

The Five Big Challenges Serialization Causes in Pharmaceutical Supply Chains

And How Blue Vector Can Help You Solve Them

blue vector

The Situation

Why serialization? Why now?

As a result of the rise in drug counterfeiting and diversion, and their attendant negative publicity, dozens of U.S. states and the federal government have either enacted or are enacting legislation requiring item-level serialization and the creation and maintenance of pedigrees (carrying drug-related and chain of custody information) for dangerous or high-consequence drugs.

This legislation poses a huge challenge and significant cost to organizations that manufacture, distribute, and sell these drugs as they seek to comply with the mandates. Government, industry organizations, and the courts have worked together to extend legislation deadlines to allow organizations enough time to comply in an effective manner, including developing processes to accommodate serialization and pedigree management, implementing appropriate technical solutions, and collaborating with partners on integration and standards.

Given the extended time period for compliance, organizations now have the opportunity to be more thoughtful in their approach. Many leading pharmaceutical companies are getting started now to make sure they have processes and systems that are tested, rolled out in a systematic way, and proven over a period of time prior to pedigree deadlines. Also, many of them are considering solutions that will not only satisfy future legislative mandates, but will also help them achieve business benefits beyond compliance. The tighter product control that serialization provides will contribute to product authentication and integrity, ultimately enhancing (or at least protecting) company brand. It will also enable organizations to realize greater revenue share by reducing the “gray market” activity that occurs when products are able to be counterfeited and diverted. It will give companies better control over and visibility into their supply chains, leading to more accurate shipments. And it will enable a fast and efficient reverse logistics or recall process.

Outside of the U.S., pharmaceutical organizations are adopting serialization to recoup payment from centralized government agencies that reimburse patients’ drug costs in a single-payer or otherwise centralized health care system.

The Five Challenges Caused by Implementing Serialization

What are pharmaceutical organizations doing to comply?

In order to comply with the state and pending federal mandates, pharmaceutical manufacturers, distributors, and retailers are undergoing a multi-phased, multi-year process to do item-level serialization in a way that protects them and enables them to reap

the greatest rewards. This process will likely entail the following phases: strategic planning; process and solution design; pilot implementation and testing; full implementation; and partner integration and alignment.

Pharmaceutical organizations are considering the purchase of technologies and implementation services, including serialization (creating, detecting, and managing serial numbers) and pedigree (creating, communicating, and managing drug pedigrees electronically) solutions as well as integration services. They are making technology decisions and grappling with the cascade of choices that follow those decisions. They are also considering how these technologies and services will fit into their existing operations (such as packaging in a manufacturing facility) as well as how they will extend the core business applications, such as warehouse management or enterprise resource planning, in which they’ve already made significant investments and which they’re already using for their business processes today.

What does this mean for their operations?

These process changes and the introduction of new technology into their environments have the potential to cause significant disruption to what have become highly-optimized operations for pharmaceutical organizations. The introduction and management of serialization in the drug supply chain have created a number of business challenges. Following are five significant operational problems that are caused by doing item-level serialization:

1. Bottlenecks

Operational bottlenecks in the physical supply chain as a result of both having to perform item-level serialization tasks but also of having to manage and interact with serialization solutions;

2. Scalability

Inability to scale serialization solutions to support distributed operations across a manufacturing facility, distribution center, warehouse, and across dispersed geographies;

3. Performance

Reduced network and system performance as a result of the introduction of centralized serialization computing solutions to address a distributed problem;

4. Time to Deploy

Long implementation cycles for serialization solutions; and

5. Ongoing Cost

Costly ongoing maintenance for serialization solutions

Organizations are seeking to solve some of these problems with both process and technology. To address physical bottlenecks, for example, they may be deploying RFID tags and readers to be able

to track goods at the item-level rapidly. They may also be deploying IT solutions that enable the serialization process, but they would like to get more value from the investments they've already made in business applications like SAP. They also need an appropriately architected solution to suit the distributed nature of their operations to facilitate the many disparate actions that are happening at once in an operations center.

