

SERIALIZATION IN THE CONTEXT OF DIGITAL SUPPLY CHAIN

Abstract

As serialization becomes a mandate across the globe, it plays a key role in driving the creation of smart, responsive, and digital supply chains.

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Introduction

The pharmaceutical supply chain is complex to begin with and continues to face challenges due to dynamic drug requirements, contract manufacturing, compliance involving different stakeholders along the value chain and multiple government regulations that must be followed. The COVID-19 pandemic exposed these long-existing challenges, calling out the need for resilient and agile supply chains. The pandemic also highlighted multiple cases of counterfeit drugs including spurious

Chloroquine¹ that needs to be eliminated with a sustainable solution.

The pharmaceutical supply chain starts with the import, warehousing and transportation of excipients and APIs (Active Pharmaceutical Ingredients) to the manufacturing sites. Once the drug is manufactured for a particular market based on pharmacopoeia, the same is then exported in adherence to the governing regulations. The drug finally reaches the end

consumer through a network of complex distribution channels.²

Government regulations are in place to ensure the integrity and security of the drug supply chain through serialization and track and trace that help authenticate every drug pack / SKU. In addition to supply chain security and patient safety, serialization is crucial in addressing the challenges faced by the industry and for making pharmaceutical supply chain more efficient.

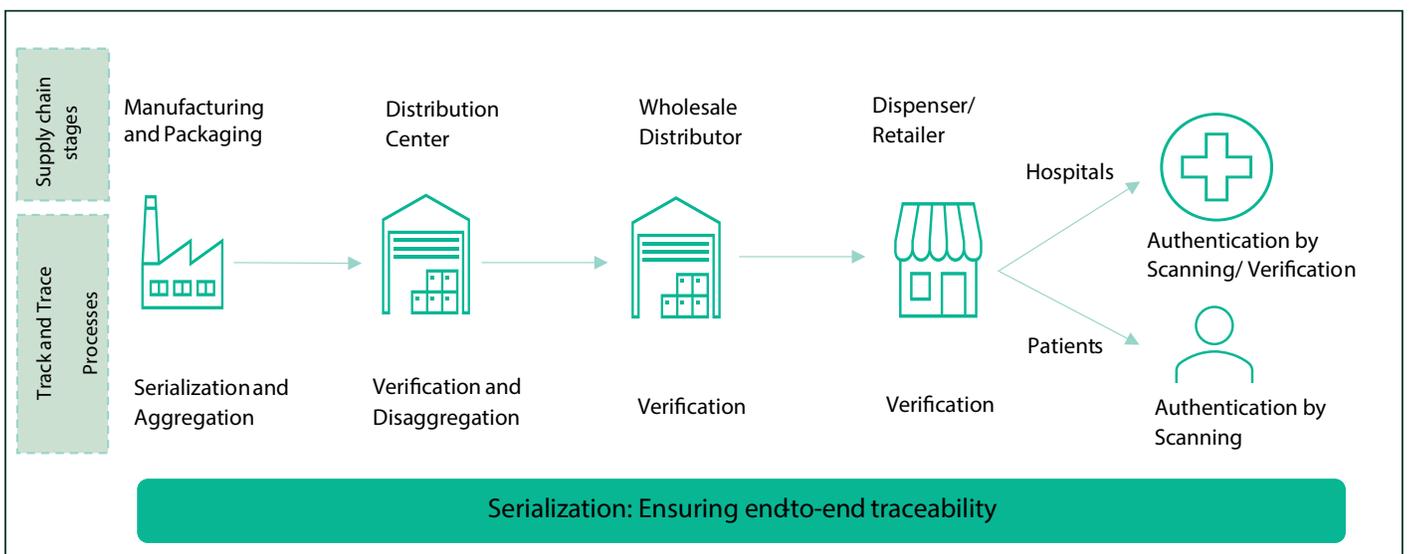
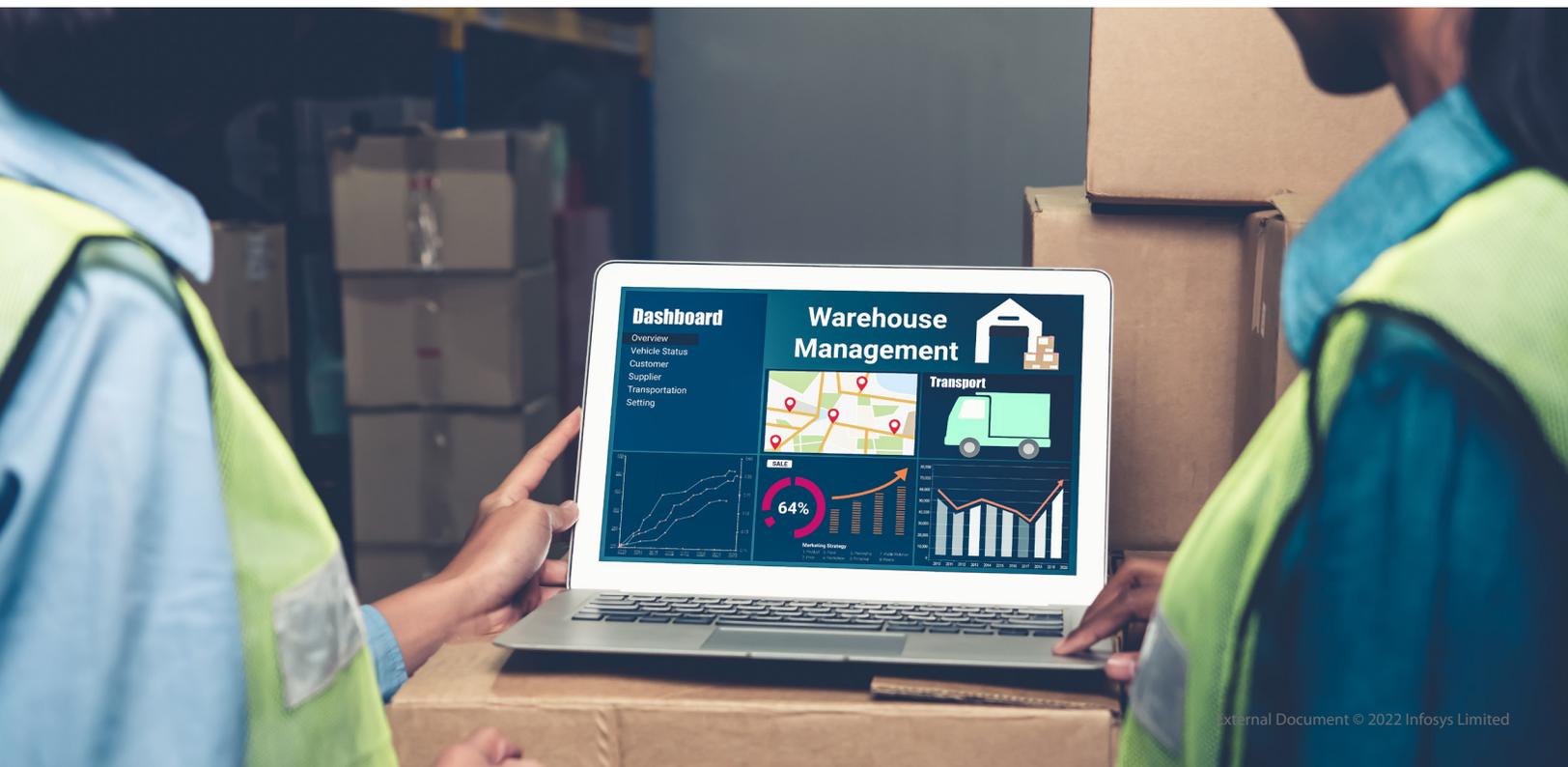


Figure 1 Traceability across the Pharmaceutical Supply Chain



Why is Serialization essential for digital supply chain transformation?

Track and Trace implementation begins with serialization but may have other components such as verification and reporting. Serialization is the assignment of unique, traceable identifier to each saleable pack of the drug. To track or trace a product, it must

have a tracking ID, which in our case is the serial number.

End-to-end traceability is ensured if each product can be tracked at an individual level, right from the raw material source, packaging at the manufacturing facility,

aggregation at a warehouse till dispatch to the end-consumer. This becomes a win-win scenario where pharmaceutical companies have complete control over their product movement and the customers have complete knowledge of the product's authenticity.

How can the end consumer be ensured about their drug authenticity?

