InfinityQS®

In-laws, Outlaws and Auditors

The guide to planning, executing and surviving the perilous business of audits

The Visitor: Remove the Element of Surprise

Much like the scheduled – or sometimes unscheduled – visits from your in-laws each year, industry audits instill a mixture of anxiety and stress for food and beverage manufacturers.

With a growing amount of food safety regulations, the probing questions and unsolicited advice are just the tip of the iceberg for most quality managers. Much of their time and energy is spent on the daunting task of preparing for an audit even while juggling the daily demands of food safety guidelines and compliance with regulations and industry standards.

During an audit, many manufacturers struggle to locate, compile and present requested data from a vast time frame within the allotted time constraints. It's enough to make even the calmest quality manager want to run for cover, but like your in-laws' visit, there's no escape.

The repercussions of failing an audit range from detrimental fines to extended suspensions. The added pressure of an audit is often compounded by the fear of being unable to produce the necessary documentation to prove compliance.

However, given the technological advances of today, these risks can be significantly reduced with the implementation of manufacturing intelligence software to house, maintain and manage quality and compliance data.

This paper will break down the audit preparation into three components: creating a plan for compliance, proving the plan works and controlling the impact when things go wrong. Additionally, this paper will detail how a technology solution can not only ensure compliance but also offer the added benefits of cost savings, reduced waste and improved overall product quality.

Creating a Plan for Compliance

To meet the demand for higher levels of food safety and farm-to-fork traceability, the first component necessary to achieve audit-readiness is to ensure compliance. While this step may seem obvious, given the intricacies of today's regulations and the $10 million[1] price tag of the average recall, maintaining compliance has become more difficult than ever.

The most notable, and likely intimidating part of the new food safety standards is the regulatory shift from responsive tactics to preventive measures. Like family visits where time invested up front in cleaning and prepping the house pays off, taking proactive measures does make a difference in meeting these requirements.

By having a plan for compliance, there's no last minute scrambling and panic to produce data and documentation. To facilitate preparedness, it's imperative that the proper checks and tests are accurately recorded and completed on time, every time.

Traditionally, compliance hinges on paperwork being available to the right people at the right time, while being up-to-date and bearing the right signatures from management. With so many variables at play, it's easy to see how relying on people and different departments to control all aspects of the system could lead to missing paperwork, inaccuracy and a lack of standardization. For companies undergoing an audit, these irregularities are what could detrimentally affect whether an audit is a pass or fail.

Another potential problem with the pieced together approach typically found is the lack of real-time visibility into production data which prevents operators from immediately correcting an issue before a large amount of bad product is produced, or worse, leaves the facility. Collecting data with pen and paper means a wait of days, weeks or months for accurate reports to find out whether processes ran correctly. Additionally, cumbersome and untimely reports don't allow your team to verify that proper procedures are being followed until it's too late, when bad or even dangerous practices have happened or become habitual.

1 "Recall Execution Effectiveness: Collaborative Approaches to Improving Consumer Safety and Confidence," Food Marketing Institute (FMI), Grocery Manufacturers Association (GMA), GS1 US, and Deloitte, May 2010.

A Welcome Permanent House Guest: The Quality Management System

Companies who have taken an enterprise approach to quality are more likely to have the tools and support to stay ahead of the myriad of rules and initiatives. A key technology capability to have in quality processes and audit preparedness is the creation and assignment of detailed workflows with precisely timed checks to ensure compliance.

The facility's specific hazard and prevention control plan creates the schedule of time-based check intervals for each variation of their products, processes or workstations. The reliance on automatic, software-driven prompts ensures operators collect the right data at the right time. These displays and countdown timers outline all the critical quality checks required at that time. Then, in the event of an audit, a report generated on these timed checks quickly demonstrates compliance; without such documentation, the manufacturer faces a laborious session of pulling paperwork to prove compliance.

