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Pharmaceutical Serialization

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Piloting Traceability With GS1 Standards

AmerisourceBergen teams with Johnson & Johnson Supply Chain for significant learnings

By Greg Bylo, VP of Healthcare, GS1 US

The Drug Supply Chain Security Act requires that the pharmaceutical industry implement end-to-end traceability by 2023. Trading partners in the supply chain have chosen to implement and test GS1 Standards-based solutions in real-world pilots to meet the deadline for interoperability.

While GS1 Standards have created a hierarchy that reaches down to the product level for serialization, several industry entities have voluntarily chosen to use GS1 EPCIS even as this standard evolves to fully meet the intent of the regulation. EPCIS allows trading partners to exchange data, in concert with the products as they move through the supply chain. An industry pilot between Johnson & Johnson Supply Chain (JJSC) and AmerisourceBergen Corporation (ABC) did just that with actionable and repeatable results.

In addition to assuring compliance and continued product access for patients and customers, serialization can potentially enable the investigation of counterfeit and diverted products, affording brand owners additional supply chain integrity and security. End-to-end visibility means that recalls, where necessary, can be executed more efficiently. As the foundational standard, the Global Trade Item Number (GTIN) helps to automate all processes and minimize errors, ultimately increasing patient safety.

PRESCRIPTION FOR A CLEARER VISION

If the subject is pharmaceutical traceability, ABC is in the thick of it as the wholesaler

With the implementation of serialization and traceability, JJSC will have the opportunity to trace a serialized product from the specific wholesaler to the end customer.

positioned between more than 450 pharmaceutical manufacturers and more than 60,000 customers, including pharmacies and healthcare providers. The company is a private label manufacturer, re-packager, 3PL service provider and specialty pharmacy, effectively placing it at the origin, middle and end of a vast global supply chain.

With this breadth, it's no wonder ABC was eager to lead a unit-level traceability pilot with trading partner, JJSC. A traceability pilot that involved serialization of individual products was sure to be instructive for the industry.

"Our collaboration with AmerisourceBergen highlights the importance of having a robust, well-implemented serialization platform — one that opens up a host of future supply chain and commercial capabilities enabling the delivery of a reliable supply of high-quality products and other services to our customers," says Mike Rose, vice president of supply chain visibility, JJSC.

Naturally, compliance is a critical issue for the pharmaceutical industry, which is why ABC and JJSC are active in industry associations like the Pharmaceutical Distribution Security Alliance (PDSA), the Healthcare

With "the global language of business" supplied through GS1 Standards, traceability mandated by DSCSA is exceedingly easier.

Distribution Alliance (HDA and formerly the Healthcare Distribution Management Association) and the Pharmaceutical Research and Manufacturers of America (PhRMA).

In fact, all three industry associations played a critical role in helping Congress draft and enact the FDA's Drug Supply Chain Security Act (DSCSA), which was signed into law on Nov. 23, 2013. The DSCSA requires the industry to institute an electronic, interoperable system to identify and trace by 2023 certain prescription drugs distributed in the United States.

Both ABC and JJSC are also long-term members of the GS1 Healthcare US Standards Initiative, the voluntary user group implementing global standards to address patient safety and deliver supply chain efficiencies. With "the global language of business" supplied through GS1 Standards, traceability mandated by DSCSA is exceedingly easier.

To enable serialized product identification and end-to-end traceability, manufacturers such as Janssen Pharmaceuticals, a pharmaceuticals company of Johnson & Johnson, have opted to leverage GS1 Standards. On the saleable unit, a GTIN with a serial number is encoded in a GS1 DataMatrix barcode to establish global uniqueness. Per the HDA standard, both a GS1-128 linear barcode and a DataMatrix barcode is leveraged by trading partners to share information about the physical movement and status of products as they travel throughout the supply chain.

LET THE PILOT BEGIN

ABC and JJSC decided on a four-week pilot program in a live production setting, excluding the several months of planning that preceded it.

Beginning at the point of manufacture, a DataMatrix barcode was applied that contained a serialized GTIN, batch/lot number and expiration date to each lowest saleable unit. The lowest saleable units were packed into cases, and a logical relationship between the "children" and "parent" was established via aggregation.

Key members of the ABC pilot team include (left to right): Matt Sample, Alex Philips, Josh Sutherland, Pat Burress and Girish Sethuram.

