RESOURCES

How Digitalizing Recall Notices and Workflows Unlocks a More Efficient Drug Recall Process



Since 2012, the FDA has issued more than 15,000 drug recalls. And while getting these medications off shelves quickly is critical to ensuring patient safety, the reality is that executing a drug recall consumes a lot of time that could otherwise be devoted to serving patients and other pressing operational challenges.

The good news is that there is a better way of executing drug recalls. This article looks at why the drug recall process has traditionally been such a challenge for the industry to solve and how recent regulatory developments and a new solution from TraceLink pave the way for a revolutionary new approach.

The 3 obstacles slowing down the drug recall process

Recalls are a continuing operational challenge and ongoing patient risk that impacts both retail pharmacies, health systems, and their wholesale distributors and 3PLs. The problem comes down to three central issues:

1. **Receiving recall notices:** Pharmacies and their suppliers could receive recall notifications in a variety of formats: letters sent through the mail, calls over the phone, emails in their inbox, and more. They may also get recall notifications for product they didn’t purchase or receive the same recall notice

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multiple times from multiple sources. Nonetheless, each recall notice must be acted upon to ensure that the organization is not impacted by the recall.

2. **Finding recalled product:** The process of coordinating and executing recalls is also extremely complex and time consuming. Wholesale distributors, 3PLs, health systems, and retail pharmacies often struggle to determine whether the product they hold in inventory (or the product that may be in transit to them) is impacted by a recall. If they have received recalled product, identifying and locating where it's stored in inventory can also be difficult—recalled product was likely shipped alongside unaffected product, so it must be sorted through.
3. **Coordinating drug recalls:** Coordinating recalls across multiple sites tends to be a very hands-on activity, requiring constant outreach and communication to get status updates. This communication is necessary to ensure recalled product is retrieved as quickly as possible, but coordinating recall activity and submitting responses is incredibly time consuming. The lack of formal systems around communication and coordination also make it difficult to demonstrate recall process adherence.

All of this is further complicated by tight deadlines for patient contact, stringent reporting requirements to regulatory bodies and suppliers, and strict audit trail requirements to demonstrate adherence to recall procedures.

Digitalizing recall notices unlocks new efficiencies

TraceLink has devised a revolutionary new approach to managing drug recalls that addresses all three of those challenges.

TraceLink's Network Services team digitalizes recall incidents from their original source (for example, the FDA website) and transforms them into a structured digital representation. A single recall notification is then sent to each member of the Digital Recalls network when an alert created or updated, which cuts down the

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amount of time pharmacy teams need to spend sourcing recalls and entering this information into their systems.

Once recall notifications have been digitalized, they can be accessed via API by other critical enterprise systems. This enables life sciences and healthcare companies to begin streamlining recall workflows and activities. For example, recall coordinators can compare the EPCIS data of their received product to the recall notice. If they have recalled product in stock, they can leverage inventory and medication management systems to identify the exact location of the recalled product, speeding up product retrieval.

TraceLink's Digital Recalls solution also helps automate recall coordination across multiple locations. The solution will surface new recalls in a convenient user interface and dashboard, which serves as a central platform for communicating, coordinating, and monitoring recall activity across multiple sites. As product is retrieved, pharmacy staff can record and report their progress in this central platform, reducing the amount of communication required for status updates.

The TraceLink Digital Recalls solution provides wholesale distributors, 3PLs, health systems, and retail pharmacies with several core capabilities to transform the recalls process. This includes:

- **Digitalized Recall Notifications:** TraceLink converts FDA recall notices into an easy-to-understand digital format that can be ingested by other core systems via API.
- **Recall Response Orchestration:** Digital workflows coordinate responses across dispensing sites and approved supply chain stakeholders.
- **Real-Time Recall Management Tracking:** Monitor recall response status across multiple locations in real-time to ensure timely completion.
- **Digital Audit Trail:** Capture a complete audit trail of the recall process to support regulatory compliance by tracking adherence to response plans.
- **Recalled Product Identification:** Identify recalled products and impacted

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locations, streamlining the removal of recalled product from inventory and stopping further distribution of recalled product.

Want to see TraceLink Digital Recalls in action? This video gives you a quick overview of how it works.



The value of digitalizing and automating the recalls process

Digitalizing and automating the drug recall process with TraceLink doesn't just reduce the risk of recalled products reaching patients. It also helps life sciences and healthcare companies reclaim their time and resources, which can then be devoted to other critical tasks and challenges. Benefits gained by customers using TraceLink Digital Recalls include:

- **30% reduction in the amount of time required to initiate a product search:** A single repository of easily accessible digitalized recall notifications eliminates the need to enter recall notification into multiple systems manually. It also frees up staff from monitoring for new recalls.
- **40% reduction in the amount of administrative work required by recalls:** Workflow automation and collaboration tools drastically streamline core recall processes, including outreach for monitoring recall status across multiple sites and communicating the impact of a recall. They also capture all the steps in the recall process for auditing purposes.
- **35% reduction in time to locate recalled products:** Serialized product data and digitalized recall notifications make it easier to identify the exact inventory location of recalled product so it can be retrieved faster. It also ensures employees don't waste time searching for items that were never received or purchased.

