



Serialization: Driving Business Value Beyond Compliance

As serialization and track-and-trace capabilities go mainstream to meet regulatory compliance mandates, pharmaceuticals companies should simultaneously explore how these tools and techniques can improve supply chain planning and operations, elevate patient and doctor engagement, and increase sales and marketing effectiveness.

Executive Summary

High-value products, complex supply chains, dependence on multiple organizations for distribution – all of these factors expose the pharmaceuticals industry to threats such as counterfeiting, theft and illegal diversions. In fact, the Pharmaceutical Security Institute counts 2,177 incidents of counterfeiting worldwide in 2014 alone.¹ To counter these threats and ensure the integrity of the pharma supply chain, regulatory initiatives are under way worldwide that mandate serialization of medical products sold globally, as well as the tracking and tracing of products throughout the supply chain. The U.S., China, South Korea, EU, Argentina, Brazil and other regions of the world are all in different phases of implementing serialization- and track-and-trace-related regulations.

While regulatory compliance remains a top priority for pharmaceuticals companies, the availability of information about serialized products throughout the supply chain provides a unique opportunity for pharmas to take a data- and analytics-driven approach to supply chain improvements that yield

greater efficiencies and effectiveness through higher visibility and collaboration. Pharmas can use serialization data in multiple ways, including collecting inventory information across supply nodes, monitoring the performance of execution partners, cold chain monitoring and recall management; by doing so, they can bolster real-time decision-making capabilities and increase supply chain agility. Serialization data can considerably strengthen fraud-prone process areas, such as returns and chargebacks, as well as illegal diversions, yielding direct savings for all supply chain partners.

Serialization also provides pharmaceuticals companies with a way to connect directly with patients through patient-centric initiatives, strengthen their patient services portfolio and ensure brand loyalty. Patient authentication data, for example, can be used to geographically map customers and ensure adequate availability at the nearest pharmacy. Serialization authentication can also help optimize refill management, appointment bookings, patient education and disease management, among other services.



Pharmaceuticals companies can also use serialization data to identify the relative performance of various market segments to drive targeted sales and marketing initiatives. They can then analyze these interventions and programs and further fine-tune them, thereby increasing sales effectiveness and marketing spend efficiency.

When initiating serialization projects, pharmaceuticals companies must look beyond regulatory compliance to design the underlying infrastructure, applications and processes that drive value through new and supplemental business capabilities.

This white paper explores the many ways that new serialization capabilities can be utilized to drive business value across corporate functions and activities, thus enhancing the return on investment (ROI) to achieve regulatory compliance, globally.

The Serialization Context

The pharmaceuticals industry has faced challenges over the years to ensure the integrity of products as they move across the supply chain, from the manufacturing base to the patient. These supply chains are also becoming increasingly complex as pharmaceuticals companies segue toward specialty products and focus on lifestyle diseases. This has made it more difficult for pharmas to devise secure supply chain strategies to close loopholes and avoid losses.

According to the World Health Organization (WHO), the pharmaceuticals industry loses nearly \$40 billion each year globally due to counterfeiting.² Product theft has also increased; according to Freight Watch International, drugs account for about 15% of the estimated \$8 billion to \$12 billion in annual cargo theft.³

Counterfeiting and theft not only leads to losses worth billions of dollars in potential sales opportunity, but it also increases patient safety risk. Industry players also incur additional costs to manage product recalls once counterfeit batches have been identified. Lastly, negative publicity related to counterfeiting and recalls have a direct impact on brand image and future sales revenues.

Tamper-proof packaging and 3-D holograms were among the earliest approaches undertaken by the industry and government regulators to address counterfeiting. However, these efforts are now viewed as insufficient, as such packaging has been found to be vulnerable to manipulation. Recent regulatory initiatives – such as product serialization (i.e., assigning a unique identification number to every saleable pharmaceuticals product unit) and product tracking in the supply chain (through pedigree documentation and/or regulatory reporting) – are under way to address counterfeit drug concerns. Serialization and track-and-trace regulations are already active and enforced in numerous countries, such as Turkey, Argentina and China. Additional countries, such as the U.S., Korea and Brazil, as well as members of the EU, are in the process of implementation or finalizing such regulations. Within the next five years, approximately 65% of the global market (by value, as of 2014 revenue data) is expected to require serialization in the supply chain.⁴

Driving Business Value from Serialization

We have worked closely with major pharmaceuticals companies to explore and define additional dimensions for creating business value and increasing the ROI of their serialization compliance-related investments. A serialization compliance infrastructure enables two primary capabilities – supply chain and consumption visibility – that can be leveraged for additional use cases and as value drivers (see Figure 1, next page).

