

# Capturing and Distributing Recall Notifications Internally with Collaborative Workflow Enablement

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## Recalls are Unavoidable and Ever-Present

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- **100+ million** units of drugs are recalled annually in the United States
- There are **ten** new drug and medical device recalls on average **every day**
- A single recall can affect **millions** of people



# Supply Chain Segments have Unique Recalls Challenges and Perspectives

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Pharma

*“I spend millions of dollars for labor and outreach and still struggle to understand the impact.”*



Wholesalers

*“Time to clear inventory and put the message out downstream.”*

*“Will I be able to fulfill all my orders?”*



Retail pharmacies

*“Are my patients at risk?”*

*“Will I get all my orders?”*

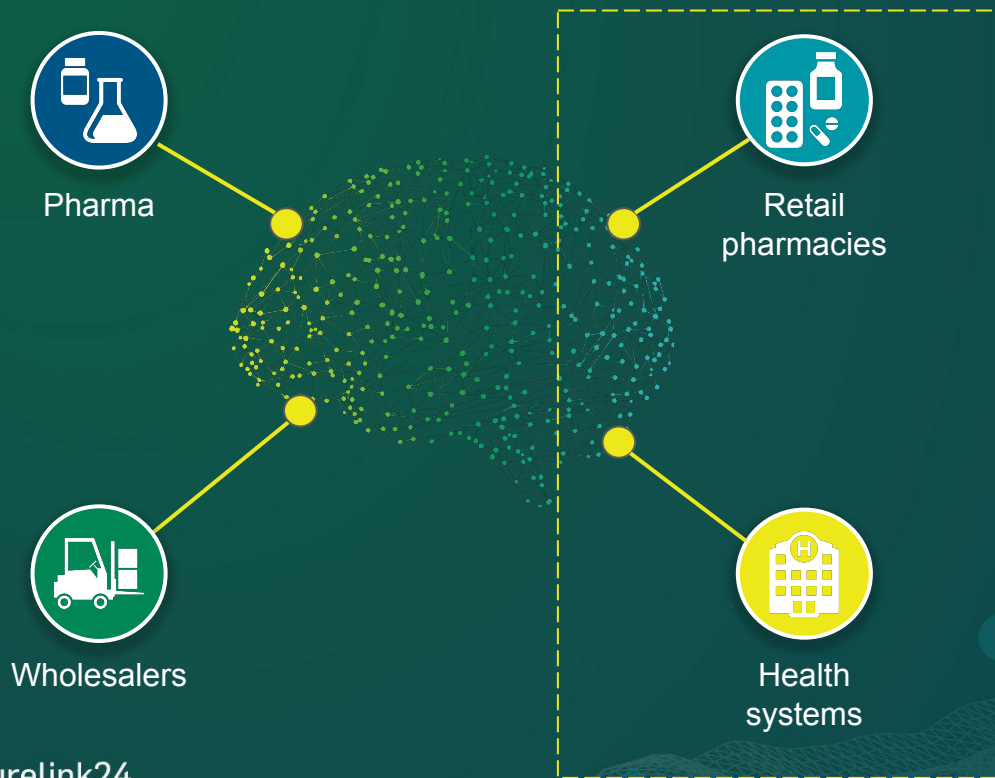
*“Are we affected by this recall at all?”*



Health systems



# What if We Had a Fully Integrated Recalls Network Today?



- ✓ Faster removal from supply chain
- ✓ Lower costs for all parties
- ✓ Better patient safety

# Getting Started at the Front Lines: Alleviating the Acute Challenges Faced by Hospitals and Retail Pharmacies

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Recalled drugs can reach patients and threaten their wellbeing



Organizations need standardized operating processes to maintain compliance



Recalls disrupt operations by creating work that warrants immediate attention



The process for receiving returned product credits is opaque



Recalls create drug shortage risks due to drugs being removed from the supply chain



Staff shortages limit resources and continually put pressure on operations

# Current Recall Management Processes Are Too Manual, Time-Consuming, and Labor-Intensive for Busy Pharmacy Staff



Overloaded recall backlog every single day



Vulnerability to notification delays



Manual response tracking to maintain compliance



Recall notices are still “analog” in nature!



Siloed communication between corporate and sites



Lack of visibility into monitoring recall response progress company-wide

**Company Announcement**

**FOR IMMEDIATE RELEASE – 3/29/2024** [redacted] is voluntarily recalling lot # AW0221A of [redacted] USP 750mg/5mL to the Consumer/User level, due to the potential *Bacillus cereus* contamination in the product found during stability testing at a 3rd party lab.

<https://www.fda.gov/safety/recalls-alerts/recalls-safety-alerts/aw0221a-is-voluntarily-recalling-lot-aw0221a-of-atovaquone-oral-suspension-csp75...> 16

5/24/24, 11:23 AM Aikare, LLC Issues Voluntary Nationwide Recall of Atovaquone Oral Suspension, USP 750 mg/5 mL Due to Potential *Bacillus...*

**Risk Statement:** In the population most at risk, immunocompromised population, there is a reasonable probability that microbial contamination of Atovaquone Oral Suspension can result in disseminated, life threatening infections such as endocarditis and necrotizing soft tissue infections. To date, [redacted] not received any reports of adverse events related to this recall.

