QMSdesk™

www.qmsdesk.com
info@akatalyst.com
India +91 77600 78606
Dubai +971 50 280 1688

REGULATION CHECKLIST

EU GMP Annex 22 (draft): section-by-section checklist

Reviewed by Abdul Azam, Founder & CEO, 25 years in regulated life-sciences quality. Last reviewed September 26, 2026.

> Annex 22 is a July 2025 consultation draft. It is not adopted and not binding. It covers the main provisions of the draft, not every clause. QMSdesk embeds no AI model: this checklist helps you assess AI you run elsewhere, and the QMSdesk records that can support it. How you meet it is established in your environment, for your intended use; the last column is yours to complete. This checklist is general information, not legal or regulatory advice.

Running AI elsewhere? The draft Annex 22 clause-to-control map (July 2025 consultation draft, not adopted)

Draft provision (section, paraphrased)	How QMSdesk supports it	Evidence the system produces	What you still own	Your evidence
§1 Scope: static, deterministic machine-learning models in critical GMP applications; generative AI and LLMs excluded	Not applicable inside QMSdesk: it embeds no AI model.	None.	Deciding which of your models and applications fall in scope, and which are critical.	
§2.1 Qualified personnel with defined responsibilities and access	Training by acknowledgment, quiz, practical assessment or external certificate; competency assessments by qualified assessors; access set by permission keys.	Training and competency records.	Defining the team (subject-matter experts, QA, data scientists, IT) and its qualifications.	
§2.2 Documentation for these activities available and reviewed by you, including when a supplier provides the model	Supplier qualification by risk tier, with signed status decisions. Supplier documents held as reference documents with issuing body, version and issue date.	Signed supplier decisions; reference documents with currency checks.	Reviewing the documentation itself.	
§2.3 Activities scaled to the risk to patient safety, product quality and data integrity	A risk register built on ISO 14971 and ICH Q9(R1) principles, with signed assessments and signed residual risk.	Signed risk records.	The risk assessment of the model's use.	
§3.1, §4.2 Intended use and acceptance criteria approved before acceptance testing	Document control with signed authoring, review and approval by different people.	Dated, signed approval, each signature with its meaning.	The content, and the subject-matter expert accountable for it.	
§3.3 Operator responsibility, training and performance, where a person makes the final call and model testing was reduced	Training assigned automatically, with recurring refreshers and competency assessments.	Training history per person.	Monitoring each operator's ongoing performance.	

Draft provision (section, paraphrased)	How QMSdesk supports it	Evidence the system produces	What you still own	Your evidence
§5, §6 Test data: representative, labeled, independent, access-controlled	Outside QMSdesk's scope. QMSdesk is not a test-data repository.	None.	Your test datasets and the controls on them.	
§7.2–7.4 Approved test plan; deviations investigated; documentation retained	Document control for the test plan. A deviation record, with investigation and signed closure, for any departure from the plan. Retention floors of 7, 10, 15 or 30 years, and no hard deletion.	Signed plan; deviation record; retained documents.	Running the test and judging its results.	
§8, §9 Explainability, confidence scores and thresholds	Outside QMSdesk's scope. They belong to the AI system.	None.	Capturing and reviewing them.	
§10.1 Change control for the model, its system and its process	Change control with risk-based routing and verification by someone other than the implementer.	Signed change records.	Deciding whether to retest, and justifying any decision not to.	
§10.2 Configuration control of the deployed model	Outside QMSdesk's scope.	None.	Configuration control in the AI system.	
§10.3–10.5 Performance and input monitoring; records of human review	Outside QMSdesk's scope for the monitoring itself. When monitoring finds a problem, record it as a deviation and raise the CAPA it needs.	A linked deviation and CAPA.	The metrics, the monitoring and the review records.	