OCTAVE

WHITE PAPER

Supplier quality and the true cost of recalls in the pharmaceutical and medical device industries



As a company's supplier list grows, so does the looming risk of supplier quality failure. With even one recall able to decimate stock value and brand reputation, it's up to manufacturers to proactively manage supplier quality — or face the eventual consequences.



Brand value and industry reputation at risk

Hardly a day goes by when consumers don't hear about a new recall. Not all recalled products pose a threat to human health and safety, but many do:

- A sleep apnea face mask with a magnetic clip that could interfere with certain implanted medical devices.
- Children's sleepwear that fails to meet flammability standards and poses a risk of burn injury.
- A medical device with pieces that could separate during removal, causing the patient serious injury or death.

Recalls can be particularly harrowing for medical device and pharmaceutical companies, as their products directly impact patient health.

Beyond the health repercussions and monetary costs, which can total millions (or even billions), recalls also threaten a company's public perception and brand reputation. When a defect originates with a supplier many companies use, the ensuing recall can impact an entire industry. The result is an ever-growing recall, many negative headlines and eroding trust in the industry.

The lesson for manufacturers

No matter how well you think you manage quality in your organization, supplier quality is only as strong as your weakest link.

This paper examines how supplier quality risks are growing for manufacturers today, why suppliers are a critical part of the quality journey and what companies can do to strengthen every link in their supply chain.

> *"According to Harvard Business School, recall risks are unique for companies with extensive research and development (R&D) operations like medical devices and pharmaceutical manufacturers."*

Growing supply chains mean growing quality risks



Across a broad spectrum of industries, global supply chains are longer and more complex than ever. According to the U.S. Food and Drug Administration (FDA), 88 percent of U.S. drug ingredients and 63 percent of finished drugs come from overseas companies. It's not unusual for manufacturers to work with thousands or even tens of thousands of suppliers.

The result is a complex web that becomes difficult to untangle when reports of defects start rolling in, potentially leading to more (and more expensive) recalls. According to FDA statistics, over 15,000 drug recalls have occurred in the past ten years.

And it's not uncommon for a drug or medical device recall to cost a company millions — sometimes hundreds of millions. For example, Baxter International Inc. recalled thousands of faulty infusion pumps in 2010 and estimated total costs of $400 million to $600 million.

Although not every recall can be ascribed to poor supplier quality, there's no doubt that today's extended supply chains are driving quality risks to epic highs. And doubly so because supply chain visibility has not kept pace with the growth of global supplier networks.

Consider a 2021 Deloitte survey of more than 400 procurement officers showing that managing risk is a top priority for more than two-thirds (67 percent) of chief procurement officers, yet a mere 26 percent report that they could confidently predict risk in their supply base.

And only 24 percent say they moderately or fully use digital supplier relationship management tools that could help address the problem.

What happens when organizations combine a vast supplier landscape with poor visibility into suppliers and inefficient manual processes? For many companies, it's a ticking time bomb — it's not a question of if but when you'll encounter quality issues with one or more of your suppliers.

Recalls involve enormous costs for corrective action and legal expenses, and they also slow innovation by as much as six months. During that time, the researchers found competitors often increase their market share at the expense of the firm facing the recall.

Supplier management and the quality journey

Without question, suppliers play a key role in the evolution from reactive, manual processes to proactive, automated quality management systems (QMS). This progression takes place in four discrete stages within the Octave Reliance (formerly ETQ Reliance) maturity model.

- Supplier challenges in the early stages of this journey include:
- Difficulty enabling employees and managers to increase quality
- Inefficient collaboration on supplier corrective action requests (SCARs)
- Lack of visibility into supplier performance and risk
- Problems with how to prioritize and scope supplier audits
- Difficult and costly coordination of in-process changes
- Poor traceability of products throughout the supply chain

The negative impacts of these challenges are wide-ranging and difficult to overstate. Outdated manual processes leave opportunities for defects to slip through the cracks unnoticed until discovered by customers. The likelihood of recalls and brand damage is higher, and poor traceability leads to the withdrawal of more products than is truly necessary out of an abundance of caution.

However, recall costs are only part of the equation when looking at the total cost of poor supplier quality, which includes:

- Time and resources required for correcting defects
- Scrap and rework
- Warranty claim costs
- Production and change order delays
- Unplanned downtime
- Increased complaints and a shrinking customer base
- Damage to profitability and brand reputation

A hidden productivity drain that's hard to ignore

As companies progress along the quality journey, an automated QMS allows them to eliminate manual data entry, incorporate suppliers into their digital quality ecosystem, and use reporting to drive more effective action.

In the final stage of this maturity model, quality processes are harmonized enterprise-wide, delivering a competitive advantage by anticipating and responding to issues before they reach the customer. The result is better visibility into supplier performance, better collaboration with suppliers, and lower risk to the company.

What does this look like on a practical level?

- Updated supplier scorecards enable simplified benchmarking
- Automatic risk ranking promotes early detection of problems
- Compliance certificates housed in a central system
- Faster resolution of problems via centralized SCAR tracking
- More effective management and enforcement of supplier quality agreements



Creating a globally harmonized QMS

One of the world's leading biopharmaceutical companies, Novo Nordisk, has 35,000+ employees in 74 countries, with production spanning multiple global facilities. Initially, the company used a largely paper-based system for change management. This manual system was error-prone and inefficient, and it wasn't easy to standardize processes across their many locations.

Novo Nordisk decided to address these challenges with the help of an automated QMS solution — Octave Reliance. With Reliance, they could configure the system to meet their precise business needs. Reliance is now Novo Nordisk's single, global point of reference for all change management and quality assurance processes.

Results

- Increased business agility and ability to respond quickly to compliance-related events
- Reduced lead time and increased efficiency through the elimination of paper-based processes
- Better transparency and visibility into compliance data and trends



Automating supplier quality for operational excellence in the medical device and pharmaceutical industries

Data from EY shows that 61 percent of supply chain execs say increased supply chain visibility is a top priority, making automation a strategic imperative for companies wanting to continue to compete. According to Gartner, it's part of what's driving increased adoption of automated quality management system (QMS) software, a market that's growing 31 percent year over year.

Implementing an automated QMS is critical for companies whose business models are built upon a deep network of suppliers — quality problems — even when due to a supplier's mistake — will always reflect the brand itself. A QMS gives you quality controls and supply chain visibility to prevent costly recalls, protect patients from product defects, and preserve your brand reputation.



About Octave

Octave is a leader in enterprise software, turning data into decisive action and intelligence into your edge. Our software solves for and simplifies complexity, from the design and build to operations and protection of people, property and assets – for any scope, at any scale. For decades, we've partnered with customers to sharpen performance, elevate efficiency, and amplify results. From factory floors to entire cities, our solutions are tuned to scale up what's possible from day one onward.

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