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GxP — 21 CFR Part 11 & EU GMP Annex 11

Audit-trail integrity, two-component e-signatures, and independent review — by structure, not by SOP.

What the regulator asks

FDA Form 483s and EU GMP critical findings cluster around **§11.10(e)** (audit trail integrity), **§11.10(j)** (independent review), and **Annex 11 §9**. The pattern is the same: audit trails exist, but the Administrator can read or alter them, and the "independent review" is performed by the same person who could have edited the records.

Clause → Magellan primitive

Clause	What it requires	How Magellan answers it
`§11.10(e)`	Audit trails shall not obscure previously recorded information.	Append-only ledger enforced twice: REVOKE UPDATE/DELETE on the role, plus a row-level trigger that raises on any modification attempt.
`§11.10(j)`	Independent review of records on a defined cadence.	Compliance Officer is a distinct role; Administrator cannot read or alter the ledger. The review is itself a signed ledger entry.
`§11.50`	Signature manifestation includes signer, datetime, meaning.	Signature manifestation lives in the same row as the signature — name, ISO-8601 timestamp, and meaning string ("draft" / "release" / "attestation").
`§11.200`	Two-component electronic signatures.	Drafter ≠ releaser, enforced at the database. Same identity attempting both signatures is rejected before commit.
`Annex 11 §9`	Audit trails generated independently and protected from alteration.	SHA-256 hash chain — verification is a script the inspector runs themselves; no verbal assurance required.
`Annex 11 §14`	Electronic signatures linked to their records.	Signature is itself a ledger entry; hash-chained to the record it signs. Severing the link breaks the chain.

Why this works on inspection

- **The independent reviewer is structurally incapable of editing what they review.** Not a process commitment — an RBAC property.
- **Reproducibility across inspectors.** An FDA inspector and an EU GMP inspector see byte-identical evidence from the same export.
- **Product-lifecycle retention.** Default retention is the longer of 6 years (HIPAA), 7 years (SOX), or product lifecycle (GxP). Shortening it requires a Compliance Officer signature.

Evidence pack the assessor receives

Ledger range with hash chain, role grants during the range, all e-signatures with §11.50 manifestation in-line, Compliance Officer attestation entries, retention-policy entries, and a verification script. The pack is the same shape an FDA inspector and an EU GMP inspector both expect.