Blue Vector helps organizations address these problems directly.

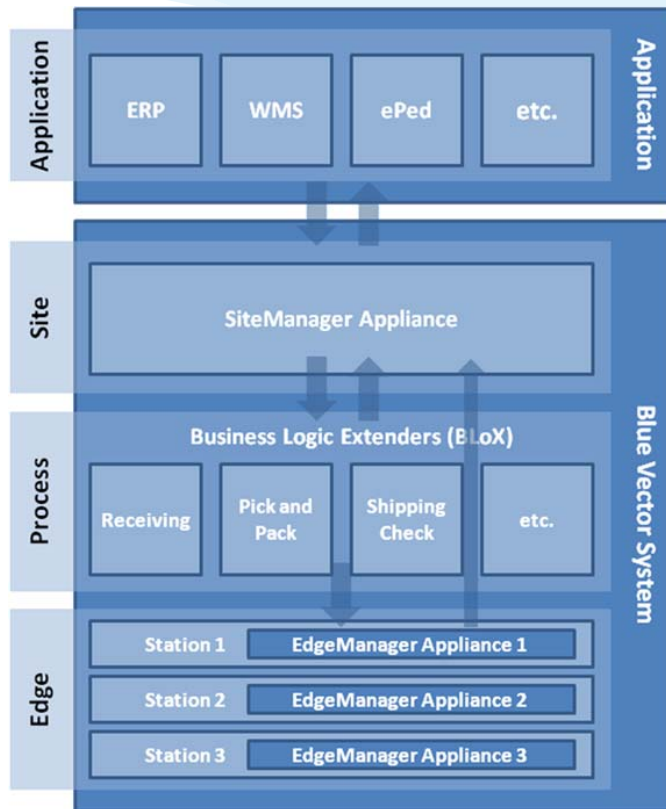
The Blue Vector Serialization Solution

About Blue Vector

Blue Vector provides a software system that enables widespread local automation with centralized control and visibility. Our Serialization solution enables our pharmaceutical customers to perform item-level serialization in an efficient and cost-effective way, while laying the groundwork for them to achieve ROI-based objectives such as improving the accuracy of their supply chains. Blue Vector makes contextual plan data and business policy information available at the edge of our customers' operations, enabling them to make decisions and take actions where the work is done – not just in a manufacturing facility, distribution center, warehouse, or retail center, but in specific work areas such as in a receiving area, in quarantine, at a pick-and-pack station, or in a cold store. Our solution enables processing to occur in a distributed way at each point, independently from the other points, thereby reducing burden on both the network and core business applications that managing these disparate processes might introduce in a monolithic computing approach.

Blue Vector provides a framework to manage and enrich information at each step of the process. Due to the added complexity that serialization introduces in a system, there is need for an infrastructure layer that senses each business step as it occurs in the operation and guides operators about what actions to take. In addition to assisting decision-making at the physical layer, Blue Vector enables and optimizes the information layer. This layer of the solution includes creating the necessary EPC events for an EPCIS or pedigree application, and authenticating electronic pedigrees in real-time for receiving, shipping or at any other intermediary step in which a product's chain of custody needs to be maintained.

The Blue Vector solution bridges the gap between the physical world and core business applications. The physical world includes RFID equipment, 2-D and linear bar code readers, displays, and printers. Business applications benefit from standards-based, two-way data integration. These include EPCIS and pedigree applications (Axway, IBM, rfxcel, and SupplyScape), warehouse management systems (Manhattan Associates and Red Prairie) and ERP applications (SAP, Oracle, legacy systems).



What are the components of Blue Vector's Serialization solution?