Inventory Optimization

We recently conducted a benchmarking study⁵ to evaluate the current state of pharmaceuticals supply chains as compared with those of fast-moving consumer goods (FMCG) companies (typically considered a best-in-class benchmark in supply chain design, execution and performance metrics). Our study found that, in general, the pharmaceuticals industry is serving its market as reliably as the FMCG industry, but at a much higher service cost.

The first set of metrics compared supply chain performance and reliability. Our analysis indicat-

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Serialization Dimensions to Drive Value Beyond Compliance

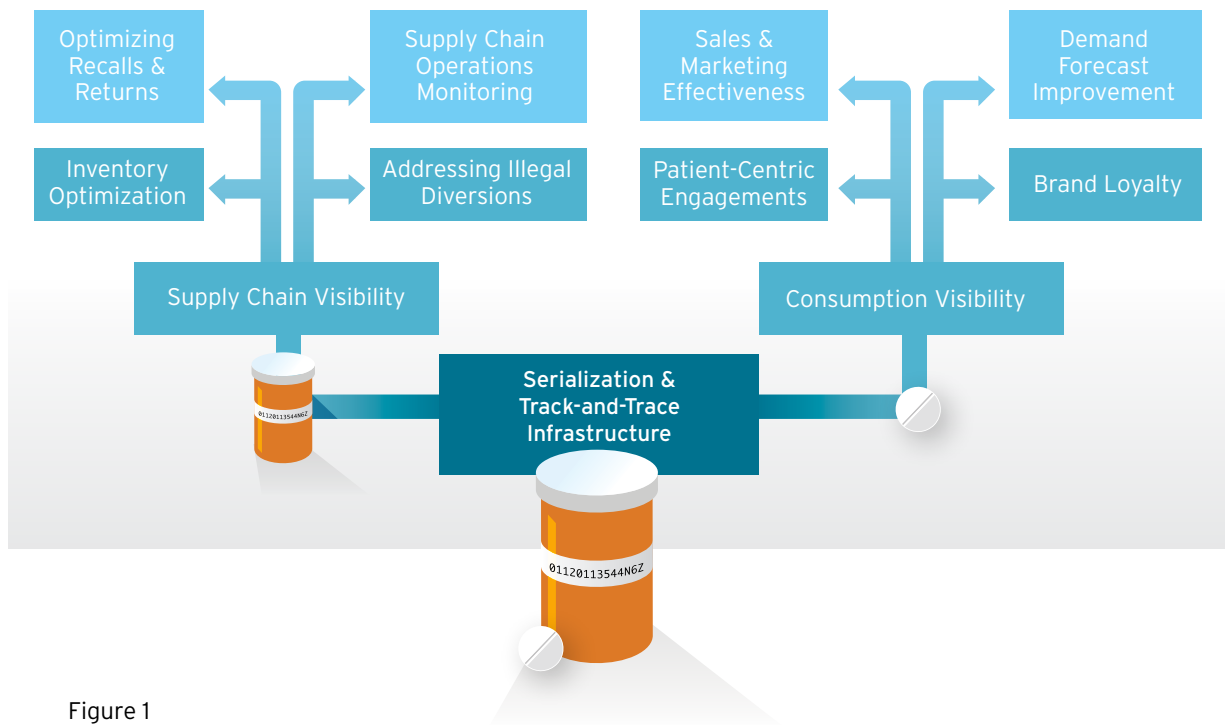


Figure 1

ed that the pharmaceuticals industry is, in general, on par with the FMCG industry in on-time-in-full (OTIF) and forecast accuracy (see Figure 2).

