



VALIDATION & SOFTWARE LIFECYCLE DOCUMENT

OptiZeus SCADA Platform · Version 2.5.4
Document: VLD-OZ-SCADA · GAMP5 Cat. 4 · 21 CFR Part 11
© 2026 Zeus Automation



1. PURPOSE & SCOPE

This document describes the validation strategy and software lifecycle approach for OptiZeus SCADA (v2.5.4), in accordance with **ISPE GAMP5** guidelines, **21 CFR Part 11** (FDA Electronic Records & Signatures), and **EU Annex 11** (Computerised Systems in regulated pharmaceutical manufacturing).

OptiZeus SCADA is classified as a **GAMP5 Category 4 — Configured Product**. The system is supplied as a standard software product that is configured (not customised at source code level) by the end user or by Zeus Automation on behalf of the client. This classification determines the level of validation effort required and the documentation that must be produced and maintained.

2. GAMP5 SOFTWARE CLASSIFICATION

Cat. 1 Infrastructure Software
OS, middleware, virtualization — minimal validation

Cat. 3 Non-Configured Products
Standard COTS software used without configuration

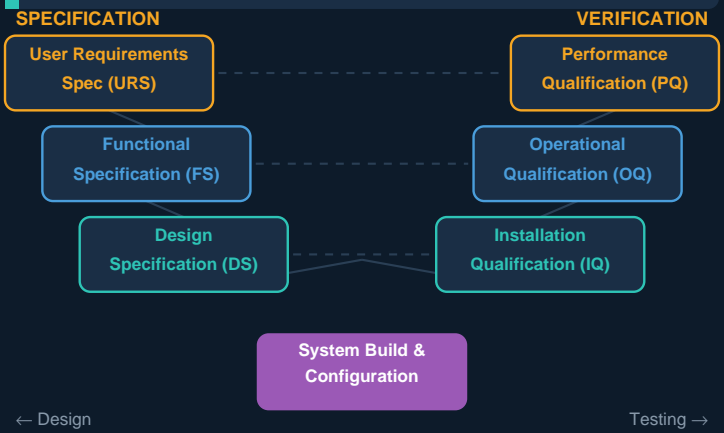
Cat. 4 Configured Products ■ **SELECTED**
OptiZeus SCADA — configured per user requirements

Cat. 5 Custom Software
Bespoke code — highest validation burden

3. APPLICABLE REGULATIONS

GAMP5	ISPE Good Automated Manufacturing Practice
21 CFR Part 11	FDA Electronic Records & Electronic Signatures
EU Annex 11	Computerised Systems — EU GMP Guideline
ICH Q10	Pharmaceutical Quality System
ISO 9001	Quality Management Systems
IEC 62443	Industrial Cybersecurity Standards
ISA-88	Batch Control Standard (S88)
ISA-18.2	Alarm Management Standard

4. VALIDATION V-MODEL



TRACEABILITY REQUIREMENT

Each URS requirement must be traceable forward through FS → DS → IQ/OQ/PQ test cases → results. The Traceability Matrix (TM) maintained in

5. VALIDATION DOCUMENT SUITE

VLD-URS	User Requirements Specification	Auto-generated
VLD-FS	Functional Specification	Auto-generated
VLD-DS	Design Specification	Auto-generated
VLD-IQ	Installation Qualification	Auto-generated
VLD-OQ	Operational Qualification	Auto-generated
VLD-PQ	Performance Qualification	Auto-generated
VLD-RA	Risk Assessment (FMEA)	Auto-generated
VLD-TM	Traceability Matrix	Auto-generated
VLD-VSR	Validation Summary Report	Auto-generated
VLD-AT	Audit Trail Configuration Report	Auto-generated





SPECIFICATION PHASE — Define What the System Must Do

6. USER REQUIREMENTS SPECIFICATION (URS)

The URS captures what the system must do from the user's perspective, independent of technical implementation. It forms the top of the V-Model and every requirement must be uniquely numbered and traceable.

Document ID	VLD-URS-OZ-001
Owner	Site Validation Manager / QA
Approval	QA Manager + System Owner signature
Format	Numbered requirements (URS-001, URS-002...)
Content	Functional, performance, compliance, interfaces
Auto-Generate	OptiZeus AI assistant generates URS template
Review Cycle	Annual review or upon major system change

7. FUNCTIONAL SPECIFICATION (FS)

The FS translates URS requirements into system functions — how OptiZeus will fulfil each requirement. Each FS item references its parent URS requirement.

