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REGULATION CHECKLIST

EU GMP Annex 11: section-by-section checklist

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> This checklist follows the 2011 text of Annex 11, in force on the review date; the July 2025 draft revision has not been adopted. QMSdesk is designed to support the controls described in the second column. Rows marked outside QMSdesk's scope, and all procedures, are yours. Compliance 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.

The Annex 11 in force today, section by section

Requirement (2011 section, paraphrased)	How QMSdesk supports it	Evidence available	What you still own	Your evidence
Principle. Validate the application and qualify the IT infrastructure. Where a system replaces a manual operation, there should be no decrease in product quality, process control or quality assurance, and no increase in the overall risk of the process.	QMSdesk's core platform is validated under a QA-approved Validation Summary Report. We'll walk you through the full record under a mutual NDA. QMSdesk is hosted with a cloud infrastructure provider that holds a SOC 2 Type II attestation; that attestation is the provider's, not ours.	Validation Summary Report, walked through under a mutual NDA	Validating for your intended use; assessing the infrastructure in your supplier assessment	
§1 Risk management. Apply risk management across the lifecycle, and base the extent of validation and data-integrity controls on a justified, documented risk assessment.	QMSdesk's core platform is validated under a QA-approved Validation Summary Report. We'll walk you through the full record under a mutual NDA. Your own risk assessment can run in QMSdesk as a controlled document, with signed review and approval.	Validation Summary Report, walked through under a mutual NDA; your signed risk assessment	Your risk assessment for your intended use	
§2 Personnel. Close cooperation; appropriate qualifications, access levels and defined responsibilities.	Nine core roles with granular permissions; training and competency records; the Administrator role holds no authority to review, approve, verify or close quality records.	Role assignments, training records	Naming process and system owners, and defining responsibilities	
§3 Suppliers and service providers. Formal agreements with clear responsibilities; audit by risk; review supplier documentation; supplier quality information available to inspectors.	Every engagement includes a written validation scope, and we'll walk you through the full validation record under a mutual NDA. The supplier quality module qualifies and reviews your suppliers by risk, us included.	Written validation scope, your supplier file	The agreement, the decision to audit us, and your review of our documentation	

Requirement (2011 section, paraphrased)	How QMSdesk supports it	Evidence available	What you still own	Your evidence
§4 Validation. Lifecycle documentation; traceable user requirements; supplier assessment; test evidence; checks on data migration.	QMSdesk's core platform is validated under a QA-approved Validation Summary Report. We'll walk you through the full record under a mutual NDA. You configure and test in your real tenant, and go-live takes two signed attestations. Migrated documents carry a signed batch attestation and a permanent "Migrated" badge.	Your go-live test records, kept in your tenant; go-live and migration attestations	Your user requirements, system inventory, intended-use validation and migration checks	
§5 Data. Built-in checks for data exchanged with other systems.	System-to-system access runs through an external API with explicit scopes and credentials tied to a named owner. An integration may carry out work but can't sign.	API credentials, managed by your administrators	Validating any interface you connect	
§6 Accuracy checks. A second check on critical data entered manually.	Workflows put an independent reviewer or approver on critical records, enforced at signing. Your procedure decides whether that review is the second check on manually entered data.	Signatures by different people	Deciding which data is critical	
§7 Data storage. Protect data; keep it accessible through the retention period; back it up.	Tenant isolation by row-level security; a retention floor set by your profiles; quality records never hard-deleted; a suspended module stays readable and exportable.	Retention sweep log	Covering backup and restore of hosted data in your supplier assessment	
§8 Printouts. Clear printed copies; for records supporting batch release, printouts that show whether data changed since original entry.	PDF reports, controlled copies and closure records. QMSdesk holds no batch records. Where its records, such as batch deviations, support batch release, the audit-trail export lists the recorded changes.	Logged downloads, audit-trail export	Deciding which QMSdesk records support batch release and how you show changes to them; batch-release printouts in your batch system	
§9 Audit trails. Based on risk, record GMP-relevant changes and deletions; document the reason; keep trails available, intelligible and regularly reviewed.	A hash-chained, insert-only audit trail capturing who, what, old and new values, the reason and the time. Export, and a signed periodic review over a risk-focused view.	Audit trail, daily verification, signed review	Your review procedure and cadence	
§10 Change and configuration management. Change only in a controlled way, by a defined procedure.	After go-live, a validation-affecting setting can't be written until approved change control reaches implementation. Administrators can't edit workflow steps.	Change-control records, signed setting changes	Your change procedure, and assessing each QMSdesk release against your validated state	

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§11 Periodic evaluation. Confirm the system stays in a valid state and in line with GMP.	The records an evaluation draws on live in QMSdesk: deviations, incidents, CAPAs, change controls, signed audit-trail and access reviews, and a signed System Boundary Statement.	Those records	Running and documenting the evaluation	
§12 Security. Restrict access; record changes to access authorizations; record who entered or changed data, and when.	Multi-factor authentication, lockout, an inactivity timeout and SAML single sign-on. Role grants and deactivations carry a signature meaning, and every audit entry records who and when.	Audit trail, access reviews	Physical security at your sites, and access decisions	
§13 Incident management. Report and assess all incidents; the root cause of a critical incident drives CAPA.	An incident workflow with containment for major and critical incidents and a signed CAPA decision, then CAPA with effectiveness checks.	Incident and CAPA records	Reporting system incidents into it	
§14 Electronic signature. Where records are signed electronically: same impact as handwritten within the company; permanently linked; time and date.	Re-authentication at every signature, a recorded meaning, and the signature committed with the change it approves. A daily job re-checks every link.	Signature records, daily linkage results	Your policy giving e-signatures handwritten weight	
§15 Batch release. Where a computerized system records certification and batch release, only Qualified Persons can certify release, by electronic signature.	Outside QMSdesk's scope. The GMP profile adds a QP role, but QMSdesk has no batch-certification workflow.	—	Batch certification in your release system	
§16 Business continuity. Documented, tested fallback arrangements.	Your procedure.	—	Your continuity plan	
§17 Archiving. Archived data stays accessible, readable and intact.	Quality records are archived, never hard-deleted, and stay readable. The audit-trail chain is verified daily.	Chain verification results	Testing retrieval in your periodic evaluation	