However, when we compared these two industries on asset efficiency measures, we found that the actual cost of attaining the same level of supply chain reliability is much higher for the pharmaceuticals industry (see Figure 3, next page). Consumer goods supply chains, on average, completed their conversion of asset resources to cash five times faster than pharmaceuticals. In terms of actual inventory turnover, the consumer goods industry was three times faster than the pharmaceuticals industry. By focusing on this area, pharmaceuticals companies could directly improve their returns on equity.

By combining serialization with track-and-trace supply chain event recording within databases that are compliant with the Electronic Product Code Information Services (EPCIS) standard, industry players and their partners could realize an additional supply chain platform to gauge product movement, facilitate tighter collaboration and/or enable more coordinated supply chain planning. The same infrastructure deployed for serialization track-and-trace regulatory compliance can also serve a broader group of

stakeholders by increasing agility and responsiveness, as well as optimizing inventory levels and costs across various supply chain levels or inventory-stocking locations.

For supply chain planners, a fundamental business goal is optimizing inventory across the

Measures of Reliability

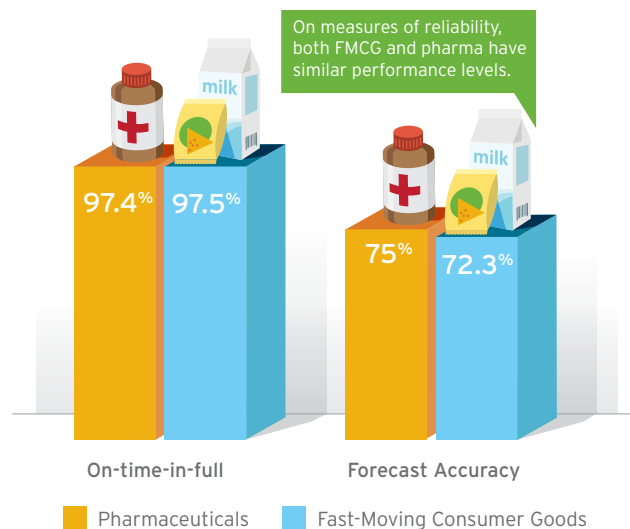


Figure 2

Measures of Asset Efficiency

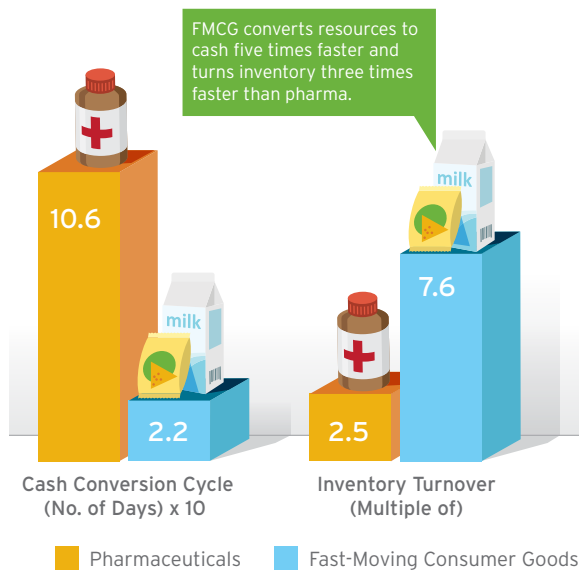


Figure 3

supply chain while improving customer service. The net inventory maintained at any customer demand location to deliver superior customer service must typically be balanced with the costs of maintaining inventory at those locations (i.e., carrying, storage, security and obsolescence). Stockouts not only result in lost opportunities for revenue generation but also may potentially impact patient health and supply chain partner performance.

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According to a 2013 report, Premier Healthcare Alliance estimated that the annual cost of drug shortages for U.S. hospitals was \$416 million.⁶ By implementing serialization technologies that enable inventory visibility across the

supply chain, pharmaceuticals companies have an additional source of near-real-time inventory event data that can be used to optimize inventory levels, shorten replenishment lead times and avoid stockouts.

Supply Chain Operations Monitoring

The ability to increase supply chain visibility and quickly respond to specific events can be a major advantage in the competitive pharma marketplace. Externalization of supply chain activities has increased dependence on service providers

in multiple areas, such as logistics. An important first step is for internal warehousing and distribution teams to develop performance metrics and benchmarks to manage external service providers. To enable a truly performance-driven supply chain, pharmaceuticals companies need mechanisms to monitor the performance indicators of different fulfillment teams and make real-time decisions.

