

ISO 13485 Medical Device QMS Starter – Quick Start

Norman Quality Tools · Veteran-Owned & Operated

Templates, not regulatory advice. Not legal advice. The kit paraphrases topics and cites clause numbers only. Example rows in the workbook are fictional; delete them before use.

Work at your own pace. Do these steps in order:

1. **Open the guide first.** Open **00_Start_Here_README.pdf**. It lists every file and a recommended order.
2. **Set scope and policy.** In **01_Quality_Manual_ISO13485**, fill in the scope table: regulatory role, devices and classes, markets, and excluded clauses with a reason. Top management signs the policy.
3. **Adopt QP-01 and QP-02 first.** From **02_Core_Procedures_QP01-QP10**, adopt document control and records first. Edit every procedure to match what you really do, then train.
4. **Start the risk file.** Use **04_Risk_Management_File_ISO14971_Structure** and the Risk Analysis sheet in **06_ISO13485_QMS_Workbook.xlsx**. Keep the matrix and the workbook rule in step.
5. **Trace your design.** If design responsible, follow QP-05, the DHF index in **03**, and the Trace Matrix sheet. Every flagged row needs evidence before design transfer.
6. **Control production records.** Set up the DMR index and a DHR per lot in **03**. Release only after the four release checks and an authorized signature.
7. **Log CAPAs and complaints from day one.** Use **05_CAPA_and_Complaint_Forms** and the workbook logs. Record a reportability decision and rationale for every complaint.
8. **Audit and review.** Run the internal audit program and hold management review (QP-10) before the certification audit.

Stuck? See normanqualitytools.com for support options. Not sure what a regulation requires? Check the current rules for each market you sell into.

Independent guidance. Not affiliated with or endorsed by ISO, IEC, AAMI, or the U.S. FDA. Clause numbers are for navigation only; buy ISO 13485 and ISO 14971 from ISO or ANSI. Reporting timelines are summaries; confirm current rules for each market. Not legal advice; does not guarantee certification or FDA marketing authorization.

Norman Quality Tools · 600 W Santa Ana Blvd, Ste 114-A3064, Santa Ana, CA 92701

© 2026 Norman Quality Tools. All rights reserved.