INTERNAL AUDIT CHECKLISTS AS PER ISO 13485:2016

An internal audit is a vital component of maintaining compliance with ISO 13485:2016 in the medical device industry. This standard ensures that organizations meet regulatory requirements and consistently deliver high-quality, safe, and effective medical devices.

The purpose of internal audits is to evaluate the effectiveness of the QMS, identify nonconformities, and provide opportunities for continuous improvement. A well-structured internal audit checklist is an essential tool for auditors, helping ensure all key aspects of the QMS are reviewed systematically and in alignment with ISO 13485 requirements.

This document is intended to be used as a practical reference and should be tailored to fit the unique needs of each organization.

Clause	Requirements	Check the box if applicable	Observation	Document evidence
4	**Quality Management system**			
4.1	**General requirements** • Has the organization established, documented, implemented and maintained a quality system and its effectiveness in accordance with the requirements of this International Standard or applicable regulatory requirements? • Has the organisation applied a risk-based approach to control the appropriate processes needed for the quality management system? • Has the interaction and sequence of these processes been identified? • Have the criteria and methods needed for effective operation and control of these processes been identified?	☐	*Mention the observations based on the documents and records reviewed*	*Mention the document details. or record details. in which the gap is identified. The detail shall include at least document name, id and version.*

	• Has the availability of resources and information necessary to support the operation and monitoring of these processes been identified? • Does the organization outsource any process that affects product conformity to requirements? • Does the organization monitor and ensure control over outsourced processes that affect product conformity to requirements, customers, and applicable regulatory requirements? • Does the organization have a procedure for validating the application of computer software used in the quality management system?			
4.2.1	• Are the quality policy and quality objectives documented? • Is the Quality Manual documented?			
4.2.2	**Quality Manual** • Does the manual include: o The scope of the quality management system, including			

	details of and justification for any exclusion or non-application ○ the documented procedures for the quality management system, or reference to them ○ a description of the interaction between the processes of the quality management system.			
4.2.3	**Medical Device File** • Does the organization have a Medical Device File for each device? • Does the Medical Device File contain - ○ General description of the medical device, intended use/purpose, and labelling, instructions for use ○ Specifications for product ○ Specifications or procedures for manufacturing, packaging,	☐		

	storage, handling and distribution ○ Procedures for measuring and monitoring ○ Requirements for installation and procedures for servicing if applicable.			
4.2.4	**Control of Documents** • Is there a documented procedure defining the needed controls? • Does the procedure define needed controls for - ○ Review and approve documents for adequacy prior to issue ○ Review, update as necessary, and re-approve documents ○ Ensuring the current revision status and changes to documents are identified ○ Ensuring the relevant versions of applicable documents are			

	available at points of use ○ Ensuring that documents remain legible and readily identifiable ○ Ensuring that documents of external origin are identified, and their distribution controlled ○ Preventing deterioration or loss of documents ○ Preventing the unintended use of obsolete documents and applying suitable identification to them. ○ Retention period defined.			
4.2.5	**Control of Records** • Are the necessary records for QMS administered? • Does a documented procedure exist defining the controls needed for identification, storage, retrieval, retention time, and disposition of records?	☐		
5.1	**Management Commitment**			

	• Has the top management provided evidence of commitment regarding Quality Policy and Quality Objective?			
5.5.1	**Responsibility and Authority** • Are the responsibilities and authorities documented and defined within the organization? • Are they communicated to all the employees in the organization?			
5.5.2	**Management Representative** • Has the top management appointed a management representative for the organization? • Is there an appointment letter available for the Management Representative (MR) role that aligns with the standard requirement?			
5.5.3	**Internal Communication** • Has the top management ensured that appropriate communication processes have been established within the organization?			
5.6	**Management Review** • Is the Management Review meeting conducted as per the planned intervals to			

	ensure its continuing suitability, adequacy, and effectiveness? • Are the records of management reviews maintained as quality records? • Does the input to management review include- ○ Feedback ○ Complaint handling ○ Reporting to regulatory authorities ○ Audits ○ Monitoring and measurement of processes ○ Monitoring and measurement of the product ○ Corrective action ○ Preventive action ○ Follow-up actions from previous management reviews ○ Changes that could affect the quality management system ○ Recommendations for improvement			