With event data enabled by serialization and track-and-trace, companies have additional information they can use to more effectively monitor – and improve – underlying business processes.

Pharmaceuticals companies are working with their supply chain partners to establish and track key performance indicators (KPIs) as part of their supply chain contracts. But challenges remain to effectively implement and monitor these metrics, as well as gain dynamic visibility into changing conditions in the supply chain. A serialization and track-and-trace infrastructure can be used to capture and extract business transaction events (i.e., shipments, receipts and suspect products) and provide data and event management feedback in real time to support KPI monitoring, supply chain dashboards, support inventory and cold chain monitoring, and decision support.

With event data enabled by serialization and track-and-trace, companies have additional information they can use to monitor underlying business processes more effectively and leverage process improvement opportunities across organizational units and supply chain partners. They can also effectively benchmark and improve service delivery standards across the organization. Cross-organizational collaboration provides visibility into the underlying processes and makes execution-related information available to all relevant stakeholders, thus allowing the entire supply chain ecosystem to improve as one unit.

Optimizing Reverse Logistics: Returns & Recalls

The pharmaceuticals industry incurs about \$2 billion annually in costs associated with processing returns, expirations and recalls, according to a study by the Healthcare Distribution Management Association (HDMA).⁷ A lack of accurate audit trails and product authentication capabilities for reverse logistics exposes the industry to fraud and inefficiencies. Serialization and track-and-

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trace capabilities fill these gaps directly and can be used to redesign reverse logistics processes.

For example, supply chain partners have many reasons for initiating a return of goods, such as expiry of products, recalls, packaging damages, etc. A product

authentication capability can greatly help various supply chain partners to verify products when initiating returns.

Once authenticated, the physical product can be shipped directly to the designated place for the manufacturer to handle it, based on its status. The ensuing supplemental information, and associated credit notes arising from the returns process, can now follow throughout the entire supply chain – all the way to the desired beneficiary, based purely on the initial shipment details of the serialized product. Doing so saves a significant amount of time and money that would otherwise have been spent on reverse logistics and verification processes across the many entities in the supply chain. An authentication process can help companies identify and stop scenarios arising from fraudulent activities or counterfeiting that exploit loopholes in the returns/recall process.

Addressing Diversions and Chargeback Reconciliation

Product diversion (from different countries or consumer segments) is a real problem for pharmaceuticals companies especially because of arbitrage opportunities arising from country or consumer segment pricing differentials. As pharmaceuticals companies have adapted to the market-driven realities of tiered pricing and rebating across customer segments (managed markets), they are increasingly challenged to ensure that discounted consignments meant for specific customers or geographies are consumed by their intended targets rather than being diverted elsewhere.

With serialization, companies can identify and segregate the products intended for different market and customer segments. Authentication capabilities can help validate whether products are consumed in the market or customer segment for which they were earmarked.

Similarly, pharmaceuticals companies have responded to pricing pressures from group purchasing organizations (GPOs), whose influence on product volumes is significant enough to allow for price discount contracts. The process of placing price discount contracts with wholesalers that sell products to GPO members has resulted in the development of a chargeback process under which the wholesaler claims the extra discount provided to GPOs from pharmaceutical companies.

From the pharmaceuticals company's viewpoint, the challenge of the chargeback reconciliation process is that wholesaler sales data is usually unavailable to the manufacturer and must be obtained from third parties. Sales reconciliation typically takes place at the product/quantity/customer level and not always at the lot level, much less at the serialized lot level. Within the U.S. market, a serialization track-and-trace infrastructure and the associated serialized lot level event (shipment) capture can provide new ways for pharmaceuticals companies and wholesalers to work together to streamline the reconciliation processes, ensure chargeback payment accuracy, save money and channel these savings into initiatives that allow for additional market incentives.

