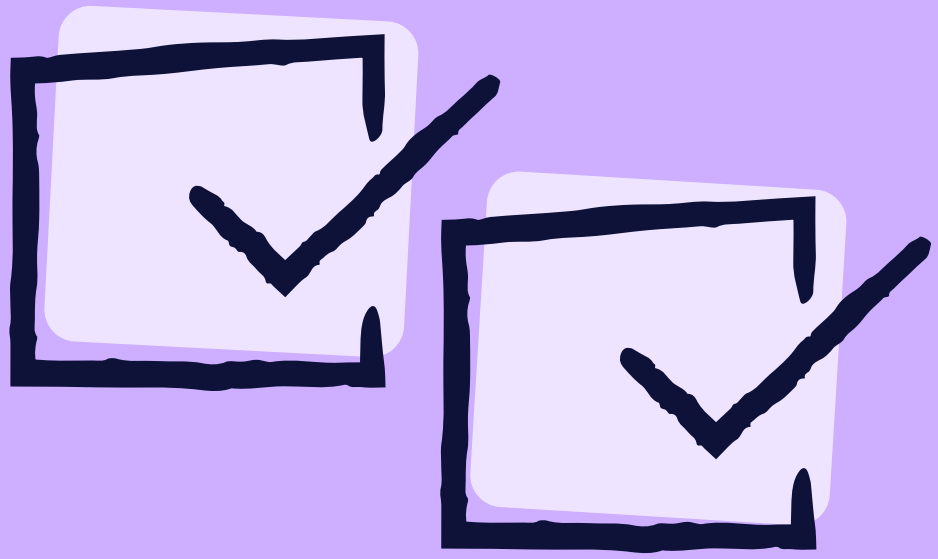
Scilife

ISO 13485 audit checklist



Introduction

This checklist gives you a high-level but practical guide to help assess compliance with ISO 13485. It's ideal for use in:

- **Internal audit training**
- **Department-specific self-assessments**
- **Spot-checks of under-audited areas like regulatory or clinical affairs**

You should use this checklist as a **starting point** to create tailored checklists based on the specific scope of each internal audit. Internal audits often focus on one area at a time, such as the CAPA and complaint system, production processes, STED files, or QMS documentation, rather than attempting to cover the entire quality system.

So go ahead and adapt this general guide (if needed) into **topic- or department-specific checklists** to effectively improve your audit depth, team preparedness, and overall quality engagement!

How to use the checklist

1. Review each tab of the checklist, **organized by ISO clause** and grouped into core QMS themes.

2. Use the "**What does it mean?**" column to clarify confusing terminology.

3. Refer to the **Examples** to better understand real-life expectations.

4. Mark your compliance status and document supporting **evidence**.

5. Use this as a base to build **scope-specific checklists**.

Bonus

Two tables at the bottom compare **ISO 13485 vs. ISO 9001**—a quick reference for those unsure about how the standards differ.

These comparisons are especially useful when explaining documentation or compliance expectations to stakeholders who may be more familiar with ISO 9001.

Don't miss any detail by diving into our full ISO 13485 audit preparation success guide!

Quality management system (Clause 4)

Checklist item	What does it mean?	Compliant?	Evidence
Is the scope of the QMS defined, including justification for exclusions?	Clearly document what parts of the ISO 13485 standard your QMS covers. If you're excluding any clauses (like design or servicing), explain why, and ensure it's legally acceptable. **Example**: A contract manufacturer might exclude design controls if they don't design products.	☐	
Are QMS processes identified, documented, and maintained?	Map out all the processes that make up your QMS (e.g., document control, purchasing, complaint handling). Maintain up-to-date documented procedures for each process. Ensure everyone follows the same steps and updates are controlled. **Example**: Use a flowchart or SOP to show how a customer complaint is received, investigated, and closed.	☐	
Are QMS records maintained per regulatory requirements?	Keep all required QMS records (e.g., training logs, CAPAs, internal audits) for the legally mandated time. Records must be legible, traceable, secure, and tamper-proof. Align retention policies with applicable country-specific regulations. **Example**: Retain post-market surveillance records for 10+ years depending on the device class and market.	☐	
Are software systems used in the QMS validated if they impact product quality?	If any software tool affects quality (e.g., CAPA system, document control platform), validate it. Validation = documented proof the software works as intended in your specific environment. Keep validation plans, protocols, test results, and approvals. **Example**: Validate a cloud-based QMS by testing workflows, access controls, audit trails, and error handling.	☐	

Management responsibility (Clause 5)

