



## Building resilience and trust into the distribution of pharmaceuticals and vaccines

BSI is working with NGO and AID organizations to maximize the availability, quality, and security of pharmaceutical and vaccine products to ensure they reach end patients safely and securely.

As the trusted global authority in supply chain standards and consulting we are providing best practice expertise and innovative technology to manage and mitigate risk, optimise global distribution, and deliver drugs to patients safely, securely, and quickly. If your organization is involved with storage and transit of pharmaceutical and vaccine products, it is imperative to ask these questions:

1

How exposed is the in-country supply chain operations and logistics to disruptions or diversion?

2

Are the third party logistics and control tower partners qualified at transporting highly secured goods or loads that may require cold chain, at scale and with appropriate controls?

3

Do you effectively and securely manage data and drive actionable analytics to enable better visibility of product traceability?

4

Have you vetted all warehousing and storage facilities in country for inventory management and internal-audit practices, to ensure all shortages and overages are investigated?

5

Have you gathered as much information as possible about the complexities behind the distribution network, including any subcontractors and last mile transportation providers?

6

Do you have strict notification protocols for in-country logistics providers for cases of suspected tampering with shipments or product diversion – including notification to law enforcement?

7

Have you thoroughly vetted all parts of the supply chain against internationally recognised standard(s) for quality and secure transport?

# How should the pharmaceutical industry proactively respond?

The solution is to fully map and examine the supply chain from end to end. Distributors should track every lane where the drugs are likely to transit, from the manufacturer down to last-mile delivery.

The focus should be on areas that are prone to higher risk, such as long-distance road transportation and particularly last-mile conveyance. It must be ensured that last-mile and other carriers have effective route mapping, risk assessment and training in place for their drivers.

Companies hired for warehousing and distribution should have effective systems for controlling, tracking and monitoring their inventory at a product level and conformance with agreed SLAs and regulation, along with ways to assess flag suspicious order patterns or buyers. They are urged to compartmentalise information on inventory, so it is only shared with those people who need to know. Warehousing and distribution companies should have robust internal audit protocols in place and have clear SLA from shippers relating to quality and security processes.

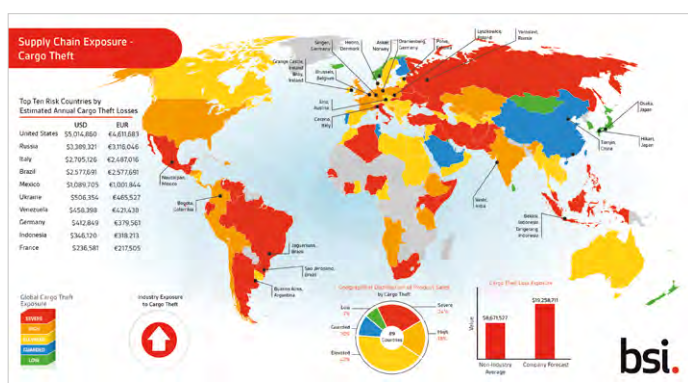
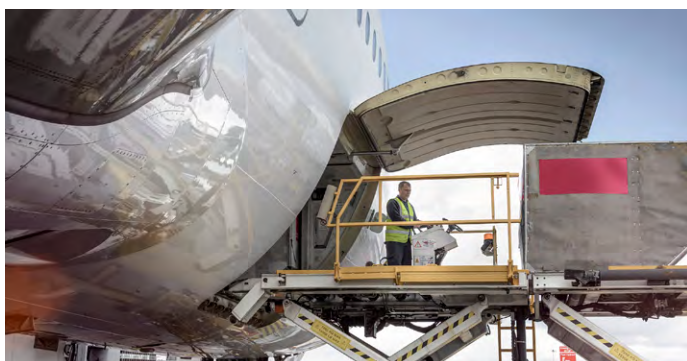
## BSI – your partner in pharmaceutical distribution best practice

BSI is supporting the global pharmaceutical distribution effort by partnering with organizations along the supply chain to address urgent issues in risk management, standardization, and data analytics. As the trusted global authority in supply chain standards we are providing best practice expertise and innovative technology to manage and mitigate risk, optimise global distribution, and deliver drugs to patients safely, securely, and quickly.

Here are some of the ways we can help your distribution operations:

### Strategic Risk Management and Standardisation

- Best practice standards, management systems frameworks, and regulatory frameworks
- Subject matter expert consultants – supply chain security, GMP/GDP, quality, safety, and resilience
- Strategic governance development
- Route risk modelling and assessment
- Security third party logistics SLA and audit development
- Third party logistics risk assessment methodology and on-going compliance monitoring
- Policy and procedure development
- In-country capacity building and focussed training



# BSI – your partner in vaccine distribution best practice

## Global presence of in-country expert auditors

- Assess distribution and storage sites for compliance and other inventory, security, and quality process requirements
- Assess and monitor adherence to SLAs and contractual requirements for security, quality, and control of pharmaceutical products

## Technology and innovation

### bsi.connect screen

BSI Connect Screen is an integrated platform that employs a risk-based approach to supply chain risk management programs. It targets the biggest global supply chain threats to help organizations inspire trust and build resilience through data-driven insight. Our platform contains the largest proprietary global supply chain risk intelligence database that analyses

more than 20 risk ratings in over 200 countries. By infusing geographic risk data and analysis into the assessment process, organizations can track compliance and risk throughout the supply chain to maximize visibility.