[redacted] USP is indicated for prevention and treatment of *Pneumocystis jirovecii* pneumonia (PCP) in adults and children 13 years of age and older who cannot tolerate other medicines, such as trimethoprim-sulfamethoxazole.

[redacted] USP was distributed between 03/18/2024 through 03/21/2024 Nationwide to Wholesalers.

The product is packaged in a carton. The identified NDC # associated with the product is 50268-086-12, UPC # 5026808612 and the affected lot# is AW0221A with an expiration date of 08/2025.

[redacted] is notifying its distributors and wholesale customers by mailings and email communications method and is arranging for returns of all recalled [redacted]

Wholesalers who have [redacted] USP 750mg/5mL, which are being recalled, should examine their inventory and cease dispensing, return any of the impacted lots to [redacted]

# TraceLink Digitalizes “Paper” Recall Notices, Eliminating the Need for Human Interpretation

**Company Announcement**

**FOR IMMEDIATE RELEASE – 3/29/2024** [REDACTED] is voluntarily recalling lot # AW0221A of [REDACTED] USP 750mg/5mL to the Consumer/User level, due to the potential *Bacillus cereus* contamination in the product found during stability testing at a 3rd party lab.

<https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/avkare-llc-issues-voluntary-nationwide-recall-atovaquone-oral-suspension-usp-750mg-5ml-to-the-consumer-user-level-due-to-potential-bacillus-cereus-contamination-in-the-product-found-during-stability-testing-at-a-3rd-party-lab>

5/24/24, 11:23 AM AvKARE, LLC. Issues Voluntary Nationwide Recall of Atovaquone Oral Suspension, USP 750 mg/5 mL Due to Potential Bacillus ...

**Risk Statement:** In the population most at risk, immunocompromised population, there is a reasonable probability that microbial contamination of Atovaquone Oral Suspension can result in disseminated, life threatening infections such as endocarditis and necrotizing soft tissue infections. To date, [REDACTED] not received any reports of adverse events related to this recall.

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AVKARE, LLC.  
AvKARE, LLC.



Product description

NDC

Lot #

Expiration date



# TraceLink Maintains a Digital Recalls Repository Around the Clock





# Recalls Are Distributed and Acted Upon Within Pharmacy Locations, and the Data is Stored in a Digital Audit Trail

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## How it works:

- View the recall
- Walk the shelves
- Record quantity found
- Change log generated automatically

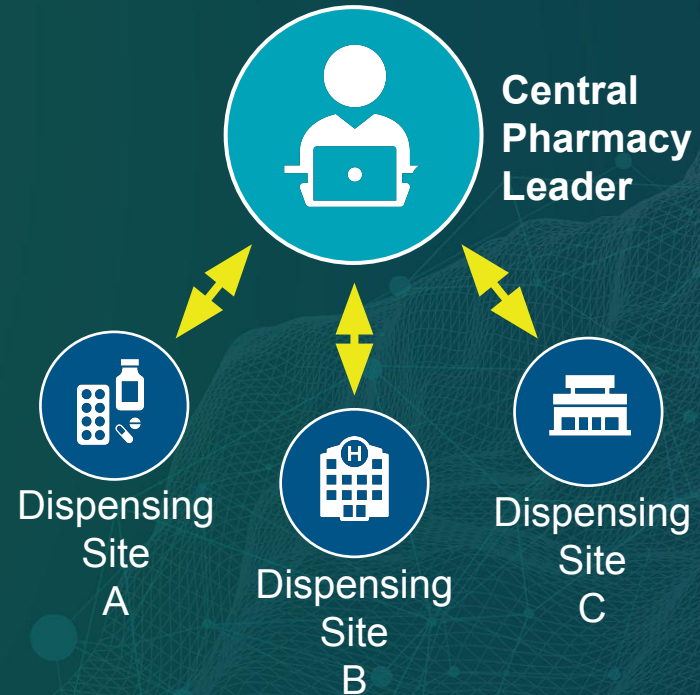
## Benefits:

- Eliminate manual recordkeeping
- Support regulatory compliance
- Clear responsibilities and ownership

# Pharmacy Leadership Has Visibility Across Sites and Can Collaborate via Built-In Communication Platform

## *Why is this important?*

- Stay informed of recall progress
- Follow up with the right people quickly
- Ensure standard operating processes are being adhered to



# TraceLink Provides Pharmacies a Recalls One-Stop Shop, Freeing Up Staff and Enhancing Patient Safety

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# Key Takeaways

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- We're building a holistic digital recalls network
- We're starting by serving health systems and retail pharmacies
- We've created a mechanism to digitalize recall notices
- We've built and launched a recalls one-stop shop... and we're still building!



A hand is shown from the bottom, holding a glowing, semi-transparent globe of the Earth. The globe is surrounded by a network of white lines and dots, representing a global communication or data network. The background is a blurred cityscape. The text "Thank You" is centered over the globe in a dark blue, bold font.

**Thank You**