Step 5 – Implementation Checklist

Define QMS Scope

Implementation Summary

Activity	Description	Responsibilities	Deliverables/Outputs
Determine and document the QMS scope, boundaries, applicability, and process architecture	Clause 4.3 requires the organization to determine the boundaries and applicability of the QMS to establish its scope. Clause 4.4 requires the organization to establish, implement, maintain and continually improve the QMS, including the processes needed and their interactions. The scope statement must specify products, services, sites and any clauses determined not applicable — with documented justification (typically Clause 8.3 Design where the organization has no design responsibility). Implement P0434-01 QMS Scope and Process Architecture. The output is the QMS Scope Statement and a process map showing the processes, their inputs, outputs, sequence, and interactions.	QMS Lead Top Management Heads of Department	• Documented QMS Scope Statement covering products, services and sites • Justified exclusions with reference to specific 9001 clauses • Process map showing process sequence and interactions • P0434-01 QMS Scope and Process Architecture procedure issued

Implementation Checklist

Description	Evidence
Check that P0434-01 QMS Scope and Process Architecture is implemented and published in the controlled document set.	
Check that the QMS Scope Statement specifies products, services, and physical locations.	
Check that the scope considers external and internal issues (4.1) and interested party requirements (4.2).	
Check that any non-applicable 9001 requirements are identified with documented justification.	
Check that a process map (or equivalent) shows the QMS processes, their sequence and their interactions.	
Check that for each process the inputs, outputs, controls, criteria and resources have been defined.	
Check that the scope statement is published, communicated, and available to interested parties as appropriate.	
Notes:	

Approval for next step:

Actioned By:	*Signature:*	*Position:*	*Date:*
Verification By:	*Signature:*	*Position:*	*Date:*

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Step 8 – Implementation Checklist

Risks and Opportunities

Implementation Summary

Activity	Description	Responsibilities	Deliverables/Outputs
Determine risks and opportunities from context, interested parties and key processes	Clause 6.1 requires the organization to determine the risks and opportunities that need to be addressed to give assurance that the QMS can achieve its intended results, enhance desirable effects, prevent undesired effects, and achieve improvement. Risk-based thinking is core to ISO 9001:2026 and replaces the formal preventive action requirement of earlier editions. Risks and opportunities are determined from clauses 4.1 (context) and 4.2 (interested parties). Implement P0611-01 Risks and Opportunities. The output is a risks register (e.g. F0611-01) and a planned actions log linking each significant risk or opportunity to a treatment.	QMS Lead Heads of Department Implementation Team	• Risks and Opportunities register established • Each significant risk or opportunity linked to planned actions • Risk treatment integrated into quality objectives where appropriate • P0611-01 Risks and Opportunities procedure issued

Implementation Checklist

Description	Evidence
Check that P0611-01 Risks and Opportunities is implemented and published in the controlled document set.	
Check that risks and opportunities have been determined considering context (4.1) and interested party requirements (4.2).	
Check that the risk methodology — scoring scale, evaluation criteria, escalation thresholds — is defined and applied consistently.	
Check that climate-related risks are considered (per Clause 4.1).	
Check that for each significant risk or opportunity a treatment action is planned with owner and target date.	
Check that risk and opportunity treatment is integrated with quality objectives (Step 10) where appropriate.	
Check that the register is reviewed at Management Review (Clause 9.3) and after significant change.	
Notes:	

Approval for next step:

	Signature:	*Position:*	*Date:*
Actioned By:			
Verification By:			

SAMPLE

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