	○ Applicable new or revised regulatory requirements • Does the output from the management review include decisions and actions related to ○ Improvement needed to maintain the suitability, adequacy, and effectiveness of the quality ○ Management system and its processes ○ Improvement of product related to customer requirements ○ Changes needed to respond to applicable new or revised regulatory requirements ○ Resource needs			
6.2	**Human Resource** • Is the competency of personnel who perform work affecting product quality based on appropriate education, training, skills, and experience? • Has the organization provided training or take			

	other actions to satisfy these needs? • Has the organization evaluated the effectiveness of the actions taken? • Has the organization ensured that all personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives? • Has the organization maintained appropriate records of education, training skills and experience?			
6.3	**Infrastructure** • Has the organization determined, provided, and maintained the infrastructure needed to achieve conformity to product requirements? • Does the infrastructure include the following - o Buildings, workspace, and associated utilities o Process equipment (both hardware and software) o Supporting services (such as			

	transport, communication, or information systems)			
6.4	**Work environment & Contamination control** • Has the organization determined and managed the needed work environment to achieve conformity to product requirements? • Does the organization have defined any procedure for the work environment and contamination control? • Have the requirements for health, cleanliness, and clothing of personnel been established, documented, and maintained? • In the case of sterile medical devices, has the organization documented requirements for control of contamination with microorganisms or particulate matter and maintained the required cleanliness during assembly or packaging processes?			
7.1	**Planning of Product realization** • Has the organization documented procedures			

	for risk management in product realization? • Has the organization-maintained risk management records for the product?			
7.2	**Customer Related Processes** • Has the organization defined and maintained a procedure that includes requirements specified by the customer, including the requirements for delivery and post-delivery activities? • Does the procedure contain requirements not stated by the customer but necessary for specified or intended use? • Has the management reviewed the requirements related to products and processes for efficient communication with customers and other related parties?			
7.2.3	**Customer communication** • Does the organization plan and document arrangements for communicating with customers in relation to: o product information			

	○ inquiries, contracts, or order handling including amendments ○ customer feedback, including complaints ○ advisory notices			
7.3	**Design and Development** • Has the organization established document procedures for design and development? • Does the organization plan and control the design and development of the product? • Are the inputs related to product requirements being determined and records maintained? • Are these inputs reviewed for adequacy and approved? • Do the results from design and development: ○ Meet the input requirements for design and development? ○ Provide appropriate information for purchasing, production and service provision?			

	- Contain or reference product acceptance criteria? - Specify the characteristics of the product that are essential for its safe and proper use? - Is a systemic review of design and development in accordance with planned arrangements, conducted at suitable stages? - Is design and development verification performed in accordance with planned arrangements to ensure that the design outputs have met the design and development input requirements? - Is the design and development validation performed in accordance with planned arrangements ensuring that resulting product is capable of meeting the requirements for the specified application or intended use? - Are the records of the validation are maintained?			

	• Are design and development changes identified and recorded? • Are results of review of changes and necessary actions maintained as records?			
7.4	**Purchasing** • Has the organisation established and documented procedures ensuring that purchased products conform to specified purchase requirements? • Are the records of supplier evaluation and any action arising from this maintained? • Has the organisation established and implemented the inspection or other activities necessary to ensure that purchased products meet specified purchase requirements?			
7.5.1	**Control of production and service provision** • Does the organisation plan and carry out production and service control under controlled condition? • Does the organization document the procedures			