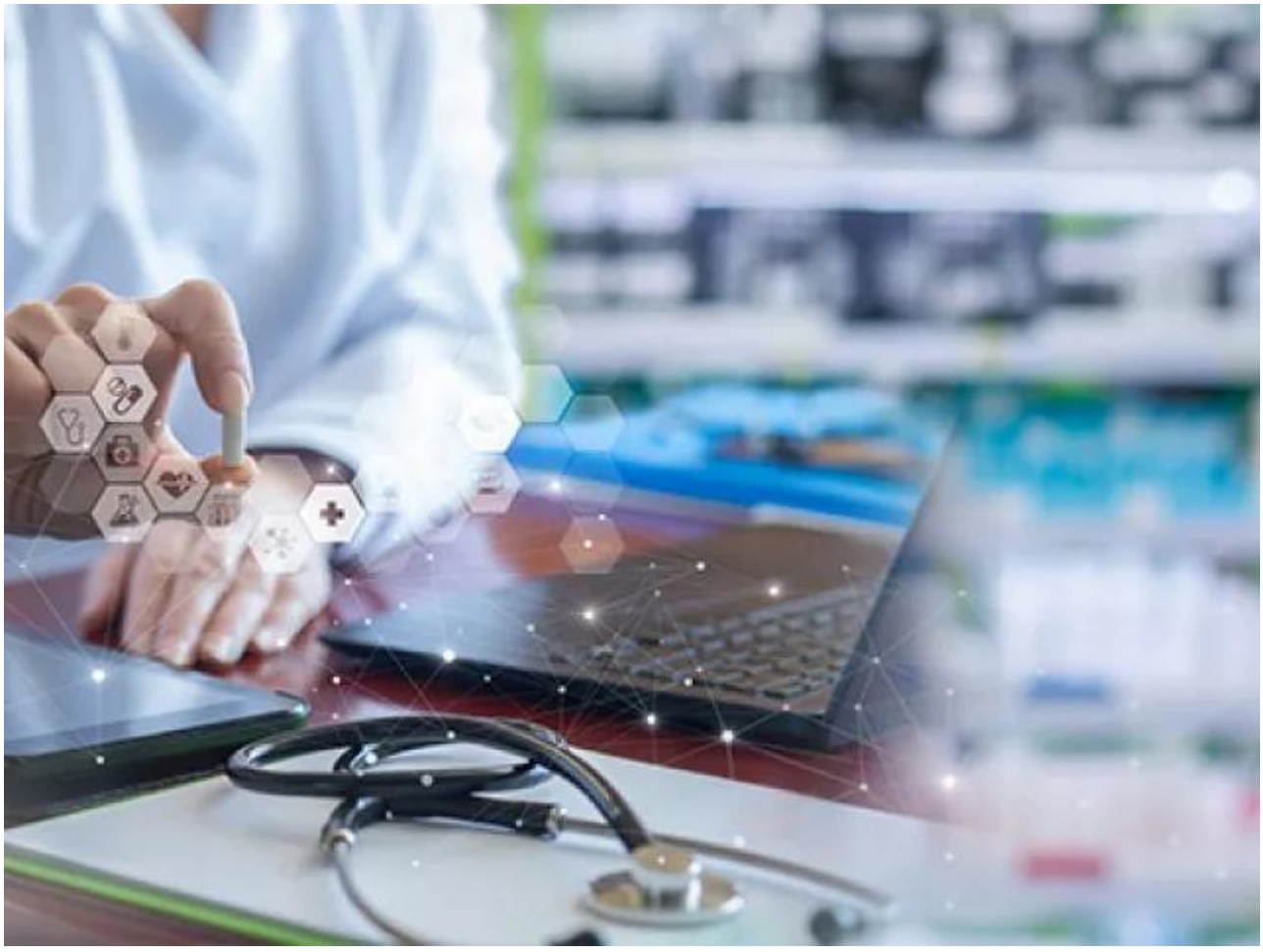
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You can learn more about our Digital Recalls solution at our upcoming webinar, **Enhance Pharmacy Inventory Management by Operationalizing DSCSA Compliance & Reverse Logistics**. You'll see how to operationalize your DSCSA data to simplify processes like product recalls, 340B inventory management, and more.

BlogTargeted Recalls
Contact TraceLink to see how you can take advantage of Digital Recalls!
Fill out the form to schedule a meeting.

Thank you for contacting us; we'll be in touch shortly.

Related Content



Streamline the Product Recall Process with TraceLink Digital Recalls

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Learn how TraceLink Digital Recalls can help your pharmacy staff reduce time spent coordinating administrative recall tasks by 40%, and reduce the number of shelf walks necessary to retrieve recalled products by 47%.

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TraceLink Unveils Game-Changing Digital Recalls Solution for Health Systems and Retail Pharmacies

In a groundbreaking effort to enhance patient safety and streamline a largely manual, paper-driven product recall process in Healthcare and Life Sciences, TraceLink is proud to introduce TraceLink Digital Recalls. This innovative solution offers health systems and retail pharmacies a new approach to receiving digitalized, structured product recall information and managing those recalls with unprecedented speed and efficiency.

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