Every drug in the market today has a barcode or identifier linked to it which allows the tracking and tracing of the product at any point within the supply chain.³ These identifiers are linked to enterprise information systems i.e., ERP and System of records by pharmaceutical majors. There also lies information at plant site level, distributors, warehouses, hospitals, pharmacies, and patients that need integration. Since most of these entities run in silos as per their operating procedures, often the visibility is restricted to their own systems resulting in a lack of end-to-end transparency. Implementing track and trace provides real-time visibility to supply chain partners and results in improved inventory management processes such as

- Batch management and recalls
- Locating good Vs bad drugs
- Shelf-life management and expiry planning

The primary identifier of a product is different for processes at these entities within the supply chain.

Process	Primary Identifier
Manufacturing	Product Family / Product ID / Product Registration name
Serialization	GTIN (Global Trade Identification Number)
Warehousing	Lot number / Batch number
Distribution	SKU number

Table 1: Key Identifiers along the Pharmaceutical Supply Chain

Below are the GS1 outlined identification keys, which outline the standards for serialization:

- **GTIN - Global Trade Item Number:** Identifies individual products or services
- **SSCC - Serial Shipping Container Code:** Identifies logistical units such as cases, cartons and totes
- **GLN - Global Location Code:** Identifies organizations and their individual locations
- **GSIN - Global Shipment Identifier:** Identifies individual shipments

As serialization becomes a mandate around the world, it plays a key role in the creation of smart, responsive, and digital supply chains. Drug companies are adopting digital into their supply chains with serial numbers embedded in the 2D bar codes. This 2D barcode serves as a unique digital identifier or single source of truth across the value chain. Information encoded in these barcodes can be shared with respective governments and trading partners to maintain complete transaction history and flag suspicious activity on time.



Industry Regulations

Serialization and track and trace regulations are being mandated by authorities across the globe to ensure drug tracking across the supply chain. This allows the verification of authentic drugs with end-to-end traceability while detecting counterfeit drugs at various touchpoints.

1. US DSCSA

The Drug Supply Chain Supply Act affects pharmaceutical manufacturers, repackaging entities, wholesale distributors, dispensers, and pharmacies.⁴

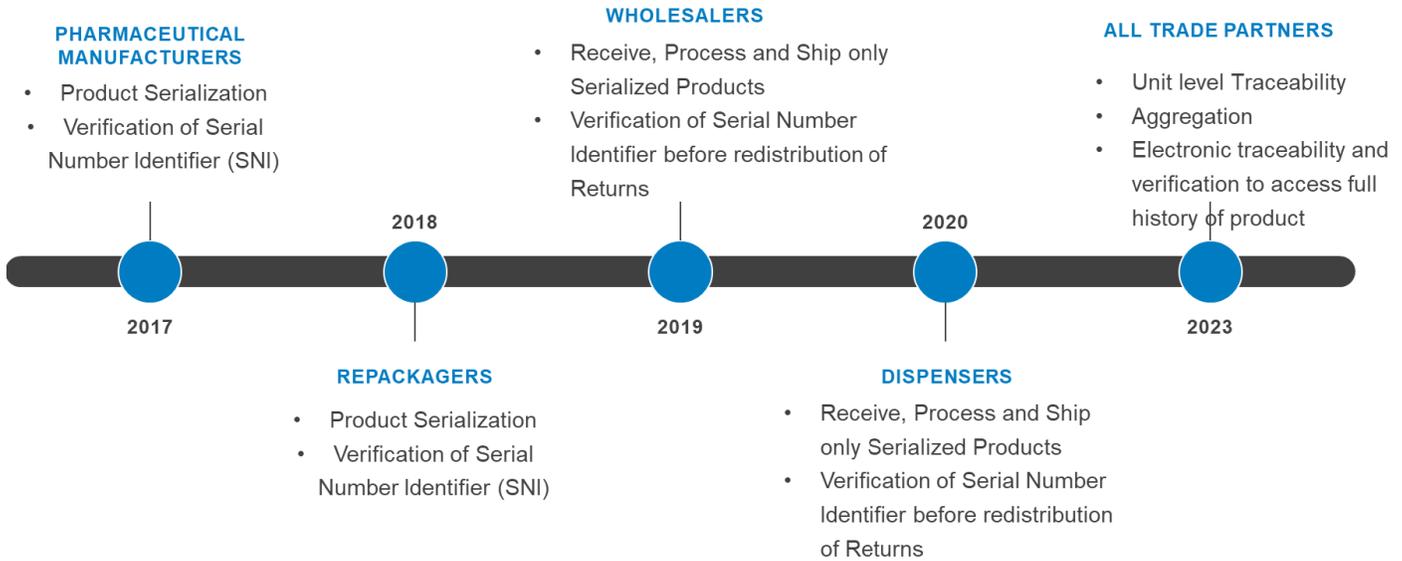


Figure 2 US DSCSA Track and Trace Regulation Guideline

2. EU FMD

EU FMD applies to every trade partner in the supply chain with different guidelines.

