Using LIMS to Maintain Regulatory Compliance in the Food Safety Laboratory
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Overview
Maintaining records in a secured electronic system such as LIMS greatly enhances the ability to demonstrate compliance with regulatory demands in the Food Safety Laboratory. Laboratory Information Management Systems (LIMS) have been deployed within organisations to manage laboratory data—collecting records from sample receipt through to producing analysis reports. Today’s LIMS can play a much more comprehensive role by ensuring regulatory compliance requirements are met by the organisation.

FSMA Regulatory Framework
The FDA’s recent efforts in implementing the Food Safety Modernization Act (FSMA) have been far-reaching in scope and in many ways are considered to be the most significant regulatory reforms in at least 70 years. FSMA is a risk-based approach to managing food safety using a system of targeted enforcement and education, as well as providing industry and consumers with a greater level of transparency.

Preventive Controls Plan
As an over-arching principle of HACCP is the requirement to maintain records of both the established processes and the monitoring, and the need to monitor and maintain records on a regular basis. New and existing food facilities required to implement Preventive Controls Plans using its 6 constant parts, and look for four LIMS functionality can help automate and capture the information required by the FDA.

Evaluating the Hazards
Knowing your process
Understanding your process is key to being able to evaluate potential hazards. The first part of this involves mapping the physical facility, and identifying where process changes occur. Physical locations are then linked to the samples collected and batched for analysis. Each location should be described by identifying its potential hazards and the potential causes. Identify the process or area where a potential hazard will occur, and link it to the hypothetical consequence.

Preventive Steps & Controls
Monitoring Controls & Maintaining Records
The source of materials used in the process also introduces risk—so being able to track where new materials come from, and ensuring potential hazards is a key part of understanding where the process occurs.

LIMS can help you in the management and risk assessment of your process, firstly by mapping the physical boundaries of your processes, and then by generating data describing, where it comes from – using batches, suppliers, dates etc. As a company grows, it becomes more important to capture the data for traceability and risk assessments. FIGURE 1. Mapping physical locations within LIMS

Materials conformance limits
Materials used in the process should be assessed against the quality criteria before a product can be released for consumption. FIGURE 2. DefiningSupplier data within LIMS

Materials conformance criteria
Materials conformance criteria is another part of the process. Past and present quality and conformance limits can be monitored within LIMS. FIGURE 3. Operator training records maintained within LIMS

Materials conformance criteria
Since the data is collected within a relational database, it is possible for reporting and data analysis usingcriterion such as statistical quality control charts. Non-conforming data can also be presented in a meaningful and actionable way for a user—example; we can now be studied on the process map, or visualized with highlighting within a list, or on a graph and a timeline for a user.

Monitoring Controls & Maintaining Records
Capturing and collecting appropriate measurements is a part of maintaining the required record of the process. FIGURE 5. Sampling schedule for each sample point maintained within LIMS

Specify the internal plant details and use this information to determine the critical control points. FIGURE 6. Materials conformance example – USDA Yoghurt Specification (2) managed within LIMS

Maintaining records
Maintaining records in a secured electronic system such as LIMS greatly enhances the ability to demonstrate compliance with regulatory demands in the Food Safety Laboratory. FIGURE 7. Incident record keeping forms both into contradiction analysis

Specifying Corrective Actions
Managing the incidents as they occur
LIMS allows organisations to capture the information associated with any incident, and also enforce a structure to how incidents are managed. Each incident, be it a non-conformance, or a failure in monitoring, can be logged into the system, and the system will allow repeatable and consistent monitoring and analysis. FIGURE 8. Preventive controls plan

Conclusion
Effective managing product quality assessment, LIMS are powerful applications that have been deployed within a number of organisations. They are often used in both critical areas of maintaining the process, and also forming the system of record for audits. As we have demonstrated LIMS can form an organisation’s after, record and enforce their Preventive Controls Plan by managing each of the required five areas:

•Specifying the hazards
•Specifying preventive steps and controls to minimize/prevent hazards
•Specifying how the facility will monitor its controls
•Specifying corrective actions to correct problems that arise
•Specifying how the facility will monitor its controls

References