CASE STUDY

Alembic Pharmaceuticals

A documented account of how one of India's largest pharmaceutical manufacturers eliminated paper-based validation across nine sites in under six weeks — and what happened next.

Published by GoVal (GoValidation) | govalidation.com

BACKGROUND

About Alembic Pharmaceuticals

Alembic Pharmaceuticals is one of India's most established pharmaceutical manufacturers, with more than a century of heritage and a manufacturing footprint spanning nine regulated facilities. The company operates across active pharmaceutical ingredients (API), formulations, and international markets, supplying US FDA, EU GMP, and WHO GMP-regulated customers globally.

With over 16,000 employees and a pipeline spanning hundreds of products across multiple therapeutic areas, Alembic runs one of the largest validation programmes among India-based pharmaceutical exporters. Maintaining GxP compliance at this scale requires coordinated validation activities across all nine sites—a coordination challenge that paper-based processes were increasingly unable to support.

Organisation Profile	
Company	Alembic Pharmaceuticals Ltd.
Headquarters	Vadodara, Gujarat, India
Founded	1907 (over a century of heritage)
Manufacturing Sites	9 regulated facilities
Regulatory Scope	US FDA, EU GMP, WHO GMP
Products	APIs, formulations, international generics
Employees	16,000+
Industry	Pharmaceutical manufacturing

THE CHALLENGE

Running Validation at Scale on Paper

Before GoVal, Alembic's validation programme operated the way most large pharma organisations do: Word documents, Excel traceability matrices, shared drives, and wet signatures collected by email or physical routing. At a single site, this is manageable. Across nine regulated facilities with hundreds of concurrent and sequential validation projects, it creates a structural compliance problem.

Five friction points became significant cost and risk drivers:

- **No single source of truth:** Documents lived on local drives and shared folders with inconsistent naming.
  Impact: Manual investigation required before every approval; high risk of wrong-version sign-off.
- **Signature routing delays:** Wet signatures added 2-5 business days to every document cycle. With 8-12 required approvals per project across protocols, deviations, and summary reports, routing alone added 3-6 weeks to the average timeline.
  Impact: Weeks of calendar time consumed by administrative process, not validation work.
- **RTM drift and traceability gaps:** The Requirements Traceability Matrix lived in Excel. As test scope evolved, it fell out of sync. Inspectors routinely found the RTM did not reflect executed test coverage—one of the most cited FDA 483 observation categories in CSV.
  Impact: Traceability gaps surfacing at inspection, triggering CAPAs and remediation costs.
- **Manual VSR compilation:** Assembling a Validation Summary Report meant pulling from multiple fragmented sources under end-of-project time pressure. Typically 20-40 hours of effort per project.
  Impact: Senior staff occupied with document assembly at the highest-risk point in the project.
- **Reactive inspection readiness:** A dedicated 3-5 day preparation period before each audit during which normal validation work stopped. For 2-3 inspections per year, this is 6-15 lost senior-staff working days annually.
  Impact: Compliance posture only confirmed retroactively; no continuous readiness.

Quantified Cost of the Status Quo

Cost Driver	Baseline (Before GoVal)	Annual Impact
FTE documentation overhead	~38% of validation FTE day on non-value admin	$190k - $420k / yr
Signature routing delays	2-5 days per cycle; 8-12 cycles per project	3-6 weeks per project
RTM maintenance	8-15 hours per project; manual reconciliation	Dedicated resource required
VSR compilation	20-40 hours per project; multiple unstructured sources	Senior staff at risk point
Audit finding remediation	3-6 findings/yr linked to documentation gaps	$45k - $150k / yr
Audit preparation overhead	3-5 days per inspection; 2-3 inspections/ yr	$30k - $80k / yr
Total avoidable cost	**(conservative mid-range)**	**$265k - $650k / yr**

> *"We knew the paper process was expensive. We didn't realise it was costing us that much until we mapped every approval cycle, every audit prep hour, and every finding remediation across the year."*
>
> **VP QUALITY ASSURANCE, ALEMBIC PHARMACEUTICALS**

THE EVALUATION

Why Alembic Selected GoVal

Alembic conducted a structured platform evaluation across several VLMS and document management solutions. Three factors separated GoVal from the alternatives.