- Manufacturers are required to serialize the product at the sellable unit level and report all transactions (Master Data, Recall Notifications, and Status Updates) to EMVO.
- Parallel Importers are required to verify the imported product, serialize it again after relabeling / repackaging and report all transactions (Master Data, Recall Notifications, and Status Updates) to EMVO.
- Wholesale distributors and dispensers are required to verify the product at the point of resale / dispense.⁵

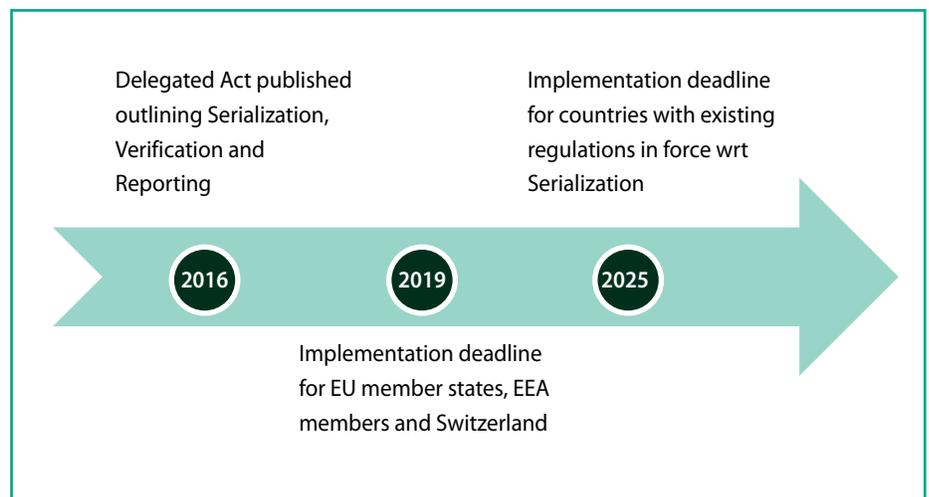


Figure 3 EU FMD Serialization Guideline

3. Other markets

Serialization, track and trace, and product authentication compliance requirements are defined for 41 countries. Legislation for the same is in draft or planning phase for many other countries.

Country	Regulatory Authority	Serialization	Tracking & Tracing	Verification	Reporting
US	FDA	X	X	X	
EU	Country Level NMVS	X		X	X
Russia	CRPT	X	X	X	X
China	CFDA	X			X
India	DGFT	X			X
Brazil	ANVISA	X	X		X
South Korea	KFDA	X			X

Table 2 Track and Trace Regulation components across the world

The Benefits of Serialization Beyond Compliance

Serialization is the basis for traceability and ensures the identification of illicit products and Counterfeit Drugs Elimination. Tracking and verification before receiving returns eliminate the possibility of drug diversions and fake products entering the supply chain.⁶ In addition to that, the benefits below can be unlocked through serialization.

Drug Recalls and Adverse Event Management	Customer Engagement	Payments Reconciliation	Inventory Management
In case of any adverse events like medicines being quarantined, stolen, or held in custody, manufacturers can alert the downstream trade partners via traceability notifications. This helps the involved parties be prepared to manage their operations without major leakages or losses.	Implementing serialization is a way for brands to leverage technology and engage customers. The 2D barcodes with data satisfy the end consumer's need for detailed information on the medicine journey (Data regarding the ingredients, product origin, allergens, testing, etc.). Product verification ensures product safety and enhances customer confidence.	Real-time visibility and reporting of transactions can automate the credit and payments processes at the wholesaler and distributor end. This reduces manual interference and delays in payment processing related to chargebacks and non-saleable returns. Serial number linked unit sale price reduces redundant workflows and eliminates the risk of over or under reimbursement.	Pharmaceutical companies will have better control on the stock levels and returns processes due to visibility at the warehouse and distributor level. Sales and operations planning can be managed efficiently, and any drug shortages could be avoided with better view of inventory levels and product flow.
Real-time visibility and Issue Resolution	Improved Brand Image/ Reputation	Automated Processes	Process Excellence

Conclusion - Future of Serialization

Building a digital and responsive supply chain ecosystem is the need of the hour due to rapid technological advancements and dynamic business requirements. Successful pharmaceutical supply chains of the future are the ones which adopt blockchain, artificial intelligence and GS1 serialization.

