conforms, NC = nonconformity (raise a NC report referencing the clause and objective evidence), OFI = opportunity for improvement. Record specific evidence (document numbers, record IDs, dates, people interviewed) in the observations column. This checklist summarises key requirements and is not a substitute for the full text of ISO 13485:2016 or applicable regulations.

Clause	Requirements to verify	Evidence / records to review	C / NC / OFI	Auditor observations
Clause 4 – Quality management system				
4.1.1 General requirements	• Organisation's role(s) under applicable regulations documented (manufacturer, authorised representative, importer, distributor, supplier) • QMS maintained in line with ISO 13485 and applicable regulatory requirements • Regulatory requirements identified for each market	• Quality manual / scope • Regulatory requirements register • Licences (e.g. CDSCO), certificates	☐ C ☐ NC ☐ OFI	
4.1.2 QMS processes	• QMS processes determined and applied across the organisation • Risk-based approach applied to control of QMS processes • Sequence and interaction of processes determined	• Process map / interaction diagram • Process risk assessments	☐ C ☐ NC ☐ OFI	
4.1.3 Process control	• Criteria and methods for effective operation and control • Resources and information available • Processes monitored, measured and analysed; actions taken to achieve results • Records demonstrate conformity	• Process KPIs, monitoring records • Management review inputs	☐ C ☐ NC ☐ OFI	
4.1.4 Changes to processes	• Changes evaluated for impact on QMS and on devices • Changes controlled in line with ISO 13485 and regulations	• Change control records • Impact assessments	☐ C ☐ NC ☐ OFI	

Clause	Requirements to verify	Evidence / records to review	C / NC / OFI	Auditor observations
4.1.5 Outsourced processes	• Outsourced processes identified and controlled in proportion to risk • Controls include written quality agreements • Organisation retains responsibility for conformity	• List of outsourced processes • Quality / supply agreements • Supplier monitoring records	☐ C ☐ NC ☐ OFI	
4.1.6 QMS software validation	• Documented procedure for validating software used in the QMS • Validation before initial use and after changes, proportionate to risk • Records of validation maintained	• Software inventory • Validation plans, protocols and reports • Change / revalidation records	☐ C ☐ NC ☐ OFI	
4.2.1 Documentation – general	• Quality policy and objectives documented • Quality manual, documented procedures and records required by the standard and regulations • Other documents needed for effective planning, operation and control	• Document master list • Procedure index	☐ C ☐ NC ☐ OFI	
4.2.2 Quality manual	• Scope of QMS, with details and justification of exclusions / non-applications • Documented procedures or references to them • Description of process interaction • Outline of documentation structure	• Quality manual (current revision)	☐ C ☐ NC ☐ OFI	
4.2.3 Medical device file	• File established for each device type or family • Includes general description, intended use / purpose and labelling • Product specifications; manufacturing, packaging, storage, handling and distribution specifications or procedures • Measuring and monitoring procedures; installation and servicing requirements where applicable	• Medical device files / technical files (sample) • Labelling and IFU	☐ C ☐ NC ☐ OFI	
4.2.4 Control of documents	• Documents reviewed and approved before issue; reviewed and updated as needed • Changes and current revision status identified • Relevant versions available at points of use; legible and identifiable • External documents identified and distribution controlled • Deterioration and loss prevented; obsolete documents identified • Retention period for obsolete controlled documents defined (at least device lifetime)	• Document control procedure • Master list, change history • Shop-floor spot checks of current versions	☐ C ☐ NC ☐ OFI	

