

Data Sharing in the Pharmaceutical Supply Chain: A Series of Case Studies

IBM's Alignment with the Center for Healthcare Supply Chain Research® Blueprint for Data Management & Data Sharing



Data Sharing in the Pharmaceutical Supply Chain: A Series of Case Studies

Introduction: Center for Healthcare Supply Chain Research

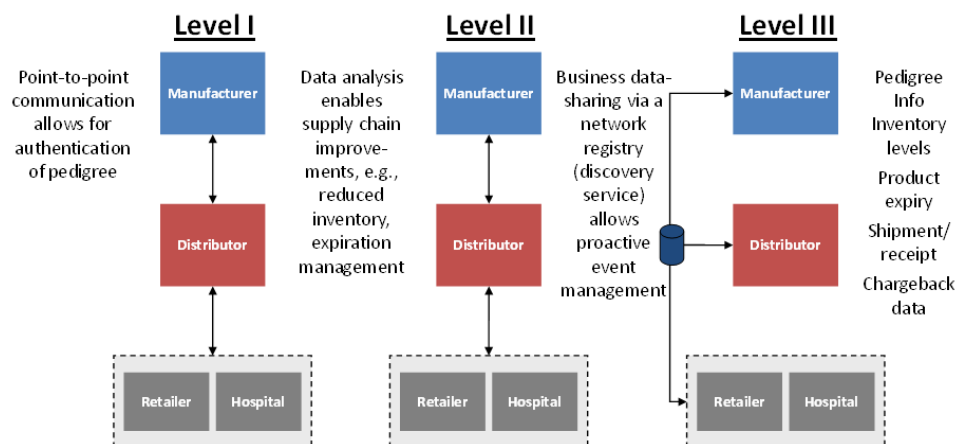
The Center for Healthcare Supply Chain Research (formerly known as the HDMA Research Foundation) has undertaken a three-phased industry study to address a critical issue in healthcare – the ability to manage and share data across the supply chain. IBM has been an active sponsor of and participant in this research, and has been incorporating the results into the successful implementation of pharmaceutical supply chain track and trace projects with its customers. Prompted by an understanding that the track and trace of individual items could further enhance patient safety and supply chain security, the Center’s research proactively helps trading partners to understand the benefits of managing and sharing vast amounts of serialized, item-level data.

The Center’s research has been conducted with the participation of leading industry manufacturers, distributors, retailers, solution providers and technology experts and was executed in the following phases:

Phase I documented a fundamental desire for greater product visibility within the supply chain, as well as the need for an industry “blueprint,” or path forward for increased levels of data management and sharing.

Phase II developed a model, or “*Blueprint*,” based on industry input and designed to provide the rationale and steps needed for companies to support meaningful data sharing across the supply chain. The *Blueprint* identified the following three levels of data sharing: Level 1 established direct-connect data sharing for regulatory compliance; Level 2 established bi-directional connectivity for data sharing for business value; and Level 3 established an industry-wide data sharing model that does not require direct connections between trading partners, but instead relies on an industry network supported by a registry or registries.

Phase II defined three Blueprint levels for data sharing



Benefits of EPCIS for Data Management and Data Sharing

The Center's Blueprint relies on an industry standard to enable data management and data sharing. The Electronic Product Code Information Services (EPCIS) specification¹ was selected as the standard based on multiple factors, including:

- Interoperability
- Serialization technology agnosticism – acceptance of any data carrier, e.g., 2D, RFID, etc.
- Bi-directional communication flow
- Extensibility of the standard for multiple use cases
- End user and technical expertise

Supply chain partners rely on standards for both internal data management and to define data sharing protocols, which reduces the need for manual customer mapping and ensures interoperability and data integrity while speeding implementations, lowering costs and increasing reliability. EPCIS was selected to facilitate the Blueprint vision of data sharing because it is the most comprehensive standard supporting, event-based data management and data sharing. EPCIS is a cross-industry initiative and has already been implemented to facilitate supply chain information sharing across a broad range of industries, including retail, food, consumer electronics and automotive.

