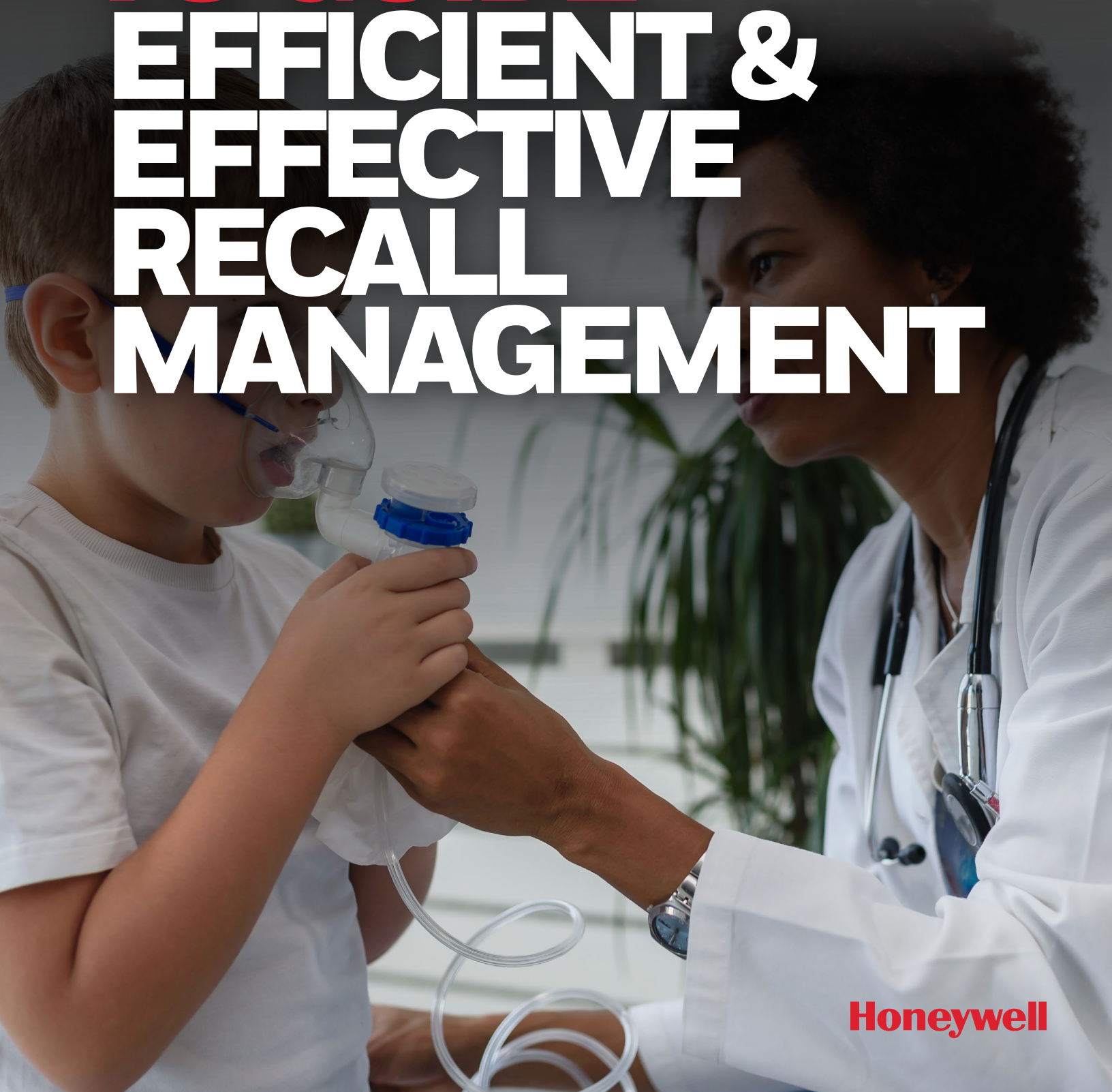


THREE KEY STRATEGIES TO GUIDE

EFFICIENT & EFFECTIVE RECALL MANAGEMENT



Honeywell

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INTRODUCTION

Over the past decade, the FDA has recalled more than 14,000 drugs, which averages almost four recalls per day¹.

Product recalls in the life sciences industry can significantly impact patient safety, regulatory compliance and brand reputation. Implementing effective recall strategies can help mitigate these risks and ensure a prompt and efficient resolution.

In today's fast-paced world, where precision and reliability are not just expected but demanded, a digital approach to recall management is more than just an operational choice. It is a strategic necessity for survival and success.

