

# Product Recall Management in Healthcare: An Essential Step to Improve Safety and Reduce Risk



WHITE PAPER

Healthcare supply chains are more critical than ever but also under more stress. Even before COVID-19, healthcare supply chains were typically struggling with their share of challenges. These include lack of integrated systems, high costs associated with technologies, and stressed resources that lead to increased risk, limited productivity and gaps in supporting the core mission of improving patient care and outcomes.



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When COVID-19 arrived, it exacerbated many of these challenges. As noted by Gartner, the pandemic ***“stressed many healthcare supply chains to the breaking point. Dramatic increase in usage of critical products, coupled with regional difficulties with manufacturing and logistics networks, left healthcare providers in difficult positions.”***<sup>1</sup>

Product recall management is a particularly critical stress point. Many legacy supply chains are ill-equipped to deal with recalls in a timely and comprehensive manner at a time when recalls are increasing and the consequences of mistakes or slow response can be dire.

Medical device recalls were up more than 30% in the second quarter of 2020 and were on pace to reach more than 1,200 total for the year, an increase of 35% versus 2019, according to the Sedgwick Recall Index.<sup>2</sup> While COVID-19 was a factor, Sedgwick cautions that there are additional significant recall-related developments not related to the pandemic. As noted, ***“Medical device companies arguably have the toughest road ahead when it comes to product safety and recalls.”***<sup>3</sup>

As clinicians and healthcare supply chain decision-makers know too well, product recalls can be a logistical nightmare—particularly if your organization still relies on manual processes and can’t act quickly and comprehensively using unified data from integrated applications.

This white paper discusses the importance of having a unified platform for healthcare supply chain and product recall management that provides a single view of the most timely, accurate data. It also explores how solutions such as Oracle Product Recall, part of Oracle Fusion Cloud Supply Chain Management, can modernize and streamline product recall management.

<sup>1</sup> “The Healthcare Supply Chain Top 25 for 2020,” Gartner, Nov. 11, 2020

<sup>2</sup> “Second Edition of the 2020 Recall Index,” Sedgwick Brand Protection, Q2, 2020

<sup>3</sup> Ibid.



## THE NEED TO TRACE AND RECALL PRODUCTS QUICKLY

When it comes to healthcare supply chains, every recall is mission-critical. The ability to respond quickly and accurately—making sure recalled products aren't used in critical situations—can be the difference between life and death. In fact, over a recent 10-year period, more than 80,000 deaths were attributed to issues related to the quality of medical devices.<sup>4</sup>

The product recall process in healthcare is complex, requiring a variety of steps to capture, locate and dispose of recalled products in a timely, accurate and provable manner. Failure to locate and properly dispose of all products could lead to dangerous situations where, for example, surgeons are putting recalled joint replacements into the bodies of their patients.

The evolution of digital healthcare supply chains has been largely organic, rather than strategic. Healthcare organizations have been using disparate systems for different functions—enterprise resource planning (ERP) systems for procurement and finance, with separate systems for inventory management, contracting and other processes.

Many critical applications were not designed to work in an integrated, unified manner and often use different methods for collecting, formatting and managing data. In addition, many legacy systems fail to take advantage of the speed, agility and elastic scalability of cloud computing as a means to unify disparate systems and provide a single, actionable view of the most accurate, timely data.

As a result, decision-makers often rely on manual processes, including notifications via hard-copy letters, phone calls or emails. Decisions are often made without the benefits of automation, intelligence and cloud agility, which, when used in combination, can enable quick, comprehensive, data-driven and accurate reactions to critical situations.

## WHAT YOU NEED IN A CLOUD SOLUTION

It's a challenge when the steps involved in managing product recalls are spread across different systems that lack consolidated real-time data. To overcome this challenge, product recall management requires a unified data model with cloud-connected electronic health record and ERP systems.

Systems and processes should also leverage automation and intelligence to keep up with rapidly changing regulations and deliver Quadruple Aim goals. As shown in the chart below, systems should span ERP, procurement, inventory management, logistics and more.