Driving Patient-Centric Engagements & Brand Loyalty

Aided by advances in technology, healthcare is undergoing a consumerism revolution. Patients are actively getting involved in decision-making processes that are informed by a variety of primary and secondary information sources. Pharmaceutical companies have scaled up their strategic capabilities to engage patients digitally across the disease lifecycle. Serialization provides a very useful entry point and interface for pharmaceuticals companies to capture patient behavior and engage directly with them.

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Authentication is a key benefit of patient-focused functionality based on serialization infrastructure. Encouraging patients to authenticate the products they buy can yield important information that can be used in a variety of ways (see Figure 4, next page).

Serialization Driving Patient Services

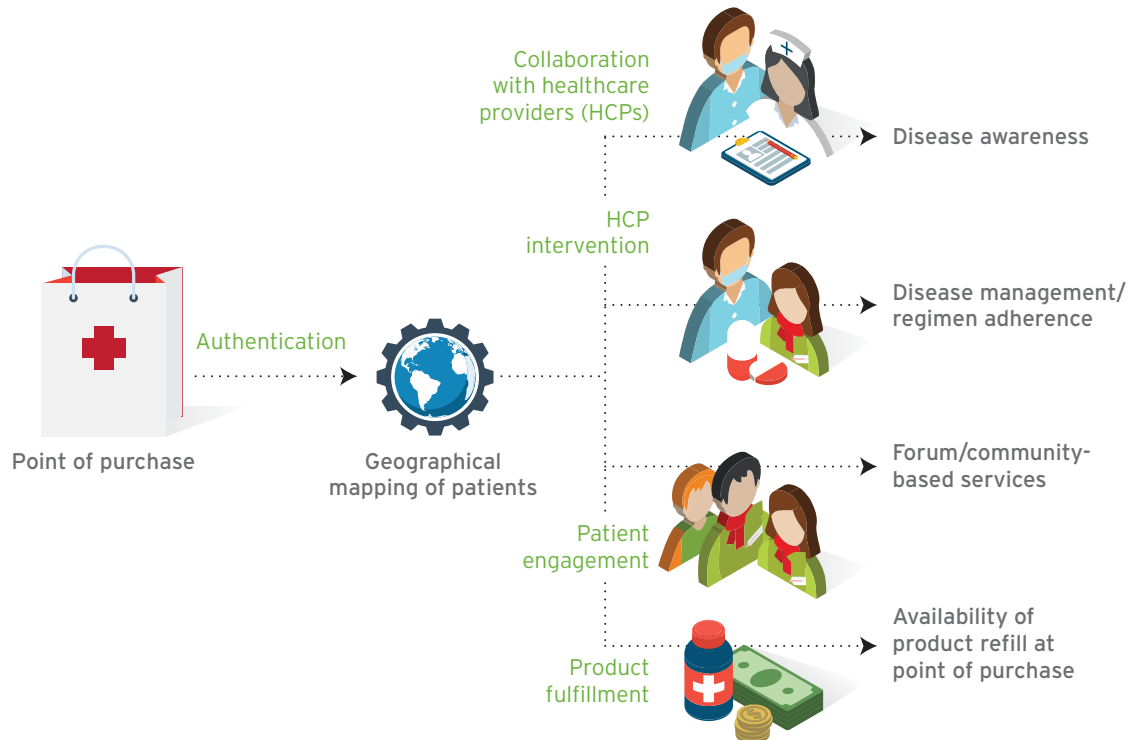


Figure 4

The ease of authentication will increase with the rise in mobility. Of the 500 million smartphone users worldwide, many will use a healthcare application by the end of this year, and by 2018, half of the more than 3.4 billion smartphone and tablet users worldwide will have downloaded a mobile health app.⁸

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A pharmaceuticals product authentication tool can be added to a mobile application via GPS tracking and location-aware software to provide geographical mapping of patients and their purchase points. This information can be helpful in that ensuring an appropriate supply of drugs is maintained at relevant pharmacies. Additionally, it can provide unparalleled visibility

into real-time sales data that can be used for just-in-time decision-making for avoiding stockouts and planning alternate fulfillment mechanisms when a pharmacy is dangerously out of stock on a particular pharmaceutical, as well as for fine-tuning forecasting models to accurately reflect future product requirements.