Communication protocols should be considered when creating a plan for compliance as well as the use of technology as a communication enabler. For example, if a failure is detected or data collection is not completed, immediate notifications can be sent via email to management, and the operator may be required to specify Assignable Cause (AC) or Corrective Actions (CA) codes. In the event of an audit, these codes provide reasonable explanations for gaps in the records and increase your credibility. Additionally, the quality team could drill into any events with AC/CA codes to get a clearer picture of what is happening on your shop floor.

An enterprise system also brings the data collection points to where the measurement needs to happen and shows results in real-time. Now, at the point of data entry, operators would immediately know if a product or process is out of spec, out of control or noncompliant.

In-system tools like visual alerts or statistical control charts help them determine if corrective action is necessary. In more critical scenarios, such as metal detection in a food line, the line is immediately shut down and all product produced since the last passed test can easily be located and removed before it is packed up for delivery.

Identifying problems before an entire batch or lot is completed limits the shipment of affected product, and drastically reduces the need for recalls. Furthermore, because the data has already been entered into and stored in a centralized database, procedures for required verification and reporting can be developed with ease.

Accountability is often the most frustrating part of an audit because regardless of whether a company has been compliant, without proof, auditors have no choice but to cite a violation.

Proving the Plan Works

As discussed earlier, manual, paper-based quality and preventive control checks often result in missed checks or lost paperwork. In terms of accountability, manufacturers have difficulty proving whether or not the checks have actually been completed. If an auditor requests to review a three-shift time period and the QA team can only find the paperwork for two of the shifts, the repercussions can include hefty fines, increased inspection frequency, or even an indefinite suspension of operations.

Another benefit to a centralized enterprise quality system is the ability to easily access quality records and electronic documentation, or create auditor-requested reports in minutes, instead of having to provide cumbersome spreadsheets or file folders.

The system's reporting capabilities can easily pull together quality, preventive control and other data to tell the full story across days or deep dive into a single shift. Customized reports provide simple answers for auditor inquiries; for example, an exceptions report shows only those records, alarms, events, assignable causes and corrective actions that did not comply. These versatile options give a clear, side-by-side comparison of the facility's plan against checks for compliance and are more likely to result in a passed audit.

User-based records also ensure that the proper checks and tests are completed by the appropriate personnel at the correct times. The two-year record retention requirement is simply met with electronic records rather than physical papers stacked in filing cabinets throughout plant offices and storage rooms. No longer do quality managers need to search through mounds of paperwork looking for a needle in a haystack.

Controlling the Impact When Things Go Wrong

Just like your mother-in-law discovering that messy junk drawer, regardless of the precautions taken to uphold a manufacturer's high-quality standards, there can still be extenuating circumstances that allow a defective product to slip through.

In terms of an audit, it is crucial to accurately document all irregularities to ensure that all the proper steps were applied. With the number of recalls increasing fourfold in just five years and reaching an unsettling high, it is vital that manufacturers have a fast and efficient means to identify, trace and locate any problematic products. Today, companies utilize technology solutions not only to ensure consumer safety, but to protect their brand image as well.

For example, a manufacturer of pre-packaged dinners makes a spinach lasagna meal and its spinach supplier has discovered E. coli in the raw spinach. At this point, either a voluntary or mandatory recall is initiated, requiring all affected foods be pulled from the shelf.

Without the assistance of technology, the manufacturer would have to pull all of its spinach lasagna meals off the shelf that were produced within the potential infection period. This is the case even if only a small percentage of the meals contained spinach from the affected supplier.

The manufacturer, especially if it produces high-risk foods, may also be subject to an administrative detention of its products or suspension of its registration with the FDA, if it cannot produce the appropriate records to prove that its products are safe.

Manufacturers with enterprise quality systems, especially those with a centralized quality hub that brings all the data together in one place, gain traceability throughout their supply chains, making it easier to identify the exact products affected. The quality hub allows the creation of reports and visualization to quickly narrow the scope of what the affected products are and where they were distributed.

