RESOURCES



Poll: Russia Crypto Codes Create Unique Operational Challenges Manufacturers Must Address Now

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.

Russia's serialization requirements are the most complicated in the world, due in no small part to the unique cryptographic codes companies must include in the 2D data matrix barcode on packaging labels for all covered medicines by January 1, 2020, and even sooner for the 12 Nosologies. While these requirements enable necessary off-line serial number authentication for locations that don't have consistent access to the internet, managing crypto codes introduces considerable operational complexity for pharmaceutical manufacturers and contract manufacturing organizations (CMO) that produce or distribute medicine in Russia.

Operational efficiency, code management across sites and systems top

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manufacturers' concerns

TraceLink's webinar, Managing Crypto Codes for Russia Compliance, highlighted the significant impact crypto code management can have on operational efficiencies if companies don't have a solution in place. Mitigating these potential inefficiencies is a clear challenge: 83% of webinar attendees say they are moderately or very concerned about the impact acquiring and managing crypto codes will have on their operations.

Because crypto codes are unique to the Russian pharmaceutical market, many manufacturers likely do not have the complex technology in place to facilitate communication between their internal packaging line level 3 (L3) systems and the CRPT, the public-private organization in Russia that provides crypto codes through its Order Management System (OMS).

Integrating and monitoring data exchanges with CRPT brings additional operational challenges when managing crypto codes across multiple sites and systems. Webinar attendees reported their top concerns related to the impact managing crypto codes across multiple sites (42%) and multiple systems (57%) will have on their businesses.

Despite uncertainty, manufacturers are moving forward with integration plans

Russia's serialization requirements have continued to evolve since first announced, perhaps tempting manufacturers to delay their preparations as the government clarified the rules. But while some of the particulars may be subject to change, crypto codes are solidified in the regulations—and many companies are no longer waiting to implement compliance plans. Of the 39% of the webinar attendees who say they are moving forward with integrating crypto code requirements into line operations, 15% are prepared to meet the deadline, and 24% are in the process of identifying and evaluating possible solutions.

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But that still leaves many manufacturers behind in their crypto code compliance preparations: 45% of attendees report their integration plans are behind schedule, while 16% say they are just starting to address the requirements. With the compliance deadline only months away, many manufacturers will struggle to ensure operations will be ready by the compliance deadline.

Let TraceLink's new Russia Crypto Code app manage the lifecycle of crypto codes

TraceLink's Russia Crypto Code app provides a single-integrated point to the CRPT for all customers and their CMO sites that package Russian product. The app manages the entire lifecycle of cryptographic codes.

The Russia Crypto Code is a standalone app but maintains integrations with TraceLink's Russia Serialization Solution modules, Master Data Exchange, Serial Number Manager (SNM), Serial Number Exchange (SNX), and Serialized Operations Manager.

Reduce the burden of operationalizing Russia's crypto code requirement with TraceLink's Russia Crypto Code app. The app integrates into your current systems to manage crypto codes across L3 systems and multiple sites. Contact us to learn more about TraceLink's Russia crypto code management solution.

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

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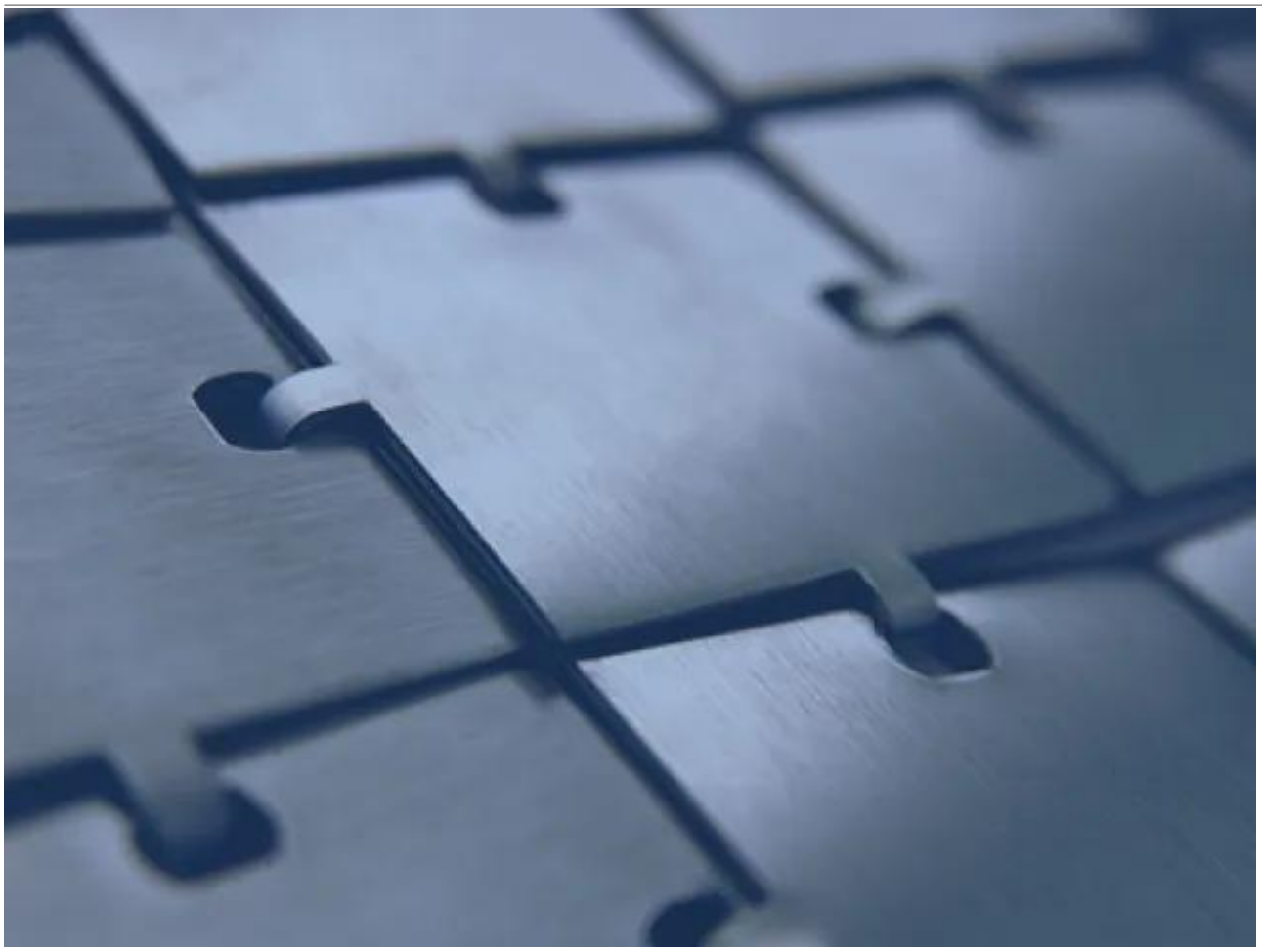