**BSI Connect Screen Edge** – our supplier assessment software infused with the latest intelligence. BSI Connect Edge can be adapted to monitor and mitigate risk and provide clear line of sight across your supply chain. This tool provides one comprehensive view of your supply chain that takes into consideration geographic and supplier compliance and risk exposure – empowering you to build a more resilient supply chain.

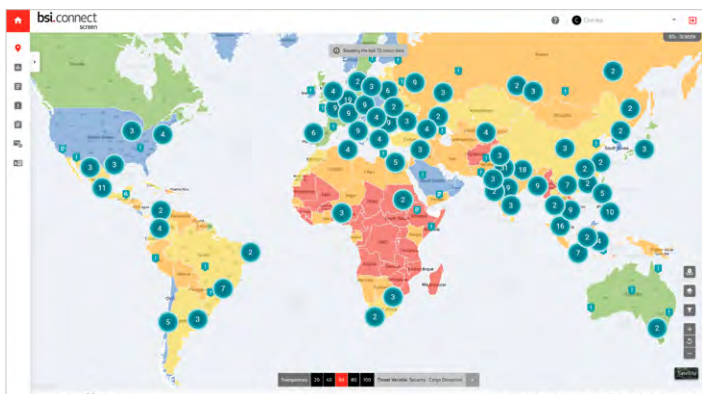
**Data management and analytics** – our data management hub is powered by standards-based data interoperability enabling real time supply chain visibility and new advance client applications. The BSI OriginTrail Decentralized

## Training and Capacity Building

- Third party or internal staff training on distribution best practice frameworks
- Technology-enabled capacity building at national and localised levels
- Lead auditor training on distribution requirements, to enable businesses to internally manage risk and implementation compliance

Knowledge Graph (DKG), combines the benefits of knowledge graphs, digital standards and blockchain technology. It enables a highly connected and trusted way of maintaining certificates, training records, supply chain events, and inventory records for distributed products based on unit-level product identifiers such as the GS1 SGTIN – allowing for global product traceability collated into patient utilization data.

**Immersive Technology Solutions** – improve warehouse assessments for inventory management, quality control, and security; innovative tools ranging from mobile, headset, spatial and aerial solutions enabled by the BSI XpertEye platform.





# Case study:

## Global Donor Organization, National Supply Chain, Quality and Security – From losing product to quality standards improvement

### Background:

In 2014 two global pharmaceutical companies, in partnership with an NGO, pledged to donate and distribute up to 1 billion international units of cold chain pharma product for use in developing countries over ten years.

Between 2015–19 over 450 million units have been provided and more than 18,000 people with have been treated. The scheme has been extended to 2025.

### Problem Statement:

The NGO distributes donated units through a global distribution network comprised of numerous treatment centres situated throughout the receiving countries. The donating parties raised initial concern regarding potential and significant product diversion and subsequent loss in the supply chain in India.



### Project Scope:

In just over six months, this single issue investigation engagement developed into a comprehensive, standards-based quality distribution strategy. BSI engaged in a long-term consultative engagement to improve the in-country management systems and governance, as well as an on the ground presence to on-going monitor implementation of the client's quality management program.

BSI provides technical support to review and assess the handling and transportation practices of the main in-country distributor. BSI assist in the identification of improvement

recommendations and potential changes which may be required to policies, practices and procedures that ultimately add value and enhance the quality and security of the Client supply chain and distribution networks.

BSI, supported by strategic partner Trace Labs, also implemented a data management hub based on the OriginTrail Decentralized Knowledge Graph (DKG) and underlying blockchains, powering a solution that enables product authentication, tracks patient utilization, and highlights any diversion or waste issues.

### Deliverables:

- End-to end, digitally enhanced supply chain visibility for the NGO client and their distribution and healthcare partner network
- Comprehensive quality distribution strategy, based on standards
- Improved management systems and governance at each point of the chain of custody
- A data management and supply chain transparency solution ensuring interoperability based on global data standards such as GS1 EPCIS:
  - › Unlocking the value of existing product data from ERP
  - › Allowing warehouse workers and medical practitioners to enrich existing product data by scanning products with their smart phones, recording additional supply chain and patient treatment events, as well as verifying product authenticity
  - › Linking and ensuring the integrity of data using OriginTrail DKG, underpinned by knowledge graph and blockchain technology
  - › Enabling analysis of linked data for informed decision making