

The use of Laboratory Information Management Systems in the food sector

Colin Thurston considers the valuable role of Laboratory Information Management Systems in the dealing with food safety issues and regulatory compliance

Introduction

Over the last few years, food safety incidents in the USA have been increasing at a fast pace, generating strong public concerns about the safety of the foods they consume. Most recently, a Salmonella outbreak linked to peanut butter and products made with peanut paste sickened at least 529 people in 43 States, sent at least 116 people to the hospital and may have contributed to 8 deaths, according to the US Centers for Disease Control and Prevention. Related to this most recent food contamination incident, the US Food and Drug Administration (FDA) has recorded more than 2,100 products in 17 categories that have been voluntarily recalled by more than 200 companies, and the list continues to grow. The large number of products and brands that have been recalled as well as the large quantities of some of these products, makes this one of the largest food recalls ever in the USA. What was once considered the ubiquitous comfort food of children in many parts of the world is now suspect and the public is left wondering what is safe and what companies are trustworthy with regards to utilising the most stringent safety practices in the preparation of food items.

Regulatory framework

Historically, the management of food safety initiatives has been spread across numerous agencies worldwide. In the USA, for example, the various regulators' staffing for food inspections has been tragically low in light of

the volume required to manage safe agriculture processes, beef, poultry and pork processing, dairy and produce. For prepared foods, separate and non-aligned inspections by different agencies are required if a finished product contains meat or dairy or both. This lack of adequate manpower and the separation of responsibilities based on the type of food are only adding to the ineffectiveness of the regulatory agencies and causing further confusion and dismay amongst the consuming public. Perhaps a look at the regulatory set-up that exists in the USA and the European Union (EU) will illustrate just how complex the issue of food safety can be.

The US and EU regulatory systems

The US regulatory landscape makes a number of different government agencies responsible for various aspects of food safety: the FDA, USDA (US Dept of Agriculture), ATF (Bureau of Alcohol, Tobacco and Firearms) and EPA (Environmental Protection Agency) all have different regulatory accountability dependent upon the segment of the food supply chain.

For example, the FDA has responsibility for general food products and beverages, except for processed egg products, meat and poultry, fruits, vegetables and other plants which are under the remit of the USDA. Combination products (e.g. stew, pizza) may fall under either the FDA or USDA depending upon their make-up ingredients. All alcoholic beverages, except wine containing less than 7%

alcohol, are regulated by the ATF. The EPA determines the safety of pesticides and tolerance levels for pesticide residues in food.

These complex multi-agency responsibilities result in a public perception of a confused government attitude to the nation's food supply. Newly-elected President Obama recently declared that the current regulatory framework "... is a hazard to public health". It is widely expected that new legislation will be proposed to overhaul the US approach to consumer safety. In the mean time, the FDA has recently received \$300m in additional funding, of which half is to be used to increase the number of domestic and overseas inspectors.

The EU enforces regulations with the aim of achieving the highest possible level of protection of human and animal life and health, plant health and the environment. In addition, the regulations aim at achieving EU-wide free movement of human food and animal feed. Adopting a comprehensive, integrated "farm-to-table" approach, the regulations cover all aspects of the food production chain, with a single overarching framework. There are specific regulations applying to imported food that contains animal products, e.g. meat, meat pies, salami, poultry, fish, eggs, milk, dairy products, and honey. These products must be presented at a border inspection post accompanied by all the relevant certificates required in EU veterinary legislation. Less strict legislation is implemented for food that has no animal content such as fruit, vegetables, cereals, certain bakery products, herbs, spices, mineral water and fruit juices.



Food companies in developing nations have a general obligation to monitor the safety of products and production processes while the competent authority of the exporting country must guarantee the compliance or equivalence with EU requirements.

In general terms, food products must be tested to ensure conformance to specifications and product safety whether they are destined for human or animal consumption. Testing must address the complete spectrum of food safety issues, including veterinary drug residues, pesticides, natural toxins such as mycotoxins and marine biotoxins, pathogens, trace elements and chemical residues including environmental pollutants. Regulatory requirements are dictated by the location of the consumer, and therefore, complex testing requirements and specifications will inevitably exist where products are provided to multiple geographic markets. This complex backdrop of laboratory analysis means that Laboratory Information Management Systems (LIMS) are an essential tool for the management of laboratory results and therefore play a significant role in this process.

LIMS capabilities in food safety testing

For food producers, traceability through all stages of production, processing and distribution is critical in the effort to monitor quality, effectively manage recalls and limit product and revenue loss. A LIMS offers a secure environment for the management of batch relationships between raw materials, processed materials and packaged goods. A LIMS automatically captures sample data, checks for out-of-specification results and assembles data into a variety of report formats, thereby identifying contaminated products and suspending their release during investigation. The suspected product can then be isolated to examine any deviations. In that way, unfit products are prevented from reaching the public and even if they do, a much more effective recall and prevention programme is initiated, minimising associated costs and possible litigation.

A LIMS enables food safety laboratories to standardise and



Modern food analytical laboratory.

harmonise operations at all stages of food production from the farm to the table and from the production of raw materials to the packaging that delivers the product to the customer. The systems can collect, store, process and report on all the different types of data generated within food safety laboratories, including sample preparation data, instrument generated data, standards, reagents and media, reference data for users and management and metric reports. Laboratory automation is one of the most important benefits associated with the use of LIMS, eliminating transcription errors, data overlaps and lost man hours associated with conventional manual data management methods. By taking advantage of the automation that a LIMS delivers, reports can be generated with uniform formats, and certificates of inspection can be stored within the LIMS for traceability and re-issue whenever needed by regulatory agencies.