¹ <http://www.epcglobalinc.org/standards/epcis>

The diagram below outlines the hierarchy of benefits as defined by the Center’s Phase I research. These benefits can be maximized through increased data sharing across the pharmaceutical supply chain. Compliance to emerging serialization and pedigree legislation, improved patient safety and brand protection, as well as operational efficiencies across the supply chain – such as improved expiration management, targeted recall, management of cost diversion, and inventory management – were identified and continue to be compelling reasons to pursue increased data sharing.

Figure 5. Hierarchy of Benefits

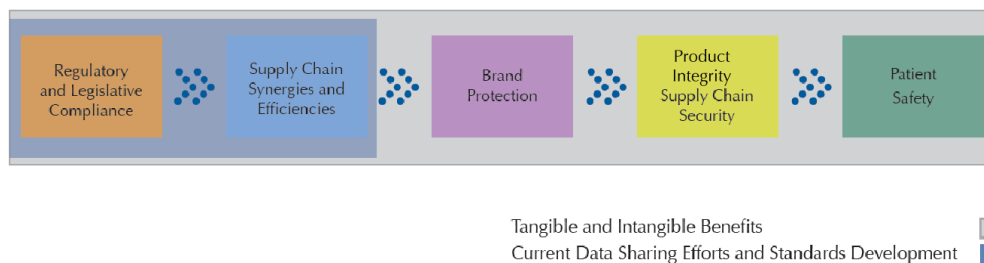


Figure 1: Hierarchy of Benefits (Phase I: A Qualitative Business Case)

The 2007 interviews initially documented companies concentrating on understanding serialization and pedigree for compliance reasons only. Now, based on extended compliance deadlines, the 2008 interviews reflect the fact that companies are able to take a more strategic approach to serialization. With a standards-based approach that enables supply chain information sharing, they are realizing that compliance driven initiatives can serve as a catalyst in undertaking action now to secure and improve the supply chain. Patient safety, brand

protection and ROI are moving to the forefront as important drivers in companies' decision making.

Data Sharing across the Pharmaceutical Supply Chain

Participants in each stage of the pharmaceutical supply chain, manufacturers, distributors, hospitals, and pharmacies are positioned to realize millions of dollars in benefits from serialization. These benefits range from improved inventory visibility to targeted recall capability to improved management of chargeback and returns. All members of the supply chain benefit from improved patient safety and business value. Increasingly, companies are taking leadership positions to begin serialization ahead of state and federal regulations. Across the supply chain, manufacturers, distributors and retailers are engaging in track-and-trace pilots to evaluate the effects of serialized information carried on RFID and 2D bar codes on operations and product integrity.

	Manufacturer	Distributor	Retailer/Hospital
Benefits			
Anti-Counterfeiting & Patient Safety	4 4	4 4	4 4
Targeted Recall Capability	4 4	4 4	4 4
Inventory Management	4	4	4 4
Diversion Management	4 4	4	4
Returns & Chargeback Mgmt.	4 4	4 4	
Improved Expiration Management	4	4	4 4
Regulatory Compliance	4 4	4 4	4 4
Key Challenge	Serialization	Interoperability	Instrumentation
Solution	Standards & Data Sharing	Standards & Data Sharing	Standards & Data Sharing

Figure 2: Benefits of Serialization for Supply Chain Participants

Manufacturers, in particular, stand to gain from serialization and increased data sharing. Specifically, within the hierarchy of benefits established in 2006 by the

Center for Healthcare Supply Chain Research's *A Qualitative Business Case*, manufacturers are most likely to focus on the benefits of brand protection, product integrity, supply chain security and enhanced patient safety. Recently, manufacturers are increasingly interested in supply chain efficiency, as well. Even though patient safety is difficult to measure, all supply chain participants are committed to ensuring a safe and secure supply chain. The following case studies highlight the various benefits which market leaders are seeking to achieve through serialization.

A Manufacturer's Point of View: Pfizer Case Study

The motivation for serialization comes in many forms – regulatory compliance, business benefits and competitive pressure. For one manufacturer, keeping patients safe by working to further secure the distribution channel and ensuring product integrity is what paved the way for its leadership in serialization. Pfizer, currently the world's largest global research-based, pharmaceutical manufacturer, is one of the first companies to commit to serialization to control the threat of counterfeits.

