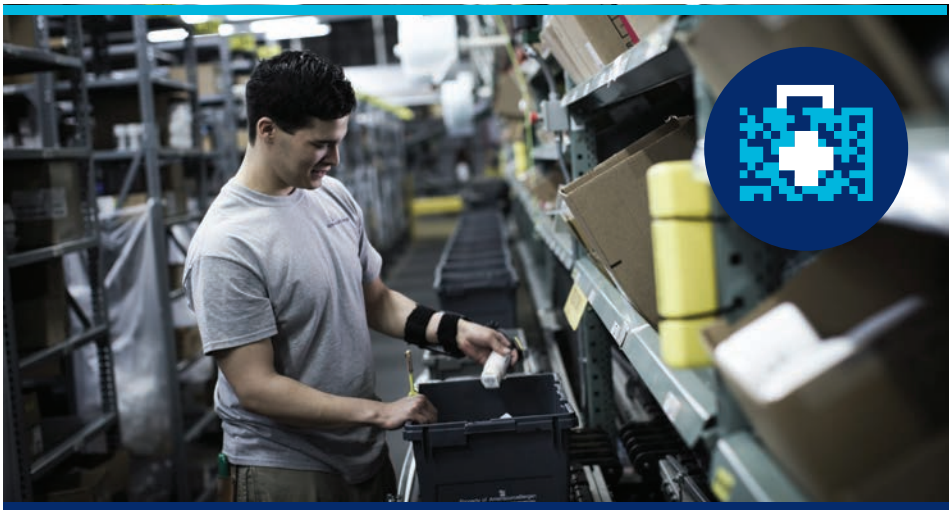
GS1 US

THE GLOBAL LANGUAGE OF BUSINESS

CASE STUDY



Piloting Traceability with GS1 Standards

AmerisourceBergen teams with Johnson & Johnson Supply Chain for significant learnings

"The key to success in meeting any instance of regulatory compliance—really comes down to collaboration. It all rests on the willingness of our industry partners across the supply chain to work toward consensus and then drive to adoption. This pilot with JJSC has been a stunning example of true partnership as we move to establish a meaningful standard that serves our industry and protects patients."

— **HEATHER ZENK**, Vice President, Secure Supply Chain, AmerisourceBergen

CHALLENGE

The Food and Drug Administration (FDA) regulation 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.

SOLUTION

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.

BENEFITS

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.

A prescription for a clearer vision

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

"This pilot was an opportunity to not only help develop the industry solution, but also provide insights that may help our patients and customers use it and leverage it beyond just compliance," says Matt Sample, senior director for Secure Supply Chain at ABC.

"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."

— **MIKE ROSE**, Vice President of Supply Chain Visibility, Johnson & Johnson Supply Chain

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 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 November 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 like the Janssen companies of Johnson & Johnson have opted to leverage GS1 Standards. At the saleable level, 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.

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 DataMatrix 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.

Key members of the JJSC pilot team include (left to right): Rebecca Hehnly, Thomas Pizzuto, Rosemary Hampton and Chris Reed.

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."

"We have a solid playbook on how to run a pilot with more than just one manufacturer and more than just one product. We have a good repeatable process for future pilots," Sample says.

"Using EPCIS message standards provides for a more streamlined process, in that systems are established with similar data file expectations across the 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."

— **JEFFERY DENTON**, Senior Director, Global Secure Supply Chain, AmerisourceBergen

"We continue to discover ways to improve our design and processes through pilots. The pilot with ABC enabled us to validate and challenge our end-to-end business processes and architecture that grew since our last round of EPCIS exchange."

— **ROSEMARY HAMPTON**, IT Manager, Supply Chain Business Systems, Johnson & Johnson Information Technology

"We have a solid playbook on how to run a pilot with more than just one manufacturer and more than just one product. We have a good repeatable process for future pilots."

— **MATT SAMPLE**, Senior Director, Secure Supply Chain, AmerisourceBergen

Benefits beyond compliance

Serialization and traceability can bring value to the respective businesses, beyond compliance.

"We see this as more than just a regulatory compliance effort," says Chris Reed, JJSC's lead for Product Serialization and Traceability. "Leveraging GS1 Standards also is intended to improve patient safety and helps provide a means to investigate counterfeit and diverted products. It improves our 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," continues Reed. "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."

Instructive indeed, interactive in deed

JJSC is a strong believer in conducting pilots. "We continue to discover ways to improve our design and processes through pilots. The pilot with ABC enabled us to validate and challenge our end-to-end business processes and architecture that grew (significantly more internal and external manufacturing sites, regional requirements, and IT complexity) since our last round of EPCIS exchange," remarks Rosemary Hampton, IT manager, Supply Chain Business Systems, Johnson & Johnson Information Technology.

