

CASE STUDY

Pharmaceutical Manufacturer Achieves **FDA 21 CFR 11, GMP, and GDP Compliance** with Shipsy

About Rubicon Research

Rubicon Research is a leading product development company and an outsourcing partner to the healthcare and pharmaceutical industry. Its manufacturing facility holds regulatory approvals including FDA certification from the US, MHRA from the UK, and EU certification. Rubicon Research's 3+ warehouses handle more than 3,000+ raw material SKUs.

Key Challenges

- Rubicon Research faced difficulties in tracking raw materials, packaging materials, and semi-finished goods throughout their life cycle. This posed a challenge in identifying the origin, movement, and usage of materials within warehouses.
- Poor traceability hindered inventory management and made quality control and regulatory compliance risky.
- Manual management of complex regulatory frameworks resulted in increased human error, risk of non-compliance, regulatory penalties and goodwill loss.
- Poor integration between weighing scales and WMS led to inefficiencies in capturing weight data, leading to manual data entry, transcription errors, and discrepancies in inventory records.
- Absence of an efficient inventory storage and retrieval system caused underutilized space, congestion, and difficulty in accessing inventory.



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The Solution

■ Digitization of Warehouse Workflows

Shipsy automated and streamlined the following processes:

- Integration with weighing balance systems to auto-capture weight data
- Implementation of checklists for goods receipt and other critical warehouse operations
- E-signatures and audit logs to enhance accountability and traceability

■ Better SKU Traceability & Inventory Accuracy

Shipsy's seamless integration with existing systems ensured real-time tracking of inventory movements, stock levels, and usage history for every SKU. This also helped identify stock-outs and overstocking, better manage inventory discrepancies and reduce errors.

■ Space Optimization for Raw Materials

Efficient storage solutions, optimized aisle layouts, and reconfigured storage racks ensured better storage capacity and

■ Supporting Statutory Compliance

Compliance digitization and automated checks and validations, empowered Rubicon Research to adhere to FDA 21 CFR 11, GMP, and GDP regulations

■ Integration With SAP S/4HANA

Seamless integration between Shipsy WMS and SAP S/4 HANA ensured data consistency, accuracy, and synchronization across business functions.

Benefits

99.9% inventory accuracy

20% improvement in space optimization

FDA 21 CFR 11, GMP, GDP Compliant