Pfizer has had experience with some of its products being counterfeited and sold through the legitimate supply chain. In 2003, Pfizer's cholesterol-lowering drug, Lipitor, was involved in a very public counterfeit event affecting many patients. This incident led Pfizer to explore options to increase the safety of the supply

chain, including implementing restrictions on authorized distributors of record, and developing a pilot about the employment of serialization. Serialization involves applying a globally unique number to each saleable unit. Pfizer has committed to serialization to ensure patient safety, as well as to protect the integrity of its products.

After analysis of its product portfolio, Pfizer committed to serializing 100 percent of its Viagra product starting in 2004. By the end of 2005, tagged product was being shipped throughout the United States.² Items are tagged on the manufacturing line at the item level with both RFID and 2D bar code tag, ensuring nearly 100 percent read rates throughout the supply chain as product is read at Pfizer manufacturing and distribution centers, wholesaler distribution centers and, eventually, at retail pharmacies for authentication. As noted by Pfizer, it is difficult to understand true read rates because the process of reading serialized items and cases is presently an exception process. According to a Pfizer spokesperson, Pfizer is not aware of any counterfeited Viagra in the “normal” (i.e., Manufacturer to Authorized Distributor of Record (ADR) to Pharmacy) supply chain since the inception of RFID tagging in 2004.

Pfizer believes in a risk-based approach to serialization and carefully selects which of its product lines will support tagging. Recently, it has expanded its serialization effort to include its Celebrex product.

² <http://www.rfidupdate.com/articles/index.php?id=1366>

Pfizer recognizes that it takes action and commitment from across the entire supply chain – manufacturers, distributors and retailers – to fully recognize the value and business benefits from exchanging serialization and related data.

Sharing information – such as product receive/ship data, lot/expiration data and quantity information based on serialization – will present an opportunity for trading partners to make informed business decisions.

A key use case Pfizer is currently assessing is how to gain internal operational efficiency from serialized data. Pfizer's network of distribution centers across the world is already managed by a leading industry inventory management process. In addition, an initiative is underway to learn from the use of serialized data and understand how to leverage that data.

In the future, Pfizer hopes to derive business value from sharing serialized data with trading partners (Level 2). Information from distributors – such as receipt confirmation, item verification and intra-company transfers – could help to reduce shipping discrepancies and streamline ordering processes. In addition, chargeback processes and validation of financial transactions could improve as a result of sharing meaningful data around which trading partners (retail/hospital pharmacy) purchase specific serialized product.

In addition, Pfizer sees value in sharing serialized data with retail chains as well as with distributors. Information such as receipt confirmation, tag

decommissioning (when a unit is consumed) and returns could enhance not only the safety of the supply chain, but also operational efficiency.

Pfizer believes that patient safety and company operational efficiencies will be gained by establishing cross-trading partner data exchange via a standard technology and utilizing data sharing for more than compliance.

A Distributor's Point of View: McKesson Case Study

Before serialization was considered a compliance requirement, McKesson looked to technology and to RFID in particular to improve patient safety and drive down costs within the pharmaceutical supply chain. From an operational standpoint, McKesson was interested in technology that could improve business processes, such as returns, recalls and inventory management and that could help to ensure only authentic products moved within their distribution centers.

After an assessment, McKesson concluded that the use of RFID was more attractive than 2D barcodes because McKesson employs automated processes within its distribution facility. Serialization with 2D technology requires line-of-sight reading and would result in operational inefficiencies that compromise McKesson's automated environment.

At present, most returns come back through the distributor with little visibility regarding the history and handling of the returned product. There is a potential for items to be returned to McKesson that it had not sold initially. From McKesson's perspective, this was unacceptable. On a return, McKesson wants to know whether the medication it is accepting was purchased directly from either the manufacturer, from McKesson or from another Authorized Distributor of Record (ADR). Additionally, McKesson wants to know whether the medications it is accepting were kept in conditions commensurate with the PDMA³.

