



Suppliers and GPOs

Piloting traceability of prescription drugs with GS1 standards

The U.S. Food and Drug Administration's (FDA) 2013 Drug Supply Chain Security Act (DSCSA) requires that the pharmaceutical industry implement end-to-end traceability by 2023. As trading partners, Johnson & Johnson Supply Chain (JJSC) and AmerisourceBergen (ABC) chose to implement and test GS1 standards-based solutions in a real-world pilot to meet the deadline for interoperability. While GS1 standards have created a hierarchy that reaches down to the product level for serialisation, several industry entities have voluntarily chosen to use GS1 EPCIS (Electronic Product Code Information Services) to fully meet the intent of the regulation. EPCIS allows trading partners to exchange data in concert with products as they move through the supply chain. The industry pilot between JJSC and ABC did just that, with actionable and repeatable results.

By Matt Sample, ABC, and Mike Rose, JJSC



A prescription for clear vision

When it comes to pharmaceutical traceability, ABC is in the thick of it as a wholesaler positioned between more than 450 pharmaceutical manufacturers and more than 60,000 customers, including pharmacies and healthcare providers. In addition to its core distribution services, ABC is also a private label manufacturer, re-packager, 3PL service provider and specialty pharmacy, operating at the origin, middle and end of a vast global supply chain.

Naturally, compliance is a critical issue for the pharmaceutical industry. The DSCSA, which was signed into law on 23 November 2013, requires the industry to institute an electronic, interoperable system to identify and trace by 2023 certain prescription drugs distributed in the United States.

ABC and JJSC agreed that a traceability pilot that involved serialisation of individual products would provide valuable information for the industry. The collaboration highlights the importance of having a robust, well-implemented serialisation 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 customers.

Both companies saw this pilot as an opportunity to not only help develop the industry solution, but also provide insights that may help customers leverage it beyond just compliance to benefit them and their patients.

ABC and JJSC are long-term members of the GS1 Healthcare US Initiative¹, the voluntary user group

¹ GS1 Healthcare US Initiative: <https://www.gs1us.org/industries/healthcare/initiative>

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 serialised product identification and end to end traceability, the Janssen Pharmaceutical Companies of Johnson & Johnson have opted to leverage GS1 standards. At the saleable level, a Global Trade Item Number® (GTIN®) with a serial number is encoded in a GS1 DataMatrix barcode to establish global uniqueness. This unique identification allows 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 GS1 DataMatrix barcode, containing a serialised GTIN, batch/lot number and expiration date, was applied to each lowest saleable unit. The lowest saleable units were packed into cases, creating a parent/child logical hierarchy, commonly referred to in the supply chain as an “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 GS1 DataMatrix barcode to capture the GTIN, serial number, batch/lot number and product expiration date.

GS1 EPCIS was used to record business events associated with the serialised GTIN at various critical points along the supply chain, including commissioning, packing and shipping, followed by receiving and unpacking by the buyer.

Serialised product was moved from manufacturing to distribution, and once the wholesaler placed an order and the truck departed, JJSC issued an EPCIS message containing the serialised GTINs and aggregated hierarchies contained in the shipment. This provided the ABC distribution centre with the details of the specific products that were on their way.

When the shipment arrived, the EPCIS events and inference of the aggregated 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 the EPCIS standard as a foundation provides for a more streamlined, interoperable process, as systems using it are designed with similar data requirements across the supply chain. Providing DSCSA-compliant EPCIS files that include master data for material attributes, as well as valid Global Location Numbers (GLNs) and GTINs, helps the process go smoothly.

Benefits beyond compliance

Serialisation and traceability can also bring value to the businesses above and beyond regulatory compliance. Leveraging GS1 standards helps improve patient safety and provide a means to investigate counterfeit and diverted products. It improves internal and external supply chain integrity.

With the implementation of serialisation and traceability, a serialised product can be traced from a manufacturer to the end customer, and used to further ensure that patients and customers receive quality, genuine products. Additional benefits such as being able to more effectively manage and verify returns are a bonus.



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

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 utilising GTINs for ordering processes.

Lessons learned

This pilot helped JJSC and ABC to validate and challenge end-to-end business processes and architecture, identifying ways to improve their processes for successful end-to-end traceability. It also showed how important it is for companies' internal management systems and traceability processes to perform in unison. For instance, JJSC found that its products were arriving on ABC's loading docks before product data arrived, because of the way JJSC had batched its data transmissions. This led them to challenge and reconfigure old ways of thinking. The pilot was a reminder of how many processes and IT systems the company has in play, and the need to synchronise them.

The pilot also proved that a missing element of data—whether it's a dosage form or a single letter in the description of the product can drastically impact the efficiency of the pharmaceutical supply chain, potentially leading to disruption for patients. A profound emphasis on cleansing

existing master data and establishing robust data governance will be crucial to success going forward. Data formatting issues—how others are encoding data using GS1 standards—are crucially important, as is thorough testing with the right amount of volume in production.

Something as seemingly simple as labelling requires careful consideration. A case displays multiple labels—a Healthcare Distribution Alliance (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 barcode capture; damage to cases can compromise label readability. For example, ABC found it was putting the 2D barcodes in the most vulnerable spot on the packaging, so that was changed for improved readability.

As a result of the pilot, JJSC and ABC are working with both GS1 US and HDA to update labelling guidelines. The pilot clearly demonstrated that this is not a casual exercise; it is a business transformation project, not to be underestimated.

Practice makes perfect

The exchange of data between businesses takes some massaging in the real world. It's advisable to start now and repeatedly test and practice implementing standards-based serialisation and traceability processes, while there's still time to work out the kinks.

Trading partners will also need to establish a clear understanding of exceptions—how often they occur, how to deal with them and what will be deemed acceptable by the regulator (in this case, the U.S. FDA). Exceptions are a reality, especially with niche products, and the industry will need to know how to deal with them.

Robust communication is imperative. For this initiative to be successful, trading partners up and down the supply chain must collaborate and communicate. Collaboration is critical to helping companies align on objectives and resolve issues. By keeping the lines of communication open and continuing to develop and refine industry standards together, we will all be prepared to fulfil DSCSA requirements and continue to provide safe and effective medicines to our patients.

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

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HEATHER ZENK, Vice President, Secure Supply Chain, AmerisourceBergen

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 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 labelling 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 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 JJSC pilot team include (left to right): Rebecca Hehny, Thomas Pizzuto, Rosemary Hampton and Chris Reed.



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About the Authors



Matt Sample is Senior Director of Secure Supply Chain at AmerisourceBergen. He is currently the business lead for the serialisation efforts at AmerisourceBergen and is responsible for managing all current and future DSCSA operations. Matt has over 15 years of experience in the

medical device, pharmaceutical and life sciences industry; working both for manufacturers, wholesalers and for a large consulting firm. He has held various roles in the areas of product development, lean six sigma, business system implementation and operational leadership. His most recent responsibilities have included leading a global medical device serialisation effort, device UDI implementation and, until joining AmerisourceBergen, he was the serialisation overall program lead at a mid-size pharmaceutical company.



Mike Rose is Vice President of Supply Chain Visibility with Johnson & Johnson Supply Chain (JJSC). He is responsible for leading JJSC's supply chain visibility program that is an enabler to delivering exceptional customer experience while improving supply chain effectiveness and integrity. Mike's responsibilities

include product identification and traceability, which includes serialisation and traceability, GS1 standards adoption, Unique Device Identification, and Global Data Synchronisation Network.

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 commercialisation 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.

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