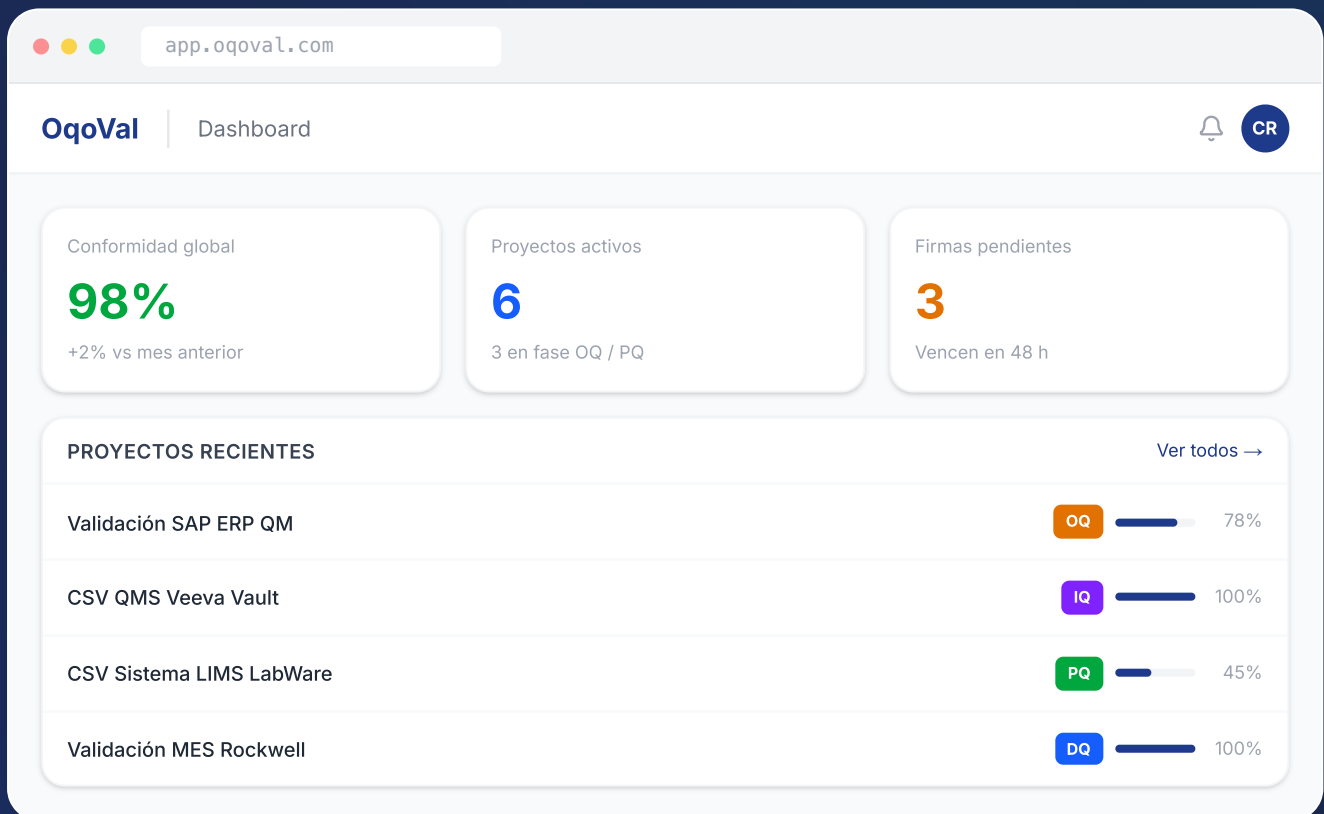


EXECUTIVE BRIEF

OqoVal

AI-driven CSV/CSA validation. Audit-ready from day one.

The validation engine that cuts up to 90% of GxP protocol drafting time, with electronic signatures compliant with 21 CFR Part 11 and EU Annex 11, and an immutable audit trail.



Traditional validation no longer scales with the business.

While GxP systems update every two weeks, validation programs still operate like in 2008. Cost, time and regulatory risk are climbing together.

+38%

Average increase in CSV validation cost across pharma IT projects over the last 5 years.

ISPE PHARMA 4.0 BENCHMARK

6 – 12

Weeks of average go-live delay caused by validation documentation.

OQOTECH INTERNAL DATA 2023 – 2025

1 / 3

FDA inspections in 2024 issuing Form 483 for Computer System Validation deficiencies.

