



The Rising Cost of Product Recalls in Life Sciences:

WHAT'S DRIVING RISK AND HOW TO RESPOND





Product contamination and product recall risk are rising in both frequency and severity across the life sciences industry. Pharmaceutical, medical device, and biologics companies are operating in an increasingly complex environment where quality issues are identified more rapidly, regulatory oversight has intensified, and reputational damage can escalate quickly.

What was once viewed as an operational challenge has evolved into a strategic business risk for life sciences organizations. Recall exposure is no longer an isolated event, but an ongoing threat with the potential to impact earnings stability, disrupt growth strategies and erode investor confidence.

Key Takeaways

- Economic losses now far outweigh bodily injury losses, shifting risk from insurance recovery to balance-sheet resilience.
- Recall preparedness, not prevention alone, determines speed of recovery and long-term value protection.
- Supply chain and regulatory failures increasingly originate outside the organization, while accountability remains with the brand owner.

What Is Product Contamination Risk in Life Sciences?

A product contamination event occurs when a product is defective, contaminated, tampered with or deemed to be injurious by a regulatory authority. These events create a credible risk of injury, regulatory enforcement or reputational harm. Importantly, the definition extends beyond confirmed defects.

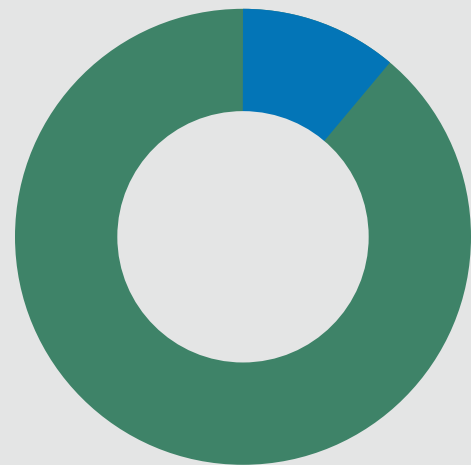
Perception, driven by regulatory announcements or media coverage, can trigger the same operational and financial consequences. In today's interconnected supply chains, a single contaminated component can result in widespread recalls across multiple products and organizations.

The Evolution of Risk

Recent data from the FDA and CDC indicate that consumable product-related losses arising from economic loss (product contamination and recall) versus actual bodily injury or property damage (general liability /product liability) are roughly 4:1 in size. This imbalance means traditional liability frameworks are increasingly misaligned with today's loss reality, leaving many organizations underprepared for the most financially damaging outcomes.

These losses often occur even when physical harm is limited. A contamination event does not need to injure patients to create a crisis. Instead, the financial impact is driven by product withdrawals, lost sales, contractual liabilities, and reputational damage that can take years to rebuild. This shift elevates product contamination risk from a technical concern to a core driver of enterprise value and financial performance.

Distribution of Life Science Product Recall Losses



80% Economic losses
(contamination, recall,
business interruption)

20% Bodily injury and
property damage losses
(general liability)





Why Product Recall Risk Is Increasing

Several structural shifts are driving higher recall frequency across the life sciences sector:

- **Advanced detection and traceability:** Improved testing capabilities allow regulators and manufacturers to identify product issues more quickly and with greater precision.
- **Increased regulatory oversight:** Regulatory bodies now have greater authority — and lower tolerance thresholds — for initiating recalls once risks are identified.
- **Greater supply chain complexity:** Global sourcing introduces additional points of failure, increasing the likelihood that a single issue can scale across multiple products.
- **Real-time information flow:** Digital media accelerates awareness, amplifying reputational risk and compressing response timelines.

Together, these dynamics are fundamentally changing how recall risk manifests and how quickly it escalates.

The Rising Cost of Product Recalls in Life Sciences

The financial impact of product recalls continues to climb, driven by both direct expenses and long-term business consequences. Whether an incident is an isolated event or a recurring issue, the financial impact can be devastating to a company's balance sheet.

■ Medical Device Recalls: The High-Volume Challenge

The medical device sector consistently leads product categories in total recall volume, with 978 recalls in 2025 involving 490.23 million units. Overall, there were fewer recall campaigns, but more units involved than in 2024. **The total impacted units in 2025 were the highest level recorded in the past four years and the second-highest total in the past 20 years.**

Device failure was the leading cause of recalls in 2025, followed by software issues and mislabeling. Device failure reached its highest level in the last 10 years. Recall events with a Class I severity designation reached a record-breaking level in 2025, with 136 (compared with 114 in 2024).

