



ISO 13485 Medical Device QMS Starter

A lean, editable QMS starter for small medical device makers and contract manufacturers.

What's inside

File	What it is / how to use it
01_Quality_Manual_ISO13485.docx	Scope, policy, org, clause-by-clause map (paraphrased) to your procedures, FDA QMSR note.
02_Core_Procedures_QP01-QP10.docx	Document control, records, training, risk management, design controls, purchasing, production/traceability/NC, CAPA, complaints & reporting, audit & management review.
03_DHF_DMR_DHR_Templates.docx	DHF index, DMR index, per-lot DHR with release checks and UDI.
04_Risk_Management_File_ISO14971_Structure.docx	Plan with acceptability matrix, intended use, controls, residual/benefit-risk, review, post-production log.
05_CAPA_and_Complaint_Forms.docx	CAPA form; complaint record with MDR/vigilance reportability decision.
06_ISO13485_QMS_Workbook.xlsx	Risk analysis with S x P before/after, trace matrix, CAPA log, complaint log with report clocks, training matrix.

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Recommended order

1. Fill the manual's scope and roles; sign the policy.
2. Adopt QP-01 and QP-02 first; everything else depends on them.
3. Start the Risk Management File per device family.
4. Run design work through QP-05 and the trace matrix (if design responsible).
5. Set up DMR/DHR for production; start CAPA and complaint logs on day one.
6. Audit and hold management review before the certification audit.

About the author

Built by Matt Norman, US Navy veteran and former SpaceX Falcon 9 quality inspector and QA supervisor. (Not affiliated with or endorsed by SpaceX.) Norman Quality Tools is Veteran-Owned & Operated. Contains no SpaceX, government, or customer proprietary information; all example data is made up.

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Quality Manual

ISO 13485 Medical Device QMS Starter - Document 01 - Rev A (2026-10)

1. Company and scope

Company		Address	
Regulatory role(s) (manufacturer, contract mfr, distributor...)		Devices / families and classes	
Markets (FDA, EU MDR, Health Canada/MDSAP...)		Excluded / not applicable clauses + justification	

2. Quality policy

[Company] designs/manufactures [devices] that are safe and perform as intended. We meet customer and applicable regulatory requirements, maintain the effectiveness of our quality management system, and train every employee to do their part. (Edit; top management signs.)

Role	Name	Signature	Date
CEO / top management			

3. Organization

Org chart (insert) and management representative named

4. How our QMS meets ISO 13485:2016 (paraphrased, clause numbers for navigation)

Clause	Topic	What it asks for (plain English)	Our procedure / record
4	Quality management system	Scope, roles (manufacturer, contract manufacturer, etc.), outsourced processes, software validation for QMS software, Medical Device File, document and record control.	QP-01, QP-02, Medical Device File
5	Management responsibility	Top management commitment, customer and regulatory focus, quality policy, objectives, management representative, internal communication, management review with the required inputs and outputs.	QP-10, Quality policy
6	Resource management	Competence and training effectiveness, infrastructure and maintenance, work environment and contamination control.	QP-03
7.1-7.2	Planning and customer processes	Product realization planning with risk management throughout, review of requirements before acceptance, communication incl.	QP-04, Risk Management File

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