The New Era of Pharma Track & Trace

AI as Copilot, Not Autopilot

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Over the past decade, the pharmaceutical serialization ecosystem has generated an unusual amount of data. Every product movement, from commissioning to aggregation, shipment, to decommissioning, creates an EPCIS event that must be captured, validated, and reported to regulators across dozens of markets. This infrastructure was built to ensure every medicine can be traced from manufacturer to patient, creating accountability at every step of the supply chain. Yet for all the data these systems generate, most supply chain teams will acknowledge a frustrating truth: we've built systems that track everything but understand very little. In short, the data exists, but the insight doesn't.

Consider a typical scenario. Your supply chain team receives an error notification at 4 PM on a Friday: "Parent-child linkage missing in aggregation event." The report is due Monday morning for a shipment already at the port. To resolve this issue, the team needs to pull the past reports, cross-reference packaging line data, verify whether it's a format issue or an operational problem, and finally determine if the batch can be shipped or needs to be quarantined. This single error could be resolved in minutes by an experienced manager with the right technology, but instead it takes hours and even days of manual debugging and cross-team collaboration. Multiply this across hundreds of SKUs, dozens of markets, and constantly evolving regulations, and you understand why supply chain teams describe their work as "firefighting."

So far, the industry's response to this has been predictable: more automation, faster validation, more sophisticated error detection. However, years of implementation have revealed that all these fixes have barely enabled teams to respond more effectively to problems that could have been prevented in the first place.

This is where artificial intelligence represents a fundamentally different approach. Unlike traditional automation that simply executes predefined rules faster, AI can learn from patterns, understand context, and surface insights that static systems miss. And now the real question isn't whether AI can analyze serialization data faster than humans; that's obvious. The question is whether it can help humans make better decisions when patient safety and regulatory compliance are at stake.

The most promising AI use cases in pharmaceutical traceability provide human judgment with better information rather than attempting to replace it. AI can flag errors, suggest corrections, and detect patterns, but one boundary remains non-negotiable: humans must review and authorize every critical decision. In an industry where every action must be auditable, explainable, and traceable to an accountable individual, being fast and being right aren't the same thing. And being right requires human judgment that no algorithm can replicate.

Where AI Excels (With Guardrails)

a. Debugging and Root Cause Analysis

Take that Friday afternoon error about the missing parent-child linkage. Instead of sending a cryptic technical notification, an AI-powered compliance assistant can analyze the error, cross-reference it against historical data, and provide a simple explanation: "This aggregation event from Line 3 is missing the parent case ID because the line controller firmware hasn't been updated to the new EPCIS 2.0 schema. This is the fourth occurrence this month from the same line. Here are the three previous resolutions."

These assistants are purpose-built for pharmaceutical serialization, trained on EPCIS event structures, GS1 standards, and country-specific regulatory schemas. They can validate file structures against market requirements, identify whether errors stem from data formatting issues or actual operational problems, and trace event lineages across complex aggregation hierarchies. Future similar events get categorized appropriately rather than triggering unnecessary alerts.

What took hours of manual analysis now takes minutes. The AI hasn't decided whether to ship or hold the batch, but it's equipped the human

decision-maker with the context needed to act confidently.

b. Asking Questions in Simple Language

Supply chain teams generate thousands of EPCIS event files monthly, and when errors occur, finding patterns across that volume becomes nearly impossible manually. Natural Language Processing (NLP) allows supply chain managers to ask conversational questions instead of manually parsing technical files: "Show me all rejected submissions in the last month due to GTIN mismatches" or "Which packaging lines consistently produce late aggregation events?" The system reads through dense error logs and provides instant, readable answers. What used to require someone to open dozens of XML files, compare timestamps, and build spreadsheets to spot patterns now happens in seconds through a simple query.

c. Learning from Context

Machine Learning (ML) brings something particularly valuable to pharmaceutical operations: systems that remember. When an experienced supply chain manager resolves a tricky error or makes a judgment call about an edge case, that knowledge is in their head, or at best, in an email thread someone might find months later. But AI changes this. Every time a manager overrides a recommendation, corrects a flagged issue, or documents why a particular batch required special handling, the system captures that decision and the reasoning behind it. Over time, it builds an understanding of how your specific operations work, which exceptions are routine, which demand escalation, and which patterns signal genuine problems versus normal variations.

Moreover, the learning capability also speeds up tasks that used to require deep expertise. When companies need to map legacy L4 data structures to newer EPCIS 2.0 schemas across multiple markets, machine learning can recognize the business context of each event type and complete reconciliation in minutes rather than weeks of manual work.

d. Reactive to Proactive Operations

AI can score the likelihood of regulatory acceptance for each compliance report before submission, analyzing it against country-specific requirements and historical approval patterns. Teams can now prioritize which batches require additional review and which are ready to file, turning firefighting into planned operations. One pharmaceutical manufacturer piloting these capabilities saw reporting errors drop 95% within four months, with issue resolution time falling from six hours to under thirty minutes. Teams that had relied on external consultants for complex debugging were now handling problems independently.

Human Judgment Remains Essential

Yet for all these capabilities, AI in pharmaceutical traceability has clear boundaries. Consider what happens when an AI system flags a serialization report as "ready for submission" because it meets all technical schema requirements. The file structure is correct, the data elements are present, and the validation checks pass. But an experienced supply chain manager might know that the regulatory authority is currently conducting enhanced scrutiny of that product category, or that a recent guideline update has created ambiguity around how certain events should be reported. These aren't pattern recognition problems AI can solve by analyzing historical data. They're judgment calls that require deep knowledge of regulatory know-how and the ability to judiciously assess risk.

The companies succeeding with AI aren't asking "How much can we automate?" They're asking, "Where do humans add the most value, and how do we build AI that supports them there?" It's not just a different question. It's a fundamentally different approach. One tries to eliminate human judgment from daily workflows. The other recognizes that in pharmaceutical operations, human judgment isn't the bottleneck to remove, but a capability to amplify.

Conclusion

Every serialization event, every EPCIS file, every validation check ultimately connects to a simple promise: the medicine in a patient's hand is genuine, safe, and exactly what it claims to be. That promise has always required both intelligent systems and accountable humans.

The question isn't whether AI will transform pharmaceutical traceability. The question is whether we'll build that transformation on a foundation of human accountability or attempt to engineer it away.