Checklist item	What does it mean?	Compliant?	Evidence
Is top management committed to the QMS and its effectiveness?	Leadership must actively support the QMS — not just delegate it to QA. This includes providing resources, reviewing data, promoting awareness, and participating in decision-making. Auditors want to see engagement, not just signatures. **Example**: Executives regularly attend management reviews and act on QMS.	☐	
Are regulatory requirements included in quality planning and objectives?	Quality objectives and planning must directly account for applicable regulatory rules (e.g., MDR, FDA QSR). Compliance isn't optional - it must be built into your strategy, goals, and operations. **Example**: A quality objective might include achieving zero overdue complaint investigations under FDA 21 CFR 820.	☐	
Is there a documented quality policy? Is it communicated and reviewed?	A written quality policy must exist, stating your commitment to product quality, regulatory compliance, and continual improvement. The policy should be understood by staff, reviewed during management review, and updated if needed. **Example**: Display the policy on-site, include it in onboarding, and discuss it during QMS training.	☐	
Are management reviews conducted at planned intervals, and do they cover regulatory and QMS performance?	Top management must hold formal, documented reviews of the QMS on a regular basis (usually annually or semi-annually). These reviews must cover: • Audit results • Customer feedback • Product performance • Nonconformities and CAPAs • Changes to regulations or risks **Example**: Minutes from a review meeting show actions taken to improve supplier controls after recurring issues.	☐	

Resource management (Clause 6)

Checklist item	What does it mean?	Compliant?	Evidence
Are personnel competent and trained for their roles?	All employees must have the necessary education, experience, training, and skills to do their work correctly, especially for activities that affect product quality or regulatory compliance. Training must be documented, evaluated for effectiveness, and repeated as needed (e.g., after a process change). **Example**: A person performing final device inspection should have specific training records and evidence they passed qualification.	☐	
Are infrastructure and work environment suitable for medical device production?	Facilities, equipment, software, and utilities must support consistent product quality - and meet applicable regulatory standards. This includes layout, cleanliness, lighting, humidity, compressed air systems, etc. **Example**: Production areas for sterile devices must meet specific ISO cleanroom classifications and be monitored.	☐	
Are health, cleanliness, and clothing requirements in place where necessary?	For any environment where contamination could affect product safety (especially implantables or sterile products), hygiene controls must be defined and enforced. This may include gowning procedures, glove use, personal hygiene policies, and restrictions on illness in the workspace. **Example**: Operators in an ISO 7 cleanroom wear sterile garments, follow entry protocols, and are trained not to wear cosmetics or jewelry.	☐	

Product realization (Clause 7)

Checklist item	What does it mean?	Compliant?	Evidence
Is there documented planning for product realization?	There must be a written plan for how your product will go from concept to customer, including design, purchasing, manufacturing, inspection, and delivery. The plan should define responsibilities, timelines, inputs/outputs, and risk controls. **Example**: A product development project plan includes process steps, risk assessments, and key milestones tied to quality checkpoints.	☐	
Are customer and regulatory requirements identified and	You must identify all requirements (technical, legal, performance) before accepting work. This includes reviewing customer contracts and applicable regulations (e.g., MDR, FDA, MDSAP) to ensure you're compliant from the start. **Example**: Before accepting a purchase order for a Class II device, QA reviews whether UDI, labeling, and documentation meet FDA expectations	☐	
Is design and development controlled, including inputs, outputs, reviews, verification, and validation?	The design process must follow a formal structure: • Inputs: What the product must do (e.g., user needs, performance criteria) • Outputs: What you build (e.g., drawings, specifications) • Reviews: Regular checks to ensure design stays on track • Verification: Did we build it right? • Validation: Did we build the right thing? Records must be kept at every step. **Example**: A design history file (DHF) includes risk analysis, prototype testing, and final validation reports.	☐	
Are risk management activities integrated into product realization?	Risk management isn't just a one-time activity - it must be applied throughout the lifecycle, in line with ISO 14971. You need to identify hazards, assess and control risks, and monitor residual risks at every phase. **Example**: A risk control measure (like adding an alarm) is traced from risk analysis through verification testing and post-market monitoring.	☐	

Product realization (Clause 7)