<sup>4</sup> "Medical Devices for Pain, Other Conditions Have Caused More Than 80,000 Deaths Since 2008," Associated Press, Nov. 25, 2018

## ORACLE PRODUCT RECALL MANAGEMENT

Oracle Product Recall Management has been designed from the ground up to meet the specific needs of supply chain and product recall decision-makers in the healthcare industry. The solution is included as part of Oracle Fusion Cloud Supply Chain Management, which connects healthcare supply chains with an integrated suite of cloud business applications.

Oracle Product Recall Management can automatically pull alerts from the FDA and other regulators into the ERP daily so organizations don't have to rely on notifications from hard-copy letters, phone calls or emails. Decision-makers can respond quickly, accurately and comprehensively to every aspect of the product recall cycle, from receiving the notice to closure.

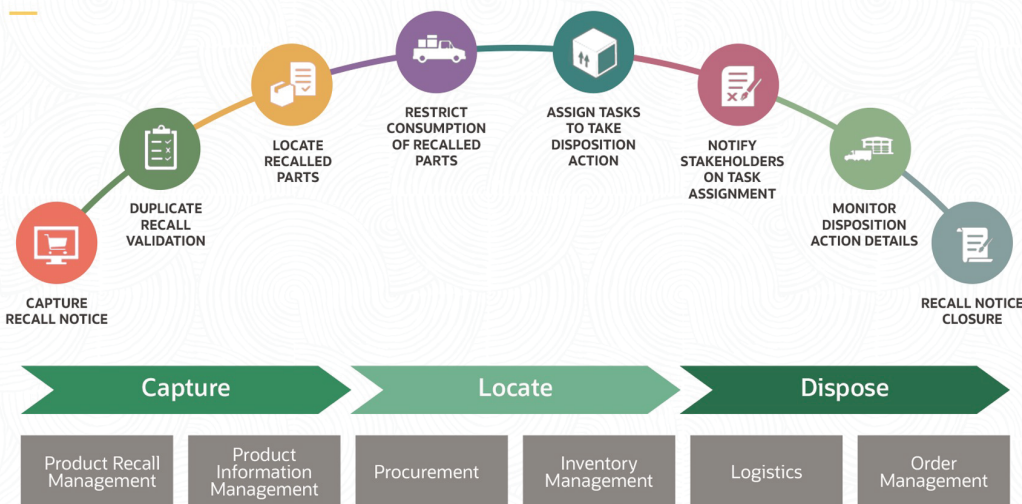
With Oracle Product Recall Management, healthcare organizations can:

**Manage recall notices:** Capture product recalls from multiple sources—including the type of recall classified by severity, recall reason, potential risk and recall instructions for replacement—and gather information on the manufacturer part along with the lot and serial numbers. This allows organizations to resolve duplicate recalls, view automated suggestions on potential duplications based on source reference number and manufacturer, and act upon automated prompts to take subsequent steps for the retained notice.

**Locate recalled parts and assign tasks:** Access a wide range of variables to find parts wherever they are located, preventing recalled items from being implanted into a patient or used in a clinical procedure. Once the goods are identified, Oracle generates a series of tasks, including pulling product from shelves, notifying clinicians and working with finance to balance the books. The system notifies all relevant stakeholders with details such as manufacturer part, lot and serial numbers, transaction reference and recall instructions.

**Monitor disposition details and closure of retail notice:** Perform a comprehensive recall count across all locations, even for parts identified in locations that are not traced; record items that are counted and physically quarantined; reference the recall notice and line number when performing returns; automatically update disposition details and complete disposition tasks; initiate the debit memo task on completion to notify the stakeholders; close the recall notice automatically when all tasks are completed; and enable the review of the task history and trace details for a closed recall notice at any given point in time.

### ORACLE PRODUCT RECALL MANAGEMENT



Oracle Fusion Cloud Supply Chain Management streamlines the entire recall process from capturing the recall notice to quarantining and disposing of recalled products. This results in higher levels of patient safety, lower costs and an improved clinical experience.