Clause	Requirements to verify	Evidence / records to review	C / NC / OFI	Auditor observations
4.2.5 Control of records	• Documented procedure for identification, storage, security, integrity, retrieval, retention and disposition • Confidential health information protected • Records legible, identifiable and retrievable; changes identifiable • Retention for device lifetime and not less than 2 years from release	• Records control procedure • Record retention schedule • Sample records (paper and electronic) • Backup and access controls	☐ C ☐ NC ☐ OFI	
Clause 5 – Management responsibility				
5.1 Management commitment	• Top management communicates importance of meeting customer and regulatory requirements • Quality policy and objectives established • Management reviews conducted; resources available	• Interviews with top management • Communication records	☐ C ☐ NC ☐ OFI	
5.2 Customer focus	• Customer requirements and applicable regulatory requirements determined and met	• Contract / order reviews • Regulatory requirement register	☐ C ☐ NC ☐ OFI	
5.3 Quality policy	• Appropriate to purpose; commitment to comply with requirements and maintain QMS effectiveness • Framework for objectives; communicated and understood; reviewed for suitability	• Quality policy • Staff interviews	☐ C ☐ NC ☐ OFI	
5.4.1 Quality objectives	• Objectives set at relevant functions and levels, including those for product and regulatory requirements • Measurable and consistent with policy	• Objectives and performance data	☐ C ☐ NC ☐ OFI	
5.4.2 QMS planning	• Planning carried out to meet 4.1 and objectives • Integrity of QMS maintained during planned changes	• QMS plans, change plans	☐ C ☐ NC ☐ OFI	
5.5.1 Responsibility and authority	• Responsibilities and authorities documented and communicated • Interrelation of personnel who manage, perform and verify work affecting quality documented; independence ensured	• Organisation chart • Job descriptions	☐ C ☐ NC ☐ OFI	
5.5.2 Management representative	• Member of management appointed with defined responsibility and authority • Ensures processes documented; reports on effectiveness; promotes awareness of regulatory and QMS requirements	• Appointment letter • MR reports	☐ C ☐ NC ☐ OFI	
5.5.3 Internal communication	• Communication processes established; communication on QMS effectiveness takes place	• Meeting minutes, notice boards, intranet	☐ C ☐ NC ☐ OFI	

Clause	Requirements to verify	Evidence / records to review	C / NC / OFI	Auditor observations
5.6 Management review	• Documented procedure; reviews at planned, documented intervals • Inputs include feedback, complaint handling, regulatory reporting, audits, process and product monitoring, CAPA, follow-ups, changes, recommendations, new or revised regulations • Outputs record improvements, changes needed to respond to regulations, and resource needs	• Management review procedure • Minutes and action tracker	☐ C ☐ NC ☐ OFI	
Clause 6 – Resource management				
6.1 Provision of resources	• Resources determined and provided to implement QMS, maintain effectiveness and meet regulatory and customer requirements	• Budget / resource plans	☐ C ☐ NC ☐ OFI	
6.2 Human resources	• Competence based on education, training, skills and experience • Documented process for establishing competence, providing training and ensuring awareness • Effectiveness of actions evaluated proportionate to risk • Records of education, training, skills and experience	• Competence matrix • Training records and effectiveness evaluations • Awareness records	☐ C ☐ NC ☐ OFI	
6.3 Infrastructure	• Infrastructure requirements documented (buildings, equipment, supporting services) • Maintenance activities and intervals documented where they affect product quality • Records of maintenance kept	• Maintenance plans and records • Equipment list	☐ C ☐ NC ☐ OFI	
6.4.1 Work environment	• Work environment requirements documented • Health, cleanliness and clothing requirements for personnel where contact could affect product • Personnel working temporarily under special conditions competent or supervised	• Work environment procedures • Monitoring records (temperature, humidity, particle counts) • Gowning records	☐ C ☐ NC ☐ OFI	
6.4.2 Contamination control	• Arrangements to control contaminated or potentially contaminated product • Requirements for control of contamination with microorganisms or particulate matter for sterile devices	• Cleanroom qualification (ISO 14644) • Environmental monitoring • Contamination control procedures	☐ C ☐ NC ☐ OFI	
Clause 7 – Product realization				

