



WHITE PAPER

An Industry Information Framework for the Pharmaceutical Supply Chain



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The Opportunities and Challenges before the Pharmaceutical Supply Chain

The goals of the pharmaceutical supply chain obviously emphasize regulatory compliance and safety of products, but also include leveraging information to be more responsive to the needs of consumers. The unique nature of the supply chain for pharmaceuticals makes managing complex information for supply chain effectiveness challenging, but clearly the rewards for doing so are significant. Companies that excel in supply chain operations perform better in almost every financial measure of success. According to AMR Research, supply chain excellence that improves demand-forecast accuracy leads to 5% higher profit margins, 15% less inventory, up to 17% stronger “perfect order” ratings, and 35% shorter cash-to-cash cycle times. Many of these findings come from the consumer products (CP) industry, where supply chain excellence means tightly aligning operations with consumer demand to become “demand driven.”

The shift to a demand-driven focus has been taking place within the CP industry for years. While perhaps leading the way in implementing demand-driven processes, the CP industry is not alone in this interest or intent. Leading pharmaceutical manufacturers also recognize the value of adopting demand-driven supply chain practices. They are benchmarking their organizations against CP manufacturers, and finding that their industry is generally behind the pace. The pharmaceutical industry is hindered by silos of information and a general lack of timely and reliable data as a result of historical business models and trading practices.

A few participants in the pharmaceutical supply chain have initiated projects to change the scope of information sharing between trading partners to focus also on becoming more demand driven. What is clear from these early efforts is that new types of data will be generated at unprecedented scale and will need to be exchanged in order to achieve measurable benefits across the supply chain. Implementing change is never easy, particularly when it involves the complex set of interoperating parties that exists within the pharmaceutical supply chain. Reengineering internal or collaborative processes may upset the complex network of systems and trade agreements that enable today’s information exchange. Enabling the opportunities presented by sharing new types of information while minimizing the initial risks of error and incompatibility requires a standardized technology architecture that can be used by all stakeholders across the supply chain.

The following paper provides a point-of-view on the drivers and requirements for a new information framework that enables the secure sharing of real-time, item-level information. This paper will also outline the high-level components of an information framework to support greater security of the supply chain and allow it to become more demand driven. While there is no “one size fits all” list of benefits, we will explain some of the initial areas of value being identified by leaders across the pharmaceutical industry. Finally, this paper identifies next steps organizations can take to align with this future framework.

The Industry Information Framework

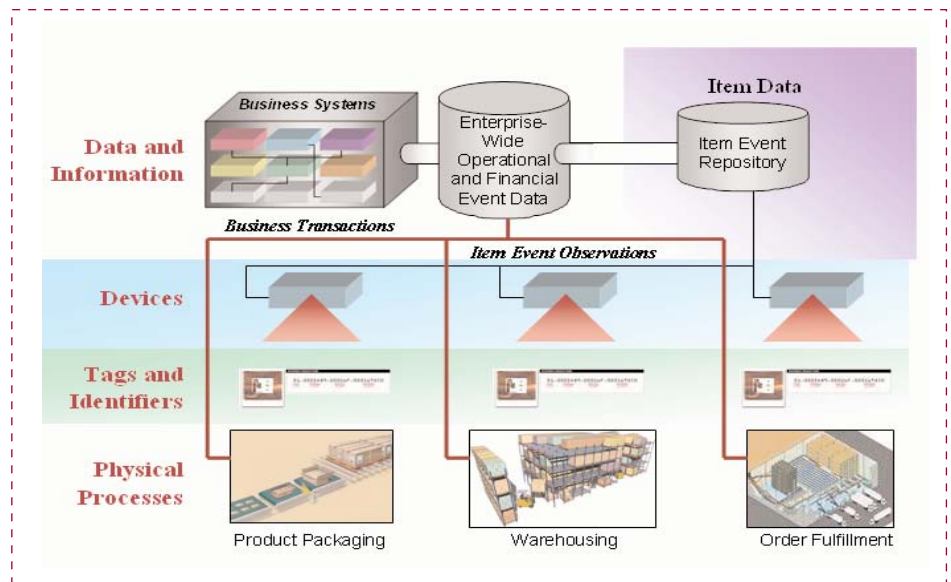
In order to robustly and reliably enhance patient safety and to become more demand driven, the pharmaceutical supply chain needs a ubiquitous technology framework that includes:

- Item-level data management
- Standards for what data is available and how it will be accessed and maintained;
- A data sharing infrastructure to accommodate cost efficient management and retrieval of data;
- A reliable trust environment to determine who can access information, if information provided can be certified as authentic, and what can be done with information provided or accessed

+ Item-level data management

Most enterprises in the pharmaceutical supply chain have the ability to manage integrated business information at a transactional level (orders, shipments, payments, etc), which provides visibility into operational and financial events. Item-level data can extend this visibility to provide rich insight into the physical movement of particular products involved in these transactions and also enhance visibility of end-user demand, contract compliance, and reverse logistics. Achieving this level of visibility requires unique identifiers in product labels or packaging. Technologies such as RFID or barcodes enable packages to carry a unique identifier, and when coupled with an infrastructure of readers, can generate data about the events related to products. Commonly, this data would be stored in an event repository; either a single central item event repository or a network of local event repositories across geographies or business units within an enterprise. Figure 1 shows a typical system with item level data management capabilities complementing operational and financial information.

Figure 1 - Typical System Architecture to Support Operational, Financial, and Item-Level Data



+ The Need for Standards

While item-level data management related to events within the enterprise may provide some incremental value, the potential for revolutionary value comes from the ability to link item-level data to events and observations outside the enterprise. In order to leverage item-level data across enterprises, standards are needed to ensure interoperability.

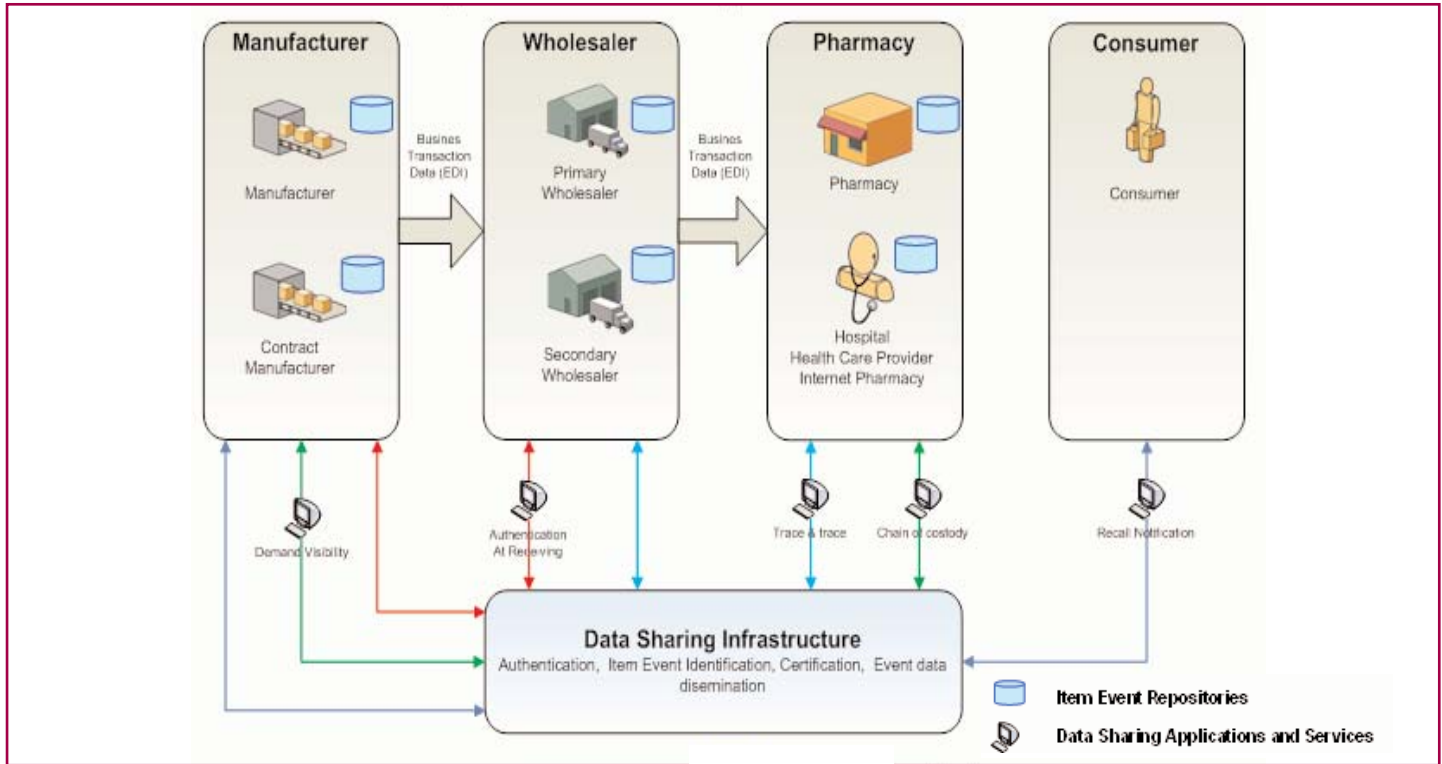
Much of the preliminary standards work for an item-level information framework has already started in organizations such as GS1 and EPCglobal. These organizations are developing and ratifying standards for how unique item identifiers are formatted, how item-level data is stored, and what technology will be used as the carrier for data on packages. While significant work has been accomplished, there are a few key areas of standards development that still need to be addressed in order to enable this framework. The question of how item-level data will be shared and made available outside of the typical two-party business relationship needs attention. This is very important in the pharmaceutical industry's multi-player, multi-tier supply chain. A second area of concern that the standards process has yet to define is how to protect the integrity of data when it is shared in multi-player, multi-tier supply chain (see the Trust Management section of this paper). As these standards processes continue, companies developing and deploying infrastructures for item-level data will need to keep their solutions flexible in order to ensure eventual interoperability with other systems.

