Cut Through the Complexity with TraceLink's Russia Compliance Solution



April 2020 Update: The current compliance deadline for all medicines manufactured in Russia or imported into Russia is July 1, 2020. As of December 31, 2019, medicines that fall under the government's HCN/7 Nosologies guidelines are expected to comply with the current serialization requirements, which comprise 4 elements: Product Code (GTIN), Serial Number, Crypto Key, and Crypto Code. Expiry Date and Batch Number are no longer required. See the latest Russia Regulatory Updates for news on Russia Track and Trace regulations.

Governments around the globe are phasing in new track and trace regulations designed to increase the safety of the pharmaceutical supply chain by protecting the public from counterfeit drugs—and Russia's new law is without question the most complex of all.

The law, which takes effect in just a few months on January 1, 2020, calls for pharmaceutical supply chain companies—manufacturers, distributors, logistics providers, and dispensers—to deal in serialized prescription and over-the-counter drugs and to meet intricate reporting requirements.

Complicating things further is the fact that requirements and interpretations of the law are continuing to evolve, making compliance an ever-moving target.

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Manufacturers that hope to achieve compliance by the deadline need a global partner with a proven track record of success, the right solution, and a local support team.

A closer look at Russia’s track and trace law

Russia's new track and trace regulation, officially known as Russian Federal Law No. 425-FZ, covers all pharmaceutical and over-the-counter medicines manufactured within or imported into Russia. The law mandates that medicines include a 2D data matrix on secondary packaging, and a 2D data matrix or linear 128 barcode on tertiary packaging.

Secondary packs must also include a unique identifier that contains four data elements: a global trade item number (GTIN), a serial number, a four-digit cryptographic key and a 44-digit cryptographic code. But the complexity of Russia’s track and trace law doesn’t end there.

The law also introduces complicated reporting requirements. For starters, the law requires tracking and digital reporting of more than 35 compliance events to Russia’s centralized reporting system using XML transactions and electronic signatures. Examples of these compliance events include:

- Product commission and decommission
- Aggregation and disaggregation
- Quality sampling and quality control release testing
- Product shipment, receipt, and transfer
- Importing and exporting
- Product withdrawal and recalls
- Product destruction

Additionally, manufacturers must be capable of receiving documents and notifications from the Russian Drug Circulation Monitoring System (MDLP), the

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electronic drug monitoring system managed by Russia's Center for Research in Perspective Technologies (CRPT). Altogether, Russia compliance requires bi-directional data exchange, message sequencing, audit trailing, and archiving among other capabilities. Manufacturers also need to communicate with Russia's Order Management System (OMS) to manage the generation, receipt, and reporting of the crypto codes.

Reduce complexity with TraceLink's Russia Compliance solution

TraceLink's Russia Compliance offering is a fully integrated solution that consists of two major components: core serialization alongside Russia compliance and reporting capabilities.

The core serialization component of TraceLink's solution covers product master data management, serial number generation, crypto code management, EPCIS event management, and serial number allocation. The Russia compliance and reporting component manages business logic for events, regulatory document creation, electronic document signature, and document archival. Additionally, the compliance component enables companies to digitally sign, send, and receive documents from Russia's regulatory authority from servers located in Russia in accordance with the law.

The solution provides automated event workflows out of the box to trigger report generation from standard serialization events. Users can also manually trigger or re-generate reports for exception management.

The solution is designed to automatically generate compliance reports that support three main use cases. These include:

- **Production outside of Russia, importation, and transfer to distribution warehouse**
  This includes reports automatically sent to the MDLP around batch production and release, foreign shipment, foreign import, control sampling, customs

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clearance, transfer and receipt in warehouse, and quality inspection.

- **Production in Russia and transfer to distribution warehouse**
  This includes automated reporting around batch production and packaging, quality sampling, quality release, and warehouse transfer and receipt.

- **Warehouse operations and distribution**
  This includes reporting on transfer between company and third-party logistics provider (3PL) locations, return to contract manufacturing organizations (CMOs) in Russia, shipments to customer, returns from customer, aggregation changes and re-labeling, and withdrawal from circulation, re-introduction to circulation, and re-export.

With TraceLink, users can receive response messages from Russia's regulatory system. These include opt-in email notifications of responses to compliance reports, and other Russian system responses to key business processes. Users can also receive messages from Russia's regulatory system related to whether product deliveries were accepted, refused, or if a return order notification was generated.

To help customers maintain visibility into operations, TraceLink's Russia compliance solution enables users to search and view compliance reporting messages that have been sent to the Russia regulatory system, as well as the Russian system's responses to those messages, and any other messages received from the system.

Global compliance, local support

For large pharmaceutical manufacturers with a presence in multiple countries, and growing organizations that hope to one day do business beyond Russia's borders, the importance of selecting a global compliance partner cannot be overstated. That's because a global compliance platform offers many business benefits over

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compliance strategies involving local point solutions from various software vendors.

Companies that choose local point solutions risk creating data silos that can lead to gaps in supply chain visibility. Additionally, the process of implementing point solutions often involves a great deal of time and expense related to validating functionality, serial number management, and building a product data repository. Local point solutions may also require costly integrations with corporate business systems, while any pre-existing integrations with CMOs or 3PLs could be rendered useless.

By selecting a proven global compliance partner like TraceLink, pharmaceutical companies can create a corporate standard for country compliance that spans the entire organization. They can handle compliance monitoring and exception management from a single “pane of glass,” and reduce the costs and risks associated with new market-specific integrations.

