



# OptiZeus SCADA Validation

Auto-Generated IQ · OQ · PQ · URS · FS · DS · RA · TM · VSR · AT

OptiZeus SCADA v2.5.4 · VLD-OZ-GAMP5 · © 2026 Zeus Automation

optizeus.org · sales@optizeus.org · 3 pages



## VALIDATION OVERVIEW

OptiZeus SCADA is a **GAMP5 Category 4 — Configured Product**. The platform includes a built-in AI assistant that auto-generates all 10 validation documents using your site-specific configuration data. Documents are produced in editable format and must be reviewed, site-adapted, and approved by the site QA team before use.

### VLD-URS User Requirements Specification

Captures what the system must do from the user perspective. All requirements numbered (URS-001...) for traceability.

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### VLD-FS Functional Specification

Translates URS requirements into system functions. Each FS item references its parent URS requirement.

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### VLD-OQ Operational Qualification

Verifies all functions operate as specified. 15+ test scripts covering alarms, historian, e-sig, batch.

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### VLD-RA Risk Assessment (FMEA)

FMEA-based risk identification per GAMP5 Appendix M9. Risk levels: High / Medium / Low with mitigations.

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### VLD-VSR Validation Summary Report

Consolidates all validation activities and provides formal declaration that the system is fit for intended use.

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### VLD-DS Design Specification

Describes system architecture, modules, DB schema, security controls, and network topology.

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### VLD-IQ Installation Qualification

Verifies the system is installed correctly. 10 test cases with acceptance criteria.

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### VLD-PQ Performance Qualification

Verifies system performs in production conditions. 30-day operation, accuracy, load, failover tests.

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### VLD-TM Traceability Matrix

Links every URS requirement through FS → DS → IQ/OQ/PQ test cases → results. Auto-maintained by the AI.

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### VLD-AT Audit Trail Configuration Report

Documents audit trail setup, record fields, retention policy, and compliance with 21 CFR Part 11 §11.10(e).

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### HOW TO GENERATE VALIDATION DOCUMENTS

- 1 Configure AI Provider**  
Settings → AI Assistant → select provider (Ollama recommended for pharma)
- 2 Go to GAMP5 Module**  
Menu → GAMP5 Validation → Generate Documents
- 3 Enter Site Info**  
Site name, system owner, QA contact, system description
- 4 Select Documents**  
Choose which documents to generate (all 10 recommended)
- 5 Review & Edit**  
AI generates in minutes — review, add site specifics, approve
- 6 QA Sign-Off**  
Print / export PDF — QA manager signs each document
- 7 Archive**  
Store signed documents in site document management system

### IQ — INSTALLATION QUALIFICATION TESTS

TEST ID	ACCEPTANCE CRITERION	
IQ-001	Software version verified as v2.5.4	■
IQ-002	Server OS and hardware matches DS	■
IQ-003	Network connectivity confirmed	■
IQ-004	Database connection tested	■
IQ-005	TLS/HTTPS certificate valid	■
IQ-006	Required ports accessible through firewall	■
IQ-007	Admin account creation successful	■
IQ-008	License key activated — correct tier	■
IQ-009	Backup procedure documented and tested	■
IQ-010	Windows service starts automatically on reboot	■

### OQ — OPERATIONAL QUALIFICATION TESTS

TEST ID	ACCEPTANCE CRITERION	
OQ-001	Login with valid credentials — access granted, audit...	■
OQ-002	Login with invalid credentials 5x — account locked	■
OQ-003	MFA/TOTP authentication — second factor required	■
OQ-004	Viewer role — cannot write tags (403 Forbidden)	■
OQ-005	OPC UA tag value read from PLC — live value displayed	■
OQ-006	Tag write to PLC with e-signature — value written, l...	■
OQ-007	Alarm trigger at HH threshold — alarm raised, notifi...	■
OQ-008	WhatsApp/SMS notification received within 60 seconds	■
OQ-009	Historian logging at configured rate — data stored i...	■
OQ-010	Historian trend retrieval — correct values displayed	■
OQ-011	Audit trail entry for tag write — user, time, old/ne...	■
OQ-012	E-signature on batch close — reason code + hash stored	■
OQ-013	ISA-88 recipe phase advance — phase completes correc...	■
OQ-014	User auto-logout after inactivity — session terminated	■
OQ-015	HTTPS enforced — HTTP connection auto-redirected	■





## PQ — PERFORMANCE QUALIFICATION TESTS

TEST ID	ACCEPTANCE CRITERION	
PQ-001	24-hour continuous operation — no errors or data gaps	■
PQ-002	Full production batch execution — EBR complete and signed	■
PQ-003	Historian accuracy vs reference $\pm 0.1\%$	■
PQ-004	Alarm response time under load $< 2$ seconds	■
PQ-005	Multi-user concurrent (5 users) — no conflicts	■
PQ-006	Network failover — client reconnects within 30 seconds	■
PQ-007	Data integrity after server restart — no data loss	■
PQ-008	Audit trail completeness — 100% of operations logged	■
PQ-009	Report generation under load — PDF correct, no errors	■
PQ-010	Annual regression — all OQ test cases pass	■

## TRACEABILITY MATRIX SAMPLE

URS Req	FS Ref	DS Ref	IQ	OQ	PQ	Status
URS-001	FS-001	DS-003	IQ-007	OQ-001	PQ-005	PASS
URS-002	FS-002	DS-003	IQ-001	OQ-011	PQ-008	PASS
URS-003	FS-003	DS-004	IQ-007	OQ-012	PQ-008	PASS
URS-004	FS-004	DS-002	IQ-003	OQ-005	PQ-003	PASS
URS-005	FS-005	DS-005	IQ-006	OQ-007	PQ-004	PASS
URS-006	FS-006	DS-006	IQ-004	OQ-009	PQ-007	PASS
URS-007	FS-007	DS-007	IQ-001	OQ-013	PQ-002	PASS
URS-008	FS-008	DS-003	IQ-007	OQ-003	PQ-005	PASS

## VALIDATION SIGN-OFF

ROLE	SIGNATURE	DATE
QA Manager	_____	____/____/____
Validation Manager	_____	____/____/____
System Owner	_____	____/____/____
Zeus Automation Rep.	_____	____/____/____

## CHANGE CONTROL PROCEDURE

- Change Request**  
Document change description and justification
- Impact Assessment**  
QA evaluates: Minor / Moderate / Major / Critical
- Testing**  
Minor: verify only · Major: full IQ/OQ/PQ retest
- Implement**  
Make change in Test server — audit trail active
- Deploy**  
1-Click deploy to Production with QA sign-off
- Document**  
Update all affected VLD documents + VSR addendum

**GAMP5 Support: [sales@optizeus.org](mailto:sales@optizeus.org) · [optizeus.org/docs](http://optizeus.org/docs) · [zeus-automation.com](http://zeus-automation.com)**

Document: VLD-OZ-GAMP5 · OptiZeus SCADA v2.5.4 · GAMP5 Category 4