Specifically, Blue Vector's solution is software delivered as a system of appliances that perform different functions and sit in distributed locations in the physical and IT value chain, but work together to enable edge processing and back-end integration. The appliances include:

- EdgeManager Appliance:** The EdgeManager Appliance sits at the point in an operational facility at which work is performed (for example, attached to a conveyor or barcode scanner where goods are passing through a system). They not only perform the basic function of managing the system of wireless readers (including RFID readers and 1D/2D barcode scanners), but they also contain centrally managed, automatically delivered data and business logic that enable them to perform specific functions in real-time, such as match incoming reader data to an inbound RxASN or pedigree, determine what steps to perform based on rules, take an action (such as sounding an alarm), and provide instructions to the operator via a user interface.
- SiteManager Appliance:** The SiteManager Appliance sits centrally at each operations center and manages the two-way data integration that must occur for EdgeManager Appliances to do their job as well as for back-end systems to receive information confirming that work has been done.

The SiteManager Appliance receives plan data (RxASN, serial numbers, drug pedigree) and, based on context (where each EdgeManager Appliance sits, what processes it is intended to perform), delivers the right plan data and business logic to the right EdgeManager Appliance. It also receives upstream data (from the EdgeManager Appliance) and delivers those data (typically confirmation of a valid transaction) back to core business applications.

• **GlobalManager Appliance:** The GlobalManager Appliance sits centrally across the Blue Vector system, even in geographically dispersed operations, and provides a single point of administration. It has a Web-based user interface, gives the operator a consolidated view of the entire system, and enables him or her to centrally configure, manage, and change the system, down to determining the specific business logic that will be delivered to each EdgeManager Appliance. The GlobalManager Appliance is also responsible for monitoring the continuous health of all Blue Vector system components via network heartbeats.

While the appliances work together, they are not interdependent, meaning that they neither rely on each other for processes to occur nor do they represent a single point of failure. EdgeManager Appliances work independently from each other¹, and while they send information back and forth with the SiteManager Appliance, they can perform their function without connection to the latter, enabling time-critical operations to continue even if the IT network experiences downtime. Likewise, the SiteManager Appliance is not dependent upon the GlobalManager Appliance for it to perform its operations.

An important component of the Blue Vector solution – and one that enables centralized management of such distributed systems – is our business logic, which we call BLoX (Business Logic Extensions). BLoX are applets of programmatic functionality that encapsulate the various processes at the edge, including:

Receiving: Check that entire advanced shipping notice is received; verify pedigree match; send items to quarantine or for returns processing

Aggregation: Combine items into cases or totes; combine cases or totes into pallets; combine everything into shipment; update or create pedigree

Special handling: Separate quarantined items from others; update aggregations as items are shifted; review status of pedigree for each item

Quality assurance/audit: Provide a double-check to ensure that items are serialized and that pedigrees are up-to-date

Destruction: Identify items that have been deemed non-saleable; send items tagged for destruction to destruction area

Shipping: Perform shipping aggregations; update pedigree; send items to quarantine or forward as part of returns processing

¹ The EdgeManager Appliance can also be configured to have coordinated processes.

Because we develop BLoX as discrete processes that can fit modularly into our customers' unique operations, the BLoX are able to support those operations by capturing each customer's best practices, local knowledge, and uniqueness of their operation without having to write customer code.

To make serialization easier for our customers, Blue Vector delivers our Serialization solution in a variety of form factors, or "stations." These integrated stations – a mobile cart, conveyor, workbench, retail-appropriate desktop, or handheld scanner – contain our EdgeManager Appliance with the appropriate business logic, as well as elements such as devices (RFID, barcode), sensors (photo eye), feedback mechanisms (touch screen, UI, LED, light stack), that make up an edge solution. This ability to smoothly interact with operations is one key to improving process capabilities without impacting productivity.