+ Data sharing infrastructure

What is clear from early initiatives in item-level data sharing is that new types of data will be generated at unprecedented scale and will need to be exchanged in order to achieve measurable benefits across the supply chain. For example, assume that a manufacturer receives an order for five different products in the quantity of 1,000 for each product. If the manufacturer ships each of the products in an individual shipment and generates an ASN (advanced shipping notice), a total of five ASNs are shared with the customer. Now assume that for each product there may be information unique to particular items that could be used by subsequent owners of the product. In the current EDI model, that would mean 5,000 additional data sets that would need to be transmitted. Conventional systems for business-to-business communications were not designed to manage this volume of data, and therefore will need to be augmented for item-level data management.

A system architecture that allows owners of products to “pull” information about item level events and observations without costly forwarding and storage of large data sets would create significant cost savings to all players in the supply chain. This architecture requires open network services to which participants can publish item observation information, and then subscribe to certain levels of information access. This infrastructure is not a “database in the sky” but rather a directory infrastructure that establishes linkage between item-level event repositories throughout the supply chain. When data sharing needs to occur between multiple points and at multiple levels or tiers, this infrastructure will locate and identify event data, authorize and certify the event data and monitor and control the dissemination of event data based on the desires of the data's owner. Figure 2 is a conceptual diagram of how infrastructure can be set up to accommodate cost effective and efficient availability of item information. The diagram is based on the assumption that manufacturers, wholesalers, pharmacy chains and hospitals establish their own item level data management capabilities (similar to Figure 1).

Figure 2 - Item level data sharing infrastructure



+ Trust Environment

Information technology professionals within the pharmaceutical industry will likely challenge the notion of exposing data to anyone beyond their immediate trading partners. Similarly, companies accustomed to selling transactional data might be concerned about the impact of these data sharing infrastructures on existing business models. As we said in the introduction, implementing change is never easy. Vital to the success of any standardized platform for information sharing within any industry is the inherent trust in the system to protect proprietary, valuable information from misuse or unauthorized access. Thus, trust management (the process of maintaining user authentication, access control and data protection) is probably the most significant challenge to network-based data sharing in the pharmaceutical supply chain. Fortunately, the issue of conducting critical business over open networks (e.g., the Internet) is well established and understood. Every significant company in the world conducts some level of business online. Enabling this is a variety of existing, proven technologies that address common security challenges for conducting trusted online commerce and communication. These same technologies can be leveraged to address the needs and challenges the pharmaceutical industry faces in extending data sharing practices.