TraceLink’s Russia Compliance solution uses validated and proven integrations to corporate business systems, CMOs, and 3PLs, saving organizations time and money. The TraceLink platform also offers proven solutions—based on the same underlying serialization and reporting technologies—for compliance in the US, European Union, Asia Pacific, and many other locations around the globe.

In addition to offering 24/7 global phone support for customers worldwide, TraceLink has English and Russian-speaking team members located in Russia to help customers with implementations and any questions that may arise. TraceLink also leverages extensive local networks and partnerships with companies like Korus, a leading Russian IT services and consulting firm, and Excellis, a TraceLink certified partner with deep life sciences industry expertise.

TraceLink’s extensive network, local and global support ecosystem, and vast experience with track and trace regulations combine to help pharmaceutical

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supply chain companies achieve compliance while reducing risk, driving down costs, and preventing operational silos.

Achieve Russia compliance with TraceLink

Russia compliance requires a partner with deep knowledge of the industry and a clear understanding of the law’s unique serialization and reporting mandates. TraceLink has a proven record of delivering serialization solutions across the globe via our world-leading, cloud-based platform and integrated digital supply network.

TraceLink is the world's largest integrated supply network, enabling digitalization and compliance strategies across the life sciences supply chain, from manufacturers to distributors to hospitals and pharmacies. Contact us to learn more about Russia Compliance today.

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Thank you for contacting us; we’ll be in touch shortly.

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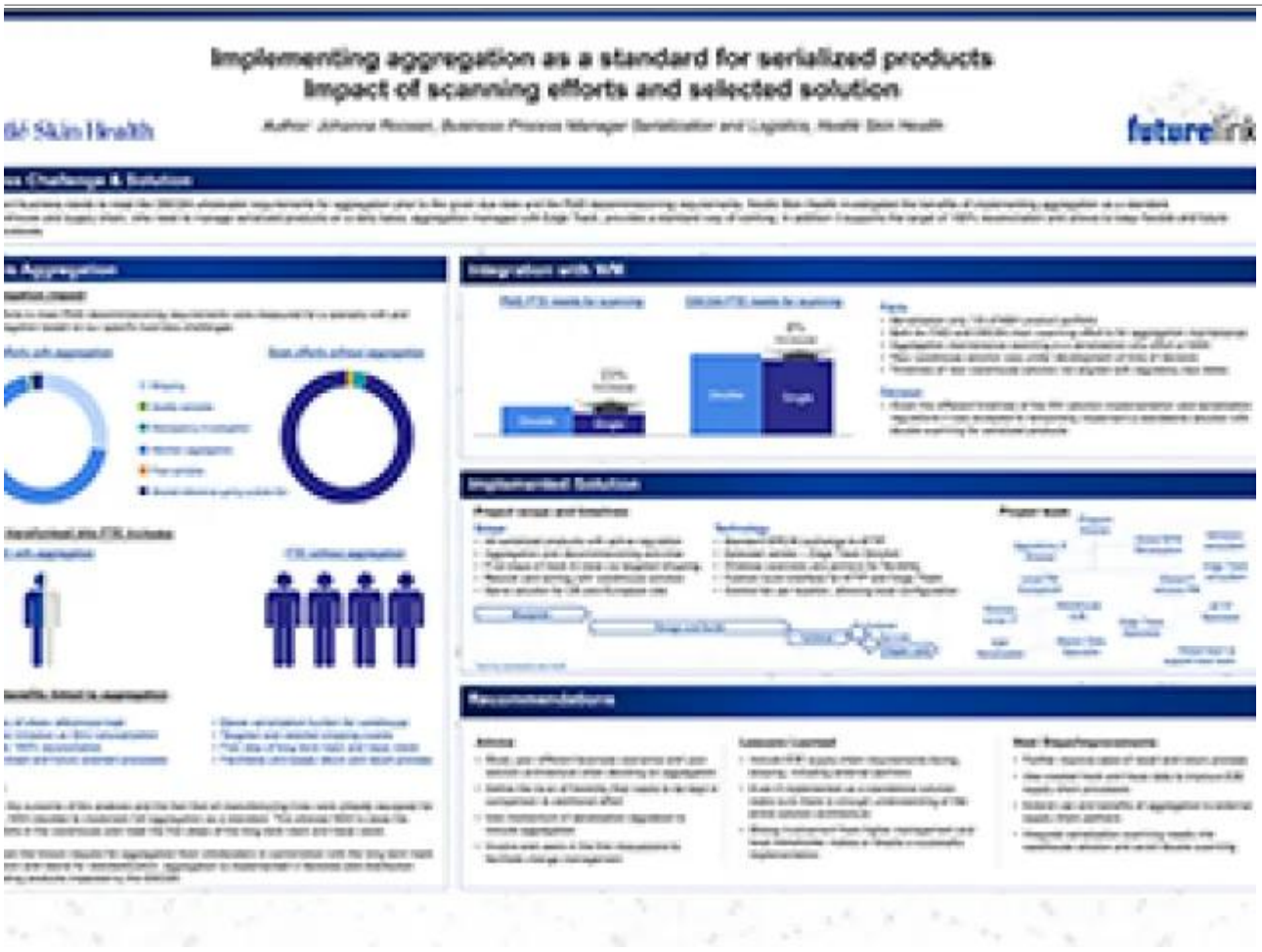
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