

## ISO 22000 and Integrated Informatics: Business Best Practices to Meet Global Food Safety Regulatory Challenges

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In KPMG'S 2014 Food, Drink and Consumer Goods Industry Outlook Survey, 22 percent of the senior managers questioned said that "staying ahead of or navigating changes in the regulatory environment" would consume most of their time in the coming 12 months. Nearly 20 percent said that geographic expansion would be one of the primary areas of investment in the coming months. Taken together, these two data points echo a common food industry refrain: we want to expand internationally, but we're increasingly aware of the difficulties and costs of doing so from a regulatory standpoint.

Navigating regulations and requirements on a country-by-country basis is fraught with challenges: some countries are exceptionally strict and onerous while others are developing and the regulatory framework is far from mature. So what's the best path forward? While there's no single formula for success, one path forward for participants in the global food supply chain is to rely on accepted international standards such as ISO 22000 as best practices for their lab operations.

Derived from the ISO 9000 family of quality management systems, ISO 22000 incorporates principles from the Hazard Analysis and Critical Control Points (HACCP) methodology and other proven food safety systems. It is widely considered the gold standard globally for food safety monitoring. In fact, the US Food Safety Modernization Ac (FSMA) has modeled much of its recent requirements legislation around the ISO 22000 and HACCP guidelines. As such, ISO is an ideal starting point for companies like those in the KPMG survey that are eager to grow but that also fear "staying ahead" will consume too much of their time.

## **Data Management for Global Compliance**

While some food and beverage companies still rely on manual data capture in some parts of their laboratory operations, spreadsheets and manual data transcription will prove incapable of handling the large volume of data that must be discoverable and auditable for ISO 22000 compliance – or as evidence to any other regulatory authority, such as under the European Union Regulation (EC) No. 178/2002, or US FDA Food Safety Modernization Act. Only an enterprise-level integrated informatics solution can handle the volume of data required of the latest food safety regulations in a secure and defensible manner. Laboratory Information Management Systems (LIMS) have an established track record across food and beverage laboratories for helping manage HACCP and ISO 22000 process and compliance efforts in particular. This makes a LIMS an essential part of any food or beverage company that markets and sells its products around the world

With a LIMS managing workflow and process, and serving as the central source of data for all sample testing, from raw materials through to the final packaged product, food and beverage companies can be assured that the data will be defensible to regulatory authorities, management will have the data necessary to routinely reduce the risk of contamination or to effectively manage a food recall if that should prove necessary. Most important, the money invested in building the brand will be secured and the consuming public will continue to have confidence in the quality and safety of the food products being sold. The adherence to regulatory requirements is one very important part of the ongoing efforts to build and support a brand. If processes are not in place to capture non-conforming product before it reaches the public, then a recall is a very real possibility and one which is badly managed or widespread will have dramatic impact on the value of the brand and shareholder confidence. HACCP guidelines can introduce another layer of data management, with five critical steps in the process



(Hazard Evaluation, Defining Preventive Steps, Establishing Monitoring Controls, Maintaining Monitoring Records, and Specifying Corrective Actions) each adding their own level of complexity to the lab's data management challenges, but ultimately improving the consumer trust in the brand.

## **Enterprise-Level Integrated Informatics - Built-In Best Practices**

For food producers, the main benefit of using LIMS to manage ISO 22000 compliance is its ability to address compliance needs in multiple geographies – meaning both "everywhere in the world" and "at every step of a process." In the sense of "everywhere in the world," a standard ISO/LIMS strategy can be implemented in any country without sacrificing regulatory rigor or compliance. At the individual process level, "global" means that a LIMS collects and manages data over the entire life cycle of a food product, from incoming ingredient deliveries to finished product shipments (and all HACCP points in between).

No matter how many laboratories are involved in a company's manufacturing processes, or where in the world they may be, the LIMS is capable of managing the levels of relationship complexity and connectivity with multiple sites and manufacturing environments. Enterprise-level LIMS can build all the ISO 22000 and HACCP steps into their workflow structure so that adherence to these regulations are routine not only in the lab but across the entire organization.

## Conclusion

Regulations are increasing every day and in every region of the world now. With our global food culture, we want to experience what the world has to offer and it is imperative that no matter where we live, and no matter where our food comes from, we can be assured that our food is safe from contaminants or impurities of any kind. An enterprise-level integrated informatics solution makes this possible. In fact, choosing to comply with a standard as comprehensive as ISO 22000 is actually a smart decision for global players in the food industry. Following ISO 22000 and HACCP guidelines is a business best practice which guarantees that processes and quality parameters meet even the most onerous requirements. The LIMS eliminates burden by automating compliance and leaves only the benefits: increased efficiency, improved product safety and reduced, well managed recalls.