1. **Pre-validated out of the box.** GoVal ships with its own IQ/OQ/PQ documentation eliminating the requirement to run a CSV project on the platform before using it. Alembic was operating in a compliant, audit-ready system from week four. Most platforms require the customer to validate the validation tool before they can use it. This can add 3-6 months and significant internal resource cost before a single real project is touched. GoVal eliminates this entirely.
2. **A native validation data model.** GoVal's architecture is built around validation as its core domain. Requirements, test cases, results, deviations, and summaries are first-class data objects with enforced relationships—not folders in a document management system. This structural difference drives every efficiency gain. A document repository stores files. GoVal maintains a queryable, structured compliance record. You can ask it which requirements lack test coverage, what the open deviation count is for a system in PQ, or which projects have overdue periodic reviews. You cannot ask that of SharePoint.
3. **Deployment measured in weeks, not months.** GoVal's structured onboarding—requirements workshop, SOP mapping, template configuration, user provisioning, training—runs in parallel and completes in 4-6 weeks. The ROI clock starts immediately. Alembic ran its first live validation project in GoVal within six weeks of the signed order. Before most platform evaluations had completed their pilot phase, Alembic was producing real, audit-ready validation evidence.

> *"GoVal's pre-validated status was decisive. We were operating in a compliant, audit-ready system from week four—before most platform evaluations finish their pilot phase."*
>
> **SENIOR VALIDATION MANAGER, ALEMBIC PHARMACEUTICALS**

THE IMPLEMENTATION

From Signed Order to Live in 6 Weeks

GoVal's deployment model eliminates the implementation risk that derails most enterprise software projects in regulated environments. Alembic's team spent their onboarding time on configuration and training—not on building workflows from scratch.

Phase	What Happened	Timeline
Onboarding	Requirements workshop with validation leads; SOP mapping; user role definition; approval hierarchy design for all nine sites	Week 1-2
Configuration	Template customisation for IQ/OQ/PQ; workflow setup; user provisioning for pilot site; training for key users	Week 2-4
Go-Live	First live IQ/OQ executed in GoVal for new process equipment at primary site	Week 5-6
Expansion	All new projects routed through GoVal; legacy data migration initiated; second site onboarded	Month 2-4
Full Rollout	All nine sites live; AI risk scoring and automated change impact activated	Month 4+

Three Immediate Changes the Team Noticed

Before the first project had completed, the Alembic team observed three fundamental shifts in how work moved through the system.

- **Signatures stopped being a bottleneck.** 21 CFR Part 11-compliant e-signatures let approvers sign from any device. The 2-5 day per-cycle routing delay became same-day. Across ten approval touchpoints, this recovered weeks from the project timeline.
- **The RTM maintained itself.** Requirements and tests linked at creation; the matrix updates automatically as scope evolves. No dedicated owner. No manual reconciliation. No traceability gaps at inspection.
- **The VSR took minutes, not weeks.** The Validation Summary Report generates with a single action from the live project record. The first GoVal VSR was ready in under 15 minutes. Previously, this consumed three to four working days.

> *"The first time we generated a VSR in GoVal, people thought something had gone wrong. It was ready in minutes. We had been spending three to four days on that task for every single project."*
>
> **SENIOR VALIDATION MANAGER, ALEMBIC PHARMACEUTICALS**

THE RESULTS

Measured Outcomes After 12 Months

By the end of year one, Alembic's validation programme had changed fundamentally—not just in tooling, but in how the team worked and what they spent their time on. The following metrics are drawn from documented tracking by Alembic's validation and quality teams.