This guide examines three key strategies for effective recall management to assist life science companies in successfully navigating recalls:

- Comprehensive Recall Preparation
- Efficient Recall Execution
- Post-Recall Actions



STRATEGY 1: COMPREHENSIVE RECALL PREPARATION

FDA guidance on voluntary recalls emphasizes companies should be “recall ready” by establishing internal procedures, training personnel, and preparing for logistics.²



Companies must have well-defined recall procedures outlining responsibilities, communication channels and escalation protocols. However, more than documenting these processes is required; companies must be fully prepared for an actual recall event.

Advancements in technology now allow organizations to test their recall procedures in a simulated recall environment. Conducting periodic mock recalls enables companies to assess their procedures' effectiveness and identify areas for improvement. Preparation for a recall starts with identifying potential risks within the supply chain and manufacturing processes as well as post-market surveillance.

Companies must ensure suppliers and third-party vendors adhere to stringent quality standards to address supply chain vulnerabilities. Strict quality control measures should be implemented in manufacturing to identify defects early. Post-market surveillance is crucial for monitoring product performance and gathering feedback to detect issues promptly.

Establishing a recall management team is another critical step. This multidisciplinary team should include members from regulatory affairs, quality assurance, legal, public relations, and logistics. Each team member's roles and responsibilities should be clearly defined to ensure a coordinated response during a recall. Regular training and recall simulations are essential to maintain the team's readiness.

Developing a detailed recall plan is fundamental. This plan should outline procedures for various recall scenarios, detailing every step from detection to resolution.

KEY COMPONENTS OF THE RECALL PLAN INCLUDE:

- **Recall initiation procedures:**
Clearly define the triggers for initiating a recall.
- **Communication protocols:**
Establish both internal and external communication strategies.
- **Product retrieval processes:**
Create clear instructions for retrieving affected products from the market.

To help mitigate the risk of recalls, companies must implement proactive detection mechanisms capable of identifying potential issues before they escalate. This involves leveraging advanced analytics, data monitoring tools and real-time surveillance systems to scrutinize manufacturing processes, detect anomalies and flag potential quality deviations.

By embracing a proactive approach to quality assurance, companies can preemptively address issues with the goal of early detection to minimize the impact and scope of recalls.



Detailed Recall Plan

Establish well-defined procedures outlining responsibilities, communication channels and escalation protocols



Simulated Recall Environment

Conduct periodic mock recalls to assess the effectiveness of procedures, identify improvement areas and ensure readiness



Risk Assessment Tools

Evaluate where recalls might originate within the supply chain manufacturing process and post-market surveillance



Recall Management Team

Include regulatory affairs, quality assurance, legal, public relations, and logistics with defined roles and regular training

MINIMIZE THE
IMPACT AND SCOPE
OF RECALLS

STRATEGY 2: EFFICIENT RECALL EXECUTION

Between 2016 and 2019, an average of 99.33 million medical device units were recalled per quarter in the U.S., totaling 595.98 million units in just 18 months³.



The successful management of a product recall relies heavily on effective communication strategies. It is crucial to ensure that all stakeholders are well-informed and that there is consistent messaging and action internally and externally. This involves transparent communication with regulatory bodies, healthcare providers and the public. A comprehensive crisis communication plan is essential for managing media relations and responding to public inquiries.

Creating an accurate list of consignees—wholesalers, retailers, healthcare providers and end-users—can be burdensome due to complex supply chains and manual data collection. This list's review and approval process requires balancing efficiency and rigor, ensuring compliance without unnecessary delays. Notifying affected consignees traditionally involves resource-intensive methods like emails, letters and phone calls, especially when contacting healthcare providers individually. Additionally, regulatory reporting adds to the challenge.

Leveraging automated notification solutions streamlines communication, enhances recall execution efficiency, and protects public health.

Efficient logistics management is critical for swiftly and safely removing affected products from the market. This requires rapid execution of the recall plan and technology to track and trace affected products to ensure product traceability. Proper management of returned inventory is also crucial to prevent the re-entry of recalled products into the market.

It is vital to maintain compliance with regulatory requirements throughout the recall process. This involves promptly notifying relevant regulatory bodies and keeping detailed records of all recall related activities for regulatory review. In addition, conducting internal audits is essential for ensuring compliance with regulations and identifying areas for improvement. These communication strategies can help companies manage recalls more effectively and safeguard their brand reputation.

According to a McKinsey study, over the past decade, an average of one company per year has witnessed a 10% decline in share price following a significant quality event, such as a major product recall.⁴

Imagine what that statistic might look like given how quickly news of a product recall spreads, often amplified by social media and online forums. How a company handles a recall can significantly impact its reputation.