Product cases were then loaded onto a pallet or other logistics units, establishing yet another level of the aggregated hierarchy.

At supply chain points downstream from packaging, automated vision systems or manual barcode scanners read the Data-Matrix barcode to capture the GTIN, serial number, batch/lot number and product expiration date.

GS1 EPCIS — Electronic Product Code Information Services — was used to record business events associated with the serialized GTIN at various critical points along the supply chain, including commissioning, packing and shipping, followed by receiving and unpacking by the buyer.

As in the past, product was moved from manufacturing to distribution with the addition of the serialized information. After the wholesaler placed an order and the truck departed, JJSC issued an EPCIS message containing the serialized GTINs and hierarchies contained in the shipment. This provided the ABC distribution center with the details of the specific products that were on their way.

When the shipment arrived, the EPCIS events and inference of the contents allowed ABC to confirm receipt — without opening a single case — of every single item that had begun its journey at the manufacturing site.

"Using EPCIS message standards provides for a more streamlined process, in that systems

are established with similar data file expectations across the supply chain," explains Jeffery Denton, senior director of ABC's Global Secure Supply Chain. "Most failures experienced during past pilots are avoidable if manufacturers provide DSCSA-compliant EPCIS v1.1 files that include master data for material attributes as well as valid GLNs (Global Location Numbers) and GTINs."

BENEFITS BEYOND COMPLIANCE

Serialization and traceability can bring value to the respective businesses, beyond compliance. Leveraging GS1 Standards was also intended to help JJSC improve patient safety and provide a means to investigate counterfeit and diverted products. Serialization and traceability can bring measurable improvements to internal and external supply chain integrity.

"With the implementation of serialization and traceability, we will have the opportunity to trace a serialized product from a specific wholesaler to the end customer," says Chris Reed, JJSC's lead for Product Serialization and Traceability. "We can use these capabilities to further ensure that our patients and customers receive quality, genuine products. We also believe that they will provide additional benefits to our business such as being able to more effectively manage and verify returns."

He adds, "With GS1 Standards, specifically the use of GLNs and GTINs, identification

of a product and its unit of measure will become clearer to the entire supply chain. In the future, there's also immense value in utilizing GTINs for ordering processes."

LESSONS LEARNED

Something as seemingly simple as labeling requires careful consideration. A case displays multiple labels — an HDA label, a two-dimensional (2D) matrix label, another put on by transport and logistics, among others. This can be a source of confusion at stops along the supply chain.

Glare resulting from shrink wrap and flashing lights can also impede automated code capture; damage to cases can compromise label readability.

"A missing element of data — whether it's a dosage form or a letter in the description of the product — may seem trivial, but it can drastically impact the efficiency of the pharmaceutical supply chain, potentially leading to disruption for our patients. I strongly recommend a profound emphasis on cleansing existing master data and establishing robust data governance going forward," says Reed.

"Data formatting issues — how others were encoding data using GS1 Standards — is important," says Matt Sample, senior director, secure supply chain, Amerisource-Bergen. "You have to test it thoroughly with the right amount of volume in

production. We found we were putting the 2D barcodes in the most vulnerable spot on the packaging, so we had to change that," says Sample.

As a result of the pilot, participants are working with both GS1 US and HDA to update labeling guidelines.

"Don't treat this as a side IT project; it's not a casual exercise," warns Sample. "It's a business transformation project, so don't underestimate it."

THE CARNEGIE HALL APPROACH

JJSC is a strong believer in conducting pilots. JJSC's Reed, who is involved with several other pilots, recommends: "Practice, practice, practice. This and other pilots have confirmed that our technological and business process implementations are sound, but the exchange of data business-to-business takes some massaging in the real world. Start now."

"It may take 25 percent more time to receive serialized cases, and about 30 percent more time to pick serialized products," Sample says, pointing to a need for a better understanding of exceptions — how often they occur, how to deal with them and what will be deemed acceptable by the FDA. "Exceptions are a reality, especially with niche products, and we need to know how to deal with them."

ABC's Sample is a strong proponent of transparency. "It's a unique situation: You've got all of these manufacturers and wholesalers and we're all competitors. But it's nice we have an opportunity to collaborate to work on standardization of these traceability issues." He goes one step further: "We had fun bringing manufacturers into our distribution center, and us visiting theirs; walking the shelves together."

