

Responsibility: Training / Functional leads.

2.11 Responsibilities and lifecycle applications — source clause 4.2–4.5.2

Source classification: Full.

DHF/QMS impact: Retain adequate development, validation, manufacturing, and QMS integration records; the detailed comparison classifies these clauses as aligned.

Recommended actions: Check interfaces with change control, deviations, CAPA, suppliers, validation, and quality review. Revise only where implementation gaps or new cross-cutting controls justify it.

Closure evidence: Interface map, existing validation/control-strategy records, gap rationale.

Responsibility: Development / Operations / QA.

2.12 Regulator inspection strategy and intervals — source clause 5.2.1–5.2.3

Source classification: Part; regulator-facing.

DHF/QMS impact: Direct impact is on authority inspection planning; manufacturer impact is primarily readiness and response documentation.

Recommended actions: RA to assess applicability and verify exact classifications and interval wording. Do not automatically adopt the source's 48-month maximum as a manufacturer internal-audit, supplier-audit, or review interval.

Closure evidence: Applicability decision, inspection-readiness index, approved regulatory interpretation.

Responsibility: RA / QA.

2.13 Complaint handling scope — source clause 5.2.4

Source classification: Part; regulator-facing.

DHF/QMS impact: Clarify quality-complaint boundaries and the interface with pharmacovigilance.

Recommended actions: Maintain quality investigations and escalation of potential quality-related adverse events. Do not interpret the scope exclusion as removal of separate reporting obligations.

Closure evidence: Complaint triage map, interface procedure, case review.

Responsibility: QA / Safety / RA.

2.14 Inspection of QRM at a manufacturing site — source clause 5.3

Source classification: Part.

DHF/QMS impact: Ensure cross-functional participation, science-based decisions against predefined criteria, and records readily available for review.

Recommended actions: Build a retrievable inspection evidence index and check additional-control decisions, management involvement, and approvals.

Closure evidence: Retrieval exercise, evidence index, assessment and approval records.

Responsibility: Site QA / Functional leads.

2.15 Authority introduction and dossier assessment — source clause 5.1; 5.4

Source classification: Full for 5.1; Part for 5.4.

DHF/QMS impact: Dossier prioritization is regulator-facing; manufacturer dossier clarity is an indirect interface.

Recommended actions: Record applicability and map scientific rationales and key risk evidence to relevant submission sections where appropriate.

Closure evidence: Applicability assessment and dossier cross-reference index.

Responsibility: RA.

2.16 Risk tools, PHA, and statistical support — source clause 6; 6.1; 6.2

Source classification: New standalone sections per source.

DHF/QMS impact: Tool choice and analytical methods need a documented rationale; new headings do not establish that every listed tool is newly introduced or compulsory.

Recommended actions: Define selection criteria for PHA, FMEA, HACCP, HAZOP, matrices, and statistical methods. Document data suitability, assumptions, limitations, and interpretation. Use only methods appropriate to the question.

Closure evidence: Tool-selection guide, completed PHA, justified statistical analysis where relevant.

Responsibility: QRM lead / Statistician / QC.

3. DHF/QMS Document-by-Document Implementation Matrix

Record	Proposed update	Owner	Indicative window
QRM SOP and applicability register	Confirm source identity, scope, governance and cross-cutting changes	QA / RA	Weeks 1–3
Product/process knowledge register	Control maps, sources, limitations and updates	Development / Operations	Weeks 2–5
Risk assessment template	Add evidence, uncertainty and control-effectiveness rationale	QRM lead	Weeks 2–5
Subjectivity and decision records	Standardize anchors, assumptions, challenge and approvals	QA / QRM lead	Weeks 3–6
Review/reporting procedure	Add reporting recipients, triggers, owners and records	QA	Weeks 3–6
Competence program	Practical effectiveness assessment and reassessment	Training	Weeks 4–8
Tool-selection guide	PHA and analytical-method selection with limitations	QRM lead / QC	Weeks 4–8
Product-specific risk files	Pilot then update affected development/validation records	Product owners	Weeks 6–10
Inspection/dossier index	Record regulator-facing applicability and retrieval links	RA / Site QA	Weeks 6–10
Transition closure report	Evidence review, unresolved items and approvals	QA / Management	Weeks 10–12