etq Quality Creates.™

Automation for the Food & Beverage Industry

Are You Ready for FSMA 2020?

It's 3:00 a.m., and another sleepless night spent worrying about the latest product recall. This time, your quality team caught the problem before anyone got sick. Next time, you might not be so lucky. Your manual tracking system is just not up to the task of tracking all of your products to their sources, and even though no one got sick, each recall is costing the company millions in lost revenue, lost good will, and production downtime. You are tired of reacting and want to be able to predict and mitigate risks before they become public-facing.

Introduction

During 2018, in the United States alone, hundreds of CEOs in the food and beverage industry experienced such a sleepless night, many of them multiple times. The US Food and Drug Administration (FDA) recorded 1,935 food/beverage-related recalls, 84% which were Class I (meaning that it involved a serious health hazard).[1] The US Department of Agriculture (USDA) recorded an additional 125 recalls, 78% of which were Class I.[2] In addition, the Stericycle Recall Index shows that recalls due to bacterial contamination and unreported allergens are on the rise, with 44% of recalls in 2017 due to bacteria and 31% due to allergens.[3] Dr. Antony Potter, of the Queen's Centre for Assured and Traceable Foods in the UK, estimated that 56% of recalls in the US, UK, and Ireland were due to operational mistakes, and therefore, preventable.[4]

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Background

Quality in the food and beverage industry is under pressure on many fronts. Compliance challenges are becoming more complex, supply chains are longer, and operating in multiple geographies is growing more complicated. Meanwhile, instant communication, the prevalence of social media, increasing customer sophistication, and a truly global market mean that the negative impact of quality-related problems on food and beverage companies is exponentially greater than it was a decade ago. In an age where one major product recall can become news around the globe in minutes, the stakes for food and beverage companies can be existential. Forward-thinking companies that master quality and take control over their supply chain will have a competitive edge over those that lag behind.

In the United States, The Food Safety Modernization Act (FSMA) seeks to encourage a more proactive and predictive approach to food safety by overhauling the food safety system in the US to emphasize prevention and granting more enforcement authority to the FDA.[5]Though FSMA was enacted in 2011, the US Congress has given companies until 2020 to fully comply with the act because many government agencies needed to update their rules to accommodate the changes to the law. With the emphasis on prevention comes a concomitant emphasis on traceability, record-keeping, risk management, and supplier accountability. Today, global regulations require companies to comply with labeling requirements in both the country of origin and the country where the product is consumed. These requirements vary by region, which also increases the complexity of compliance.

Of course, most companies in this industry understand that quality and compliance are important, yet they may have only just begun their quality journey and are handling all their quality management needs with "paper" systems and email only. Such manual tracking limits traceability, transparency and creates silos of information and data on quality processes and outcomes — data that could be used to provide insight into opportunities for preventing issues before they become a public crisis.

Companies should never wait until that crisis comes to start automating their quality management systems (QMS). With the understanding that any failure is a threat to the corporate brand and reputation, and that recalls are vastly more expensive than the cost of good quality, food and beverage leaders can no longer afford to manage reactively with disconnected and manual system.

Recall Direct Cost Calculator

Researchers Moises Resende-Filho and Brian Burr developed a formula to put an actual monetary value estimate on the cost of product recall.

Price Of Recalled Product

+

Quantity Of Recalled Product

+

Notification Costs

+

Transportation Costs

=

Direct Cost Of Recall

Solution

As in many fields today, automation holds the key. By automating key quality management processes, a firm takes a major step in its quality journey. Initially, this step may be a launch into the world of automated QMS that allows a company to meet its compliance obligations under FSMA and other standards more efficiently while establishing an electronic order for critical document control and audit response. By automating workflows, document tracking, compliance tracking, HACCP, supply chain tracking, and other activities, companies can quickly gain control and insight into their quality ecosystem. Automation also enables predictive analysis, which allows a company to understand potential points of failure before they result in production stoppages, public embarrassment or other negative business consequences.

Ideally, as a company travels further along its quality journey and its QMS scales to meet new product requirements and new markets, it will incorporate more expansive and sophisticated quality processes such as nonconformance reporting and complaint handling. It may also choose to integrate its QMS with other mission critical enterprise systems like ERP, PLM, CRM, and BI packages as means of creating and integrated "quality hub" that can deliver a measurable business impact to the company.

As the company and its processes mature, it should consider using richer data analytics (beyond simple reporting) to encompass its entire supply chain. Doing so gives the company a more robust view of potential risks outside of its owned manufacturing facilities and provides an opportunity to improve supply chain efficiency and quality at scale. For companies at the most advanced level of the quality journey, the notion of maximum quality can fundamentally transform the culture and capabilities of an entire global organization and deliver compelling leverage to stay ahead of competition, introduce new and better products more quickly, and deliver positive financial results.

