A Digitally Savvy Approach to Recalls

A survey has shown that members of the industry, including manufacturers, distributors, and dispensers, are eager to enhance serialisation data analytics to ease the product recall process

David Greenberg at TraceLink

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Stakeholders within the pharmaceutical supply chain are becoming increasingly aware of the opportunities created by serialisation requirements, including how serialisation data can be leveraged to help digitally transform business processes, trade partner communication, and even patient-centric engagement opportunities.

As a result of being one of the most resource-intensive processes within the pharma supply chain, companies and regulatory bodies have begun evaluating innovative, digital approaches to managing the existing process of product recalls. The FDA is increasingly more vocal about product recalls, stating just recently that the agency's "ability to detect, track, and trace potential or known problems with products continues to improve as we implement new technologies across the agency and as companies implement their own technological advances throughout their supply chains."

Serialisation provides a standardised data model for creating unique, digital representations of physical products, which, in turn, creates the opportunity to revolutionise how unintended supply chain occurrences, such as product recalls, can be managed through more effective trade partner information exchange. This article will explore how, if equipped with serialisation data, digital recall solutions could optimise and transform recall administration for the pharma industry.

Today's paper-based, manual product recall notification process is slow and difficult to manage in an operationally efficient manner.

In 2018, 1,405 drug recalls were reported to the FDA, 104 of which were classified as Class 1 in nature (a classification that represents the most severe threat to patient safety) (1). When these recall events occur today, recall notifications are often communicated by the manufacturer via overnight letter to any and all potential partners (wholesale distributor, hospital, pharmacy, or physician) that may have received the affected product.

For the supply chain member that receives the letter, a manual process then ensues. If the product has been distributed by a wholesaler, they will often forward the recall on behalf of the manufacturer or repackager, alerting the pharmacy via email, fax, or mail indicating severity, National Drug Code/Lot, and instructions on how to respond. Downstream recipients often receive duplicate notifications from multiple sources, including the manufacturers, wholesalers, press releases, and the media. As a result, this process is typically inefficient, disrupts important operational workflow, and wastes valuable time and resources across the entire supply chain.

At the edges of the supply chain, pharmacies and hospitals are constantly receiving a high volume of recall notifications, including many for products they may never have ordered or received into inventory. For this reason, the problem is often most severe for these stakeholders who must wade through an ocean of paper notices to ensure that patient safety is preserved at the cost of valuable staff time spent investigating many false positive notices.

Better Visibility to Improve Recall Process Execution

According to responses from survey participants at FutureLink Chicago, US, attendees attributed manual processes as one of the most significant barriers to executing recalls efficiently. Of those responding to the survey, 57% indicated that manual processes were the root cause of delay and error within their operations. Given the patient

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safety implications involved with recalls, precisely identifying a recalled product was also on attendees' minds, with 39% of respondents indicating concern with quickly and accurately finding and placing specific products into quarantine.

Pharmacies and healthcare systems hope to use digital recall notifications in future to identify, locate, and remove affected products more quickly to better serve patients. In fact, 76% of those attending the event indicated that targeted lot level or serialised recall notifications were the greatest potential benefit of a digital recall solution.

Manufacturers, distributors, healthcare systems, and pharmacies are all anticipating that serialisation will drive significant supply chain transparency and a more unified industry standard approach to how product recalls are initiated, communicated, and resolved. For instance, serialised data from the manufacturer can help wholesale distributors associate the lot number to the serial numbers that have been distributed to their downstream partners, thereby enabling a more automated and precise recall communication process.

When asked what a practical long-term digital recall solution might entail, attendees were aspirational in their responses, hoping that serialisation data and analytics will provide the ability to target and prioritise recall notifications with greater precision than what is feasible today.

Targeting Drug Recalls

Currently, processing recalls is an incredibly labour- and resource-intensive process that rarely yields 100% recovery of affected product. Few manufacturers have direct, accurate insight into where their products travel within the supply chain and through which partners' hands they have passed. According to some estimates, it takes five hours on average to respond to one recall, with an associated labour and lost productivity cost of US $100 per hour. Every year, between 130-270 million person-hours are spent on recall processing and administration, which results in a multibillion dollar cost that the pharma industry must bear.

As new advances in digital solutions that leverage serialisation materialise in the coming years, the ability to deploy tools that can identify recalled drugs while preventing the unnecessary returns of unaffected products will become possible at scale. Manufacturers, wholesale distributors, and pharmacies will gain the ability to leverage these interoperable solutions as part of an integrated digital supply network that can enable data exchange between direct and indirect trade partners. Through this real-time digital recalls channel, companies will be armed with the ability to initiate, track, and resolve a recall, reduce 'alert' fatigue for pharmacies and hospitals, and dramatically increase patient safety.

References
1. Visit: https://datadashboard.fda.gov/ora/cd/recalls.htm

David Greenberg is the Director of TraceLink's US Healthcare Practice and is responsible for platform solutions designed to improve data connectivity between supply chain partners. David has over 15 years of hospital and healthcare supply chain experience with a focus on strategic vendor relations, inventory management, and value analysis. He has worked with a range of hospitals and health systems, implementing processes with the goal of improving workflow, reducing costs, and ensuring regulatory compliance. Recently, David was Director of Global Supply Chain at Partners In Health, where he led international sourcing of pharma products and inventory delivering products to six country sites in the Americas and Africa.