

Chapter 8 Checklist: QMS Setup from Scratch

Subtract to Ship: MDR Certification*, Chapter 8: QMS, Building Quality from Scratch

Instructions

Set up your QMS from Day 1. Not Day 30. Not "when we have a prototype." This checklist walks you through the six-month build timeline. Start with the five core elements (8-14 pages total), then expand. A lean QMS that describes your real company beats a 500-page template with your name pasted on it.

Day 1 QMS: The Five Core Documents

Create these five documents this week. Total: 8-14 pages.

#	Document	Pages	Status	Date Completed
1	Quality Policy (signed by CEO)	1	☐	
2	Document Control Procedure	1-2	☐	
3	Risk Management Plan	3-5	☐	
4	Design and Development Procedure	2-4	☐	
5	CAPA Procedure	1-2	☐	

Quality Policy Self-Check

- ☐ Written by someone in this company (not downloaded from the internet)
- ☐ Signed by the CEO
- ☐ States THIS company's commitment to quality in specific terms
- ☐ A team member could read it and say "yes, that describes how we work"

Document Control Self-Check

- ☐ Naming convention defined
- ☐ Version numbering defined

- ☐ Approval workflow defined (who approves, how)
- ☐ Storage location defined (one location for current documents)
- ☐ Obsolete version handling defined

Six-Month Implementation Timeline

Weeks 1-2: Foundation

Task	Owner	Status
Write quality policy		☐
Establish document control procedure		☐
Set up QMS folder structure		☐
Brief entire team on QMS purpose and approach		☐

Weeks 3-6: Core Processes

Task	Owner	Status
Risk management plan + initial risk analysis		☐
Design and development procedure		☐
CAPA procedure		☐
Begin purchasing and supplier management procedures		☐

Weeks 7-12: Expansion

Task	Owner	Status
Production processes (if applicable)		☐
Competence management (training records, qualifications)		☐
Internal audit procedure		☐
First internal audit conducted		☐
First management review held		☐
PMS plan (initial version)		☐

Weeks 13-18: Refinement

Task	Owner	Status
Close findings from first internal audit		☐
Refine processes based on actual use		☐
Add device-specific procedures (EN 62304, EN 62366-1, EN ISO 10993 as applicable)		☐
Second internal audit		☐

Weeks 19-24: Maturation

Task	Owner	Status
Full management review cycle completed		☐
All core processes audited at least once		☐
Training records current for all team members		☐
QMS ready for NB pre-assessment or Stage 1 audit		☐

MDR Article 10(9) Compliance Check

Your QMS must address each of these. Map to your procedures:

MDR Requirement	Your Procedure	Status
(a) Regulatory compliance strategy		☐
(b) Safety and performance requirements (Annex I)		☐
(c) Management responsibility		☐
(d) Resource management / supplier control		☐
(e) Risk management		☐
(f) Clinical evaluation incl. PMCF		☐
(g) Product realisation (design, development, production)		☐
(h) UDI assignment verification		☐
(i) Post-market surveillance system		☐
(j) Communication with authorities, NB, stakeholders		☐
(k) Serious incident and FSCA reporting		☐
(l) CAPA management		☐
(m) Monitoring, measurement, data analysis		☐

Template Trap Avoidance Checklist

If you are using templates as a starting point:

- ☐ I have READ every section of every template (not skimmed)
- ☐ I have DELETED everything that does not apply to my company
- ☐ I have REWRITTEN everything that remains in my company's language
- ☐ I have VERIFIED against EN ISO 13485 that nothing required was accidentally deleted
- ☐ I have had someone experienced REVIEW the customised result

The test: Can every team member describe their QMS processes without opening a binder?

Audit Readiness Self-Check

The NB auditor checks three things:

- 1. Does the QMS exist?** - Required procedures are documented - Required records are maintained - Quality policy is in place - Management review is happening
- 2. Does the team follow it?** - Team members can describe their processes (matches documentation) - Design changes follow the documented procedure - CAPAs are conducted per the documented procedure - Document control is followed (current versions are identifiable)
- 3. Does it improve?** - Internal audit findings led to changes - Management review decisions resulted in actions - CAPA records show root cause investigation (not just symptom treatment)

Date completed:

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Completed by:

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QM Representative: