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REGULATION CHECKLIST

ICH Q10: section-by-section checklist (guideline)

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> ICH Q10 (Step 4, June 4, 2008) is a guideline, not a regulation; its content beyond current regional GMP requirements is optional. QMSdesk is designed to support it. How you apply it is decided and evidenced in your own pharmaceutical quality system; the last column is yours to complete. This checklist is general information, not legal or regulatory advice.

The ICH Q10 section-to-control map

ICH Q10 section (paraphrased)	How QMSdesk supports it	Evidence the system produces	What you still own	Your evidence
§1.8, §2.1–2.5 Quality manual, management commitment, quality policy, planning, resources, communication	Document control holds your quality manual and policy, with signed authoring, review and approval. The author never reviews or approves their own document, and training is assigned on approval.	Signed document history with each signature's meaning; training records.	The content: your policy, objectives, plans and resourcing decisions.	
§1.6.1 Knowledge management	Controlled and reference documents with typed cross-references; typed, attributed links between quality records; global search across documents, events, changes, audits, suppliers, training and risks.	A navigable record of what's linked to what, by whom and why.	Product and process knowledge from development, technology transfer and validation, much of which lives outside a QMS.	
§1.6.2 Quality risk management	A risk register built on ISO 14971 and ICH Q9(R1) principles: 5×5 or FMEA scoring, severity dominance, signed assessments and signed residual risk. Event investigation depth scales with severity.	Signed risk assessments and residual-risk decisions in the audit trail.	Your risk-management procedure and the scientific judgment behind each assessment.	
§2.7 Outsourced activities and purchased materials	Supplier qualification by risk tier, with review every 6, 12 or 24 months; corrective-action requests answered through a single-use link; quality agreements held as reference documents. The Contract operations profile adds QA-agreement deviation events.	Signed supplier status decisions; a supplier scorecard; SCAR history.	Supplier audits, the written agreements themselves, and incoming-material controls.	

ICH Q10 section (paraphrased)	How QMSdesk supports it	Evidence the system produces	What you still own	Your evidence
§2.8 Change in product ownership	No dedicated workflow. Change control can record the transfer as a planned change.	The change record, if you use one.	Defining each company's ongoing responsibilities and transferring the information needed.	
§3.2.1(a)–(d), (f) Control strategy; measuring and analyzing parameters and attributes; sources of variation; process knowledge	Outside QMSdesk's scope. QMSdesk doesn't hold batch, process or in-process data.	None.	Your control strategy, and the batch, process, statistical and stability data in your manufacturing and laboratory systems.	
§3.2.1(e) Feedback from complaints, rejections, nonconformances, recalls, deviations, audits and regulatory inspections	Complaints, deviations and audit findings are recorded in QMSdesk, nonconformances with signed disposition and recalls under the GMP profile. Events trend by type, severity, site, product and root cause. OOS lab-error invalidations trend by method, analyst and instrument.	Trend views by type, severity, site, product and root cause, and the lab-error trend.	Deciding what the feedback and trends mean for your processes, including inspection findings, and acting on them.	
§3.2.2 CAPA from complaints, rejections, nonconformances, recalls, deviations, audits, inspections and trends; root cause; effort in proportion to risk	CAPA as its own record, raised from events, audit findings, trends, reviews or directly. Root cause and category recorded. QA reviews each action item for moderate, major and critical CAPAs.	Signed action-plan review, verification and closure; action items with evidence.	Your CAPA procedure and the quality of each investigation.	
§3.2.2 (Table II) Evaluate CAPA effectiveness	Effectiveness verification can't be skipped. After closure, a scheduled check confirms the effect held, over an interval you set.	Scheduled checks and their outcomes; a new linked CAPA if a fix didn't hold.	Setting the effectiveness criteria for each CAPA, and the check interval.	
§3.2.3(a), (c) Evaluate changes by risk, with the right expertise	Risk-based approval routing: high-impact changes need the Change Manager and the Quality Manager. Classification can raise a tier, never lower it. Approvers can be added, never removed.	Signed approvals, each with its recorded meaning.	Choosing the experts, and setting prospective evaluation criteria.	
§3.2.3(b) Assess whether a change affects the regulatory filing	Your procedure. The Assessment stage records the change's impact and risk.	The assessment on the change record.	The regulatory-filing determination and any submission.	
§3.2.3(d) Evaluate the change after implementation	A Verification stage, signed by someone other than the implementer. When a change affects training, training for affected roles is assigned on implementation.	Signed verification; training assignments linked to the change.	Confirming the change met its objectives without harming product quality.	

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§3.2.4, §2.6 Management review of process performance and product quality	A signed, frozen snapshot of your quality records, taken across your whole organization as of the period end: CAPA aging, events trending, training compliance, audit findings, the risk register, the supplier scorecard and document status. Minutes and decisions signed at closure; follow-up actions tracked afterwards.	The snapshot, signed minutes and decisions, and open follow-ups.	Conclusions on process performance and product quality, such as product quality review outcomes and the effectiveness of changes, and your leadership's decisions.	
§4.1 Management review of the PQS itself	The same snapshot covers complaint, deviation, CAPA and audit performance. A CAPA can be raised from a review with no triggering event.	A CAPA linked back to the review.	Your quality objectives and performance indicators.	
§4.2 Monitoring of internal and external factors	Reference documents record external standards and guidance with their issuing body and version, and a periodic currency check asks whether each is still the current issue.	Reference documents with their provenance and currency checks.	Watching for new regulations, guidance, quality issues, innovations and business changes, and acting on them.	
§4.3 Outcomes of management review and monitoring	Minutes and decisions signed at closure; follow-up actions stay assignable after closure until they're done.	Signed minutes and decisions; follow-up actions.	Improvements, resource and training decisions, revisions to your quality policy and objectives, and communicating the results.	