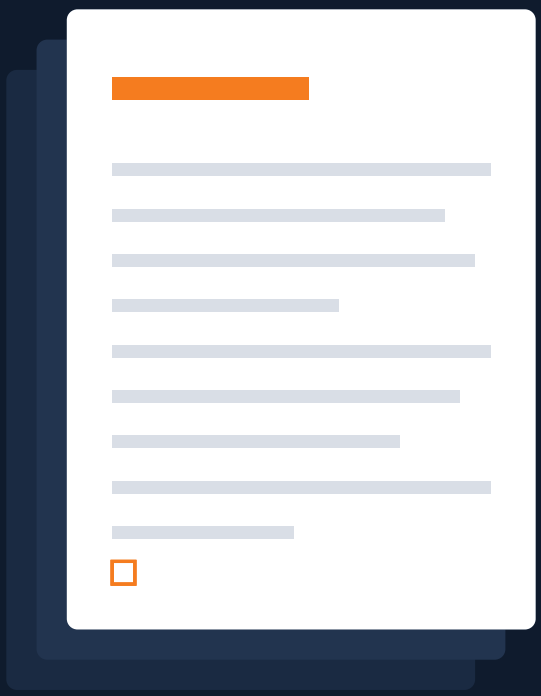
Documentation
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FREE TEMPLATE

QUALITY & COMPLIANCE

Quality Manual & Policy

The top-level description of your Quality Management System and quality commitment.

PRIMARY FOCUS

Top-level QMS structure and commitment

BEST FOR

ISO 9001 / 13485 certification

About this template

The Quality Manual describes how your Quality Management System (QMS) is organised: scope, policy, objectives, processes and how they interact, and where each ISO clause is addressed. It is usually the first document a certification auditor reads.

Detail	
Primary focus	Top-level QMS structure and commitment
Best for	ISO 9001 / 13485 certification

How to use it

- Replace every *[grey bracketed placeholder]* with your own details.
- Delete the orange **Guidance** boxes and green **Example** boxes before you publish or circulate it.
- Add or remove table rows as needed; keep the section order so readers can find things quickly.

Document Control

Document title		**Document no.**	
Revision		**Owner**	
Approved by		**Effective date**	
Next review date			

Version	Date	Author	Summary of changes
[1.0]	*[DD/MM/YYYY]*	*[Name]*	*[Initial release]*

01 Company Overview

Organisation name	
Products / services	
Sites covered	
Number of employees	

02 QMS Scope

GUIDANCE *State what the QMS covers and justify any ISO clauses that do not apply.*

Excluded / not applicable clause	Justification

03 Quality Policy

GUIDANCE *A short, signed statement of commitment to quality, customers, compliance and improvement.*

EXAMPLE We are committed to delivering products that meet customer and regulatory requirements, and to continually improving our processes through measurable objectives, trained people and listening to our customers.

04 Quality Objectives

GUIDANCE *Objectives must be measurable and consistent with the policy.*

Objective	Measure	Target	Owner	Review

05 Organisation & Responsibilities

Organisation chart
[Insert org chart]

Role	Quality responsibilities
Top management	
Quality manager	
Process owners	

06 Process Interaction

GUIDANCE *Show the core, management and support processes and how they connect.*



07 ISO Clause Cross-Reference

GUIDANCE *Map each clause to the procedure that addresses it.*

ISO clause	Title	Procedure / document
4	Context of the organisation	
5	Leadership	
6	Planning	
7	Support	
8	Operation	
9	Performance evaluation	
10	Improvement	

08 Management Approval

Role	Name	Signature	Date
Quality Manager			
Managing Director / CEO			

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