"To facilitate just this relatively small pilot, our resource planning instance, warehouse management system and traceability processes needed to perform in unison," says Reed. "We found that products were arriving on ABC's loading docks before product data arrived, because of the way we had batched our data transmissions between these three large systems. This led us to challenge and reconfigure our old way of thinking. The pilot was a reminder of how many processes and IT systems we have in play."

"With the implementation of serialization and traceability, we will have the opportunity to trace a serialized product from the specific wholesaler to the end customer. We can use these capabilities to further ensure that our patients receive quality, genuine products."

— **CHRIS REED**, Lead, Product Serialization and Traceability, Johnson & Johnson Supply Chain

Lessons learned

"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," Sample agrees. "You have to test it thoroughly with the right amount of volume in production."

Something as seemingly simple as labeling requires careful consideration. A case displays multiple labels—an HDA label, a 2-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.

"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."

"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."

— **CHRIS REED**, Lead, Product Serialization and Traceability, Johnson & Johnson Supply Chain

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

— **MATT SAMPLE**, Senior Director, Secure Supply Chain, AmerisourceBergen

The Carnegie Hall approach

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."

Heather Zenk, vice president of ABC's Secure Supply Chain, sums up the companies' pilot in this way. "The key to success in meeting any instance of regulatory compliance—really comes down to collaboration. It all rests on the willingness of our industry partners across the supply chain to work toward consensus and then drive to adoption. This pilot with JJSC has been a stunning example of true partnership as we move to establish a meaningful standard that serves our industry and protects patients."

Revelations of the pilot

The natural order of things. The GS1 GTIN is not only foundational, but has tremendous value to enhance ordering processes and unit of measure ambiguity in the future.

The devil is in the details. What may seem like an inconsequential piece of data can actually derail communications between trading partners. Clean, quality data is imperative.

Timing is everything. Make sure data transmissions precede product arrivals.

Too much information. With multiple labels on a case, be sure to follow labeling guidelines of those who have gone before--industry leaders share their expertise through the GS1 community.

Not trivial, transformational. Treat this as the business transformation that it is. Assign proper resources in time, investment and decision-makers.

The Carnegie Hall approach. Start now and practice, practice, practice.

Take the chance. This industry transformation presents the unusual opportunity of sharing best practices among partners, customers and and even competitors. Everyone wins.

Bask in the benefits. End-to-end traceability also helps trace counterfeit and diverted products, and delivers supply chain integrity and safe medicines for patients.

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

About the Companies

ABOUT AMERISOURCEBERGEN

AmerisourceBergen maintains partnerships with global manufacturers, providers and pharmacies to provide product access and efficiency throughout the healthcare supply chain. AmerisourceBergen is part of the largest global generics purchasing organization, the leading specialty pharmaceutical services provider, and the partner with more community and health system pharmacy relationships than any other. From product commercialization and distribution to pharmacy, provider and manufacturer solutions, AmerisourceBergen is a leader patient care. www.amerisourcebergen.com

ABOUT JOHNSON & JOHNSON SUPPLY CHAIN

Johnson & Johnson Supply Chain encompasses four segment supply chains (Pharmaceuticals, Consumer Products, Medical Devices, and Diabetes & Vision Care) that cover planning, sourcing, internal and external manufacturing, Customer Logistics Services and the Supply Chain Strategy and Deployment. Additional enterprise-wide functions that are part of Johnson & Johnson Supply Chain include Quality & Compliance, Environment, Health, Safety & Sustainability and Engineering & Technical Operations. www.jnj.com

ABOUT GS1 US®

GS1 US, a member of GS1®, is an information standards organization that brings industry communities together to solve supply-chain problems through the adoption and implementation of GS1 Standards. More than 300,000 businesses in 25 industries rely on GS1 US for trading-partner collaboration and for maximizing the cost effectiveness, speed, visibility, security and sustainability of their business processes. They achieve these benefits through solutions based on GS1 global unique numbering and identification systems, barcodes, Electronic Product Code (EPC®)-based Radio Frequency Identification (RFID), data synchronization, and electronic information exchange. GS1 US also manages the United Nations Standard Products and Services Code® (UNSPSC®). www.GS1US.org

THE GLOBAL LANGUAGE OF BUSINESS

GS1 US Corporate Headquarters
Princeton Pike Corporate Center
1009 Lenox Drive, Suite 202, Lawrenceville, NJ 08648
USA

FOLLOW US:

6 14141 02222 9