Document ID	VLD-FS-OZ-001
Owner	Zeus Automation
Traceability	Each FS item references URS requirement ID
Content	Screen flows, tag logic, alarm rules, batch steps
Interfaces	PLC connections, DB schema, user roles defined
Auto-Generate	OptiZeus AI generates FS from URS input
Approval	Engineering Manager + QA sign-off required

EXAMPLE URS REQUIREMENTS	
URS-001	The system shall require unique user credentials for login
URS-002	The system shall record all operator actions in an audit trail
URS-003	The system shall support electronic signatures per CFR 11
URS-004	The system shall acquire data from PLCs via OPC UA
URS-005	The system shall generate alarm notifications via email/SMS
URS-006	The system shall store process data for minimum 5 years
URS-007	The system shall support ISA-88 batch recipe execution

FS → URS TRACEABILITY EXAMPLES	
FS-001	→ URS-001 Login page requires username + password + MFA
FS-002	→ URS-002 All tag writes logged: user, time, old/new value
FS-003	→ URS-003 E-sig dialog: password + reason code on batch close
FS-004	→ URS-004 OPC UA client configured per server endpoint list
FS-005	→ URS-005 Alarm engine sends email/SMS on HH/H priority
FS-006	→ URS-006 Historian retention = configurable, default unlimited
FS-007	→ URS-007 S88 batch engine executes SFC recipe phases

8. DESIGN SPECIFICATION (DS)

The DS describes the technical implementation — architecture, modules, database schema, communication interfaces, and security controls.

Document ID	VLD-DS-OZ-001
Owner	Zeus Automation / System Integrator
Covers	Architecture, modules, DB schema, interfaces
Security Sec.	Authentication, RBAC, encryption, audit
Network Diag.	OT/IT topology, firewall zones, protocols
Config Baseline	All configured parameters documented
Auto-Generate	OptiZeus AI generates DS template

9. SYSTEM CONFIGURATION & BUILD

OptiZeus SCADA is configured — not coded — by the end user. All configuration is performed through the web interface and recorded in the audit trail.

Tag Database	Define all I/O tags, addresses, scaling, alarms
HMI Screens	Build synoptic displays using SVG component library
Alarm Rules	Configure thresholds, priorities, notification routing
User Accounts	Create roles, assign permissions, enable MFA
PLC Connections	Configure driver instances, endpoints, scan rates
Historian	Set logging rates, compression, retention per tag
Batch Recipes	Define S88 equipment model, phases, parameters
Reports	Configure scheduled PDF/CSV report templates
Config Backup	Export full configuration to versioned backup files
Change Control	All changes logged in audit trail with user + reason

10. RISK ASSESSMENT (FMEA — GAMP5 Appendix M9)

Ref	Failure Mode	Effect	Cause	Risk Level	Mitigation in OptiZeus
RA-001	Unauthorized access	Data breach / wrong control	Weak credentials	HIGH	MFA + RBAC + LDAP + auto-logout
RA-002	Audit trail corruption	Regulatory non-compliance	SW bug / hack	HIGH	Append-only DB + admin read-only
RA-003	PLC connection loss	Loss of monitoring	Network failure	MEDIUM	Store & Forward + alarm on disconnect
RA-004	Wrong tag write	Process out of control	Operator error	HIGH	E-signature + confirm dialog + audit
RA-005	Data loss — historian	Loss of process history	DB failure	MEDIUM	Store & Forward + DB backup + redundancy
RA-006	Batch record error	Product release failure	Config error	HIGH	EBR + e-signature + OQ test coverage





QUALIFICATION PHASE — Verify the System Was Built Right & Works as Required

INSTALLATION QUALIFICATION (IQ)

VLD-IQ-OZ-001

Verifies the system is installed correctly and all components are present and properly documented.

Test ID	Test Description
IQ-001	Software version verification AC: OptiZeus v2.5.4 installed
IQ-002	Server OS and hardware check AC: Per DS specification
IQ-003	Network connectivity test AC: Server reachable on LAN
IQ-004	Database installation check AC: SQL Server connected
IQ-005	TLS/HTTPS certificate verification AC: Valid cert, no warnings
IQ-006	All required ports accessible AC: Firewall rules verified
IQ-007	Admin account creation AC: Login successful
IQ-008	License key activation AC: Tier features enabled
IQ-009	Backup procedure documented AC: Backup tested + restored
IQ-010	Windows service running (WinSvc) AC: Auto-start on reboot

OPERATIONAL QUALIFICATION (OQ)

VLD-OQ-OZ-001

Verifies the system operates as specified across all functional requirements under normal and boundary conditions.

