Complere CSV + CSA Validation Pack

Table of contents - nine artifacts per module, delivered on day one, included in the licence

Each artifact is generated against the customer tenant during onboarding and re-issued on releases that affect validated functionality. The pack covers all seven core modules - Document Control, CAPA & Deviations, Quality Events, Audit Management, Change Control, Risk Assessments, and Training & Competency - plus the platform core and administration layer. Built using a risk-based approach aligned to FDA's Computer Software Assurance Final Guidance (February 3, 2026).

#	Artifact	What it covers	Maps to
1	**VMP - Validation Master Plan**	Scope, validation strategy, deliverables, roles, schedule, acceptance criteria for the module under validation.	GAMP 5 lifecycle; 21 CFR Part 11 §11.10(a)
2	**URS - User Requirements Specification**	Tenant-specific functional, regulatory, performance, and integration requirements; unique IDs for traceability.	GAMP 5 (URS); EU Annex 11 §4.4
3	**RA - Risk Assessment**	Per-requirement risk tier under a CSA-aligned methodology; drives scripted vs lighter test rigour.	FDA CSA Final Guidance; ICH Q9
4	**TM - Traceability Matrix**	Maps every URS requirement to risk tier, test cases, and implementation evidence end-to-end.	GAMP 5; 21 CFR Part 11 §11.10(a)
5	**IQP - Installation Qualification Protocol**	Verifies tenant infrastructure: region, application version, database, storage, SSO, audit-trail enablement.	GAMP 5 (IQ); EU Annex 11 §11
6	**OQP - Operational Qualification Protocol**	Tests platform functions against URS/TM: workflows, e-signatures, RBAC, audit trail, lifecycle transitions.	GAMP 5 (OQ); Part 11 §11.10(b)-(k), §11.50, §11.70
7	**PQT - Performance Qualification Test**	End-to-end customer-process validation in the production tenant: real users, real records.	GAMP 5 (PQ); EU Annex 11 §4.7
8	**Part 11 checklist**	Maps each 21 CFR Part 11 sub-clause (§11.10(a)-(k), §11.50, §11.70, §11.100-11.300) to implementation evidence.	21 CFR Part 11 (entire)
9	**ATS - Audit Trail Specification**	What the audit trail captures, retention, immutability, export format, reviewer workflow.	Part 11 §11.10(e); ALCOA+; EU Annex 11 §9

How the pack behaves on upgrades: release notes map each platform change to affected URS/TM rows; only affected scripts regenerate, and re-execution scope is risk-based. Audit trail integrity is preserved across upgrades.

Full artifact descriptions: complere.tech/validation-pack | Validation methodology: complere.tech/compliance/validation-approach | Request a validation-focused demo: complere.tech/request-demo

This document describes the deliverables Complere ships. Validation remains the regulated company's responsibility - the pack is designed to carry most of that effort, not to replace your QA approval.