Clause	Requirements to verify	Evidence / records to review	C / NC / OFI	Auditor observations
7.1 Planning of product realization	• Product realization processes planned and documented, consistent with other QMS processes • Documented risk management process(es) for product realization; records maintained • Planning defines quality objectives, processes, documents, resources, verification, validation, monitoring, inspection, handling, storage, distribution, traceability and acceptance criteria	• Quality plans • Risk management file (ISO 14971)	☐ C ☐ NC ☐ OFI	
7.2.1 Determination of product requirements	• Customer-specified requirements incl. delivery and post-delivery • Requirements not stated but necessary for intended use • Applicable regulatory requirements; user training needed; additional organisation requirements	• Product specifications • Regulatory checklists	☐ C ☐ NC ☐ OFI	
7.2.2 Review of requirements	• Review before commitment to supply; requirements defined and documented • Differences resolved; regulatory requirements met; user training available • Organisation able to meet requirements; records of review and actions kept	• Tender / order review records • Amendment records	☐ C ☐ NC ☐ OFI	
7.2.3 Customer communication	• Arrangements for product information, enquiries, orders and amendments, feedback and complaints, and advisory notices • Communication with regulatory authorities as required	• Communication procedure • Advisory notice records	☐ C ☐ NC ☐ OFI	
7.3.1–7.3.2 Design and development – general and planning	• Documented design and development procedures • Plans include stages, reviews, verification, validation, transfer, responsibilities, traceability of outputs to inputs, and resources • Plans maintained and updated	• D&D procedure • Design plans	☐ C ☐ NC ☐ OFI	
7.3.3 Design inputs	• Functional, performance, usability and safety requirements; regulatory requirements; risk management outputs; information from previous designs • Inputs reviewed, approved, complete, unambiguous and verifiable	• Design input documents • Input review records	☐ C ☐ NC ☐ OFI	
7.3.4 Design outputs	• Meet input requirements; provide information for purchasing, production and service • Contain or reference acceptance criteria; specify characteristics essential for safe and proper use • Approved before release	• Drawings, specifications, BOM • Output approvals	☐ C ☐ NC ☐ OFI	

Clause	Requirements to verify	Evidence / records to review	C / NC / OFI	Auditor observations
7.3.5 Design review	• Systematic reviews at suitable stages per plan • Participants include functions concerned and independent reviewer where required • Records include design identified, participants and date	• Design review minutes	☐ C ☐ NC ☐ OFI	
7.3.6 Design verification	• Verification per plan to ensure outputs meet inputs • Plans include methods, acceptance criteria and statistical techniques with sample-size rationale • Interfaces verified where device is connected to other devices	• Verification protocols and reports • Test data	☐ C ☐ NC ☐ OFI	
7.3.7 Design validation	• Validation per plan on representative product (initial production units, batches or equivalents) • Clinical evaluation and / or performance evaluation per regulations • Completed before release for use; records maintained	• Validation reports • Clinical / performance evaluation • Usability validation	☐ C ☐ NC ☐ OFI	
7.3.8 Design transfer	• Documented procedures to transfer outputs to manufacturing • Outputs verified as suitable for manufacturing before becoming final production specifications; production capability confirmed	• Transfer checklists • Pilot batch / process validation records	☐ C ☐ NC ☐ OFI	
7.3.9 Design changes	• Changes identified, reviewed, verified, validated as appropriate and approved before implementation • Significance evaluated for function, performance, usability, safety and regulatory requirements • Effect on parts, product in process or delivered, risk management inputs and outputs evaluated	• Design change records • Updated risk file	☐ C ☐ NC ☐ OFI	
7.3.10 Design and development files	• File maintained for each device type or family • Includes or references records demonstrating conformity and records of design changes	• Design history / D&D files	☐ C ☐ NC ☐ OFI	
7.4.1 Purchasing process	• Documented criteria for evaluating and selecting suppliers based on ability, performance, effect on quality and risk • Supplier monitoring and re-evaluation planned • Non-fulfilment addressed proportionate to risk and regulatory requirements • Records of evaluation, selection, monitoring and actions kept	• Approved supplier list • Supplier evaluations and audits • Supplier performance data	☐ C ☐ NC ☐ OFI	