Reed also recommends robust communication. "For this initiative to be successful, trading partners up and down the supply chain must collaborate and communicate. We found that collaboration with our customers was critical to helping us align on objectives and resolve issues. If we keep the lines of communication open and continue to develop and refine industry standards together, we will all be prepared for the DSCSA requirements and continue to provide safe and effective medicines to our patients."

The key to success in meeting any instance of regulatory compliance comes down to collaboration. It rests on the willingness of industry partners across the supply chain to work toward consensus and then drive to adoption. The pilot between Johnson & Johnson Supply Chain and Amerisource-Bergen Corporation was a great example of true partnership as pharma moves to establish a meaningful standard that serves the industry and protects patients.

Serialization: Driving Business Value Beyond Compliance

The availability of information about serialized products provides an opportunity to take a data- and analytics-driven approach to supply chain improvements

By Michael Zirkle, Associate Vice President, Cognizant Business Consulting, Life Sciences and Healthcare

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

High-value products, complex supply chains and dependence on multiple organizations for distribution all expose the pharmaceutical industry to threats such as counterfeiting, theft and illegal diversions. According to the Pharmaceutical Security Institute, 2,177 incidents of counterfeiting occurred worldwide in 2014 alone. To counter these threats and ensure supply chain integrity, global regulatory initiatives mandating serialization of products

as well as tracking and tracing products throughout the supply chain are currently underway. Within the next five years, approximately 65 percent of the global market is expected to require serialization in the supply chain.[1]

While regulatory compliance remains a top priority, the availability of information about serialized products throughout the supply chain provides a unique opportunity to take a data- and analytics-driven approach to supply chain improvements through greater visibility and collaboration.

It is important that pharma looks beyond regulatory compliance and design underlying infrastructure, applications and processes that drive value through new and supplemental business capabilities. There

are many ways that serialization capabilities can be used to drive business value and enhance the return on investment (ROI) of achieving global regulatory compliance.

THE SERIALIZATION CONTEXT

Ensuring the integrity of products as they move across the supply chain remains a challenge. Pharma supply chains are becoming increasingly complex, making it more difficult to create secure supply chain strategies.

According to the World Health Organization (WHO), the pharmaceutical industry loses nearly $40 billion each year globally due to counterfeiting.[2] Product theft has also increased, according to Freight Watch International, with drugs accounting for about 15 percent of the estimated $8-$12 billion in annual cargo theft.[3]

DRIVING BUSINESS VALUE FROM SERIALIZATION

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.

Inventory Optimization

A recent Cognizant benchmarking study evaluated the current state of pharmaceutical supply chains against those of fast-moving consumer goods (FMCG) companies. The study found that pharma is serving its market as reliably as the FMCG industry but at a much higher service cost. While metrics indicate that pharma is generally on par with FMCG in on-time-in-full (OTIF) and forecast accuracy, when compared against asset efficiency measures, the actual cost of attaining the same level of supply chain reliability was much higher for the pharmaceutical industry. FMCG supply chains, on average, completed conversion of asset resources to cash five times faster than pharma. In terms of actual inventory turnover, FMCG was three times faster than pharma. By focusing on asset efficiency, pharmaceutical companies can directly improve ROI.

Combining serialization and track-and-trace supply chain event recording that is compliant with the Electronic Product Code Information Services (EPCIS) standard, enables pharma to gauge product movement, facilitate collaboration and improve supply chain planning. The same infrastructure deployed for serialization track-and-trace regulatory compliance can serve a broader group of stakeholders by increasing agility and responsiveness, and optimizing inventory levels and costs across various supply chain levels or inventory-stocking locations.

While supply chain planners strive to optimize inventory while improving customer service, in a 2013 report, Premier Healthcare Alliance estimated that the annual cost of

> It is important to develop performance metrics and benchmarks to manage external service providers and monitor key performance indicators.

drug shortages for U.S. hospitals was $416 million.[4] Implementing serialization technologies that enable inventory visibility across the supply chain provides 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 creates significant competitive advantage. Externalization of supply chain activities has increased dependence on service providers in areas such as logistics. It is important to develop performance metrics and benchmarks to manage external service providers and monitor key performance indicators (KPIs). A serialization infrastructure captures and extracts transaction events and provides real-time data and event management feedback to support monitoring, enable performance-driven supply chains and allow real-time decision-making.