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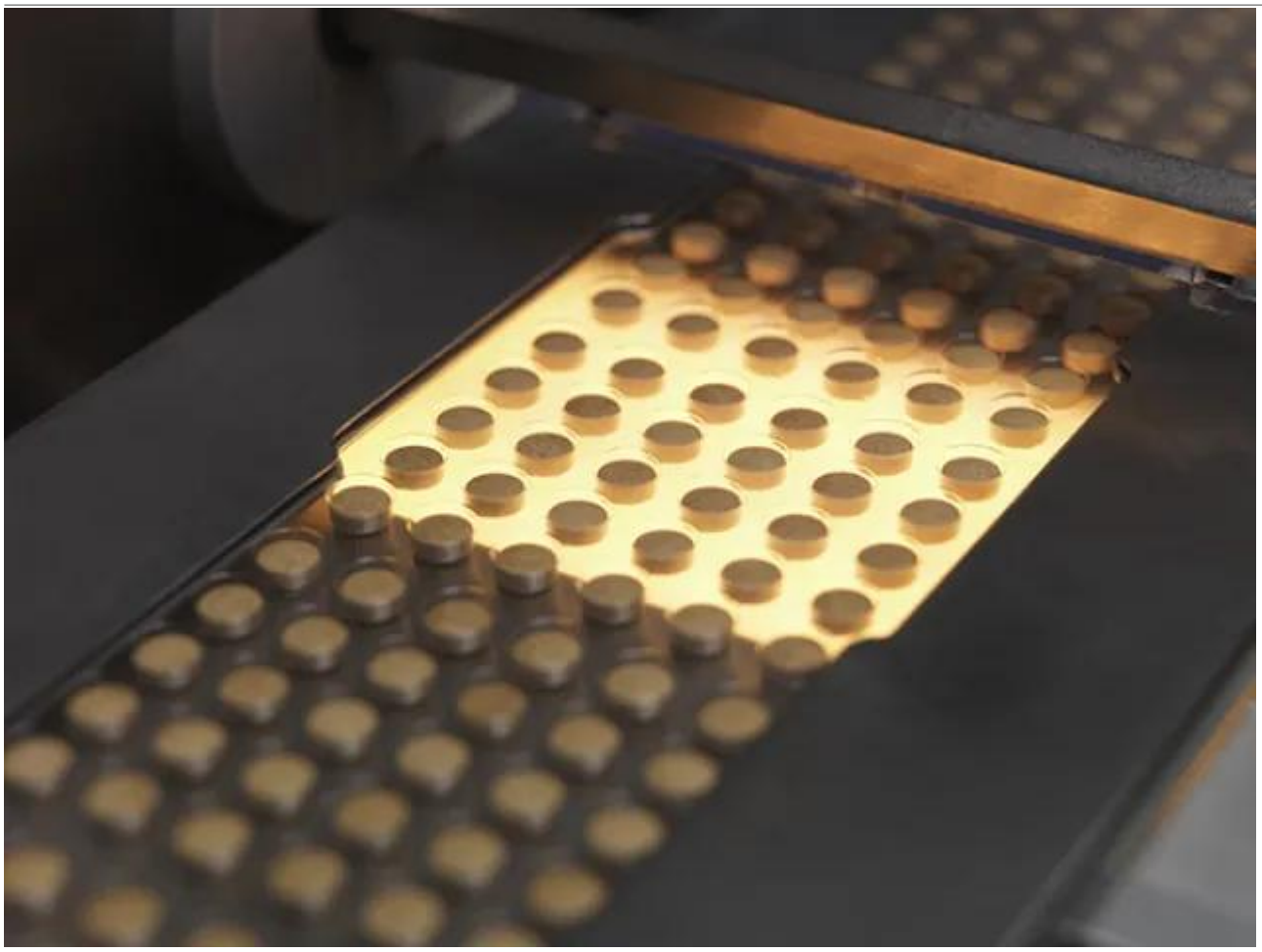
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