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Proactive Supply Chain Monitoring: The Key to Risk Avoidance in Russia's Demanding Regulatory Environment



Virtually everything that happens to a pharmaceutical product in Russia's demanding regulatory environment—from the initial request for serial numbers, to manufacturing, aggregation, transportation, and each handoff and status change that occurs on the journey to the patient—must be successfully reported to the Russian Drug Circulation Monitoring System (MDLP) in the correct order at the right time. And there's no shortage of things that can go wrong.

Serialized Product Intelligence enables you to quickly review and reconcile lots, so you can reduce delivery delays, sales losses, and the amount of time it takes to identify and resolve disruptions.

That's why you can't afford to be reactive in Russia.

To be successful in Russia's challenging market—and to avoid risks like critical drug shortages and fines for non-compliance—you need to establish proactive monitoring of your end-to-end serialized supply chain and detect potential problems before they lead to costly disruptions.

Serialized Product Intelligence is a new solution from TraceLink that provides

fast access to the complete history and hierarchy of serial numbers at all levels of aggregation, empowering you to proactively monitor your serialized products and avoid or mitigate the compliance risks that threaten your operational excellence and on-time, in-full (OTIF) delivery objectives for the Russian marketplace.

Let's take a closer look at some of the ways Serialized Product Intelligence enables you to **proactively monitor the serialized drug supply chain** and avoid the risks associated with compliance issues in Russia.

Proactively monitor commissioned lots for compliance problems

Whether your organization manufactures products itself or works with CMOs and other Marketing Authorization Holders (MAHs) in Russia, you need a way to proactively monitor commissioned lots for discrepancies, serialization errors, and aggregation issues. Failure to detect compliance problems early can result in shipping delays, lost sales, and damaged reputations.

- **How is this typically addressed today?**

In the past, monitoring commissioned lots meant collecting information from various systems and manually combining the data using tools like Microsoft Excel, a process which is time-consuming and error prone, and often involves requesting help from the IT department.

- **How can Serialized Product Intelligence help?**

Serialized Product Intelligence's "Monitor Commissioned Lots" feature enables you to quickly review data for your last 100 commissioned products in Russia within a specific time frame of your choosing. You can view all manufactured products on a single screen and monitor actual commissioned and aggregated quantities across CMOs. Additionally, stakeholders can monitor commissioned lots in a self-service manner without having to overburden the IT team.

- **What is the business value?**

With Serialized Product Intelligence, you can proactively monitor commissioned lots in Russia to increase demand forecast accuracy, make better inventory decisions, reduce shortages, and decrease disruptions across the serialized supply chain.



Proactively validate the accuracy of aggregation data

It's important to get aggregation right in **Russia**, because if even one serial number is aggregated incorrectly, it can result in a product shipment that is stuck somewhere along the supply route.

And on occasions when reports to the MDLP fail, it's important to quickly find out which products are affected. But obtaining this information can be difficult because MDLP reports show only the highest level of aggregation.

Whether the goal is to proactively verify the accuracy of aggregation data, or troubleshoot a failed report from the MDLP, you need a way to rapidly understand the complete hierarchy of serial numbers.

- **How is this typically addressed today?**

To verify the accuracy of aggregation data or troubleshoot failed MDLP reports, stakeholders typically need to download multiple XML files and manually examine them line by line in an effort to identify mismatches and other anomalies.

- **How can Serialized Product Intelligence help?**

With Serialized Product Intelligence, you can quickly pull up the most current

aggregation data, examine it at all levels of granularity, and verify that the data is accurate.

- **What is the business value?**

Serialized Product Intelligence enables you to proactively monitor and reconcile production quantities across products and aggregation levels to enable continuous and compliant operations.

Proactively review and reconcile lots

Russia's regulatory authorities are known for strict policies—that's one reason why it is critical to make sure that the product data you send to the MDLP matches the physical products being shipped. In Russia, it's important to regularly review and reconcile lot quantities between compliance and operations, as well as between shipping and delivery locations.

- **How is this typically addressed today?**

The process for reconciling lots usually involves pulling data from multiple systems and combining it into a spreadsheet for manual data analysis.

- **How can Serialized Product Intelligence help?**

Serialized Product Intelligence gives you a consolidated view of items in a given batch, lot, or pallet, as well as complete visibility into the status—commissioned, shipped, damaged, sampled, blocked, destroyed, etc.—of all serial numbers moving through the supply chain in Russia.

- **What is the business value?**

With easy access to a consolidated view of the most current status of all items moving through the supply chain, Serialized Product Intelligence enables you to quickly review and reconcile lots, so you can reduce delivery delays, sales losses, and the amount of time it takes to identify and resolve disruptions.

Gain a competitive edge in Russia with Serialized Product Intelligence

Serialized Product Intelligence enables you to **proactively manage serialized operations**, maximize the business value of serialization investments, and gain a competitive advantage that stems from your ability to maintain control despite Russia's immense regulatory complexity.

With Serialized Product Intelligence, you can establish proactive supply chain monitoring and controls in Russia, and you can rapidly investigate exceptions in a self-service manner.