In addition, a LIMS can help laboratories achieve full compliance with even the strictest regulatory requirements. With a LIMS monitoring the testing of samples, a producer can be assured that the samples are handled correctly and processed within allowed timeframes. A LIMS will also monitor any established requirements for instrument calibration and replacement of parts, as well as the training qualifications for all users of the equipment or software, ensuring that only authorised users are performing testing and that all instrumentation is within specified settings. A LIMS can provide a producer with the knowledge that the quality of the product they are delivering meets the highest standards

set by legislation and regulatory authorities.

Sophisticated LIMS solutions are capable of integrating with instruments and other critical systems already in use within the laboratory, as well as with enterprise resource planning (ERP) systems in place throughout the organisation. By having a LIMS integrated with the existing ERP systems, management can make use of the data generated in the laboratory in a way that informs their day-to-day decision making. This type of integration is especially critical when a contamination has been identified and a recall has to be issued. As a result of integrating the LIMS with the organisation's ERP, test data are immediately available to plant process and control systems, making results instantly available to managers. This will enable more efficient tracking of the source of contamination, minimise the company's exposure to distributing contaminated product to the public and reduce the company's loss of revenue that will result if a recall is ordered.

Application examples Chr. Hansen

One of the largest food ingredient companies in the world, Chr. Hansen operates six culture production sites in Denmark, France, Germany and the USA. Following a considerable productivity boost, the company standardised on Thermo Scientific SampleManager LIMS™ across all of its six facilities to enable finest quality control in starter culture production. The system's central server has been installed in Denmark while an infonet connection has been established between the culture production

laboratories and the rest of the Chr. Hansen plants. In total, the LIMS is being used by more than 100 research scientists.

Since its implementation, SampleManager LIMS has allowed the company's scientists to automatically enter and process all test-related data, accelerating sample turnaround, producing real-time results and enhancing productivity. In addition, the LIMS has been able to seamlessly integrate with the company's ERP system, meaning that the test results are immediately available to all users once they are introduced and authorised in the LIMS. Identical product specifications and performance indicators are being used across all sites allowing for timely detection of global bottlenecks. Overall, this implementation has helped Chr. Hansen achieve its goal for optimum product quality.

Sino Analytica

Sino Analytica is a world-class contract analytical services provider, performing food testing as well as monitoring the entire food chain on behalf of a large number of food suppliers, trading companies and retailers from China and all over the world. Analysis of pesticide residues, drug residues, heavy metals, microbiological contaminants, colours, physical testing and formaldehyde release from wood composite products are just some of the many applications undertaken at the company's state-of-the-art facility. The company required a powerful system that would automate data management in the laboratory, coping with a monthly load of more than 1,200 samples while meeting the internal quality standards and accreditation requirements.

Following a strong recommendation by Central Science Laboratory, Sino Analytica chose Thermo Scientific Nautilus LIMS™. The LIMS has achieved a number of immediate benefits, including quicker assembly, collation and review of data used in QA/AC activities. Additionally, the system has facilitated increased dissemination and sharing of data, allowing for faster realisation of multiple user inputs and resulting

actions. Nautilus LIMS has been also able to support accreditation activities such as audit trails and traceability, demonstrating that the company meets the requirements of auditors and providing documentation for processing internal QC data.

Ingredia

Ingredia is a top European dairy ingredient processing company performing around 5,000 unique tests each week using 200 different analytical methods to evaluate product appearance, performance, texture and taste. In total, the company processes 100,000 tons of dairy ingredients each year. In order to control the laboratory testing procedures and achieve repeatable production levels, Ingredia implemented Thermo Scientific SampleManager LIMS™.

The LIMS has enabled Ingredia to monitor all products, samples and test results in the most accurate and timely manner. Data reports follow a format that satisfies the entire organisation, allowing for continuous, uninterrupted production. In addition, the company has benefited from the system's capability to apply appropriate test method definitions to each sample matrix received from customers. Integration of the LIMS with the existing ERP and other critical systems has ensured direct, real-time access to results. The secure, auditable environment of SampleManager LIMS has enabled regulatory compliance with GMP, NAMAS, EPA, FDA and GLP guidelines.

Conclusion

As a result of reoccurring food safety incidents, consumers are aware and concerned about the safety of their food. Food producers, suffering enormous loss of revenue and public confidence if their products are suspected of being unsafe, are likewise aware of their responsibility to ensure safe processes and to deliver food items safe from contamination. In response, legislative authorities have issued a number of regulations to ensure the safety of food manufactured, distributed, exported and imported in Europe and the USA. The aim of this legislation is the prevention

of outbreaks of foodborne disease and illness as well as appropriate intervention and response in the event they occur. Food manufacturers must ensure that operations throughout the supply chain are in compliance with industry regulations and standards. As a consequence, raw materials, packaging and finished product as well as environmental and process safety testing must be conducted on a regular basis.

Competent LIMS solutions ensure that test data from all parts of the delivery chain are captured and analysed so that the safety of consumers is guaranteed. A LIMS manages and controls the quality assurance process, organising and storing analytical data and converting this data into valuable information that can be used by management to make informed business decisions. Achieving complete automation of all laboratory operations, a LIMS provides food producers with the confidence that sample results are within regulated limits, while any failures will be highlighted to trigger follow up investigation and prevented from being distributed throughout the rest of the supply chain and ultimately to the consumer.

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