ISO 13485:2016 Compliance Checklist

Summary

This checklist is designed to help organizations in the medical device sector assess and implement the core requirements of ISO 13485:2016. Each requirement is mapped to its relevant clause and sub-clause, and now includes a column with examples of evidence you might provide during an audit or compliance review. Use this as a practical tool to document your compliance status and identify any gaps.

1. Quality Management System

Checklist Item	Clause	Sub-Clause(s)	Evidence Required (Example)	✓	Comments
Is there a documented QMS maintained and regularly reviewed?	4.1	4.1.1 -- 4.1.6	Documented QMS manual, review meeting minutes	☐	
Are all organizational roles (manufacturer, distributor, importer, etc.) clearly defined?	4.1	4.1.1	Organizational chart, role descriptions	☐	
Are QMS processes identified, risk-based controls applied, and interactions documented?	4.1	4.1.2 -- 4.1.4	Process maps, risk assessment reports	☐	
Are changes to QMS processes evaluated and controlled?	4.1	4.1.4	Change control records, impact assessments	☐	
Are outsourced processes monitored and controlled?	4.1	4.1.5	Supplier quality agreements, monitoring reports	☐	
Is software used in the QMS validated and records maintained?	4.1	4.1.6	Software validation protocols, validation records	☐	

2. Documentation & Records

Checklist Item	Clause	Sub-Clause(s)	Evidence Required (Example)	✓	Comments
Is there a quality manual outlining scope, procedures, and process interactions?	4.2	4.2.2	Quality manual document	☐	
Are medical device files maintained for each product/family, including specifications?	4.2	4.2.3	Medical device files, product specifications	☐	
Are document and record controls in place (approval, revision, retention, confidentiality)?	4.2	4.2.4 -- 4.2.5	Document control procedures, record logs	☐	

3. Management Responsibility

Checklist Item	Clause	Sub-Clause(s)	Evidence Required (Example)	✓	Comments
Has top management established and communicated a quality policy and objectives?	5	5.1 -- 5.3	Quality policy document, communication records	☐	
Are responsibilities and authorities documented and communicated?	5	5.5.1	Responsibility matrix, communication logs	☐	
Are regular management reviews conducted, with records of inputs and outputs?	5	5.6.1 -- 5.6.3	Management review meeting minutes, action plans	☐	

4. Resource Management

Checklist Item	Clause	Sub-Clause(s)	Evidence Required (Example)	✓	Comments
Are adequate resources (personnel, infrastructure, environment) provided and maintained?	6	6.1 -- 6.4	Resource allocation records, maintenance logs	☐	
Is personnel competence ensured through education, training, and records?	6	6.2	Training records, competency assessments	☐	
Are infrastructure and maintenance requirements documented and followed?	6	6.3	Infrastructure maintenance records	☐	
Are work environment and contamination controls documented and implemented?	6	6.4	Environmental monitoring records, contamination control logs	☐	

5. Product Realization

Checklist Item	Clause	Sub-Clause(s)	Evidence Required (Example)	✓	Comments
Is there a documented process for planning product realization, including risk management?	7.1	7.1	Product realization plan, risk management records	☐	
Are customer and regulatory requirements determined and reviewed before accepting orders?	7.2	7.2.1 -- 7.2.2	Customer requirement documents, regulatory review records	☐	
Are communication processes with customers and regulatory authorities established?	7.2	7.2.3	Communication logs, correspondence records	☐	

Is there a documented design and development process, including reviews, verification, and validation?	7.3	7.3.1 -- 7.3.10	Design and development procedures, review minutes, verification and validation reports	☐	
Are purchasing controls in place for supplier evaluation, selection, and monitoring?	7.4	7.4.1 -- 7.4.3	Supplier evaluation records, purchase orders, monitoring reports	☐	
Are production and service provision processes controlled and documented?	7.5	7.5.1 -- 7.5.11	Production records, process control documents	☐	
Are cleanliness, installation, and servicing activities documented and controlled?	7.5	7.5.2 -- 7.5.4	Cleaning procedures, installation records, service reports	☐	
Are particular requirements for sterile medical devices and process validation addressed?	7.5	7.5.5 -- 7.5.7	Sterilization records, validation protocols	☐	
Is product identification and traceability maintained throughout realization?	7.5	7.5.8 -- 7.5.9	Identification procedures, traceability logs	☐	
Is customer property identified, verified, protected, and safeguarded?	7.5	7.5.10	Customer property logs, incident reports	☐	
Is product preserved during processing, storage, handling, and distribution?	7.5	7.5.11	Preservation procedures, storage records	☐	
Is monitoring and measuring equipment controlled and validated?	7.6	7.6	Calibration records, equipment validation reports	☐	

6. Measurement, Analysis, and Improvement

Checklist Item	Clause	Sub-Clause(s)	Evidence Required (Example)	✓	Comments
Are monitoring, measurement, analysis, and improvement processes planned and implemented?	8.1	8.1	Monitoring plans, analysis reports	☐	
Are feedback and complaint handling procedures documented and implemented?	8.2	8.2.1 -- 8.2.2	Feedback logs, complaint records	☐	
Are procedures in place for reporting to regulatory authorities when required?	8.2	8.2.3	Regulatory reporting records, notification logs	☐	
Are internal audits conducted at planned intervals, with corrective actions as needed?	8.2	8.2.4	Audit reports, corrective action records	☐	
Are processes and products monitored and measured to ensure conformity?	8.2	8.2.5 -- 8.2.6	Process monitoring records, product inspection reports	☐	
Are nonconforming products controlled, with documented procedures for identification, evaluation, and disposition?	8.3	8.3.1 -- 8.3.4	Nonconformance reports, disposition records	☐	
Are data analysis and improvement processes in place to monitor QMS effectiveness?	8.4	8.4	Data analysis reports, improvement plans	☐	
Are corrective and preventive actions documented and their effectiveness reviewed?	8.5	8.5.2 -- 8.5.3	CAPA records, effectiveness review reports	☐	

Tips for Effective Use

- Review each checklist item for compliance.
- Document supporting evidence or notes using the examples as a guide.
- Identify gaps and develop an action plan.
- Refer to the mapped clauses for detailed requirements in the official ISO 13485:2016 standard.

This checklist is a comprehensive yet practical guide. For full implementation, always refer to the official ISO 13485:2016 standard or consult BPRhub.