Case Study: Pharma Line Validation & Digital Batch Records (EU)

Industry: Pharmaceuticals & Biotechnology (Europe)

Service Domain: Compliance Automation & SCADA Integration

Prepared by GIBES INOV
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1 Executive Summary

A European pharmaceutical packaging facility required a complete digital transformation of its batch validation workflow to comply with **21 CFR Part 11** and modern EU regulatory frameworks. Before partnering with **GIBES INOV**, the client faced slow QA cycles, manual record errors, and high non-compliance risk.

GIBES INOV designed and deployed a fully validated, audit-ready digital batch recording architecture using Siemens PLCs and an MES-integrated SCADA system—achieving **zero compliance failures** post-deployment.

2 Performance Metrics

Metric	**Before GIBES INOV**	**After GIBES INOV**	**Result (KPI)**
Compliance Failure Rate (21 CFR)	Manual, error-prone entries	Fully automated digital logs	**100% reduction**
QA/QC Release Cycle Time	48 hours	29 hours	**40% faster**
Data Integrity Risk	High (paper-based)	Digital, encrypted records	Near-zero

3 Problem Description

The facility relied heavily on paper batch records for validation. This caused:

- Frequent transcription errors and lost documentation
- High non-compliance risk during FDA and EU audits
- Slow QA release cycles due to manual checks
- Limited traceability and poor data integrity

The client required **full digitalization** while maintaining uninterrupted production and regulatory alignment.

4 Solution Architecture by GIBES INOV

4.1 Hardware Layer

- Siemens **S7-1500 PLC** retrofitted into existing production islands
- Industrial HMI panels for operator interface
- Secure industrial network configuration (VLAN, redundant power)

4.2 Control Logic Layer

- Sequential Function Charts (SFC) implemented for strict batch sequencing
- Recipe management modules integrated for batch-to-batch consistency
- Automatic validation checkpoints built into each step

4.3 Data & SCADA/MES Layer

- Deployment of InduSoft SCADA with encrypted audit trail storage
- Direct integration with MES for:
  - Batch genealogy tracking
  - Digital signatures
  - Automated compliance enforcement
- Tamper-proof logs meeting **21 CFR Part 11** requirements

5 Deliverables

- Full IQ/OQ/PQ validation package
- Updated P&IDs and wiring diagrams
- Encrypted digital batch record system
- SCADA–MES integration framework
- Operator training and SOP development

6 Project Timeline

Total Duration: 12 Weeks

- 2 Weeks – Compliance Audit & Process Mapping
- 5 Weeks – Architecture Design & Software Development
- 3 Weeks – Deployment & Integration
- 2 Weeks – Validation (IQ/OQ/PQ) & Operator Training

7 Conclusion

Through targeted automation and compliance-focused system design, **GIBES INOV eliminated the client's compliance failures and accelerated QA release times by 40%**. The pharmaceutical facility is now fully aligned with European and FDA audit standards and benefits from continuous, error-free batch documentation.