The ability to precisely track the affected spinach from the supplier is made possible through lot genealogy and by tagging products with production data (line, shift, operator) and supplier data (name, date, inspection). The manufacturer can quickly dispose of them before they ship or at the very least be more specific in which products to pull off of shelves.

Such farm-to-fork and boat-to-plate traceability directly supports the requirement for manufacturers to enhance their ability to track and trace both domestic and imported foods. Rather than waiting for product to arrive on your loading dock where you may or may not realize that there is a problem during spot checks, shared data with your suppliers and customers gives you visibility into production data so that you know product meets your specification before they arrive.

In the unlikely event that bad product made it into production and left the facility, utilizing lot genealogy data, manufacturers would be able to mitigate the amount of lost revenue by identifying and salvaging the products that were not part of the tainted batch.

Furthermore, the collected data would provide a governing body the information necessary to rapidly and effectively identify recipients of tainted food to prevent and control a foodborne illness outbreak. This built-in accountability protects the manufacturer from failed inspections, delays while waiting for new inventory and equally as important, a tarnished brand image.

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Technology in Action:

Fast Food Supplier Leans on Manufacturing Intelligence for Compliance

Leading global foodservice retailers depend on multiple suppliers to deliver high-quality ingredients for the creation of recognizable products that will be consumed by millions of people around the world each day.

To ensure the quality and consistency of these products, retail food service companies must demand that their suppliers adhere to a very specific set of quality requirements. In turn, these suppliers must implement an enterprise quality system to ensure that they meet the strict requirements handed down from their customers.

For example, one supplier, an innovative leader in the seafood industry, supplies fish filets to one of the most beloved fast food restaurants in the world. The fast food company is adamant about continuous improvement, electronic data collection and monitoring of the quality of the fish filet lines.

To meet its stringent requirements, the seafood company invested in Manufacturing Intelligence software. Powered by Statistical Process Control (SPC), the technology gives them extensive versatility as to the type of data they are able to leverage, such as pass/fail attribute data, checklists and analytical data. It provides the ability to automate data collection from the Programmable Logic Controller (PLC) for belt speed, temperatures and rejects. It also offers end-to-end visibility to identify opportunities for continuous improvement across operations.

Perhaps more importantly, the software is an enterprise quality system that keeps the company's data secure and offers the necessary features and reporting capabilities to ensure compliance with both the fast food restaurant's stringent guidelines and federal food safety regulations.

Full integration with the company's Manufacturing Execution System (MES) enables more accurate planning since work orders and lot numbers are immediately available with descriptor data pre-populated in data collection screens.

Deployment

The seafood company deployed the software and immediately converted all data and inspection paperwork for the fast food restaurant to electronic documentation in the quality database. Because of the high volume of complicated taste and texture checks, scores, indexes and calculations, real-time alerts and direct data input sped up documentation and resulted in fewer errors in the database. With this realization, the seafood company's quality team incorporated other checks that would improve manufacturing processes and lead to fewer defects and reduced waste.

The seafood manufacturer utilized the software's data collection and data management capabilities to automate data collection from PLCs and track downtime events. Full integration with the company's Manufacturing Execution System (MES) enables more accurate planning since work orders and lot numbers are immediately available with descriptor data pre-populated in data collection screens. Additional checks are completed with PCs, scales and solids analyzers on the lines, noting weights and defects information while production is in process.

To facilitate food safety checks, the seafood company employed mobile PCs that could be moved from one critical control point to the next, enabling data collection and entry directly into the system for allergen label testing, batter temping, metal detection and sanitation checks. Labs use either automated or manual data entry to add test results ranging from packaging label accuracy, bag counts per box, piece counts per bag, moisture, ingredient ratios, look, feel, taste and other attributes.

The software's extensive reporting capabilities can provide pre-made reports or custom reports can be created to the specifications of varying departments or initiatives. Operations and planning efforts focus on the efficiency of different production lines to identify opportunities to optimize processes, produce less waste and achieve Overall Equipment Efficiency (OEE). Engineering management is interested in downtime data to decide which equipment needs to be tuned or repaired and quality assurance teams use SPC and control charts to determine how capable a certain line is at producing a specific product.