An enterprise's own item level data management infrastructure (tags and identifiers, devices, and item event repository) will be protected within its umbrella of security controls, procedures and policies. Each stakeholder within the supply chain needs a reliable, standards-based system to manage who can access what information, how that information can be used, and to certify information as authentic. Enterprises will define the level of authorization and certification necessary for other stakeholders to access information in their repositories and to update or use the information. In this way, all parties in the supply chain will be able to define what information they provide to whom and under what terms the information can be used within the context of the unique trading relationship.

The Value of the Industry Information Framework

A new framework for data exchange within the pharmaceutical supply chain will provide a basis for associating detailed information (chain of custody, authenticity, condition, location, pricing and contract terms, and adverse events) to a specific drug packaging units. The value of this framework will stem from cost saving and growth driving applications of the information, such as:

- Recovery or avoidance of lost productivity to track ambiguous chain of custody records (current pedigree model)
- Product recalls and product being classified as unsaleable due to condition excursions can be more focused thereby reducing costs
- Chargebacks and returned product can be precisely associated with original sales reducing disputed claims and associated administrative costs
- Products involved in theft can be quickly and specifically identified to authorities to aid in investigations and speed convictions.

Trading partners will know specifically what information is be available to them and in what format thereby reducing the cost and time associated with establishing data sharing between entities. Surpluses which drive up returns and unsaleables will be reduced, as will shortages that threaten patient health or drive up transportation costs. Disputes which cost administrative time, tie up working capital and strain relationships will also be minimized. All of these factors will reduce the cost of compliance with regulatory requirements and minimize the likelihood that:

- Drugs appear without a complete chain of custody
- Drugs leave the supply chain either through recalls, returns, destruction, dispensing, or theft and then reappear
- Drugs considered unsafe due to their exposure condition or expiry date remain in the supply chain

Aligning with the Framework

Individual enterprises within the pharmaceutical industry need to start developing plans to enhance their existing information management capabilities to include item-level data management. These plans should balance immediate project goals, evolving industry standards, and the longer-term needs and benefits of deploying a data sharing framework. Leading companies within the industry are already engaged in practical pilots encompassing each layer of item-level data management (tags and identifiers, devices, and an item event repository). Enterprises also need to work with their trading partners to understand the basic elements of trust to provide visibility cost effectively and with a minimal amount proprietary integration while protecting and enhance the economic value of strategic data.

VeriSign and the Pharmaceutical Supply Chain

At VeriSign, we have a wealth of experience deploying and managing what we call “intelligent infrastructure services,” the transformational systems and services that help industries usher in new levels of collaboration and operational efficiency. Every day, we process over 18 billion Internet interactions and provide the services that help over 3,000 enterprises and 500,000 Web sites to operate securely, reliably, and efficiently.

VeriSign has been an active participant in the ongoing evolution of the pharmaceutical supply chain. We are involved in the standards setting process around item-level data management as member of EPCglobal and its Healthcare and Life Sciences Business Action Group. We also provide the enabling infrastructure for EPCglobal Network, the Object Naming Service that links individual Electronic Product Codes (EPCs) to product information throughout the supply chain.

To help enterprises in the pharmaceutical supply chain prepare for the future, VeriSign offers practical and focused consulting services around item-level data management in preparation for future track and track and visibility requirements. VeriSign’s experienced supply chain consultants are available to help organizations formulate practical strategies in an uncertain world and to pilot those strategies both internally and with trading partners. VeriSign has worked with leading pharmaceutical manufacturers and all three of the major wholesalers. We also support data management for all major chain drug retailers through our POS data services. These organizations are leading the way in realizing the opportunities of the framework described in this paper.

To learn more about how VeriSign can help your company assess opportunities and next steps in developing strategies and deployment plans for item-level data management capabilities, visit us at www.verisign.com/supplychain.