These capabilities also enable companies to monitor underlying business processes, leverage process improvement opportunities, and benchmark and improve service delivery standards across the organization. Cross-organizational collaboration provides visibility to relevant stakeholders, improving the overall supply chain ecosystem.

Optimizing Reverse Logistics: Returns and Recalls

Processing returns, expirations and recalls costs the pharmaceutical industry about $2 billion annually. [5] A lack of accurate audit trails and product authentication capabilities for reverse logistics exposes the industry to fraud and inefficiencies. Serialization and track-and-trace capabilities fill these gaps and can be used to redesign reverse logistics processes.

Product authentication can help supply chain partners verify products when initiating returns. Once authenticated, a product can be returned to the manufacturer, and

supplemental information can flow throughout the supply chain based on the details of the serialized product, saving both time and money. An authentication process can help companies identify and stop scenarios arising from fraudulent activities that exploit loopholes in the returns/recall process.

Addressing Diversions and Chargeback Reconciliation

Product diversion from different countries or consumer segments is an issue for pharmaceutical companies, especially given arbitrage opportunities. As pharmaceutical companies adapt to the market-driven realities of tiered pricing and rebating across customer segments, they are increasingly challenged to ensure that discounts meant for specific customers or geographies are consumed by their intended targets.

Serialization can help companies identify and segregate products intended for specific market and customer segments. Authentication capabilities can validate whether products are consumed in the market or customer segment for which they were intended.

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

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. Within the U.S. market, a serialization track-and-trace infrastructure and associated serialized lot level shipment capture can provide new ways for pharmaceutical companies and wholesalers to streamline the reconciliation processes and ensure chargeback payment accuracy.

Driving Patient-Centric Engagements

Aided by advances in technology, patients are actively involved in decision-making processes, and pharma companies have scaled their strategic capabilities to engage patients digitally. Serialization provides a useful entry point and interface for pharma to capture patient behavior and create engagement opportunities.

Authentication based on serialization infrastructure is a key benefit of patient-focused functionality. Encouraging patients to authenticate products purchased can yield important information and will become easier with the rise in mobility. By 2018, half of the more than 3.4 billion smartphone and tablet users worldwide will have downloaded a mobile health app.[6]

Geographic information about patient populations that consume a given product can help pharmaceutical companies design disease awareness and management programs for those communities. This enables active collaboration with healthcare practitioners, fostering a sense of partnership and increasing brand loyalty.

Authentication tools can also be used to capture product SKUs. When merged with patient prescription data, authentication data can track regimen compliance, predict refill timing and proactively send refill reminders. In addition, relevant supply side entities can be notified when a patient needs a product at a particular location, helping to transform the supply chain into a demand-driven engine that will power the emerging era of personalized medicine.

We believe that pharmaceutical companies should integrate serialization capabilities within patient-connected digital initiatives. The industry is just starting to develop mobile applications related to disease and products, so the time is right to launch and promote authentication services through remote platforms. To deliver personalized services for patients and practitioners, pharma must develop back-end business processes that leverage data collected through authentication workflows, a move that would benefit the entire healthcare ecosystem.

Improving Sales and Marketing Effectiveness

Pharma spends enormous amounts of money promoting and educating healthcare practitioners about their products. As of 2012, the industry spent $24 billion marketing to physicians.[7] While secondary information sources from market research organizations (MROs) can be used to assess sales performance, serialization capabilities can gather performance-related indicators and generate intelligence that can increase sales and marketing effectiveness.

Serialization helps marketing departments identify micro-markets that need intervention and evaluate the effectiveness of such intervention. Both are important to assess the effectiveness of marketing spend. Patient authentication data can generate geographic information on patient populations to evaluate the effectiveness of brand promotions and determine specific actions that can be taken in areas that are lagging. These insights can then be used to design better, more personalized marketing programs.

LAYING THE FOUNDATION

There is a strong business case for using serialization data to optimize existing processes or develop new capabilities. But to successfully implement use cases, the industry needs to address the foundational issues that will provide a framework for developing serialization capabilities.

One challenge pharma faces 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. Once security and cost-related concerns are adequately addressed, technologies such as cloud-based big data analytics could provide some answers.