Checklist item	What does it mean?	Compliant?	Evidence
Are purchasing controls in place, and are suppliers evaluated for quality and regulatory compliance?	Suppliers must be qualified based on their ability to meet your quality and regulatory requirements. You need criteria for selection, performance monitoring, and re-evaluation, plus purchasing documents with clear expectations. **Example**: A supplier audit shows they follow ISO 13485, and your purchasing agreement includes specs and inspection criteria.	☐	
Is there traceability of components, materials, and subassemblies?	You must be able to trace all critical parts and materials used in a medical device, both forward (to the customer) and backward (to the supplier or batch). Especially required for implantable devices, sterile products, or when required by regulations. **Example**: You can identify which lot of tubing was used in a specific batch of IV catheters shipped to a hospital.	☐	
Are cleanliness, contamination control, and sterile conditions managed and validated?	If cleanliness or sterility impacts safety or function, you must define limits, control conditions, and validate cleaning/sterilization processes. Environmental monitoring, equipment cleaning, and sterile packaging must be documented. **Example**: Sterilization cycles are validated and revalidated periodically, with biological indicators and temperature mapping.	☐	
Is product preserved during internal processing and delivery (e.g., packaging, storage, handling)?	Devices must be protected against damage, contamination, or deterioration while being manufactured, stored, and shipped. Include packaging design, shelf-life validation, handling protocols, and special storage conditions (like temperature or humidity). **Example**: Fragile diagnostic cartridges are stored in temperature-controlled rooms and labeled with handling instructions.	☐	

Measurement, analysis, and improvement (Clause 8)

Checklist item	What does it mean?	Compliant?	Evidence
Are monitoring and measurement processes established and documented?	You need to define how you monitor product, process, and QMS performance - and document those methods. This includes inspection plans, quality metrics (KPIs), and test procedures. **Example**: You track and document in-process inspection results for every batch of devices, including tolerances and pass/fail criteria.	☐	
Are customer complaints reviewed, investigated, and documented?	All complaints must be formally recorded, assessed for impact, and investigated - with documented conclusions. Determine if a complaint is reportable (see 5.3) and if corrective action is needed. **Example**: A complaint about a faulty connector is investigated, root cause is found, and a report is filed in the complaint log.	☐	
Is there a documented process for reporting to regulatory authorities (e.g., adverse events, recalls)?	You must have procedures for timely reporting of serious incidents or product issues to regulators (e.g., FDA, EU, Health Canada). This includes vigilance, MDRs, FSCA/FSNs, and recall notifications. **Example**: A reportable malfunction under 21 CFR 803 is filed within the required timeframe and documented internally.	☐	
Are internal audits conducted at planned intervals, with documented procedures and corrective actions?	Internal audits must be scheduled, carried out by trained personnel, and follow a documented process. You must cover all QMS processes over time and ensure corrective actions are taken for any findings. **Example**: An audit uncovers missing training records; a CAPA is opened, records are updated, and effectiveness is verified later.	☐	

Measurement, analysis, and improvement (Clause 8)

Checklist item	What does it mean?	Compliant?	Evidence
Are CAPA (Corrective and Preventive Actions) processes effective and verified?	CAPAs must follow a structured, documented process: root cause analysis, implementation, and verification of effectiveness. Prevent recurrence or future issues and document every step. **Example**: A recurring packaging defect triggers a CAPA that leads to process redesign and follow-up monitoring to confirm success.	☐	
Are nonconforming products identified, segregated, and dispositioned properly?	Any product that doesn't meet requirements must be clearly labeled, separated from conforming products, and reviewed for disposition (e.g., rework, scrap). All steps must be documented and traceable. **Example**: A mislabeled syringe is caught during inspection, tagged as nonconforming, and documented in the NCR log with final decision.	☐	
Are data and trends analyzed to detect quality issues?	Use data (e.g., complaints, audit results, scrap rates) to find patterns or trends that indicate quality risks. Trend analysis should feed into management review and preventive action. **Example**: A rise in customer returns over three months prompts a review of production equipment and supplier quality.	☐	

Documentation requirements checklist: **ISO 13485 vs ISO 9001**

Document or record	Required by ISO 13485?	Required by ISO 9001?	Notes
Quality Manual	Yes	No (optional in ISO 9001)	
Medical device file (per product type)	Yes	No	Includes design, production, use, labeling, and servicing details.
Procedures (documented QMS processes)	Yes	Yes	Must cover all required processes.
Software validation records	Yes	No	Required for QMS-impacting software.
Supplier evaluation and re-evaluation	Yes	Yes	Stricter documentation required in 13485.
Complaint handling and reporting	Yes	No	Must align with regulatory obligations.
Traceability records	Yes (for specific device types)	No	

Key differences from ISO 9001

Area	ISO 13485 Focus	ISO 9001 Focus
Regulatory compliance	Central to the standard	Referenced but not core
Risk management	Throughout product lifecycle	Only mentioned in planning
Design control	Mandatory for devices	Optional depending on context
Validation (processes & software)	Required and documented	Not always required
Cleanliness / Sterility	Specifically addressed	Not addressed
Complaint & vigilance handling	Mandatory & regulated	Flexible
Traceability	Required for medical devices	Not required

Effortlessly maintain **ISO 13485 compliance.**

We integrate ISO 13485 compliance into daily workflows, **saving you time, stress, and risk during audits**.

Get in touch with our team

www.scilife.io

Scilife