

POLYMORPH-LITE v5.0

21 CFR Part 11 Gap Analysis

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21 CFR Part 11 Requirement	POLYMORPH Implementation	SOP Requirement
11.10(a) Validation	Automated IQ/OQ/PQ scripts	Execute & Sign Validation Protocols
11.10(b) Copies of Records	PDF Export, JSON Audit Trail	Regular Backup Verification
11.10(c) Protection of Records	Database Encryption, RBAC	Manage User Access Levels
11.10(d) Limiting System Access	JWT Auth, Unique User IDs	Password Policy Enforcement
11.10(e) Audit Trails	Immutable DB Log, SHA-256 Hashes	Periodic Audit Trail Review