Acceptance Sampling

To further extend quality assurance, the seafood manufacturer has incorporated the enterprise quality system into its acceptance sampling for its own suppliers. It receives a sample pallet from a supplier and conducts a number of tests over the course of several days including measuring the amount of water in a fish block, conducting a cook test to be sure the fish cooks properly, and carrying out smell tests.

In its labs, tests are conducted to check mercury levels and identify other potential contaminants. Once the sample of the lot is qualified, the manufacturer can choose to receive the entire lot. Results from these tests are entered into a Laboratory Information Management System (LIMS), which is also integrated into the quality system.

By pulling data from incoming inspections and in-production quality and quality checks into a centralized database, the seafood company is able to create an end-to-end view of quality assurance across its operations, identifying non-conforming variables to improve manufacturing processes.

Audit Readiness

Typically, when an audit occurs, it becomes an all-hands-on-deck situation where entire teams work for days to compile and share the necessary documents with an auditor. However, manufacturers are able to streamline this multifaceted process with the use of a technology solution.

In addition to automatically storing all quality and compliance data into a single database, pre-made reports based on reoccurring audit requirements are readily available. If additional documentation is requested, the seafood manufacturer's quality teams have the option to create reports, charts, and graphs as needed to represent exactly what the auditor requests in reference to planning, quality assurance and quality control.

Auditors are especially focused on exceptions or events that are not in compliance with regulations. Instead of scouring data to locate these exceptions, the seafood company uses technology that verifies that quality checks occur at required times and manages Standard Operating Procedures (SOP) for heightened process states.

The software is used to create an exceptions report that only includes the events that are not in compliance, such as sampling non-compliances, specification violations and control limit violations. The system is setup to require cause and corrective action data in a non-complying event before an operator or technician is able to proceed with other checks. If this step is not completed, an email is instantly sent to management to document and ultimately resolve the situation.

Results

Since making this approach a key component of its enterprise quality and continuous improvement efforts, the seafood manufacturer has seen:

- Significant time savings in data collection efforts
- Higher levels of product consistency
- Increased visibility across the entire supply chain
- Deeper understanding of manufacturing processes
- Continuous improvements using real-time data
- Ability to fine-tune settings to ensure optimal line performance in a changing environment
- Attention to certain KPIs such as downtime, non-complying products, parts and staffing
- Significant cost savings, especially in the reduction of waste

The overall success of the seafood company's quality efforts initiated the deployment of the same practices to its own retail production lines. The ability to maintain compliance with food regulations and its foodservice customer's high quality standards has resulted in an increased level of customer satisfaction and the permeation of its best practices and technology tools to additional suppliers for the same fast food customer.

Time Well Spent

While there may never be enough you can do to prepare for the next visit from your in-laws, the outlook for food and beverage manufacturers is much brighter. Not only will a centralized quality system reduce the stress and worry associated with audits, but the everyday benefits to your organization help your operations maintain compliance and run smoothly year round, to the tune of greater insights and accountability, higher cost savings and visibility into your supply chain.

About InfinityQS International, Inc.

InfinityQS is the global authority on Manufacturing Intelligence and real-time enterprise quality. The company's enterprise quality hub, ProFicient™, delivers real-time visibility on the shop floor, across the enterprise and throughout the supply chain, allowing top manufacturers to take control of quality. Powered by a centralized Statistical Process Control (SPC) analysis engine, ProFicient leverages Manufacturing Intelligence to help global manufacturers improve product quality, decrease costs, maintain compliance and make strategic, data-driven business decisions. Headquartered in Fairfax, Va., and founded in 1989, InfinityQS now serves more than 2,500 of the world's top manufacturers with over 40,000 active licenses globally.

For more information, visit www.infinityqs.com.