FDA INSPECTION DATA 2024



Digital tools and intelligent systems used in GMP operations must demonstrate traceability, integrity and human oversight of every decision — including AI-assisted ones.

— EU GMP Annex 22 — draft July 2025

Three decades of regulation. One conclusion.

Every major regulatory shift was answered with more paperwork. AI changes the equation: evidence is generated, not drafted.

1997

21 CFR Part 11

Electronic records equivalent to paper. The era of mass documentation begins.

2008

GAMP 5

Risk-based approach. The industry learns to categorize but accumulates templates.

2022

FDA CSA

Computer Software Assurance. Stop documenting for the sake of it; prove the system works.

2025

EU Annex 22 + FDA AI Guidance

AI in GxP decisions. Traceability of algorithmic proposals and mandatory human oversight.

OqoVal on one page.

A SaaS platform that automates the full CSV/CSA validation cycle while keeping qualified people at the heart of every decision.



Generate

VP, URS, DQ, IQ, OQ, PQ, RA and TM produced from project context. Ready for human review in hours, not weeks.



Sign

Electronic signatures compliant with 21 CFR Part 11 and EU Annex 11. Multi-level workflow with mandatory justification.



Audit

Immutable audit trail, inspector-ready export and full traceability of every AI-assisted decision.



IQ-001 — Protocolo de Verificación de Instalación

v2.1 · CSV Sistema LIMS LabWare · 25 abr 2025

2 / 3 firmas



Carlos Ruiz

Redactor



Firmado

28 abr · 09:14



Laura Fuentes

Revisora QA



Firmado

28 abr · 14:32



Dra. Ana Vidal

Resp. Regulatorio



Pendiente

Notificación enviada



FOUNDING PRINCIPLE

AI proposes. Qualified people decide and sign. The system never approves nor validates autonomously.

Defensible ROI in year one.

Comparison based on industry benchmarks (ISPE GAMP 5 v2, FDA inspection data 2024 and OqoTech internal data 2023 – 2025). Actual results depend on scope and QA maturity.

Metric	Traditional validation	With OqoVal	Reduction
IQ/OQ/PQ protocol drafting time per system	40 – 80 h	4 – 8 h	–85 to –90%
Average validation cost (medium-complexity GxP system)	€25 – 60 k	€8 – 20 k	–60 to –70%
Time-to-audit (inspection readiness)	2 – 6 weeks	< 48 h	–95%
Inconsistencies detected pre-inspection	Manual / sample	Automatic / 100%	—
Qualified team hours freed for expert judgment	—	60 – 70%	+ high value

Indicative figures. Not a contractual guarantee. A detailed projection for your organization is delivered after a 30-minute technical session.

Designed against the frameworks that matter.

OqoVal complies by default with the four regulatory authorities that affect pharma industries in Europe, the Americas and Latin America.

21 CFR Part 11

FDA · USA

Electronic records and signatures.



EU Annex 11

EMA · EUROPE

Computerised systems in GMP.



GAMP 5 v2

ISPE · INTERNATIONAL

Risk-based validation.



EU Annex 22

EMA · 2025 (DRAFT)

AI in GMP operations.



ISO 9001:2015

OqoTech, OqoVal manufacturer, operates under certified QMS.

EU infrastructure

Data hosted in European data centers. Encryption at rest and in transit.

Auditable end-to-end

Every action logged with timestamp, user, reason and integrity hash.

By sector and system type.

Four customer profiles where OqoVal returns the highest value within the first 90 days.



Pharmaceutical industry

Multi-site manufacturers validating SAP, MES, LIMS and SCADA on a recurring basis.

- > **Validation load: -65% on recurring IT projects.**



Medical devices

Companies under MDR + FDA QSR integrating CSV into their QMS without doubling headcount.

- > **Time-to-market: -4 to -8 weeks per release.**



Biotech and ATMP

Highly complex processes where data integrity is critical for batch release.

- > **Traceability: 100% auditable events in real time.**



CROs and clinical units

Operators handling trial data under GCP needing to demonstrate Part 11 to sponsors.

- > **Inspectorate readiness: < 48 h for any sponsor audit.**

Let's talk without a sales pitch.


A 30-minute conversation with OqoTech's CEO. No generic material: we review your current validation program and tell you honestly where OqoVal can help and where it cannot.

[Request executive demo](#)




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