CASE STUDY

API Manufacturers

Pharma Supply Chain Intelligence

Manual lot traceability was a compliance liability. Audit prep took 14 working days per cycle. Both problems now solved - in one platform.

Active Pharmaceutical Ingredient manufacturer · 2 plants · 60+ API SKUs · Regulated markets

Innovacio Technologies · +91 90072 71601 · hello@innovaciotech.com

1. Overview

An API manufacturer supplying regulated domestic and export markets maintained batch documentation and lot traceability records using a combination of SAP manual entry, paper batch records, and Excel reconciliation sheets. Their compliance team of six spent approximately 30% of their time on documentation - recording, cross-referencing, and preparing records for customer audits and regulatory inspections. Audit preparation for a major customer audit consumed an average of 14 working days of three people's time - a cost that repeated every quarter.

A regulatory inspection by a major pharmaceutical customer identified gaps in their raw material lot traceability records. Specifically, the customer's auditor could not establish a complete chain from finished API batch back through the production batch to the raw material supplier's certificate of analysis (CoA). The finding was a critical observation. The customer issued a corrective action request with a 60-day deadline. The root cause was structural: their documentation system simply could not generate this traceability chain reliably from the data it held.

2. Key Results

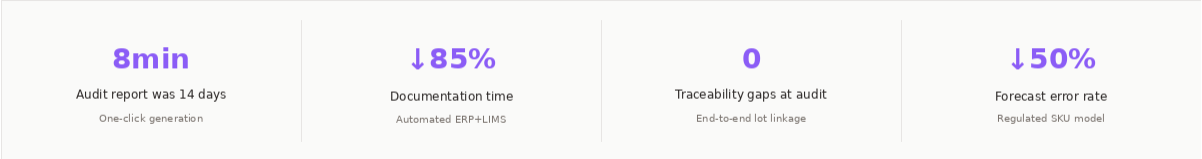

Figure 1: Key compliance and operational outcomes

3. Challenges

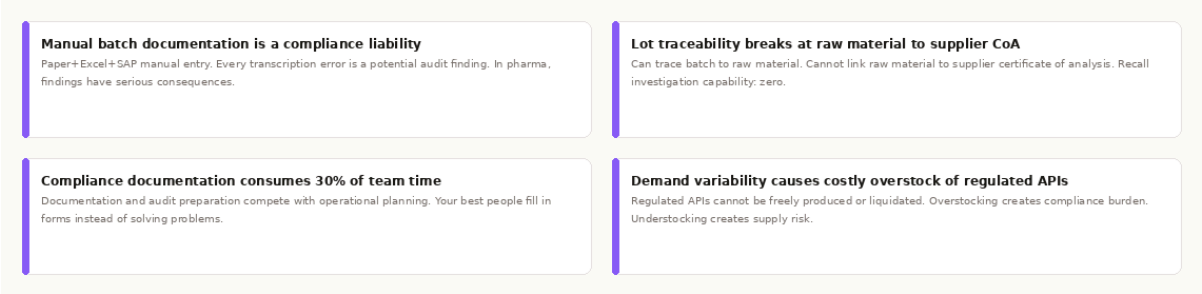

Figure 2: Four compliance and planning challenges in API manufacturing

Manual Batch Documentation Is a Compliance Liability

Paper forms, Excel sheets, and SAP manual entry - data from multiple sources manually reconciled for each batch. Every human transcription error is a potential audit finding. In regulated pharma, audit findings have

consequences: warning letters, import alerts, consent decrees. The documentation system was the single biggest compliance risk in the operation.

Lot Traceability Chain Broke at Raw Material to Supplier CoA

They could trace a finished API batch to the raw material lots used. They could not systematically link those raw material lots to the supplier CoA that certified quality at receipt. This gap meant any quality event requiring raw material source investigation - recall, complaint, deviation - could not be resolved with a complete audit trail.