	and methods for the control of production?			
7.5.2	**Cleanliness of product** • Has the organization established and maintained documented cleanliness requirements of the product?			
7.5.3	**Installation activities** • If appropriate, have instructions and acceptance criteria for installation and verification of medical devices been established and documented? • Have records of both installation and the verification performed by the organization been maintained?			
7.5.4	**Servicing activities** • Has the organization established and maintained documented procedures, as necessary for performing servicing activities? • Are records of servicing being maintained?			
7.5.5	**Particular requirements for sterile medical devices** • Are the records of the sterilization process parameters used for each			

	sterilization batch been maintained? • Are the sterilization records traceable to each production batch of medical devices?			
7.5.6	**Validation of processes for production and service provision** • Has the organization validated 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? • Are there established documented procedures for the validation of the application of computer software for production and service provision that affect the product?			
7.5.7	**Particular requirements for sterile medical devices** • Has the organization established and documented procedures for the validation of sterilization processes?			

	• Are these procedures validated prior to initial use?			
7.5.8 & 7.5.9	**Identification and Traceability** • Has the organization established procedures for the product identification and traceability? • Does the organization include records of all components, materials and work environment conditions if these could cause the medical devices not to satisfy the specified requirements (for implantable devices)? • Are records of the name and address of the shipping package consignee maintained?			
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? • Are the records maintained when customer property is lost, damaged or otherwise found to be unsuitable for			

	use, is reported to the customer?			
7.5.11	**Preservation of product** • Does the organization documented procedures for preserving the conformity of product to requirements during processing, storage, handling, and distribution?			
7.6	**Control of monitoring and measuring equipment** • Has the organization determined the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements? • Has the organization established and documented calibration procedure in case of measuring instruments?			
8.2.1	**Feedback** • Has a document feedback system been established and maintained to provide early warning of quality problems?			

	• Are the methods for obtaining and using the information determined?			
8.2.2	**Complaint Handling** • Is the organization established and documented procedures for timely complaint handling in accordance with applicable regulatory requirements? • Does the organization maintain a justification record for cases where no investigation is conducted? • Has the organization maintained a complaint log for recording complaint details?			
8.2.3	**Reporting to regulatory authorities** • Has the organization documented procedures for providing notification to the appropriate regulatory authorities? • Has the organization reported any adverse event to the regulatory bodies and maintained the record for the same?			
8.2.4	**Internal audit** • Is internal audit conducted at planned intervals to determine			

	whether the quality management system conforms to the planned arrangements? • Are the audit programs planned taking into consideration the status and importance of the processes and areas to be audited, as well as the results pf previous audits? • Are the records of the audits and their results, including identification of the processes and areas audited and the conclusions maintained?			
8.2.5	**Monitoring and measurement of processes** • Does the organization apply suitable methods for monitoring and measurement of the quality management system processes? • Are the records of correction and corrective action maintained when planned results are not achieved?			
8.2.6	**Monitoring and measurement of products** • Does the organization monitor and measure the characteristics of the product to verify that			

	product requirements have been met? • Has the organization-maintained records of evidence of conformity to the acceptance criteria? • In the case of implantable devices, has the organization recorded the identity of personnel performing any inspection or testing?			
8.3	**Control of nonconforming product** • Has the organization established and maintained any non-conformity procedure? • Have the organization-maintained records of actions taken in case of nonconformity products? • Has the organization established and documented procedures for issuing advisory notices in accordance with applicable regulatory requirements?			
8.4	**Analysis of data** • Has the organization established and documented procedures to determine, collect, and analyse appropriate data to demonstrate the suitability and			

	effectiveness of the QMS?
	• Does the analyse of data provide information relating to:
	  ○ Feedback?
	  ○ Conformity to product requirements?
	  ○ Characteristics and trends of processes and products including opportunities for preventive actions?
	  ○ Suppliers?			

8.5	**Improvement** • Does the organization take action to eliminate the cause of nonconformities in order to prevent recurrence? • Does the organization establish and document corrective and preventive action procedures? • Have the organization-maintained records of the results of any investigation and of actions taken? • Has the CAPA reviewed and verified and its effectiveness performed?			