



Leading India Pharma Co. Gains Edge in Operational Efficiency, Compliance

One of the leading pharmaceutical companies in India operates in a complex manufacturing and distribution environment—in addition to managing manufacturing and shipping processes together in one facility, they also ship products globally, including to the United States (US) and the European Union (EU). If not properly managed, everyday occurrences like shipping changes or damaged product can trigger an avalanche of headaches, risking precious time, resources, and worse, introduce potential errors to data required for compliance.

More than three years ago, the manufacturer selected TraceLink as their Level 4 serialization and compliance partner, and approximately two years ago, they implemented TraceLink's flexible Edge solution, which helps them:

- **Improve operational efficiency** by automating warehouse processes, including receiving, returns, picking, packing, and shipping.
- **Manage complex compliance requirements** when products change configuration after leaving the line, commonly referred to as 'rework'.
- **Reduce the potential for human error** associated with manual data entry.

The company's competitive advantage stems from world-class manufacturing facilities, an extensive domestic network, and a widespread global presence in more than three dozen countries. Even when everything is running smoothly, they require speed, flexibility, and precision in their shipping and post-batch rework to optimize efficiency and manage US and EU serialization compliance requirements.

Use Case #1: Automating Complex Shipping Processes

Challenge: The company ships to both the US and the EU in packed batches that can include 1,000 serial numbers or less in a single batch, and two or more batches per pallet. At times, these products are packed before it is known where they are shipping, or there is a need to reconfigure the pallets after it has reached the distribution center. For example, multiple pallets may need to be split prior to shipping, and one of those pallets might now require the serial numbers to be commissioned to the EU hub.

Risk: Without a proper Edge solution in place, changes in shipping at the enterprise level (L4) can mean bringing the product all the way back to the packaging line level (L2 or L3) for reserialization, causing disruption to the work stream that costs time and resources.

Solution: Upon QA complete for a batch, the company will automatically post all serial number data to the TraceLink network. TraceLink's Edge solution then gives them the flexibility to make decisions at the time of

shipping and handles the serial number commissioning right there in the distribution center instead of sending it back to the packaging line. With a single scan, the warehouse operators can verify inventory data and serialization data, without the need for costly customizations to Warehouse Management Systems (WMS) and Enterprise Resource Planning (ERP) systems.

Use Case #2: Streamlining Post-Batch Rework

Challenge: Like many India pharmaceutical companies, the company packages product in one section of their facilities and manages distribution in another. As products are packaged and the lot passes a quality assurance (QA) check on the line, product is moved to the distribution center, and from L3 to L4 serialization. If there are no issues, the process flow is as follows:



Packing → Pallet → Distribution → Shipping

Risk: Once product moves off the lines and into the distribution center, several things can happen that impact the product's serialization hierarchy. For example, the serialized containers or labels could be damaged during transport, or the QA team could come and take samples. Such changes can result in a range of post-batch rework needs and, without an Edge system in place, can trigger time-consuming and error-prone manual processes.

Solution: Upon QA complete for a batch, the company will automatically post all serial number data to the TraceLink network. With TraceLink's Edge solution, they can then perform several highly sophisticated post-batch rework scenarios without sending product back to the line, including the capability to:

- Aggregate and de-aggregate—for example, combining or splitting pallets of product.
- Commission or decommission serial numbers.
- Seamlessly update the product status in the serialization repository, WMS, and ERP.

By enabling rework and scanning at the distribution level, TraceLink's Edge solution improves operational efficiency by simplifying complex requirements and, in turn, saving time, lowering costs, and reducing risks throughout the process.

Expanding After Efficiency Gains

As the company's business has grown, so has the need for a highly sophisticated Edge solution, which is why the company is now expanding its partnership with TraceLink to include additional sites, and several handheld devices to cover its entire network. As companies continue to expand, their investment in TraceLink's flexible Edge solution scales with them, providing global compliance with full traceability.

Benefits of an Edge Solution

- Confirm received product and verify serial number states.
- Pick and pack against a pick list and print SSCC tags for parent containers.
- Receive delivery orders from WMS or ERP and verify through scanning that the correct product, lot, and quantity are packed.
- Manage rework associated with sampling, verification, and management of damaged product.
- Maintain compliance with an easy to use, single scan.
- Update your WMS, ERP, and TraceLink serialization repository with warehouse events.
- Print and verify labels for new labeling or re-labeling activities.
- Support returns and destruction processes for serialized product.
- Enable inventory management functions for transfers and cycle counting.