Also of concern is the lack of global/regional security guidelines for data access by supply chain partners. Visibility of serialization data is currently limited by regulatory constraints imposed by regional authorities who dictate the standards for data access and exchange.

IMPLEMENTATION FRAMEWORK

Given external dependencies, a phased approach to implementing serialization initiatives is necessary. Technical capabilities, such as authentication services, geographical mapping and EPCIS event capturing can be leveraged to ensure higher ROI.

As pharmaceutical companies establish serialization capabilities, it is essential to establish future use cases where serialization can enable additional business processes to create value and scalability. We suggest that pharma proactively engages supply chain partners to drive consensus around common business benefits that can be enabled through serialization.

LOOKING FORWARD

The pharmaceutical industry is projected to invest heavily 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 those already in existence.

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Pharma's Digital Supply Chain Transformation

Serialization and track-and-trace mandates can expedite pharma supply chain digitization

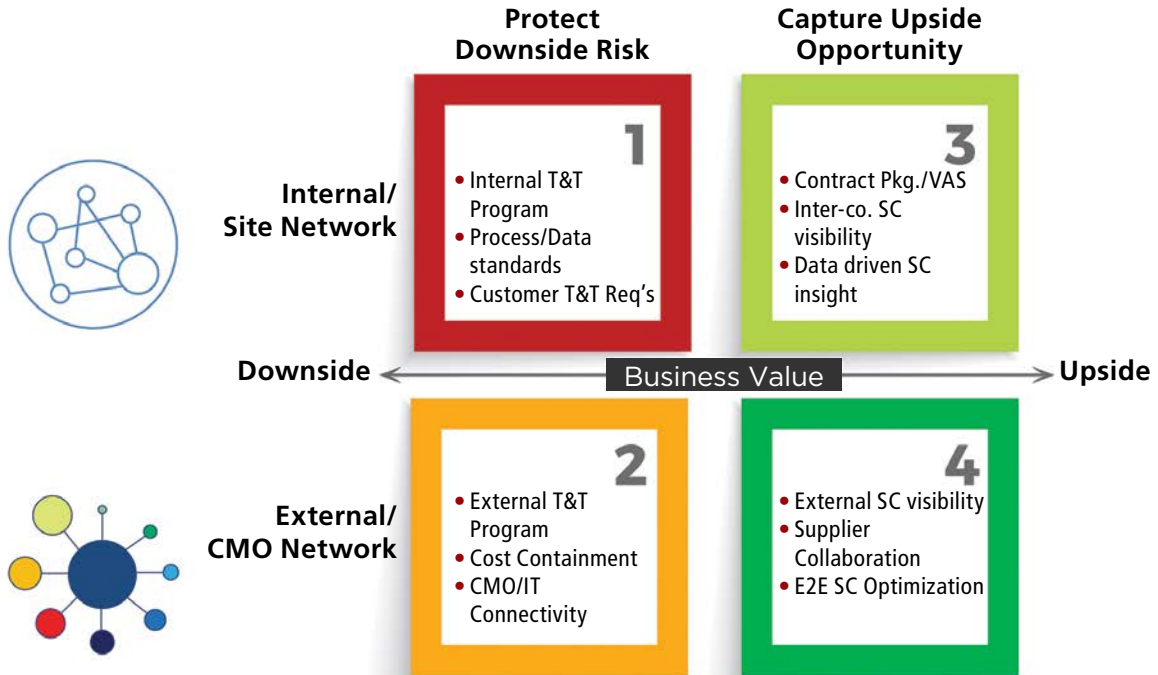By Evren Ozkaya, Ph.D., Founder & CEO, Supply Chain Wizard

Amid the increasingly crowded discussion of pharmaceutical supply chain digitization, buzzwords abound — Industry 4.0, Internet of Things (IoT), Big Data, Machine Learning, Artificial Intelligence — and, of course, digital supply chain transformation.

In parsing the pharma industry's current tech-leaning vernacular, there is a strong relationship between pharmaceutical serialization and the digital supply chain: simply put, the former is a prerequisite infrastructure investment for the latter to be realized. The most forward-thinking pharma companies are starting to grasp this — and capitalize on it.

Having a well-oiled digital supply chain, whose foundation is built on web-enabled capabilities and technologies, gives a company a tremendous advantage. A pharma company with a digitized supply chain — or any of its suppliers or customers, for that matter — will be more adept at moving resources, assets, inventory and personnel in just-in-time fashion, optimizing enterprise-wide resource allocation and planning both quickly and effectively.