Geographical information about patient populations that are consuming a given product can help pharma design disease awareness and management programs for the patient community located in those specific geographies. Pharmaceuticals companies can actively collaborate with healthcare practitioners based on patient density and help engender practitioner and patient trust, fostering a sense of partnership and increasing brand loyalty.

Pharmaceutical product authentication tools can also be used to capture product SKUs purchased by patients. When merged with prescription data, authentication data can help track regimen compliance, which remains an area of concern for all healthcare practitioners. Such data can also help pharmaceuticals companies more effectively predict when a patient will run out of a medication and proactively send refill reminders. Relevant entities on the supply side can also be notified about the need for a particular product at a particular location as designated by the patient, thus helping to transform the entire supply chain into a demand-driven engine that will power the emerging era of personalized medicine.

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We believe that pharmaceuticals companies should integrate serialization-related capabilities within their patient-connect-related digital initiatives. In general, the industry is just starting to develop mobile applications related to disease and products. As a result, the time is right to launch and promote authentication services through remote platforms. Pharma companies must develop back-end business processes that leverage data collected through authentication workflows to build and deliver personalized services for patients and practitioners, a move that would benefit the entire healthcare ecosystem.

Improving Sales and Marketing Effectiveness

Pharmaceuticals companies spend enormous amounts of money on educating healthcare practitioners about the benefits of their brands and promoting their products to this community. While secondary information sources are available from various market research organizations (MROs) that can be used to assess sales performance across target segments and geographical regions, serialization capabilities can also be used to gather performance-related indicators to generate ground-level intelligence, thus leading to increased sales and marketing effectiveness. In fact, as of 2012 (the last year for which data is available), \$24 billion was spent by the pharmaceuticals industry on marketing to physicians.⁹

Serialization can help marketing departments identify micro-markets that need intervention and evaluate the effectiveness of intervention.

Geographical information on patient populations can be generated through patient authentication data. The overall effectiveness of the sales force around brand promotions can be quantitatively evaluated, and specific counter-measures can be taken in areas that are lagging. This geographical data can be further used to segment healthcare providers and take appropriate measures (i.e., educating and addressing practitioner concerns or extending patient services). The outcome of these sales/marketing measures can be measured through

increased authentication data and can loop back to the decision model, fueling sales or marketing activities.

Serialization can help marketing departments address two challenges: identifying micro-markets that need intervention (where to spend) and evaluating the effectiveness of intervention (what to spend on); both are important dimensions to assess ways of increasing marketing spend effectiveness. Authentication data arising from serialization-related capabilities can help with identifying market segments that need intervention, enabling targeted initiatives to be undertaken. Serialization provides an additional tool to evaluate the effectiveness of intervention, as any insight into authentication volume (positive, negative or no change) is a good measure of the effect of intervention. These insights can then be used to design better, more personalized marketing programs.

Laying the Foundation

The business case is highly favorable for utilizing serialization data to optimize existing processes or develop new capabilities to address underlying unmet need. But to successfully implement the use cases, the pharmaceuticals industry needs to address the foundational issues that will provide a framework for all to benefit when investments are made in developing serialization capabilities.

Data related to EPCIS events across supply chain entities needs to be accessed, collated and analyzed for supply chain visibility-related initiatives. This data may be available in a central repository in countries like China, where regulatory agencies are the sole custodian of data that is recorded and exchanged between different entities in the pharmaceuticals supply chain. In other countries, such as Turkey, data may be captured in local repositories of different supply chain entities, such as CMOs, distributors, wholesalers and pharmacies. The industry needs to work with the regulatory agencies and their supply chain partners to drive consensus and formulate data-sharing agreements.

Another challenge that pharma face is the limited focus on aggregating vast amounts of serialization data to enable business intelligence. Niche product vendors are providing capabilities that address regulatory compliance, while infrastructure providers are addressing activities that keep the business running as usual. Utilization of technologies such as cloud-based big data analyt-

ics could provide some answers – if security and cost-related concerns are adequately addressed.

Another area of deliberation is the lack of a global/regional security model that defines the guidelines for data access by various supply chain partners. Visibility of serialization data is currently limited by regulatory constraints imposed by regional authorities. These regional regulatory authorities dictate the standards for data access and data exchange. A step in the right direction was taken by member companies of Rx-360,¹⁰ an international pharmaceuticals supply chain consortium, when they met to establish a global traceability data exchange architecture in order

to facilitate interoperable data exchange – but much more needs to be done.