Now, achieving "quality bliss" like the above example is most definitely a journey and every organization takes that trip at its own pace. That said, with the market and regulatory pressures growing daily, the most import step in the journey is the first one. There is no good reason to wait until something terrible happens with your company and its products before embarking on the journey.

...uses its sophisticated QMS to automate its contract management process and has seen a 5,000% ROI

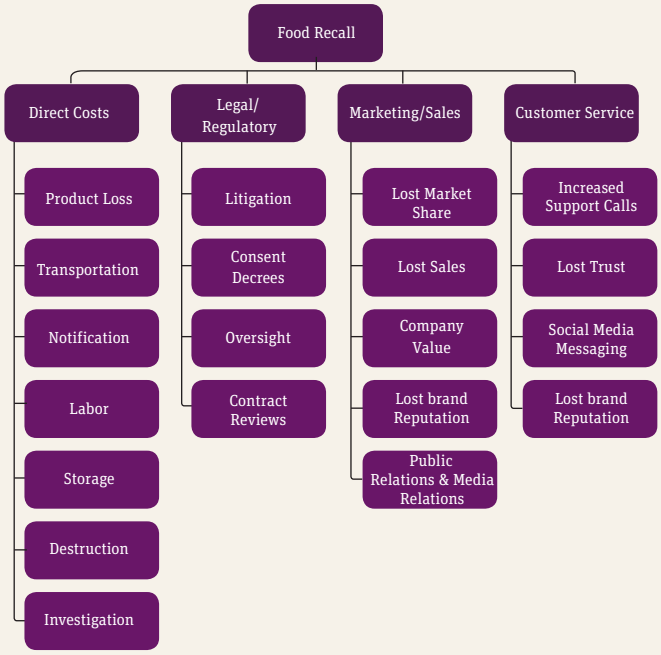
In the past, companies may have resisted automation because of the up-front cost and ramp-up time required. However, today's cloud-based systems are user-friendly and modular in nature so that even the smallest food and beverage company can get started quickly using "out of the box" best practices to gain a measure of quality process control. From there, the modular QMS can be rolled out in as many stages as needed to match the evolution of the company and its quality ecosystem over time. For example, a smaller manufacturer of duck products sought to improve and automate record-keeping and document control so that the company could become a Global Food Safety Initiative (GFSI)-certified facility. In this case, a phased deployment of a modular QMS allowed the company to take its first confident steps in the quality journey.[6] At the same time, a larger global provider uses its sophisticated QMS to automate its contract management process and has seen a 5,000% return on investment (ROI) thanks to the efficiency gains the QMS enables. Another national fast-food chain centralized and automated its vendor approval system, which allowed them to shave weeks off their vendor approval process and get new products to market faster.[7]

companies in the US are losing almost $200 billion US dollars per year due to recalls

When moving from a manual system to an automated QMS, companies should understand that there will be some upfront analysis and planning to do before the software is deployed. It is recommended that companies begin by looking closely at their own manufacturing environment and processes and identify areas of greatest risk and concern. While every customer installation is unique and carries its own challenges, there are some strong similarities for firms at the earliest stage of the quality journey. For example, the first step in a company's quality journey often involves building an automated quality system that handles document control and audit management. Not only does this help with data sharing and control but also makes audit response and reporting much easier than manual methods. In fact, these steps are often required to achieve industry certifications such as GFSI and FSMA certification.

Cost Factors in Product Recalls [8]

When calculating the cost of a recall, there are both direct and indirect costs associated with the recall, as shown below. Often, the less quantitative costs, such as loss of reputation are more costly long-term than the recall itself.



This emphasis by regulatory agencies and standards bodies makes sense when you consider that a single recall averages $10 million USD in direct costs alone (which doesn't take into consideration the more intangible costs of lost market share, time, and productivity, or the indirect costs of litigation, lost reputation, public health, and so on.)[9] The Grocery Manufacturers Association found that 5% of companies incurred over $100 million USD in direct and indirect costs for a single recall, and Locton (product recall insurers) "estimates that 80% of the total cost of a recall are incurred long after the recall has been dealt with."[10] When multiplied by the 1,935 FDA recalls last year, it means that, just in the US, companies are losing almost $200 billion USD per year due to recalls, most of which are preventable—a pretty compelling argument for automation.

Automated QMS enables food and beverage companies of all sizes to prevent recalls and other quality issues before they happen. Additionally, companies gain efficiencies across the organization that can result in faster time to market, lower risk, stronger brand reputation and increased profit margins. With QMS data that delivers a comprehensive view of the production environment, any organization can truly manage risk and create a quality of culture that serves as a business differentiator.

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