


TraceLink Russia Biologically Active Food Supplements (BAFS) Compliance

Reduce the cost and time of complying with BAFS mandates with a solution pre-integrated into the industry-leading global compliance and supply chain network platform.

On May 31, 2023, the Russian government signed Decree 886 into law, which establishes new track-and-trace requirements covering biologically active food supplements (BAFS) such as vitamins and minerals. Now, pharmaceutical manufacturers distributing food supplement products in Russia must take action to meet these requirements in line with a series of rolling deadlines extending through 2025. Manufacturers that fail to comply with these complex requirements cannot distribute their products into and throughout Russia and may face government fines or trade partner penalties.



Comprehensive Solution for Russia BAFS Compliance

The TraceLink Russia BAFS Compliance solution supports manufacturers that import and distribute food supplements into Russia. Natively integrated into the TraceLink Global Compliance Platform, the solution enables customers to meet the complex requirements established by the food supplements regulations.

The TraceLink Russia BAFS Compliance solution is composed of two products:

- **Russia BAFS Crypto Code:** The BAFS Crypto Code application provides manufacturers with the capability to manage cryptographic codes used to comply with serialization requirements. It facilitates the request and retrieval of crypto codes from the OMS system, maintains a record of requests for crypto codes, and tracks their usage by line management systems (LMSs) and contract manufacturing organizations (CMOs), enabling better record keeping and billing reconciliation.
- **Russia BAFS Compliance:** The BAFS Compliance solution enables manufacturers to automatically generate and submit event reports with serialization, crypto code, and supply chain data to TT GIS. As transactions are processed, the solution continually monitors for compliance events. When these events are detected, the solution assembles and submits reports using pre-configured business logic and workflows.

The Russia BAFS Compliance solution runs on the TraceLink network, which makes integrating and orchestrating workflows with CMOs or third-party logistics providers easy.

With the TraceLink platform's innovative architecture, manufacturers only need to create a single integration to the TraceLink network to begin sharing compliance data with trading partners and government systems.

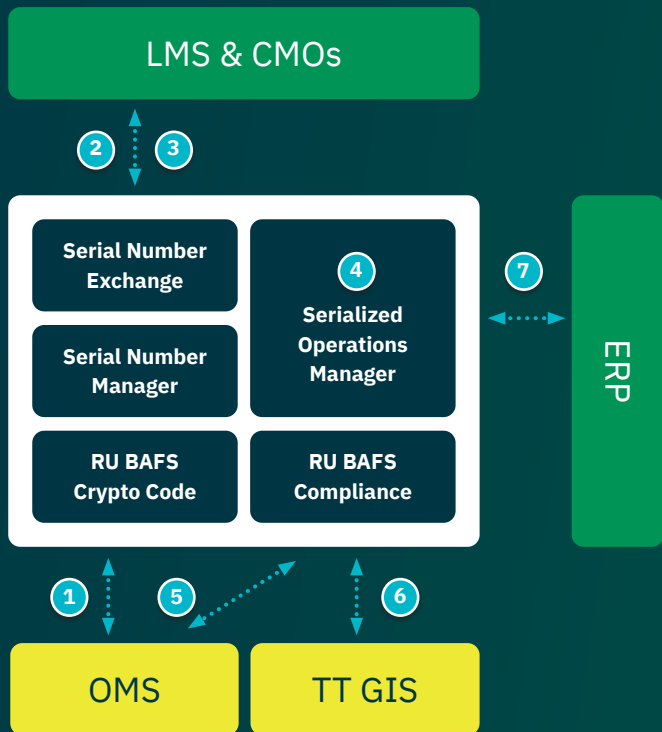


Russia BAFS Compliance Requirements

Russia's complex BAFS requirements include a high number of compliance events and complicated reporting mandates. To ensure compliance, manufacturers must have capabilities in place to:

- Request and receive crypto codes from the the OMS system.
- Provide crypto codes to line management systems and CMOs using existing integrations.
- Generate reports automatically when regulated supply chain events are detected.
- Support various manufacturer, importer, and wholesale distributor use cases.
- Connect to TT GIS to submit reports and capture government acknowledgments.

Solution Approach: Russia BAFS Compliance



- 1 The Russia BAFS Crypto Code application requests and receives crypto codes from the OMS system.
- 2 Serial numbers and crypto codes are allocated to LMS and CMO partners as required.
- 3 Commissioning and aggregation information is sent to TraceLink once serial numbers/crypto codes have been applied.
- 4 Data is stored in SOM and event triggers send compliance events to Russia BAFS Compliance.
- 5 Russia BAFS Compliance sends utilization and aggregation reports to the OMS system.
- 6 Russia BAFS Compliance sends release to circulation, withdrawal, and other compliance events to TT GIS.
- 7 The SOM API is utilized to request serialization data to the customer's ERP for further sale/receipt reporting via the EDO.