Implementation Framework

Given the external dependencies that need to be factored in, pharmaceuticals companies must undertake a phased approach to implementing serialization initiatives. Technical capabilities, such as authentication services, geographical mapping and EPCIS event capturing, can be leveraged across different use cases to ensure higher ROI on those fronts. Figure 5 outlines considerations that can help pharmaceuticals companies advance their decision-making.

A Serialization Decision Matrix

Initiatives	Business Value	Technology Requirements	External Dependency	Our Recommendations
Inventory optimization	High	<ul style="list-style-type: none"> Access to EPCIS events across supply chain entities. Analytics platform to collate and process EPCIS event data addressing different business use cases, such as reorder level, stockout warnings, inventory imbalances, etc. 	<ul style="list-style-type: none"> Consensus among supply chain partners for sharing event information. Adherence to common technology standards, such as EPCIS, across organizations. 	<ul style="list-style-type: none"> Make inventory optimization across the supply chain a shared business goal for all supply chain partners. Establish a high degree of transparency and collaboration, as both are crucial for the initiative to succeed.
Supply chain operations monitoring	Medium	<ul style="list-style-type: none"> Access to EPCIS events across supply chain entities. Analytics platform to collate and process EPCIS event data. Dashboard for real-time monitoring of KPIs for supply chain execution vendors. 	<ul style="list-style-type: none"> Consensus among supply chain partners for sharing event information. Adherence to technology standards, such as EPCIS, across organizations. Agreement on KPIs with supply chain execution vendors. 	<ul style="list-style-type: none"> Establish common benefits for supply chain partners to deploy reliable and cost-effective services with real-time capabilities to monitor and take timely actions. Establish KPIs to monitor, and include these KPIs in vendor contracts.
Optimizing recalls/returns	High	<ul style="list-style-type: none"> Querying across partners' EPCIS repositories to track batch movement. Authentication services across the supply chain. Reporting and integration with ERP to enable financial workflow. 	<ul style="list-style-type: none"> Access to EPCIS repositories/data of supply chain partners for tracking batches. Agreement on new authentication, logistics and financial processes. 	<ul style="list-style-type: none"> Establish common benefits for supply chain partners to improve recalls/returns efficiency and prevent fraud. Critically evaluate existing processes and prepare the business case.

Figure 5 | Continued on next page

A Serialization Decision Matrix (from previous page)

Initiatives	Business Value	Technology Requirements	External Dependency	Our Recommendation
Addressing illegal diversions	Medium	<ul style="list-style-type: none"> Authentication services across platforms (Web, mobile application, SMS, etc.). Analytics platform to map consignments and authentication requests. Workflow platform to manage identified cases and support investigation. 	<ul style="list-style-type: none"> Education of patients on the usefulness of authentication and promotion of wider adoption. Access to EPCIS repositories/ event data of pharmacies. 	<ul style="list-style-type: none"> Start leveraging the sales forces to authenticate and geographically track their consignments. Build authentication capabilities on mobile applications currently being supported. Perform product pricing policies and portfolio assessment to identify susceptible products and prioritize efforts.
Driving patient-centric engagements	High	<ul style="list-style-type: none"> Authentication services across platforms. Analytics platform for geographical mapping. Patient applications to enable different use cases. 	<ul style="list-style-type: none"> Education of patients on the usefulness of authentication and promotion of wider adoption. Access to EPCIS repositories/ event data of pharmacies. 	<ul style="list-style-type: none"> Integrate authentication capabilities with patient digital services and interaction platforms.
Improving sales and marketing effectiveness	High	<ul style="list-style-type: none"> Authentication services across platforms. Analytics platform for geographical mapping. Integration with sales force automation and marketing spend platforms. 	<ul style="list-style-type: none"> Education of patients about the usefulness of authentication and promotion of wider adoption. Access to EPCIS repositories/ event data of pharmacies. 	<ul style="list-style-type: none"> Translate established benchmarks to evaluate marketing and sales effectiveness across territories to authentication data. Develop a framework to integrate authentication data with other market-sensing data to increase demand forecasting accuracy.