McKesson identified serialization as a means to counter potential illicit returns. If a product is serialized, distributors can check its pedigree to validate the product's history. By increasing company controls across the supply chain, these systems protect the patient by eliminating the threat of counterfeit drugs from entering the normal main-stream supply chain.

A spokesperson from McKesson also noted an interest in technologies that can drive a more targeted recall notification process. With serialization, manufacturers and distributors will each know exactly what products they sold and to whom. Today, manufacturers control product recall by lots, which can consist of thousands of items. Instead of sending out up to 35,000 notifications for each recall, McKesson looks forward to the day when it can send out specific notifications based on knowledge of where each serialized item in the affected batch/lot was distributed. Further, from a manufacturer and regulatory

³ <http://www.fda.gov/cder/regulatory/PDMA/default.htm>

perspective, it would be helpful to see what percentage is actually returned and what product remains in the marketplace.

The recent Heparin recall provides a good example. Heparin is not serialized, so there was insufficient granular data to send specific notifications to the specific trading partner that had the affected product or to monitor the progress of the recall. Instead, blanket notifications were sent out across different rounds of recalls. With the lack of item-level visibility, officials were still finding quantities of recalled Heparin in the system well after the time that it should have been removed. The inefficiencies surrounding the recent Heparin recall process, and the inability to confirm that the affected bottles have been recalled, highlight the need for a targeted process based upon serialized data.

In addition to operational benefits and patient safety gained through greater visibility and better recall practices, expiry management is another opportunity where serialization and data exchange can be effective in reducing risk and cost in the supply chain. Currently, there is no automated way to verify expiration date. McKesson noted that the supply chain is poised to benefit from a better way to manage inventory and ensure that no expired product gets into the hands of patients.

Internally, McKesson wishes to gain the benefits of increased product movement visibility by instituting automated decision making around expiry date. By

systematically tracking at the item level and generating automated alerts, decisions will be made faster and more accurately, keeping expired product from moving forward in the supply chain. In addition, data exchange via EPCIS will enable McKesson to assist its downstream trading partners to more effectively control their inventories by sharing key expiry information and even producing alerts for their customers based upon designated criteria.

McKesson is a leader in identifying key use cases where serialization can enable business benefits and EPCIS can strengthen automated communication channels across the supply chain. Communication via EPCIS may be leveraged to improve forecasting with upstream trading partners and to increase efficiency of expiry management for downstream trading partners. By enhancing communication and visibility of granular data, supply chain and patient safety benefits are achievable.

A Retailer's Point of View: Wal-Mart Case Study

As for manufacturers and distributors, patient safety is the main concern for retailers. The desire to provide customers with the right product at the right time, thus ensuring patient safety, is a motivational factor for increased data sharing throughout the supply chain.

Wal-Mart has made automated methods for identifying products and product expiry date a priority. It is Wal-Mart's belief that the same data captured and

shared for pedigree compliance can be utilized to ensure patient safety and continuous business process improvements within the supply chain.

Wal-Mart is known for having world class distribution capabilities and for being a leader in technology, piloting serialization through RFID prior to the issuance of specific regulatory compliance proposals. A spokesperson from Wal-Mart notes that Wal-Mart has set its sights on employing item-level serialized data, as it becomes available across the industry, to improve internal processes.

One specific example of how Wal-Mart is planning to use serialized data is to increase visibility of inbound shipments. Wal-Mart has assessed this as an opportunity to enhance its ability to prioritize receipt of goods based upon store inventory requirements and replenishment needs, thus reducing out-of-stock (OOS) situations. Wal-Mart notes that better decisions can be made the earlier it is able to gain visibility into inbound shipments. This visibility facilitates expediting shipments that may be at risk for OOS at a specific store location and ensures customer satisfaction. Wal-Mart recognizes EPCIS can make this visibility possible through data exchange with key business partners and also can make the process more automated.

Another area of benefit Wal-Mart recognizes is upstream inventory visibility. Wal-Mart believes that gaining insight into upstream inventory levels will result in multiple areas of efficiencies. Challenges around data ownership and contract

negotiations may be a potential barrier to this type of data exchange. However, benefits such as complete and accurate forecasting and planning efficiencies will be considered and evaluated on a partner-by-partner basis.