Test ID	Test Description
OQ-001	User login with valid credentials AC: Access granted, audit logged
OQ-002	Login with invalid credentials AC: Account locked, alert raised (SX)
OQ-003	MFA/TOTP authentication AC: Second factor required
OQ-004	Role-based screen access AC: Viewer cannot write tags
OQ-005	Tag value read from PLC via OPC UA AC: Live value displayed
OQ-006	Tag write to PLC with e-signature AC: Value written, logged
OQ-007	Alarm trigger at HH threshold AC: Alarm raised, notification sent
OQ-008	Alarm WhatsApp/SMS notification AC: Message received <30s
OQ-009	Historian logging at configured rate AC: Data stored in DB
OQ-010	Historian trend retrieval AC: Correct values displayed
OQ-011	Audit trail entry for tag write AC: User, time, old/new value
OQ-012	E-signature on batch close AC: Reason code + hash stored
OQ-013	ISA-88 recipe execution — phase advance AC: Phase completes correctly
OQ-014	User auto-logout after inactivity AC: Session terminated, logged
OQ-015	HTTPS enforced — HTTP redirected AC: Secure connection only

PERFORMANCE QUALIFICATION (PQ)

VLD-PQ-OZ-001

Verifies the system performs consistently under actual production conditions and meets all user requirements in the intended environment.

Test ID	Test Description
PQ-001	24-hour continuous operation AC: No errors / data gaps
PQ-002	Full production batch execution (S88) AC: EBR complete + signed
PQ-003	Historian accuracy vs reference instrument AC: Within ±0.1% tolerance
PQ-004	Alarm response time under load AC: <2s from trigger to display
PQ-005	Multi-user concurrent operation (5 users) AC: No conflicts, all logged
PQ-006	Network failover — backup server AC: Client reconnects <30s
PQ-007	Data integrity after server restart AC: No data loss confirmed
PQ-008	Audit trail completeness review AC: 100% of ops logged
PQ-009	Report generation under production load AC: PDF correct, no errors
PQ-010	Annual revalidation — regression suite AC: All OQ tests pass





11. CHANGE CONTROL PROCEDURE

All changes to a validated OptiZeus installation must follow a formal change control procedure to maintain the validated state.



12. CHANGE IMPACT CLASSIFICATION

MINOR

Config param change (tag scaling, alarm limit)
Action: Verify + document, no retest

MODERATE

New PLC connection, new screen, user role change
Action: Targeted OQ tests + document

MAJOR

Core function change, DB schema, security model
Action: Full IQ/OQ/PQ retest cycle

CRITICAL

Software version upgrade, architecture change
Action: Complete revalidation + VSR

13. PERIODIC REVIEW & REVALIDATION

Validated computerised systems must be periodically reviewed to confirm they remain in a validated state. GAMP5 recommends annual reviews.

Review Frequency	Annual minimum — or triggered by change
Trigger Events	Software update, hardware change, deviation
Review Scope	Audit trail analysis, SOPs, user accounts
Regression Tests	Critical OQ test suite re-executed
Change Review	All CRs since last review assessed
Incident Review	All deviations/OOS investigated
User Review	Access rights audit — remove leavers
Backup Test	Restore from backup verified
Output	Periodic Review Report — QA signed
Archive	All review records retained per SOPs

14. VALIDATION SUMMARY REPORT (VSR)

The VSR consolidates all validation activities and provides the formal declaration that OptiZeus SCADA is fit for its intended use.

Document ID	VLD-VSR-OZ-001
Owner	Validation Manager
Approval	QA Director signature required
Contents	Summary of URS, FS, DS, IQ, OQ, PQ
Deviations	All deviations documented + justified
Open Items	Any open items with closure dates
Conclusion	Formal statement of validated state
Auto-Generate	OptiZeus AI generates VSR from test records

15. TRACEABILITY MATRIX (TM)

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

16. CONTINUOUS LIFECYCLE — VALIDATED STATE MAINTENANCE



VALIDATION DOCUMENT APPROVAL & SIGN-OFF

ROLE	NAME	SIGNATURE	DATE
System Owner	_____	_____	___/___/___
Validation Manager	_____	_____	___/___/___
QA Manager	_____	_____	___/___/___
IT / Automation Mgr	_____	_____	___/___/___

Validation support: sales@optizeus.org · Zeus Automation: info@zeus-automation.com · optizeus.org