Figure 5

As pharmaceuticals companies establish serialization capabilities, it is essential to establish future use cases in which the serialization platform can be used to enable additional business processes and create value. Pharmaceuticals companies should evaluate serialization solutions in light of these future use cases to ensure scalability. We suggest that pharma proactively engage their supply chain partners to drive consensus around common business benefits that can be enabled through serialization and undertake technology proofs of concept to reinforce its virtues.

Looking Forward

The pharmaceuticals industry is projected to invest a substantial amount of money and time in the coming years to develop serialization capabilities to ensure regulatory compliance. While the immediate benefits around ensuring product integrity and eliminating counterfeiting are immense, there are compelling business scenarios in which serialization can be used to develop new processes and capabilities or supplement existing ones for tangible operational gains.

The pharmaceuticals industry needs to work on many fronts, internal and external, to maximize current and future ROI of serialization. As the industry establishes a foundation for a serialized supply chain, some of the imperatives include the following:

- **Engage with supply chain partners and regulatory agencies to develop a framework and standards for data interoperability and accessibility.** Plan joint initiatives with supply chain partners to improve supply chain efficiencies benefiting the entire delivery ecosystem.
- **Design a serialization architecture and solution platforms,** keeping in mind future reusability and enablement of use cases to improve supply chain visibility and consumption visibility.
- **Design, implement and integrate authentication-related capabilities and workflows with patient-centric digital initiatives to gain consumption visibility.** Undertake proofs of concept to integrate consumption-related data to fine-tune existing business processes.

Footnotes

- ¹ The Pharmaceutical Security Institute (PSI) is a not-for-profit membership organization established in 2002 by the security directors from 14 major pharmaceutical companies. Today, PSI membership includes 28 pharmaceuticals manufacturers from many nations. For more information, see <http://www.psi-inc.org/index.cfm>.
- ² "Track & Trace in the Pharmaceutical Industry: Serialization Strategies and a Roadmap for Procurement," Procurement Leaders, March 10, 2015, <http://www.procurementleaders.com/whitepapers/online-directory-gepl/track--trace-in-the-pharmaceutical-industry-serialization-strategies-and-a-roadmap-for-procurement>.
- ³ Katherin Eban, "Drug Theft Goes Big," *Fortune*, March 31, 2011, <http://fortune.com/2011/03/31/drug-theft-goes-big/>.
- ⁴ Results obtained from Cognizant's internal secondary research after forecasting the growth of the pharmaceuticals market in various countries in which serialization infrastructure, in some form, will be implemented by 2018.
- ⁵ A Cognizant supply chain benchmarking study was conducted in 2014 to evaluate the current state of pharmaceuticals supply chains, compared with the fast-moving consumer goods (FMCG) industry, using publicly available information. The metrics reflect the average of four years, from 2010 to 2013.
- ⁶ "Report of the International Summit on Medicines Shortage," Fédération Internationale Pharmaceutique (FIP), June 2013, http://www.fip.org/files/fip/publications/FIP_Summit_on_Medicines_Shortage.pdf.
- ⁷ "Healthcare Distribution Management Association (HDMA) Offers Industry Report on Pharmaceutical Returned Goods," PR Newsire, March 22, 2002, <http://www.prnewswire.com/news-releases/health-care-distribution-management-association-hdma-offers-industry-report-on-pharmaceutical-returned-goods-76593747.html>.
- ⁸ "Mobile Medical Applications," U.S. Food & Drug Administration, <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ConnectedHealth/MobileMedicalApplications/ucm255978.htm>.
- ⁹ 2012 U.S. Pharmaceutical Company Promotion Spending, Cegedim Strategic Data, January 2013, http://www.skainfo.com/health_care_market_reports/2012_promotional_spending.pdf.
- ¹⁰ "Pharma Supply Chain Companies Organize to Establish Global Traceability Data Exchange Architecture," RxTrace, Aug. 25, 2014, <http://www.rxtrace.com/2014/08/pharma-supply-chain-companies-organize-to-establish-global-traceability-data-exchange-architecture.html>.

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