eBook

InfinityQS®
Quality Re-imagined

Nothing to Fear

Planning, Executing, & Surviving Audits

Remove Anxiety from Audits

Industry audits instill a mixture of anxiety and stress for manufacturers.

As the number of safety regulations grows, the probing questions and unsolicited advice are just the beginning 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 safety guidelines and compliance with regulations and industry standards.

During an audit, many manufacturers struggle to locate, compile, and present requested data covering 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 the black cat crossing your path, there's no escape.

The repercussions of failing an audit can 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 today's technological advances, these risks can be significantly reduced with the implementation of Quality Intelligence software to ensure compliance in the first place and make reporting easy.

On the following pages we break down the audit preparation into three components:

- Creating a plan for compliance
- Proving the plan works
- Controlling the impact when things go wrong

We'll also detail how a technology solution can ensure compliance while offering the added benefits of cost savings, reduced waste, and improved overall product quality.

Creating a Plan for Compliance

The first component necessary to achieve audit-readiness is to ensure compliance. While this step may seem obvious, maintaining compliance has become more difficult than ever.

The most notable part of new safety standards is the regulatory shift from responsive tactics to preventive measures. Taking proactive measures makes a difference in meeting these requirements. When you have 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 making paperwork available to the right people at the right time, ensuring it's up-to-date, and obtaining the right signatures from management. Relying on people across 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 can affect whether you pass or fail.

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Another potential problem is the lack of real-time visibility into production data that 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.

And cumbersome, 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 occurred or become habitual.

The Quality Management System

Companies that have taken an enterprise approach to quality are more likely to have the tools and support to stay ahead of the myriad 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. But there's so much more. *That's just the tip of the iceberg.*

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 that 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.

For 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 plant floor.

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

In-system tools like visual alerts or statistical control charts help operators determine whether 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. Because the data has already been entered and stored in a centralized database, procedures for required verification and reporting can be developed with ease.

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Proving the Plan Works

As mentioned earlier, manual, paper-based quality and preventive control checks often result in missed checks or lost paperwork. Manufacturers can have difficulty proving whether checks have actually been completed. If an auditor requests to review a three-shift time period and the QA team can find the paperwork for only two of the shifts, the repercussions can include hefty fines, increased inspection frequency, or even an indefinite suspension of operations.

A centralized enterprise quality system 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.

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

Controlling the Impact When Things Go Wrong

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.

With an audit, it is crucial to accurately document all irregularities to ensure that all the proper steps were applied. It is vital that manufacturers have a fast and efficient means to identify, trace, and locate any problematic products. Today, companies utilize technology solutions to ensure consumer safety and to protect their brand images.

Manufacturers with enterprise quality systems, especially those with a centralized data collection, gain traceability throughout their supply chains, making it easier to identify the exact products affected. The centralized data enables the creation of reports and visualization to quickly narrow the scope of affected products and where they were distributed.

The ability to precisely track a defective product 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 products before they ship and be precise about which products to pull off shelves.

Such traceability directly supports the requirement for manufacturers to enhance their ability to track and trace both domestic and imported products. 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 you know that your suppliers' products meet your specifications before they arrive.

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 bad products before things got out of hand. This built-in accountability protects the manufacturer from failed inspections, delays while waiting for new inventory, and—equally important—a tarnished brand image.

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Time Well Spent

The outlook for manufacturers is bright. A centralized quality system reduces the stress and worry associated with those sometimes scary audits. And your organization will enjoy everyday benefits that help your operations maintain compliance and run smoothly year-round, to the tune of greater insights and accountability, cost savings, and visibility into your supply chain.

About InfinityQS

In business for more than 30 years, InfinityQS is the leading provider of Statistical Process Control (SPC) software and services to manufacturers worldwide. Our solutions automate data collection and analysis during the manufacturing process, so you can make real-time process improvement decisions and prevent defects before they occur. Developed by industrial statisticians using proven methodologies for quality analysis and control, InfinityQS solutions are saving leading manufacturers millions of dollars each year.

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