Key Capabilities

The TraceLink Russia BAFS Compliance solution comes with several capabilities that streamline compliance with the food supplements requirements.

- Serial Number and Crypto Code Management:** Simplify and automate the creation of secure serial numbers for food supplement products and allocate serial numbers to internal packaging lines and contract packaging partners.
- Integration with Critical Internal, Partner, and Government Systems:** Securely exchange data with all trading partners and government systems without modifying your existing systems through a single connection to the TraceLink network. Connect to the Russian OMS crypto code system to request and retrieve crypto codes, and integrate with partners and the TT GIS system for report submission and orchestration.
- Business Process Orchestration for Commissioning and Aggregation:** Receive commissioning and aggregation information from packaging lines and contract packagers, manage changes to packaging hierarchies and corresponding aggregation, and capture serial numbers of sampled, destroyed, and otherwise decommissioned products.
- Event Triggers for Report Automation:** Configurable through a point-and-click user interface, event triggers automate reporting after certain business process events. Create properly formatted reports for submission and maintain history and audit trails of reports submitted to the OMS and TT GIS central system.

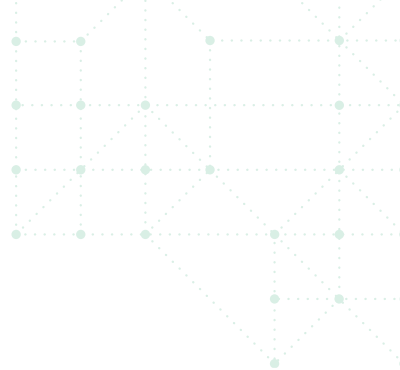


Key Benefits

Compared to solutions offered by other providers or built in-house, TraceLink Russia BAFS Compliance is the best solution for meeting the BAFS requirements.

- **Fastest Time to Compliance:** Russia BAFS Compliance is deployed on the TraceLink Global Compliance Platform, which greatly speeds initial configuration and minimizes reliance on IT for maintenance. The solution provides manufacturers with pre-integrated business logic to detect compliance events and automatically submit reports to the central authority. Additionally, the solution provides crypto code capabilities, enabling the manufacturer to request and retrieve crypto codes and distribute those codes to LMSs and CMOs using existing integrations.
- **Lowest Total Cost of Ownership:** TraceLink Russia BAFS Compliance capitalizes on the platform's "Integrate Once, Interoperate with Everyone™" capability, which enables manufacturers to connect with partners without configuring costly point-to-point integrations. The TraceLink Network Success Team manages the onboarding and integration with any new trade partners at no additional cost—they simply create a new integration across the TraceLink network or use a pre-existing integration if the partner is already a TraceLink customer.
- **Proven Compliance Expertise:** TraceLink has been supplying compliance solutions for Russia since 2019, with more than 130 manufacturers and CMOs relying on TraceLink to meet Russia compliance requirements. Globally, TraceLink serves more than 1,500 customers and is the largest track-and-trace and compliance provider in healthcare and life sciences. Our support team operates 24x7, and two-thirds of our employees are in roles dedicated to improving our solutions or providing high-quality customer service.
- **Continuous Compliance:** With our commitment to maintaining compliance alongside evolving requirements, standards, and technical guidelines, you can rest assured knowing your solution will always be up to date. And as compliance projects move from implementation into an operational state, TraceLink provides additional solutions and service engagements to ensure your compliance programs continue to run smoothly. These services span everything from training to consultations designed to resolve compliance issues before they strike.





Why TraceLink?

TraceLink is the only solution provider proven to effectively manage compliance requirements while tackling multienterprise business challenges at global network scale.

With over 130 manufacturers using our Russia Medicines Compliance solution, TraceLink also has unsurpassed domain expertise in helping manufacturers meet what are some of the most complex serialization requirements in the world. Additionally, TraceLink hosts a dedicated EAEU and Russia Special Interest Group, a community group dedicated to sharing information about new regulatory updates, discussing common customer compliance obstacles, and providing best practices and insights.

TraceLink Russia BAFS Compliance is built and hosted on the TraceLink network, the healthcare and life sciences industry's largest digital supply chain network. With just a single integration, the TraceLink network enables organizations to seamlessly exchange serialization data and compliance information with trade partners across the end-to-end pharmaceutical supply chain. Key network metrics include:

130+

customers using TraceLink
Russia compliance solutions

919M+

regulatory documents
processed and exchanged

930+

distribution and logistics
customers and partners

290K+

authenticated and onboarded
network members

7.3K+

live CMO connections across
more than 1,300 customers

41.1B+

serial numbers
commissioned to date

14.9K+

live serialization connections

\$4.7B+

in customer savings by avoiding
point-to-point integrations

[Contact TraceLink today to schedule a demo](#)