Serialized Product Intelligence gives you a complete view of all Russia compliance reports, including the listing count for each report type, and clear visibility into whether reports failed or were successful. With Serialized Product Intelligence, you'll spend less time worrying about Russia compliance complexity—and more time ensuring products are delivered to patients.

Russia PharmaceuticalsRussia

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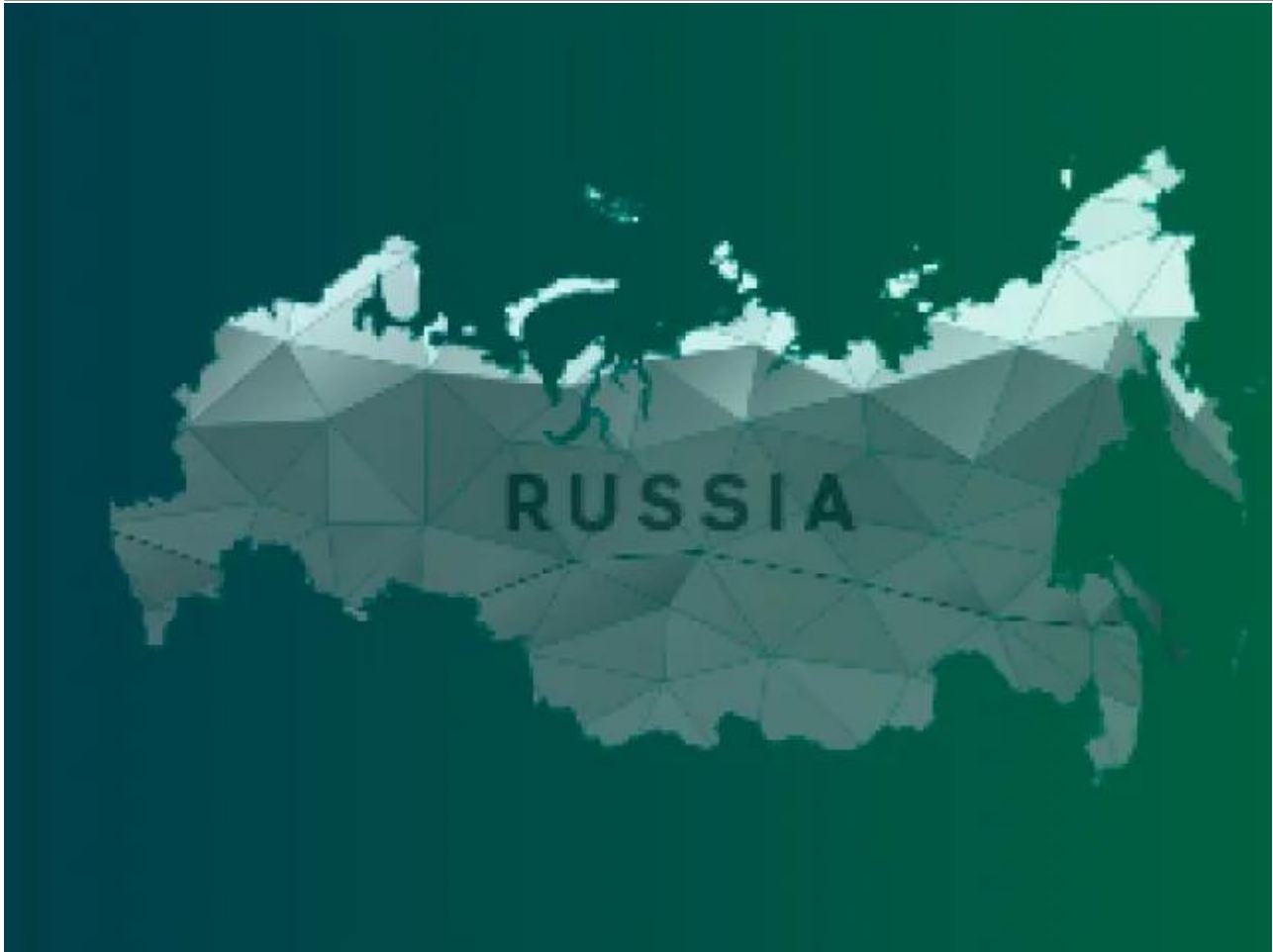
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Learn more about Serialized Product Intelligence



Turn Russia Compliance into a Competitive Advantage with Serialized Product Intelligence from TraceLink

Watch this on-demand webinar to learn how Serialized Product Intelligence can help you turn your serialized operations in Russia into a competitive advantage.

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Rising to the Challenge of Russia Compliance: An Interview with Santen Pharmaceutical's Pasi Kempainen

Learn how Santen Pharmaceutical is navigating Russia's highly complex and demanding serialization and track and trace regulations.

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Introducing Serialized Product Intelligence: Take Control of Your Serialized Supply Chain

Learn about Santen Pharmaceutical's journey of serialization and digitization, transforming challenges into opportunities. Watch the webinar.

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