■ Pharmaceutical Recalls: Low Volume, High Unit Impact

While pharmaceutical recalls occur less frequently than medical device recalls, their scale and the volume of units affected can be immense. There were 362 pharmaceutical recalls in 2025 involving 99.73 million units. That is a **140% increase in the number of units impacted** compared to 2024. Failed specifications, cGMP deviations and sterility were the leading causes. In terms of units, contamination was the leading cause, affecting 25.41 million units. This marks a ten-year high for this risk.

Recall Volume by Sector

Annualized totals in 2025

978

Medical devices

362

Pharmaceuticals

Total recalls across five subsectors in 2025

3,295

(a 1.9% increase from 2024)



Understanding the Full Cost of a Recall

The true cost of a recall extends well beyond immediate expenses.

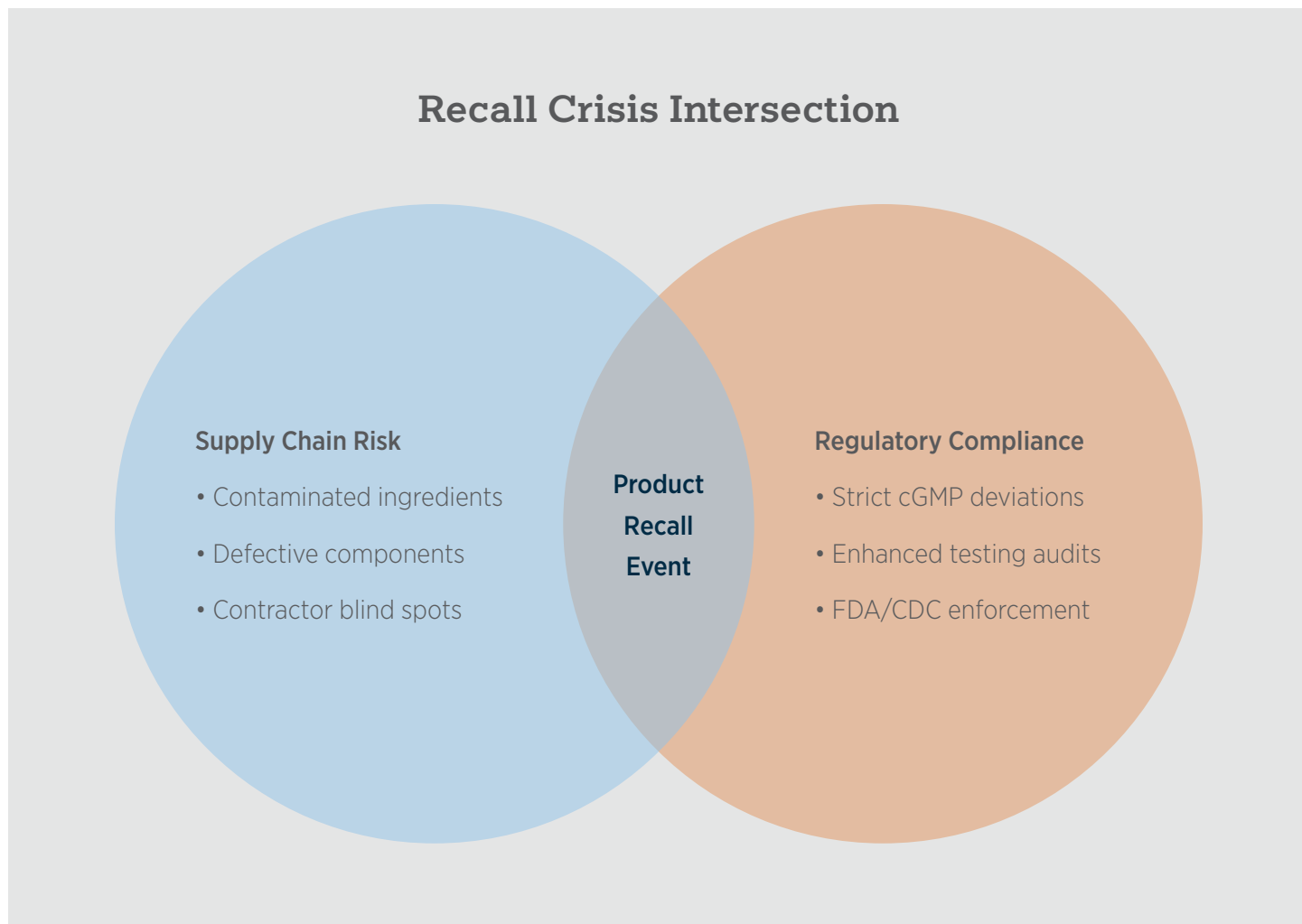
Direct Costs (Immediate, Tangible)	Indirect Costs (Long-Term, Enterprise)
Product retrieval: Transportation and logistics to pull items from distribution.	Stock price decline: Immediate and prolonged erosion of shareholder value.
Storage and destruction: Safe handling, material containment and certified disposal.	Brand damage: Deep erosion of market trust and hard-earned brand equity.
Replacement and rework: Manufacturing, repairing and distributing new inventory.	Lost sales and plant shutdowns: Lost revenue from customers switching or from forced plant closures.
Labor and testing: Employee overtime, customer support and laboratory defect analysis.	Operational disruptions: Delays in production schedules and postponed product launches.
Communication and compliance: Legal, regulatory filings and widespread customer notifications.	Reputation management: Prolonged public relations campaigns and crisis communication.

