



Track and Trace for Phase 3 Pharmaceutical Manufacturers

Manage all global track-and-trace mandates with a proven serialization solution suite used by more than 80% of pharmaceutical companies launching their first product to market.

For Phase 3 pharmaceutical companies, reducing the commercialization timeline is critical to providing innovative new therapies to patients and achieving desired business and financial outcomes. However, around the world, a surging number of serialization and track-and-trace compliance requirements have introduced a new hurdle that Phase 3 companies must overcome to successfully bring their products to the commercial market. Any disruption or delay in implementing a scalable track-and-trace compliance program can lead to a significant lengthening of the commercialization cycle, a loss of potential revenue, and a loss of first-mover advantage. With internal teams predominantly focused on R&D, clinical trial execution, and technical operations, forward-thinking Phase 3 pharmaceutical companies turn to the market's leading solution suite that provides the breadth of software solutions and managed services required to rapidly deploy a turnkey track-and-trace program.

Track and Trace for Phase 3 Pharmaceutical Manufacturers

The TraceLink Track and Trace for Phase 3 Pharmaceutical Manufacturers solution suite provides serialization and global track-and-trace on a powerful supply chain network digitalization platform that connects Phase 3 companies with all contract development and manufacturing organizations (CDMOs), third-party logistics (3PL) providers, specialty pharmacies, and other downstream partners across the end-to-end supply chain. Track and Trace for Phase 3 Pharmaceutical Manufacturers enables the seamless exchange of serialization and traceability data in compliance with more than 20 distinct national or regional requirements, including the U.S. Drug Supply Chain Security Act (DSCSA).

With CDMO integration managed by TraceLink, flexible control over the entire serialization, commissioning, aggregation, and shipping process, a highly experienced services team, and an “always-on” team to rely on, TraceLink Track and Trace for Phase 3 Pharmaceutical Manufacturers ensures that Phase 3 companies can focus on commercialization while leaving track-and-trace compliance to a trusted partner.

Key Capabilities

- **Serial Number Management:** Manage serial number creation for global product identifiers and serialization requirements. Generate serial numbers for multiple packaging hierarchies, including saleable units, bundles, cases, pallets, etc.
- **Serialization Visibility:** Manage the allocation of serial numbers to provide better visibility into serialization processes and the status of serialized products produced. Gain a single view into serial number inventory across multiple dimensions, including at the product and the packaging site levels.
- **Manage Incoming Serial Number Requests:** Manage, control, and tailor incoming serial number requests from supply chain partners, commissioning processes, and aggregation processes.
- **CDMO/CPO/3PL Integration:** The TraceLink “Integrate Once, Interoperate with Everyone™” network model ensures that manufacturing partners and packaging site onboarding is fast and seamless. Your CDMOs, contract packaging organizations (CPOs), 3PLs, and wholesale distributors are most likely already pre-integrated into the TraceLink network. Leverage predefined integrations with leading line management systems to get new sites quickly connected.
- **Global Compliance:** Integrate with more than 20 TraceLink regulatory compliance solutions, including solutions that cover DSCSA, the European Union Falsified Medicines Directive, and many more regional mandates around the globe. All compliance solutions are automatically updated to ensure continuous compliance and can be configured based on each country’s unique regulations, specifications, processes, and workflows, reducing the time and cost of compliance and giving Phase 3 pharmaceutical manufacturers greater control across global markets.



REAL-WORLD USE CASE

COMPANY PROFILE:

U.S.-based Phase 3
pharmaceutical manufacturer

BUSINESS CHALLENGES:

- Proactively implement serialization and track-and-trace compliance systems before Prescription Drug User Fee Act (PDUFA) date to ensure the company can legally begin marketing a new drug immediately upon U.S. Food and Drug Administration approval.
- Small company with limited resources to devote to serialization.

SOLUTION:

- TraceLink Track and Trace for Phase 3 Pharmaceutical Manufacturers

RESULTS:

- Full implementation complete and running nine months before PDUFA date.
- TraceLink managed onboarding of all contract manufacturing organization (CMO) and 3PL partners at no additional cost to the customer.
- Working with TraceLink, the customer can focus on its core competencies of research and development without expending additional resources on serialization and compliance.

FROM THE CUSTOMER:

“ We don’t have the resources to dedicate a team entirely to just serialization while we’re also thinking about launching a product, building a supply chain, and building up quality systems. Ultimately, we selected TraceLink as our vendor because we knew we could leverage their capabilities as industry leaders. ”

— Vice President of Technical
Operations and Supply Chain

Key Benefits

- **Ensure Supply:** TraceLink is the serialization and track-and-trace leader with a track record of quickly and reliably integrating CDMOs around the globe with zero downtime and 24x7 support to ensure your products reach the market on-time, in-full (OTIF). Since 2020, more than 50 Phase 3 pharmaceutical manufacturers have chosen TraceLink for its proven serialization and compliance capabilities. With TraceLink, Phase 3 manufacturers ensure new products are launched on time, every time.
- **Continuous Compliance:** TraceLink monitors all global compliance initiatives and rapidly responds to changes, providing continuous compliance so pharmaceutical manufacturers can focus on commercialization in new regions. Automatic updates support new and evolving global regulations and guidelines, technical standards, and workflows.
- **Integrate Once, Interoperate with Everyone™:** The TraceLink network platform eliminates costly and difficult-to-manage point-to-point integrations by enabling all customers and trading partners to integrate only once and then interoperate with anyone else on the network with point-and-click configuration. With just one integration to the TraceLink network, Phase 3 manufacturers can connect with new CDMOs and 3PLs in new regions as Phase 3 manufacturers add new products. Partner onboarding is provided by TraceLink at no additional cost.
- **Lowest Total Cost of Ownership (TCO):** TraceLink is a premium solution that enables product commercialization at the lowest TCO. Save time and expense by centrally managing serial number allocation, which provides greater control to fine-tune serial number requests and better visibility into serialization processes, including product status updates, commissioning, and aggregation. Achieve operational excellence with automated workflows that link serialized product operations to existing product packaging, warehousing, distribution, and supply chain operations.
- **Scalability:** As your company's product volumes grow, the TraceLink native cloud architecture and global services capabilities will grow with you to help ensure consistent OTIF delivery performance, continuous compliance, customer satisfaction, and patient safety.
- **Improve Patient Outcomes:** Protect the drug supply chain while increasing patient safety, improving patient access to medicine, and helping to ensure positive patient outcomes.



About the TraceLink Network

TraceLink is the leading provider of end-to-end product orchestration on a digital network platform. TraceLink Track and Trace for Phase 3 Pharmaceutical Manufacturers is built and hosted on TraceLink Opus, the world's largest supply chain network digitalization platform for pharma and life sciences. Opus enables Phase 3 organizations to seamlessly exchange serialization data and traceability information with direct and indirect trade partners across the supply chain. Key network metrics include:

50+

Phase 3 pharmaceutical companies have deployed their serialization program on TraceLink since 2020

2,645+

pharmaceutical manufacturer customers and partners

850+

CMOs and CPOs already integrated into the network

870+

3PLs and distributors already integrated into the network

14,937+

live serialization connections

7,300+

live CMO/CDMO connections across more than 1,300 customers

919M+

regulatory documents processed and exchanged

284K+

healthcare and retail pharmacies

41.1B+

serial numbers commissioned to date

\$4.7B+

in customer savings by avoiding point-to-point integrations

Contact TraceLink to learn more about Track and Trace for Phase 3 Pharmaceutical Manufacturers.