The more precise and more granular the data used to guide its digitization effort, the more likely a company will be able to effectively respond to any issues or risks that arise — and to do so at the right level and with the right focus. The more skilled a company becomes at doing this, the greater its realized savings will be in terms of money, time and resources.

	Protect Downside Risk	**Capture Upside Opportunity**
Internal/ Site Network	**1** • Internal T&T Program • Process/Data standards • Customer T&T Req's	**3** • Contract Pkg./VAS • Inter-co. SC visibility • Data driven SC insight
External/ CMO Network	**2** • External T&T Program • Cost Containment • CMO/IT Connectivity	**4** • External SC visibility • Supplier Collaboration • E2E SC Optimization

Downside ← Business Value → Upside

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OPPORTUNITY ABOUNDS

There is a disconnect, however, when it comes to general understanding of the important connection between serialization and the digital supply chain — specifically the need to make the necessary investment in digitization.

According to recent McKinsey & Company research[1], "The biggest future impact on revenue and EBIT growth, is set to occur through the digitization of supply chains" among other dimensions of the business. And yet, "only 2 percent, in fact, report that supply chains are the focus of their forward-looking digital strategies" across all industries. This compares, for example, with a "49 percent focus on marketing and distribution." In other words, while the supply chain has the greatest potential to influence future revenue and EBIT growth, it is often the most neglected area when it comes to investment in digitization.

A unique opportunity now presents itself for the pharma industry. Because the investment and focus on digitization of the supply chain is essentially being force-fed by serialization mandates, pharma executives need only continue a bit further down the digitization pathway to completely and positively transform their supply chains for truly valuable competitive advantages. In doing so, pharma companies can turn something they have to do into something they should want to do: reap the economic benefits of improved customer service through optimized production and distribution processes.

SUPPLY CHAINS FORCED TO GO DIGITAL DUE TO SERIALIZATION REGS

About 90 percent of world GDP is already under some level of regulatory requirement (active, final or draft) for serialization (see map).

These regulations require trading partners — manufacturers, wholesalers, pharmacies, etc. — to implement electronic systems of records for serializing each sellable unit (e.g. cartons, packs, bottles), and to put in place the required processes for exchanging serialized data. The resulting end-to-end drug supply chain traceability is, in most cases, monitored by government agencies.

The primary motivation behind these regulations is the improvement of patient safety and supply chain security, with a goal of reducing a level of worldwide drug counterfeiting that the World Health Organization estimates at 10 percent of global drug supply.[2]

MAJOR CAPITAL INVESTMENT TO MEET SERIALIZATION MANDATES

The world's leading pharmaceutical drug manufacturers have already started implementing major capital investment programs to comply with regulations. Turkey, Argentina and China were among the first to require these investments, followed by larger western economies, such as the United States and the European Union. According to Supply Chain Wizard surveys and research, by the end of 2016, more than 50 percent of pharma manufacturers and Contract Manufacturing Organizations had some level of their capital budgets allocated to complying with the initial U.S.