30% of Team Time Consumed by Compliance Documentation

Three compliance team members spending 30% of their time on documentation, reconciliation, and audit preparation represent a significant resource allocation to a non-value-adding activity. That time could be redirected to quality improvement, process optimisation, and customer service - if the documentation were automated.

Demand Variability Causes Overstocking of Regulated APIs

Regulated APIs cannot be produced or liquidated freely. Overstocking creates compliance burden - holding, testing, and storage costs for inventory that generates no revenue. Understocking creates supply risk and potential contract penalties. Forecasting precision is commercially and regulatorily critical.

4. Our Solution

We connected to their SAP ERP and LIMS via read-only API. Our batch tracking module automatically captured data from both systems - creating a digital lot traceability chain that linked every finished API batch to its production batch, raw material lots, and the supplier CoA for each raw material. The traceability chain was built from existing data without any new data entry by the compliance team.

Modules Deployed

Automated Batch Traceability	**Supplier CoA Integration**	**FEFO Inventory Enforcement**
Automated Compliance Reporting	**Expiry Alert System**	**AI Assistant**

Implementation Timeline

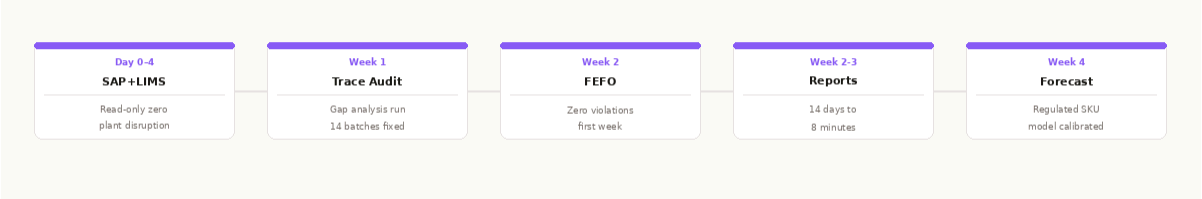

Figure 3: From SAP+LIMS connection to corrective action closed - 35 days

Key Capabilities

- **Complete traceability:** Full lot traceability - every API batch linked to production batch, raw material lots, and supplier CoA - automatically, from existing ERP and LIMS data
- **Automated reporting:** Compliance report generation in one click - audit-ready batch documentation formatted for FDA, EMA, and customer audit requirements
- **FEFO enforcement:** FEFO enforcement - oldest expiry raw materials always used first in production, system-enforced
- **Expiry management:** Expiry alerts at 30, 60, 90 days - fires to QA, procurement, and warehouse manager simultaneously
- **AI chatbot:** AI Assistant: 'Show me full lot traceability for API Batch #A-4421' - complete chain in 30 seconds

5. Results - Before & After

Area	Before	With Innovacio
Audit report prep	14 working days per cycle	8 minutes — one click
Lot traceability	Batch to raw material only	Full chain batch to CoA
Documentation time	30% of team time	↓85% reduction
FEFO compliance	Manual — inconsistent	System-enforced zero violations
Expiry alerts	Manual — gaps exist	30/60/90-day automated
Forecast error	~45% MAPE baseline	↓50% regulated SKU model

Figure 4: Compliance and operational metrics - before and after

"

> The auditor asked to see the complete lot traceability for any batch in the last 12 months - his choice. He picked a batch from 8 months ago. We pulled the complete chain - raw material suppliers, CoAs, production records, QC release - in 35 seconds. He told us he had never seen that before in a site of our size.

- Rajiv Menon, Head of Quality Compliance · PureAPI Pharmaceuticals

6. See It in Your Operation

We connect to your SAP and LIMS and demonstrate full lot traceability for any batch in your last 12 months - in a 30-minute call, on your actual data.

Innovacio Technologies AI in Supply Chain	**Book a Free Discovery Call** 30 minutes · No commitment · Your data	Phone Email Web	+91 90072 71601 hello@innovaciotech.com innovaciotech.com