STRATEGY 3: POST-RECALL ACTIONS

A decade-plus review of drug recall trends from 2011 to 2023 reveals insights into the changing landscape of pharmaceutical recalls.⁵



Companies need to stay informed about these trends to enhance recall management strategies. Defective medical devices or pharmaceutical products can put patient safety at risk, leading to adverse reactions, injuries, or even fatalities. Traditional recall management is labor-intensive, often burdened by manual tasks,

disparate systems and a need for more standardization. Information related to recalls, corrections, and removals is scattered across various platforms, making it challenging to consolidate and analyze. In a recall, swift and efficient execution is critical to minimize patient/consumer impact and maintain brand reputation.

Automated systems play a pivotal role in this process, facilitating rapid stakeholder notification, efficient product retrieval, and effective dissemination of corrective actions. Moreover, automation ensures adherence to standardized procedures, promoting consistency and collaboration across the entire organization, ultimately leading to more efficient recall management execution.

ROOT CAUSE ANALYSIS

Conduct a thorough investigation to identify the underlying cause of the recall.

- **Data Collection:**
Gather data from all stages of the product lifecycle.
- **Analysis Techniques:**
Use root cause analysis methods like the 5 Whys or Fishbone Diagram.
- **Findings and Reporting:**
Document findings and report to regulatory bodies as required.

IMPLEMENTING CORRECTIVE AND PREVENTIVE ACTIONS

Develop and implement corrective actions to prevent recurrence based on the root cause analysis.

- **Process Improvements:**
Modify processes to address identified issues.
- **Employee Training:**
Provide additional training to employees on new procedures.
- **Technology Upgrades:**
Invest in technology to enhance quality control and traceability.

TRUST, BRAND IMAGE, AND STAKEHOLDER CONFIDENCE

Rebuilding trust, brand image and restoring confidence among stakeholders is crucial post-recall.

- **Transparent Communication:**
Keep stakeholders informed about corrective actions and improvements.
- **Marketing and PR Campaigns:**
Launch campaigns to rebuild brand reputation.
- **Continuous Improvement:**
Commit to ongoing improvements and preventive measures.

CONCLUSION: PRECISION IS PARAMOUNT

Precision is crucial in rebuilding credibility after a recall, which can devastate company operations and success.



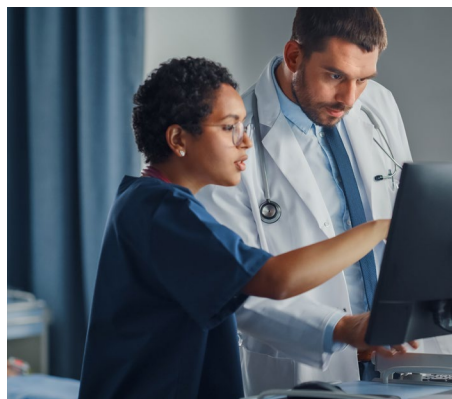
It requires extensive public relations efforts and transparency. The numerous ongoing tasks of recall management, from initiating the recall process, reporting to regulatory bodies and tracking effectiveness to conducting investigations and implementing corrective actions, can quickly spiral out of control.

In the life sciences industry, precision and reliability are non-negotiable. Indirect costs, such as market share reduction and damage to brand equity, can persist for years⁶. Proactive quality management is a necessity and a paramount strategy that must be woven throughout all facets of the recall management process. By fostering a

culture of continuous improvement and preparedness, implementing stringent quality control and detection measures, and investing in advanced technologies, companies set the bar for efficient recall management and truly put patient safety and commitment to quality at the forefront of their mission.



PREPARE



EXECUTE



ACT

An effective recall strategy is vital for life science companies to protect patient safety, comply with regulations, and maintain brand integrity. By focusing on comprehensive preparation, efficient execution, and thorough post-recall actions, companies can manage recalls effectively and emerge stronger.

¹ <https://www.pharmaceuticalprocessingworld.com/pharmaceutical-drug-recall-trends-2011-2023/>

² <https://www.lifescienceslegalupdate.com/2022/04/articles/product-liability/product-recalls/fda-finalizes-guidance-on-voluntary-recalls-issues-recommendations-for-industry/>

³ <https://www.statista.com/statistics/618239/quarterly-number-of-class-ii-medical-device-recalls/>

⁴ <https://www.statista.com/study/38527/pharmaceutical-and-medicaldevice-recalls-statista-dossier/>

⁵ <https://www.pharmaceuticalprocessingworld.com/pharmaceutical-drug-recall-trends-2011-2023/>

⁶ <https://www.spartasystems.com/resources/unveiling-the-hidden-costs-of-recalls-in-the-life-sciences-industry/>

For more information

To learn more, visit
www.spartasystems.com

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