Serialization Legislation Global View

- ■ Active legislation
- ■ Final legislation
- ■ Draft legislation

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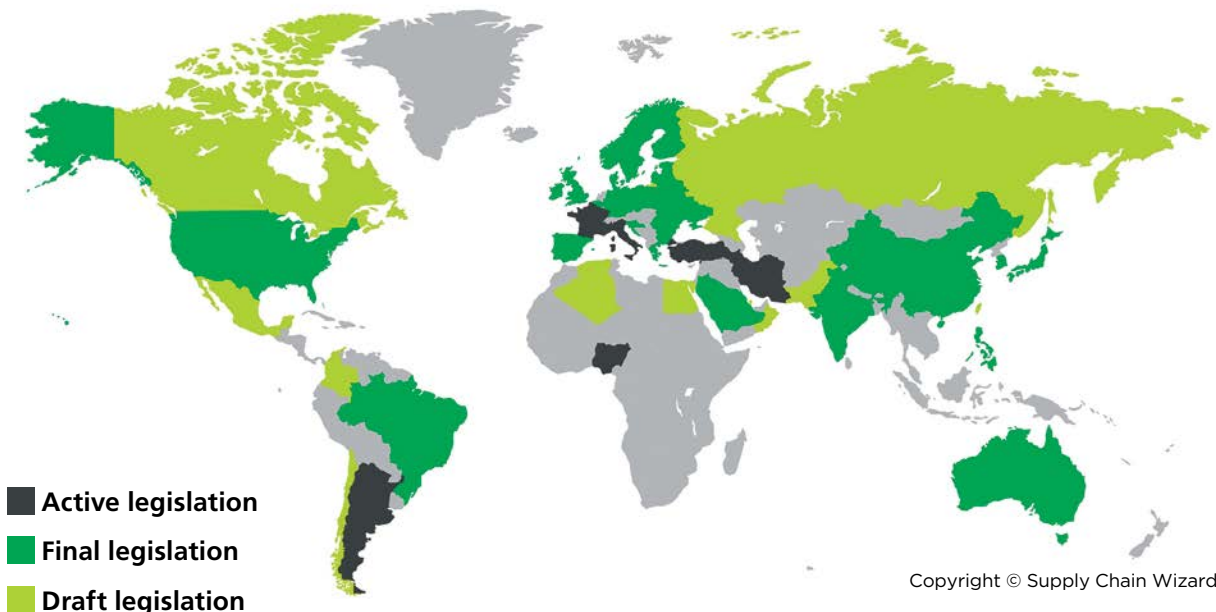
serialization deadline of Nov. 27, 2017, and the EU serialization deadline of Feb. 9, 2019. Considering more than 10,000 pharmaceutical packaging lines in the world to be eventually upgraded with capital equipment, plus additional IT systems at the site and enterprise level, the total global capital investment required in the next 10 years would be estimated at tens of billions of dollars, with cost per packaging line upgrade reaching up to $1 million for most complex implementations or less than $100,000 for manual hand-packing operations. While investment amounts would vary dramatically depending on the selected solution or the country/location, this compliance program is for sure one of the most expensive investments pharma companies are ever making.

The complexities and high costs of these serialization implementation projects are creating economic difficulties for the majority of small- to medium-size manufacturers. But the upside is that this is fomenting dialogue about how companies can improve their trade-partner collaborations for minimum disruption, and how they can turn these challenges into opportunities by leveraging their ongoing serialization infrastructure investment projects.

SOME DELICIOUS LEMONADE

When initially faced with the challenging deadlines and sticker shock of the investment needed to comply with serialization mandates, many manufacturers experience the five stages of grief: denial, anger, bargain, depression and, finally, acceptance.

The good news is that leading manufacturers have started to emerge from this cycle, accepting the new reality. Many are now realizing that the huge amount of data and

insights generated via serialization systems can be used to increase their level of connectivity and collaboration with global trading partners.

Manufacturers who have started to see the big picture are turning perceived lemons into lemonade by moving toward "compliance-plus" programs. They are coming to understand that focusing on "internal" compliance programs to protect downside compliance risk is not enough, and have started expanding their programs to their "external networks" through collaboration with their CMOs and CPOs.

Leading large manufacturers, for example, have launched formal "CMO Serialization Programs" to support their partners in their compliance journeys, while proactively managing the costs and IT connectivity aspects of their partner networks. This is where the sorts of tools introduced by companies, such as Supply Chain Wizard, can become vital. Through a set of solutions that includes a first-of-its-kind Management Dashboard and Supplier/Customer Portal, pharma manufacturers are being introduced to web-based/cloud solutions that not only sufficiently address collaboration among trading partners, but significantly enhance them.

Hundreds of companies have since experienced what a "digital supply chain" might look like when supply chain partners exchange information on project/program status, product readiness and other pertinent management data via digital technologies at increased efficiency, lower cost and fewer resources.

As these companies have begun to focus on upside opportunities (both internally and externally), some of the early initiatives of a digital factory and digital supply chain have emerged — ones that focus on more "operational visibility" and "efficiency improvement" on the factory side, and on "end-to-end supply chain visibility" and "supplier/customer collaboration" on the supply chain side.

The adoption of global standards, together with the global macro trend of implementing serialization and track-and-trace infrastructure demanded by all major countries over the next few years, are all coming together to set the foundation for a digital pharma supply chain.

