

2.13 External providers and supplied outputs — Clauses 8.4.1–8.4.3

DHF/QMS impact: Supplier and outsourced-design records support the DHF; the assessment contains conflicting omission and continuation statements.

Recommended actions: Keep qualification, selection, monitoring and reevaluation. Define controls for providers and deliverables, acceptance evidence, communicated requirements, changes and performance monitoring. Validate deltas before revising agreements.

Closure evidence: Approved supplier record; agreement/specification; scorecard; deliverable acceptance.

Owner and priority: Supplier Quality / Purchasing / R&D | High

2.14 Production, traceability and release — Clauses 8.5.1–8.5.4; 8.5.2; 8.6

DHF/QMS impact: Mostly aligned operational controls plus evidence wording changes. Records remain necessary to link configuration, verification and authorized release.

Recommended actions: Confirm product/configuration identification, status, supplier/customer property controls, preservation and acceptance evidence. Verify traceability to authorized release personnel. Update only identified gaps.

Closure evidence: Production/inspection records; traceability sample; release authorization; DHF references.

Owner and priority: Operations / QC / QA | High

2.15 Post-delivery and customer feedback — Clauses 8.5.5; 9.1.2

DHF/QMS impact: Feedback may create design inputs, complaint investigations or improvement actions. The source lists digital/social channels as examples.

Recommended actions: Assess relevant feedback channels and justify selection; do not assume every channel must be monitored. Define review, deduplication, complaint/safety escalation and product-change interfaces. Verify whether claimed post-delivery additions are genuinely new.

Closure evidence: Feedback plan; channel rationale; complaint triage; post-delivery review.

Owner and priority: Customer Quality / Service / RA | Medium

2.16 Analysis and effectiveness evaluation — Clauses 9.1.1–9.1.3

DHF/QMS impact: Risk-action and opportunity-action effectiveness should be separately identifiable in performance reviews.

Recommended actions: Update dashboards with conformity, customer satisfaction, project/process performance and supplier results. Distinguish actions on risks from opportunities, with data sources, owners and review periods.

Closure evidence: Dashboard; analysis report; separate effectiveness conclusions.

Owner and priority: QA / Data Owners | High

2.17 Internal audit — Clauses 9.2.1–9.2.2

DHF/QMS impact: The audit framework is substantially aligned; the assessment is inconsistent about retention. Audit evidence supports transition verification.

Recommended actions: Retain audit program, scope, criteria, auditor impartiality, reports, findings and corrective-action closure. Add confirmed transition topics to audit coverage; do not delete records before authoritative verification.

Closure evidence: Audit program/report; findings; follow-up; record-retention decision.

Owner and priority: Internal Audit / QA | High

2.18 Management review — Clauses 9.3.1–9.3.3

DHF/QMS impact: Supporting QMS impact: distinguish risk and opportunity actions and document decisions, resources and changes.

Recommended actions: Update agenda and input pack for context, stakeholders, objectives, performance trends, suppliers, resources and separate risk/opportunity effectiveness. Assign owners and dates to review decisions.

Closure evidence: Review pack; approved minutes; decisions and action tracker.

Owner and priority: Management / QA | High

2.19 Continual improvement and CAPA — Clauses 10.1; 10.2; legacy 10.3

DHF/QMS impact: The source describes improvement consolidation; CAPA is marked aligned. Maintain linkage between lessons, verified changes and measured outcomes.

Recommended actions: Map old/new improvement references. Track selected improvements with baseline, target, action, outcome and unintended-effect review. Preserve CAPA investigation and effectiveness evidence; use design change control for product modifications.

Closure evidence: Improvement log; CAPA report; benefits/effectiveness review; design-change links.

Owner and priority: QA / Process Owners / R&D | Medium

3. Document-by-Document Implementation Matrix

DHF/QMS record	Proposed revision	Owner	Planning window
Context, interested parties and scope (4.1–4.3)	Context register; stakeholder matrix; scope approval; product applicability decision.	QA / RA / Management	Weeks 2–8
Process documentation and evidence availability (4.4.1–4.4.2; 7.5)	Process map; record matrix; access/retrieval test; retention review.	QA / Document Control	Weeks 2–8
Leadership, quality culture and ethical behavior (5.1.1; 5.1.2)	Leadership action plan; communications; management decisions; escalation process.	Management / QA / HR	Weeks 2–8
Policy, roles and authorities (5.2; 5.3)	Approved policy; responsibility matrix; communication records.	Management / QA	Weeks 2–8
Risks and opportunities (6.1.1–6.1.3)	Risk/opportunity action register; approved criteria; effectiveness results; design links.	QA / Process Owners / R&D	Weeks 2–8
Objectives and plans (6.2.1–6.2.2)	Objective dashboard; project quality plan; action/effectiveness review.	Management / QA / Project Leads	Weeks 2–8
Change planning and effectiveness (6.3; 8.2.4; 8.3.6; 8.5.6)	Approved change record; impact assessment; communication; effectiveness closure.	Change Owner / QA / RA / R&D	Weeks 2–8
Organizational knowledge (7.1.6)	Knowledge register; handover record; lessons-learned review;	R&D / QA / IT	Weeks 2–8