In addition to supply chain benefits, serialization can improve customer confidence through the use of medication pedigree verification. Wal-Mart considers pedigree to be an enabler for automatically being able to verify the lot and expiration date of prescription medications. Through this automated verification – being able to match pedigree to product – Wal-Mart can ensure its customers are receiving accurate and safe products. Today, much of the verification is manual with potential for information gaps. The automated transmission of serialized pedigree will greatly enhance this process as well as boost customer confidence.

The spokesperson from Wal-Mart added, “There are several challenges companies, especially retailers, face when implementing and managing serialization and pedigree. For example, different trading partners may interpret various data fields differently, such as invoice number versus order number. Establishing a standard vocabulary, as currently being done within EPCglobal for the EPCIS standard, will help to minimize this risk. It is important to establish, test and troubleshoot each connection point and not rush implementation.

Overall, retailers such as Wal-Mart plan to use item level serialization, pedigree and the EPCIS standard to ensure safe product and safe patients while establishing more automatic procedures and operations that enhance business value.

A Solution Provider's Implementation: IBM's *Solution for Pharmaceutical Track & Trace*

Through its extensive presence in the pharmaceutical industry and the *IBM Solution for Pharmaceutical Track & Trace*, IBM is working today with the HDMA, EPCglobal and GS1 Healthcare standards bodies and pharmaceutical industry manufacturers, distributors and retailers to:

- Improve patient safety and reduce product counterfeiting and diversion by mass serialization and item level tracking;
- Meet global, federal and state regulations as well as future mandates for pharmaceutical safety;
- Grow revenues by improving product availability and ensuring product quality to meet patient and government expectations; and
- Dramatically reduce inefficiencies throughout the supply chain (e.g., charge backs, recalls).

As one of the leading technology vendors to fully support the EPCIS standard, as well as the Center's *Blueprint for Data Sharing and Data Management*, the *IBM*

*Solution for Pharmaceutical Track & Trace*⁴ supports Level 2, bi-directional information sharing for regulatory compliance through the ePedigree application. IBM believes additional business value can be achieved through item level serialization and visibility of information across the total supply chain. The Center's Level 2 data sharing can be achieved through IBM's unique business driven use cases and reporting capabilities. It is important to note that track-and-trace technologies, including IBM's solution, can be integrated with existing ERP systems. *IBM's Solution for Pharmaceutical Track & Trace* also offers proactive supply chain intelligence, which includes analytics and can provide event notifications (e.g., "inventory threshold exceeded, duplicate EPC detected") for Level 3 data sharing.

Summary

Pharmaceutical companies are recognizing the potential value of standards-based track-and-trace solutions beyond compliance to secure and improve the performance of the supply chain. The Center's *Blueprint*, supported by the EPCIS standard, is the most comprehensive approach to achieve a secure and efficient supply chain. The Wal-Mart case study highlights the importance of standards in achieving full data sharing benefits. The McKesson case study identifies use cases, such as returns processing, targeted recall and expiry management, in which serialized data is used for business benefit rather than for compliance only. Finally, as demonstrated in the Pfizer case, item level

⁴ <http://www-03.ibm.com/solutions/businesssolutions/sensors/doc/content/solution/1624269129.html>

serialization can be used to prevent counterfeiting and thereby increase patient safety, as well as to enable internal operational efficiencies and derive business value across the entire supply chain. Solutions for pharmaceutical track and trace that leverage the Center's *Blueprint* and applicable Global Standards, and which can improve patient safety and supply chain visibility and efficiency, are available from IBM today.

With all the business value generated for each partner in the supply chain, managing and sharing data via EPCIS according to the Center's *Blueprint* is no longer just a vision; it is an actionable plan.

For more information

Please visit The Center for Healthcare Supply Chain Research's web site at <http://www.hcsupplychainresearch.org/> to learn more about the Center's empirical research studies, educational programs and events designed to benefit the entire healthcare supply chain.

To learn more about EPCIS and Electronic Pedigree solution offerings, please visit IBM's websites focused on Pharmaceutical Track & Trace at

www.ibm.com/solutions/sensors

www.ibm.com/software/data/infosphere/traceability-server