Benefits of the Blue Vector Solution: Solving the Five Problems

Given the business challenges that implementing a serialization process introduces into a pharmaceutical supply chain (operational bottlenecks, inability to scale to support distributed operations, reduced network and system performance, long implementation cycles, and costly ongoing maintenance), pharmaceutical organizations require highly-scalable, cost-effective, and easy-to-manage solutions that fit their distributed environments, and should not have to retrofit their already-optimized operational processes to fit into their – usually monolithic – IT systems. Blue Vector understands this, and has built its solutions from the ground up to fit into, and scale across, its customers' operations. Our distributed edge processing and modular approach to business logic delivery enable us address the business challenges our customers are experiencing in the three following ways:

Reducing Bottlenecks

Verifying item-level information causes operational and system bottlenecks. The distributed nature of the Blue Vector system, together with its edge intelligence, enable decisions to be made and instructions to be delivered rapidly to where the work is performed and keeps intensive computing contained at the edge. For example, rather than having an operator open cases in a receiving area to check

individual items, Blue Vector allows the closed case and all the items in it to be scanned, validated, information automatically recorded and communicated to the right systems, and provides operator instructions. Likewise, because Blue Vector enables all system processing (plan data queries and business logic processes) to occur at the point of automation, only meaningful events (such as the completion of a valid transaction) would be sent upstream to core applications. This means better IT systems availability, fewer disruptions, and lower IT cost. Blue Vector's combination of edge intelligence and processing helps our customers reduce or eliminate the bottlenecks item-level serialization introduces into their operations.

Scalability and Performance

Unlike traditional, monolithic computing systems, Blue Vector scales out in a horizontal fashion, handling not only many, but disparate and diverse, points of automation. This enables the right process to occur at the right place, many different processes to occur at once, and organizations to increase the many processes they do in their operations facilities. For example, an organization can have an EdgeManager Appliance attached to a handheld scanner performing receiving operations, another inside a quarantine area providing operators with next steps, and a third with a printer attached creating barcode labels on the fly for non-serialized items. The system's architecture and robust capabilities enable these diverse operations – whether a few or a thousand – across a large and highly distributed supply chain.

Faster Deployment and Lower TCO

Unlike solutions requiring custom development, costly integration services, and manual ongoing maintenance, Blue Vector's system is delivered as a set of pre-software loaded appliances that are plug-and-play and enable two-way data integration built-in, a group of configurable, modular BLoX, and an array of form factors that fit into and support our customers' operations. These elements enable rapid solution deployment and allow our customers to spend their service dollars on higher-value activities than nuts-and-bolts implementation and integration. Furthermore, Blue Vector's centralized administration, along with the ability to deliver and reconfigure functionality at the edge, make for efficient ongoing maintenance.

Administrators can add new or reconfigure existing EdgeManager Appliances individually or in groups, temporarily disable parts of the network, and add or change integration touch-points relatively quickly and from one central point. Ease and speed of implementation, together with efficient ongoing maintenance, make the Blue Vector Serialization solution among the fastest to deploy and most cost-effective on the market.

Through its unique architecture and customer-focused feature development, Blue Vector delivers business benefits that not only address the five problems presented by item-level serialization but also set the stage for our pharmaceutical customers to derive business value from deploying our edge processing solution.

Next Steps

If you are experiencing the business challenges outlined above and would like to implement a solution with the capabilities and benefits described, please contact us to learn more about Blue Vector's solution.

If you are a:	We have solutions to your operational requirements for:
Pharmaceutical or biotech manufacturer	<ul style="list-style-type: none"> • Serialization during packaging (by unit/case/pallet) • Warehouse or distribution center operations for picking, packing, and shipping of serialized product • Returns processing
Wholesaler or distributor	<ul style="list-style-type: none"> • Receiving serialized product • Picking serialized product • Packing and shipping serialized product • Returns processing of serialized product • Receiving serialized product in independent pharmacies you serve • RFID-enabled vendor managed inventory
Retail pharmacy	<ul style="list-style-type: none"> • Receiving serialized product at your distribution center(s), retail pharmacies, or both • Returns processing of serialized product
Hospital or other patient care center	<ul style="list-style-type: none"> • Receiving serialized product at your in-patient pharmacies or central fill operation • Returns processing of serialized product

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