Food safety concerns drive LIMS and HACCP integration

Food safety continues to drive the US FDA, and equivalent international bodies, to tighten oversight. Food manufacturers should therefore plan to put the integrity of their HACCP and QC testing regimes at the heart of their business, using LIMS as the binding ingredient to drive food safety and quality.

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Food safety continues to be in the news following public outcry about the safety of certain foods. This is not new, as over the years there have been many food safety scandals brought to light. Contamination can occur at all stages of the supply chain and include physical, biological and chemical contamination.

Three well documented recent examples include:

● Blue Bell ice cream:
This product was recalled after five people became sick, three of whom died. Listeria infection was confirmed in the ice cream and traced back to the processing plant. Operations were halted, a root cause analysis undertaken, and the plant was deep cleaned, with some equipment requiring replacement.

The shutdown forced employee layoffs, and were severe enough to threaten the future of the company. Outside investment was accepted and a loan taken out for the business.

In 2020 Blue Bell Creameries was fined $19.35M, the largest ever paid in a food safety case, after pleading guilty to the outbreak. A hold-and-test procedure now stops ice cream shipping before tests are complete.

● Peter Pan peanut butter:
Salmonella was found in the peanut butter causing illness in over 400 people across 43 US states. A fine of $11.2M was paid after a guilty plea in 2016. The root cause was eventually traced to lack of enforcement of hygiene at the plant in Georgia.

● Cadbury chocolate:
Salmonella was found in product in 2006 causing a large product recall costing £20M. A leaking pipe in the plant was thought to be the most likely cause. In 2008 Cadbury was fined £1M for breaching safety laws over thresholds for salmonella. It now has a hold-and-test procedure in place to provide food safety assurance.

Contamination can invariably be traced back to weak QC control regimes. The learning point from these examples is that to eliminate risk food manufacturers need to closely monitor raw, intermediate and final products throughout the supply chain and manufacturing process and provide their QC staff with the technical competence, authority, and management support to enforce food safety standards.

A proficient QC laboratory

The best food testing laboratories follow ISO17025 procedures to ensure accurate testing to provide data that can be relied upon. Without effective data manufacturers risk compromised product quality and regulatory non-compliance.

A Laboratory Information Management System (LIMS) enables food manufacturers to meet regulatory requirements and ensure consumer confidence in their products. Apart from managing sampling and test data, creating certificates of analysis, and providing essential management information, a LIMS provides a framework for enforcing and confirming good laboratory and manufacturing practice.

The latest version of ISO17025 (ISO17025:2017) puts more emphasis on a risk-based approach to laboratory management and an increased focus on the laboratory information management systems in use. The FDA has also issued a notice that by February 2022 food testing, in certain circumstances, must be conducted in compliance with ISO 17025.

This means that food QC laboratories will need to implement processes to achieve and maintain compliance with the standard, confirming the competence, impartiality and consistent operation of the laboratory. Food manufacturers therefore have a renewed

Matrix Gemini LIMS Environmental module drives food safety.

incentive to put QC labs at the heart of their food business, giving them the resources to enforce a safety-first culture.

Matrix Gemini LIMS is built to comply with ISO 17025. Key elements include traceability of data, automated capture of results from instruments, validation of results, instrument and calibration maintenance management, and staff competency. Functionality to help organisations achieve ISO17025 accreditation are part of the LIMS which also simplifies data management and data reporting.

Two halves to food testing

There are two components to food safety testing. As you would expect food QC laboratories should be testing samples from the raw materials, intermediate and finished goods both within the manufacturing plant and in the supply chain. Ensuring a safe product is obviously the key function of such a laboratory. Each batch of product can have a certificate of analysis providing assurance as to its quality and safety. In addition, it must be possible to track the constituent ingredients of a batch.

However, ensuring the cleanliness of the manufacturing plant is also an essential element of food safety. Swabs and samples are typically taken from throughout the plant to monitor potential contamination.

The well-established Hazard Analysis and Critical Control Points (HACCP) principles codify a risk-based methodology to identify, evaluate and address all risks associated with food safety.

HACCP consists of seven steps:

● **Conduct a hazard analysis:**
Ensure food safety risks are thoroughly assessed using current and previous data.

● **Determine the critical control points (CCPs):**
Log each CCP into LIMS with enough detail to locate it in future (diagram, photograph etc).

● **Establish critical limits:**
Set the test specifications to be performed for each CCP and the analytical limits in LIMS.

● **Establish monitoring procedures:**
Define the sampling schedules of the CCPs in the LIMS.

● **Establish corrective actions:**
Establish robust corrective and preventative action (CAPA) procedures to ensure traceability.

● **Establish record-keeping and documentation procedures:**
Using a LIMS all data, user interaction, instrument calibration and test results are kept secure in case later inspection is needed.

● **Establish verification procedures:**
A LIMS ensures repeatable procedures for each CCP which should be regularly reviewed and improved..

The Environmental module within Autoscribe's Matrix Gemini LIMS is designed specifically to support HACCP. The HACCP control points can be defined on an outline plan of the manufacturing plant. Pre-defined sample tests along with their limits and their sampling frequency are also defined. A list of CCPs is produced as required enabling the technician to collect the samples from the correct locations and at the correct time for analysis. Analytical results are mapped back onto the plan of the manufacturing plant. These may be graphically compared to previous results from the same CCP to quickly identify trends. Out of specification results can be logged into the integrated Corrective Action Preventive Action (CAPA) management system for further investigation.

Across several large sites food manufacturers can generate thousands of data points per day from HACCP sampling. Using LIMS to manage that data links the field sampling and laboratory results and puts all the data in one place, enabling instant recall of data months or even years later.

Using LIMS to demonstrate compliance

Results from the quality control (QC) samples and environmental (HACCP) monitoring can be associated with the final product so that investigations can track back through the data to find the root cause of any issues identified. The process of trending results from QC and HACCP testing is designed to warn personnel of concerns before they become critical.

If limits are breached then manufacturing lines need to be stopped for deep cleaning, or product recalls are needed. These actions are far more costly to the business in terms of lost revenue and brand reputation, than the cost of implementing an effective HACCP protocol supported by the implementation of a LIMS.

Matrix Gemini LIMS is designed to enable food manufacturers to meet the compliance requirements of ISO17025 and support HACCP testing, providing traceability from individual batches of raw materials all the way through to the finished product. A LIMS offers laboratories an integrated workflow, automated procedures, and electronic record-keeping, making the whole process more efficient and productive.

Food testing laboratories that adopt a LIMS for ISO17025 will be one step ahead of the upcoming mandate by the FDA to ensure rigorous record keeping and effective management to ensure food safety.

Global food safety concerns continue to drive manufacturing quality oversight. Food manufacturers must therefore put the integrity of their HACCP and QC testing regimes at the heart of their business plans. A LIMS is the essential ingredient that drives food safety and quality. ∎