In many cases, indirect costs surpass direct financial losses, particularly when brand reputation and market confidence are affected.



The Intersection of Supply Chain Risk and Regulatory Compliance

Navigating modern risk requires balancing rigorous supply chain oversight with strict regulatory alignment. Product recalls frequently trace back to vulnerabilities at this exact intersection.



■ Supply Chain Vulnerabilities (CMOs and Sourcing)

Life sciences organizations are uniquely exposed to upstream risk. Whether utilizing a Contract Manufacturing Organization (CMO) or sourcing specialized active ingredients and components, errors in the early stages become embedded in the your final product. Under the law and regulatory guidelines, the brand owner remains responsible for the integrity of these components. If a supplier introduces a defect, your organization faces the full financial and operational burden of extracting that product from the market.

■ Regulatory Compliance Triggers (cGMP and Enforcement)

Government bodies now use tracking and traceability technologies that match the sophistication of industry laboratories. Compliance deviations, such as minor cGMP failures or a mislabeled bottle, are caught rapidly. When an agency like the FDA identifies a variance that creates a bona fide threat of injury, regulatory enforcement leaves no room for hesitation. Companies are directed to take immediate action, making regulatory alignment a matter of fundamental business survival.

Tailoring Product Recall Insurance

Every insurance underwriter defines a product contamination incident differently. Relying on standard, off-the-shelf policy language is a dangerous gamble during a crisis because boilerplate wording rarely anticipates the intricate operational realities of a biotechnology or pharmaceutical operation.

For instance, standard general liability policies written in the US almost universally exclude the economic loss or consequential damages you are legally obligated to pay commercial customers due to a defect you caused. If you manufacture products or components for other brands, a standard policy could leave you entirely exposed to their business interruption and brand rehabilitation costs.

A standard application alone will not clarify which endorsements, amendments or enhancements are necessary to secure your revenue stream. A truly resilient product contamination and recall program must be precision-tailored. The insured events, covered losses, and underlying conditions must be explicitly aligned with your manufacturing processes, supply chain dependencies, and corporate partnerships.

Prevention and Partnership

As recall costs continue to rise, life sciences leaders face increasing pressure to protect enterprise value, brand trust and patient safety. The most effective approach combines rigorous prevention with strategic risk transfer — ensuring the organization can withstand and recover from a recall without long-term financial or reputational damage.

Protecting your business requires dual investment in:

- Building robust quality control systems, rigorous testing protocols and meticulous validation standards.
- Designing a specialized product contamination and recall insurance program built specifically for the life sciences space, ensuring your brand, your balance sheet and your reputation remain secure if the unforeseen occurs.

When integrated, these measures help reduce both direct and indirect costs while preserving market confidence.

As your trusted advisor, we partner with executive teams to translate complex recall exposure into clear, defensible business decisions. Our precision-tailored product contamination and recall programs close critical coverage gaps and strengthen organizational resilience, turning recall preparedness into your strategic advantage





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