Clause	Requirements to verify	Evidence / records to review	C / NC / OFI	Auditor observations
7.4.2 Purchasing information	• Product specifications, acceptance requirements, personnel qualification, QMS requirements • Written agreement that supplier notifies changes before implementation • Adequacy of requirements ensured before communication	• Purchase orders • Specifications and quality agreements	☐ C ☐ NC ☐ OFI	
7.4.3 Verification of purchased product	• Inspection or other activities established based on supplier evaluation and risk • Changes to purchased product assessed • Verification at supplier premises stated in purchasing information where needed; records kept	• Incoming inspection records • Certificates of analysis / conformity	☐ C ☐ NC ☐ OFI	
7.5.1 Control of production and service provision	• Production planned, carried out, monitored and controlled • Documented procedures, qualified infrastructure, monitoring, labelling and packaging operations, release, delivery and post-delivery activities implemented • Record for each device or batch providing traceability and quantities manufactured and approved for distribution, verified and approved	• Work instructions • Device history records / batch records • Line clearance and labelling controls	☐ C ☐ NC ☐ OFI	
7.5.2 Cleanliness of product	• Documented requirements for cleanliness where product is cleaned before sterilization or use, supplied non-sterile but cleaned before use, or where process agents must be removed	• Cleaning validation • Cleanliness test records	☐ C ☐ NC ☐ OFI	
7.5.3 Installation activities	• Requirements for installation and acceptance criteria for verification documented • Records of installation and verification maintained, including by external parties	• Installation reports • Installation qualification records	☐ C ☐ NC ☐ OFI	
7.5.4 Servicing activities	• Documented servicing procedures, reference materials and measurements where servicing is required • Servicing records analysed to identify complaints and improvement input	• Service reports • Service data analysis	☐ C ☐ NC ☐ OFI	
7.5.5 Sterile medical devices	• Records of sterilization process parameters for each sterilization batch • Records traceable to each production batch	• Sterilization batch records • Load reports, BI results	☐ C ☐ NC ☐ OFI	
7.5.6 Process validation	• Processes whose output cannot be verified are validated • Procedures cover review and approval criteria, equipment qualification, personnel qualification, methods, statistical techniques with sample-size rationale, records, revalidation and approval of changes • Validation of software used in production and service provision	• Validation master plan • IQ / OQ / PQ protocols and reports • Revalidation records	☐ C ☐ NC ☐ OFI	

Clause	Requirements to verify	Evidence / records to review	C / NC / OFI	Auditor observations
7.5.7 Validation of sterilization and sterile barrier systems	• Documented procedures for validating sterilization and sterile barrier system processes • Validation before implementation and after product or process changes • Records of results and conclusions maintained	• Sterilization validation (ISO 11135 / 11137 / 17665) • Packaging validation (ISO 11607)	☐ C ☐ NC ☐ OFI	
7.5.8 Identification	• Documented procedures for product identification throughout realization • Product status identified with respect to monitoring and measurement • UDI system implemented where required by regulations • Returned product identified and distinguished from conforming product	• Labels, tags, status indicators • UDI records	☐ C ☐ NC ☐ OFI	
7.5.9 Traceability	• Documented traceability procedures defining extent and records • Implantable devices: records of components, materials and work environment conditions • Distributors required to maintain distribution records; records of consignee name and address for implantables	• Traceability records (forward and backward) • Mock recall / traceability test	☐ C ☐ NC ☐ OFI	
7.5.10 Customer property	• Customer property identified, verified, protected and safeguarded • Loss, damage or unsuitability reported to customer; records maintained	• Customer property log	☐ C ☐ NC ☐ OFI	
7.5.11 Preservation of product	• Documented procedures to preserve conformity during processing, storage, handling and distribution • Packaging and shipping containers designed to protect product; special conditions controlled and recorded	• Storage condition monitoring • Shelf-life and FIFO / FEFO records • Transport validation	☐ C ☐ NC ☐ OFI	
7.6 Control of monitoring and measuring equipment	• Documented procedures for monitoring and measurement • Equipment calibrated or verified at intervals against traceable standards; adjusted; identified; safeguarded; protected • Validity of previous results assessed when equipment found nonconforming; actions recorded • Software used for monitoring and measurement validated	• Calibration register and certificates • Out-of-tolerance impact assessments	☐ C ☐ NC ☐ OFI	
Clause 8 – Measurement, analysis and improvement				
8.1 General	• Monitoring, measurement, analysis and improvement processes planned and implemented, including statistical techniques	• Monitoring plans	☐ C ☐ NC ☐ OFI	