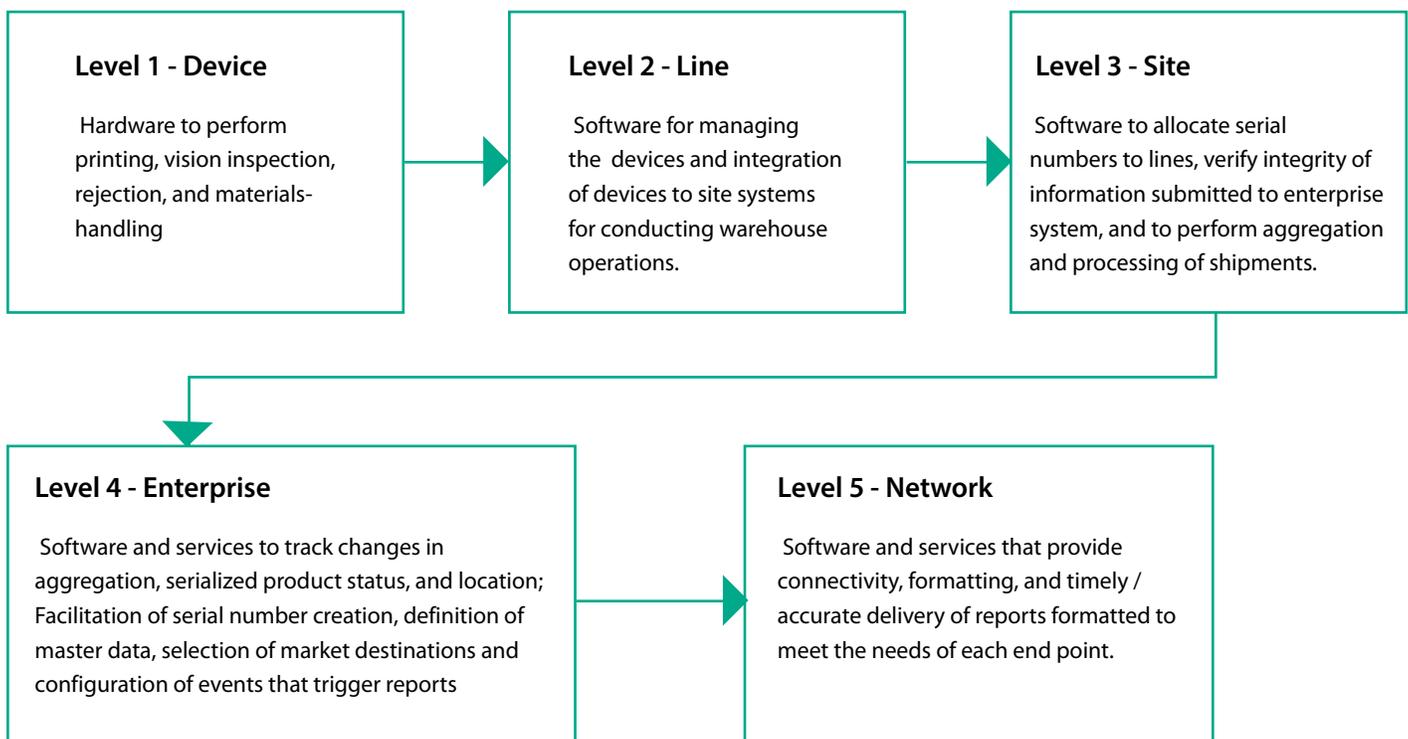
Once serialization is implemented as a regular business process, firms will start looking for opportunities to create value beyond compliance. Firms could start looking at advanced solutions backed by analytics and IoT for inventory tracking and drug transfers to balance between cost of lost sales

and high inventory. Transparency and visibility achieved through established track and trace systems lay the foundation for Integrated Business Planning with synergy between supply chain, regulatory compliance, and advanced analytics.



How can Infosys help you in your Serialization journey?

Infosys provides customized solutions to support track and trace compliance and serialization programs with L1- L3 on-premise serialization support integrated with L4- L5 Cloud Based Data Hub supported by Program Management, end-to-end Implementation and Change Management services.



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