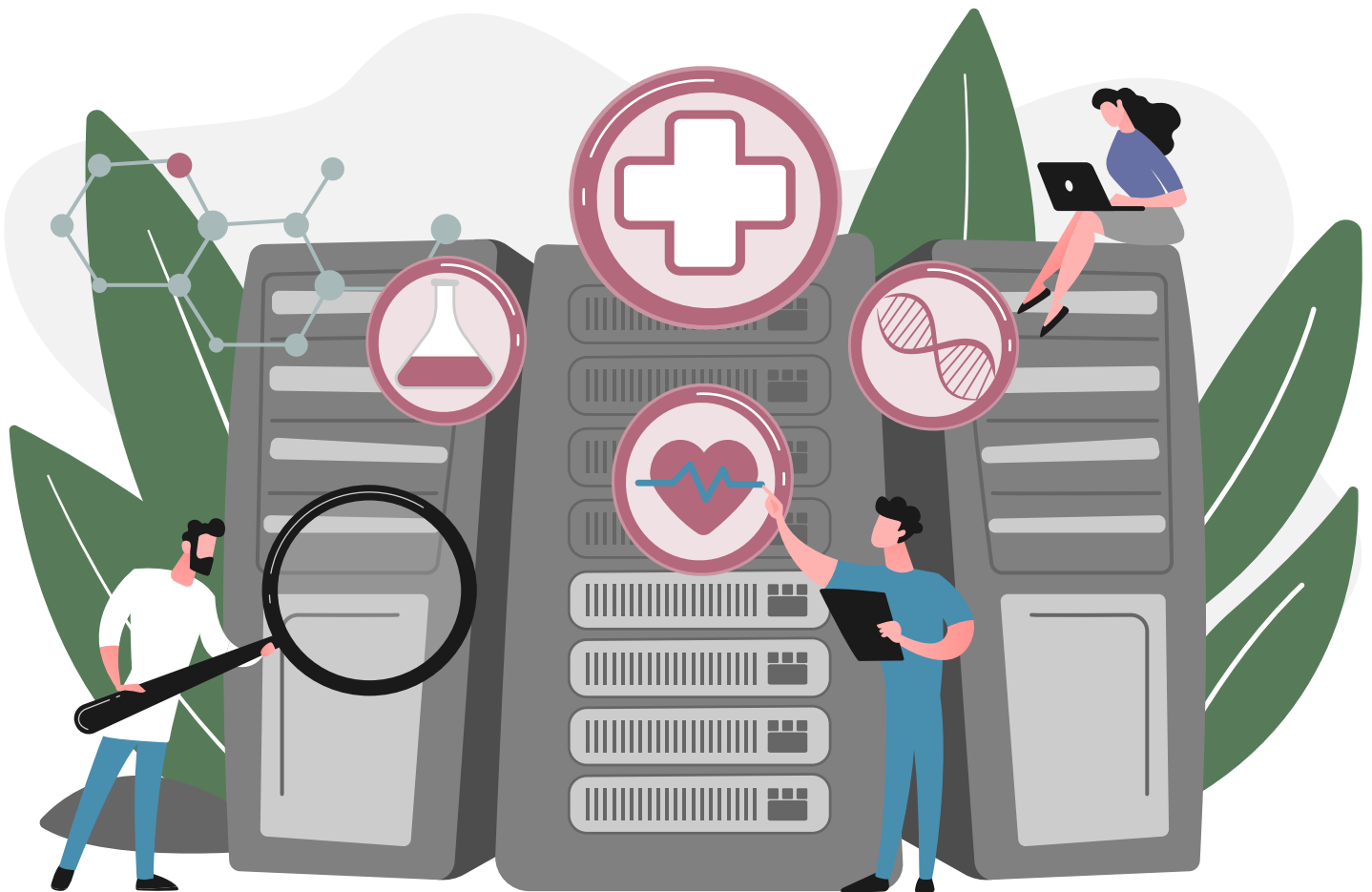
## TAKING THE NEXT STEP

In healthcare, it is essential that all aspects of product recall management are coordinated and unified so no mistakes can slip through potential gaps in the supply chain. Lives are at stake.

Existing disconnected manual systems are typically not up to the task in today's dynamic environment. They lack the speed, automation, integration and intelligence to react in real time based on a single version of the truth.

Oracle Product Recall Management is a unified cloud unified solution that meets the specific needs of healthcare supply chains, including Quadruple Aim imperatives and regulatory compliance.

**Learn how your healthcare organization can benefit from modernizing with Oracle Supply Chain Management Cloud.**



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### About Oracle

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