Metric	Before GoVal	After GoVal	Change
Avg. project cycle time	14-18 weeks	7-9 weeks	~50% reduction
FTE hrs / project Document approval	~160-180 hrs 2-5 days per cycle	60-80 hrs Same day	102 hrs saved Delays eliminated
VSR compilation time	20-40 hours	<30 minutes	97% reduction
Audit preparation time	3-5 days per audit	<2 hours	Continuous readiness
Manual RTM maintenance	8-15 hrs per project	0 hrs (automated)	Fully eliminated
Documentation 483s	3-6 per year	0 in 12 months	Eliminated

INSPECTION READINESS

The Outcome That Cannot Be Fully Quantified

The measurable metrics—cycle time, FTE hours, VSR speed—are the visible part of the return. The deeper value is structural: Alembic moved from an organisation that assembled compliance evidence before each inspection to one that maintains it continuously.

Before GoVal, preparing for a regulatory audit meant a dedicated 3-5 day preparation period during which normal validation work stopped. Records had to be located, extracted, organised, and verified for completeness. With GoVal, every project record is complete, indexed, and retrievable in seconds at all times.

Every executed test result carries a tamper-evident audit trail. Every deviation links to its CAPA resolution. Every approval carries a 21 CFR Part 11-compliant e-signature with timestamp. There is no preparation period because there is nothing to prepare—the system is always audit-ready.

> *"We had an unannounced internal audit six months after go-live. The team pulled every validation record the auditors requested in under two hours. That simply was not possible before."*
>
> **HEAD OF QUALITY ASSURANCE, ALEMBIC PHARMACEUTICALS**

What Made This Possible

- **Structured, linked data—not files.** Requirements, tests, results, and deviations are interconnected data objects. Any inspector query returns an immediate, complete, accurate answer directly from the system.
- **Continuous audit trail.** Every action in GoVal generates a timestamped, user-attributed audit trail entry automatically. This is a platform requirement, not a configuration choice.
- **Full-text indexed search across all projects.** Any validation record from any of the nine sites is retrievable in seconds. No shared drives to navigate, no naming conventions to remember.

ABOUT GOVAL

Purpose-Built for GxP Validation

GoVal is a cloud-based Validation Lifecycle Management System (VLMS) built specifically for pharmaceutical, biotech, and medical device organisations. Founded in 2020 and headquartered in Bengaluru, India, GoVal is trusted by over 2,000 users across 30+ deployed sites globally, with more than 1,000 GxP systems validated on the platform.

Platform Feature	What It Means in Practice
Pre-validated (IQ/OQ/PQ included)	No CSV project required before use. Live in a compliant system from day 28.
Native 21 CFR Part 11 & EU Annex 11	e-Signatures, audit trail, access controls built into the architecture, not added on.
Live automatic RTM	Requirements and tests linked at creation; matrix updates automatically as scope changes.
One-click VSR generation	Validation Summary Report generated from live project record in under 15 minutes.
GoVal AI	Risk scoring, test coverage analysis, and automated change impact included in standard licence.
Multi-site architecture	Single platform instance for all nine Alembic sites with standardised workflows.
4-6 week deployment	ROI clock starts immediately; first live project within a month of signed order.
FDA CSA alignment	Workflows designed for FDA's Computer Software Assurance final guidance (Sept 2025).

See What GoVal Can Do for Your Validation Programme

Join Alembic Pharmaceuticals and hundreds of pharma, biotech, and medical device companies running GoVal. Book a 30-minute working session—your numbers, your process, no slides.

govalidation.com/contact-us

Related Resources

- ROI of Paperless Validation in Pharma - *govalidation.com/blog/roi-paperless-validation-pharma/*
- Paperless Validation Benefits & Challenges Guide - *govalidation.com/blog/paperless-validation-pharma-benefits-challenges-guide/*
- GoVal vs Excel & SharePoint Comparison - *govalidation.com/blog/excel-word-sharepoint-vs-goval-paperless-validation/*
- 21 CFR Part 11 Electronic Records Checklist - *govalidation.com/blog/21-cfr-part-11-electronic-records-checklist/*