JOURNEY FROM DATA TO DASHBOARDS TO DECISIONS

While the digital supply chain transformation has begun, it will take multiple years to get to where it needs to be. There is a clear path for companies to pursue, as they learn to make the connections and begin the journey from data to dashboards to decisions. A massive infrastructure is being put in place to track supply chain movements at the "unit level," which is set to generate

thousands of times more data than previous supply chain mode of operation at the "batch" level. Therefore, the transformation journey starts with the abundance of data in the new world of a serialized supply chain, and evolve into business and management "dashboards," and finally to "decisions" to complete the three major pillars of digital transformation to add real value.

Data

The journey starts with data as the new currency of the world. Serialization systems and the infrastructure surrounding them establish a great foundation, but serial number data and the visibility of products in the supply chain is just the beginning. Rapid emergence of Internet of Things technologies, such as wireless sensors and gateways, are providing unlimited opportunities to enhance the datasets collected by traditional "transaction-based" systems like ERP, MES and WMS. Environmental and location-based data, as well as product and unit-level specific data sets, tremendously enrich traditional data sets and make them accessible, which was previously not possible. As a result of these new technologies, tomorrow's supply chain executives will have access to significantly larger data sets at far greater granularity.

Dashboard

The journey continues with the ability to convert raw data into actionable insights through the use of business and management dashboards, which are made available to people at every level in the organization depending on their role and objectives. For example, a digital factory manager would be able to see a live dashboard of all her production lines, with access to pre-configured reports that analyze exceptions, trends and downtimes like never before. Using these dashboards, future leaders will be able to respond to undesirable situations faster and more effectively, while also identifying desirable outcomes and the conditions that created those outcomes. By providing a crystal-clear lens through which to view business operations, these dashboards yield a major increase in transparency and clarity. Digital factory leaders will also be able to design "automated" alert systems that are driven by the data and dashboards, and controlled by the business control limits set at granular levels (e.g., site head receiving an alert if Overall Equipment Effectiveness — OEE — of a specific production line falls below acceptable levels, or maintenance crew being alerted when a specific type of failure occurs).

Digital supply chain leaders, on the other hand, could design dashboards and live controls to receive alerts on unit-level profitability for a specific product falling below an acceptable level, and identifying the root-cause being "expedited shipments," having access to control levers to "stop" further rush shipments to improve bottom line.

Decisions

The real value of the transformation journey is delivered by the decision-making capabilities of organizations, where data and dashboards are effectively used to make critical resourcing and prioritization decisions. For example, the scheduling of work orders at the shop floor using real time data and historical trends can bring much improvement in resource utilization and overtime/waste reduction.

For one of Supply Chain Wizard's clients, digital decision-making technologies applied to a packaging-line scheduling problem resulted in 10 to 20 percent reduction in required labor costs, by significantly reducing unnecessary overtime due to more accurate and granular planning. This came about as a result of better data (tracked by digital technologies, including IoT sensors) provided to insight-rich dashboards to identify most-pressing problems, combined with smart decision-making systems applied to solve these problems utilizing advanced analytics and machine learning. For a medium-sized packaging site of up to 10 packaging lines, the resulting annualized savings could reach to $1 million.

For another client, Supply Chain Wizard enabled collaborative decision-making on how best to support struggling suppliers with their serialization programs through the use of cloud-based supplier/customer portal solutions that made data sharing, collaboration and data-driven risk assessments and prioritization easier and more accessible to decision makers. Through these solutions, required number of resources on the project has been reduced dramatically, while the responsibilities of generating and maintaining accurate project data is easily distributed to global internal and external stakeholders, automatically monitored for regular updating, leaving program managers valuable time to focus on core program actions and decision-making, rather than data-gathering, analysis and reporting.

DIGITAL SUPPLY CHAIN OF THE FUTURE

While a fully digitized pharma supply chain remains a goal of the future, today's leading pharma companies are hard at work creating a connected, smart and highly efficient supply chain ecosystem. Those that stay at the front of the pack will not only measurably improve their business performance, but ultimately transform the way they do business with trading partners.

The necessary prerequisites are now in place — thanks to the demands of serialization — with a higher level of transparency and responsiveness now attainable. The companies that can recognize and act upon strategic opportunities will be able to provide their customers with the most efficient and transparent service delivery, and the best will be able to develop new business

models and revenue streams. The opportunity for the pharmaceutical digital supply chain to come roaring to life is there for the taking.

ABOUT THE AUTHOR

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