

ISO 13485 Implementation and Certification Readiness Checklist

Assess your current readiness for ISO 13485:2016 and identify key gaps before implementation or certification.

#	Area	Key Questions	Yes	Partial	No	N/A	Evidence Available (Examples)	Gap / Action Required
1	 QMS Foundation	Is the QMS scope defined and documented? Are QMS processes mapped and established? Are roles and responsibilities defined?	☐	☐	☐	☐	Quality Manual, Process Maps, Organization Chart	
2	 Document Control	Are procedures for document control in place? Are documents reviewed, approved and current? Is version control and change history maintained?	☐	☐	☐	☐	Document Control Procedure, Controlled Documents List	
3	 Records Management	Are quality records identified and maintained? Are records legible, retrievable and protected? Are record retention periods defined?	☐	☐	☐	☐	Records Control Procedure, Quality Records (e.g., training, audit, CAPA)	
4	 Management Responsibility	Are quality objectives defined and monitored? Is management review conducted periodically? Is the QMS adequately resourced?	☐	☐	☐	☐	Quality Objectives, Management Review Records	
5	 Resource Management	Are personnel competent and trained? Are infrastructure and work environment adequate? Are training records maintained?	☐	☐	☐	☐	Training Procedure, Training Records, Facility Records	
6	 Product Realization	Are design and development controls implemented (if applicable)? Are supplier controls established? Are production and service processes controlled?	☐	☐	☐	☐	Design Control Records, Supplier Evaluation Records, Production Records	
7	 Risk Management	Is a risk management process in place (ISO 14971)? Are risks reviewed across the product lifecycle? Are risk management records maintained?	☐	☐	☐	☐	Risk Management Plan, Risk Analysis File, Risk Review Records	
8	 Measurement and Monitoring	Are internal audits conducted as per plan? Is product and process monitoring performed? Are measurement equipment calibrated (if applicable)?	☐	☐	☐	☐	Internal Audit Reports, Monitoring Records, Calibration Records	
9	 Nonconformity, CAPA and Complaints	Are nonconformities documented and investigated? Are CAPA processes effective and closed on time? Is a complaint handling process established?	☐	☐	☐	☐	NCR/CAPA Records, Complaint Handling Records	
10	 Continuous Improvement	Are trends analysed for improvement opportunities? Are improvement actions tracked and effective? Is the QMS regularly reviewed for continual improvement?	☐	☐	☐	☐	Trend Analysis Reports, Improvement Plans, Management Review Records	



Identify your QMS gaps and get expert support for ISO 13485 implementation and certification.

Assess Your Medical Device QMS Gaps >