21 CFR Part 11 Electronic Records and Signatures

by Nick Clark | Published April 25, 2026

21 CFR Part 11 Frame

21 CFR Part 11 establishes FDA requirements for electronic records and signatures, with substantial impact on pharmaceutical clinical trials, medical device manufacturing records, and emerging AI/ML training operations.

Architecture Implications

AI/ML training operations increasingly face Part 11 record-integrity requirements. Per-example provenance, training-event lineage, and signature attestation all benefit from architectural substrate.

Architectural Mapping

Training-governance per-example provenance maps to Part 11 audit-trail requirements. Credentialed authority signatures map to electronic-signature requirements.

Part 11 Evolution

FDA emerging Part 11 modernization and emerging AI/ML-specific Part 11 guidance push toward structurally-supported architecture.