Clause	Requirements to verify	Evidence / records to review	C / NC / OFI	Auditor observations
8.2.1 Feedback	• Documented feedback procedure with data from production and post-production activities • Feedback used as input to risk management and product realization or improvement • Post-market surveillance aligned with regulatory requirements	• Feedback / PMS procedure • PMS reports and trend data	☐ C ☐ NC ☐ OFI	
8.2.2 Complaint handling	• Documented procedure for timely complaint handling: receiving, evaluating, investigating, deciding on reporting, correction and corrective action • Justification recorded where no investigation is done • Records of complaint handling maintained	• Complaint log and files • Investigation reports	☐ C ☐ NC ☐ OFI	
8.2.3 Reporting to regulatory authorities	• Documented procedures for notifying adverse events and issuing advisory notices as required by regulations • Records of reporting maintained	• Vigilance / MDR reports • Advisory notices, field safety notices	☐ C ☐ NC ☐ OFI	
8.2.4 Internal audit	• Audits at planned intervals to determine conformity with arrangements, ISO 13485, organisation and regulatory requirements • Audit programme considers status, importance of processes and previous results • Auditors do not audit their own work • Corrections and corrective actions taken without undue delay; follow-up verifies actions	• Audit programme and plans • Audit reports and auditor qualifications • NC and follow-up records	☐ C ☐ NC ☐ OFI	
8.2.5 Monitoring of processes	• Suitable methods applied to monitor and measure QMS processes • Correction and corrective action when planned results are not achieved	• Process KPIs • Trend reports	☐ C ☐ NC ☐ OFI	
8.2.6 Monitoring of product	• Product characteristics monitored and measured at applicable stages per planned arrangements • Evidence of conformity to acceptance criteria and identity of person authorising release • Test equipment identified for implantables	• Inspection and test records • Release records	☐ C ☐ NC ☐ OFI	

Clause	Requirements to verify	Evidence / records to review	C / NC / OFI	Auditor observations
8.3 Control of nonconforming product	• Documented procedure for identification, documentation, segregation, evaluation and disposition • Evaluation includes need for investigation and notification of external parties • Concessions only with justification, approval and regulatory compliance • Nonconforming product after delivery: actions appropriate to effects, advisory notices • Rework per documented procedure with evaluation of adverse effects	• NC reports • Concession records • Rework and re-verification records	☐ C ☐ NC ☐ OFI	
8.4 Analysis of data	• Documented procedures to determine, collect and analyse data • Analysis covers feedback, conformity to requirements, process and product trends, suppliers, audits and service reports • Records of analysis results maintained	• Data analysis reports • Management review inputs	☐ C ☐ NC ☐ OFI	
8.5.1 Improvement – general	• Changes necessary to ensure continued suitability, adequacy and effectiveness of QMS and device safety and performance identified and implemented	• Improvement projects	☐ C ☐ NC ☐ OFI	
8.5.2 Corrective action	• Documented procedure: review nonconformities, determine causes, evaluate need for action, plan and document action • Actions implemented without undue delay; effectiveness verified • Verification that actions do not adversely affect regulatory compliance or device safety and performance	• CAPA procedure and log • Root-cause analysis • Effectiveness checks	☐ C ☐ NC ☐ OFI	
8.5.3 Preventive action	• Documented procedure to determine potential nonconformities and their causes • Actions planned, documented, implemented and effectiveness reviewed	• Preventive action records • Risk review outputs	☐ C ☐ NC ☐ OFI	

Audit summary

Total clauses audited	Conformities (C)	Nonconformities (NC)	Opportunities for improvement (OFI)

Key findings and conclusions

Sign-off

Lead auditor: name, signature, date	Auditee representative: name, signature, date	Management representative: name, signature, date