Using LIMS to Maintain Regulatory Compliance in the Food Safety Laboratory

Colin Thurston, Thermo Fisher Scientific, Tewksbury, MA

Overview

Preventing food-borne illness has been identified as a critical issue for food producers and safety agencies alike. LIMS can help organizations manage laboratory data, ensuring regulatory compliance.

Introduction

The Food Safety Modernization Act (FSMA) was signed into law in January 2011 to add a systematic approach to food safety by requiring all activities and systems to be monitored and recorded. This includes prevention, detection, and recall capabilities. The act places significant emphasis on the prevention of foodborne illness rather than relying on post-consumption testing. All food facilities are required to prepare a written Preventive Controls Plan (PCP) that outlines the following:

- Evaluating the hazards
- Specifying preventive steps and controls to prevent identified hazards
- Objecting the facility will monitor its controls
- Developing records of monitoring
- Specifying corrective actions to correct problems that arise

These facilities are required to implement a Hazard Analysis Critical Control Point (HACCP) system. HACCP is a risk-based approach to managing food safety using a program of analysis points in the process which could adversely affect the safety of the food being produced, the establishment of acceptance limits and measurement criteria for those control points, and an established action plan to mitigate any issues found in the process.

FIGURE 1: Mapping physical locations within LIMS as part of the Hazard Evaluation stage

Developing a comprehensive Preventive Controls Plan is essential for maintaining regulatory compliance. LIMS can help automate and capture the information required by the FDA.

Evaluating the Hazards

Knowing your process

Understanding your process is the key to being able to evaluate potential hazards. The first part of this includes mapping the physical facility, and identifying where process changes occur. Physical records are then documented and any defects present are identified. Product information is collected, along with support documents.

The source of materials used in the process will introduce risks – so being able to track where new materials come from, and assessing potential hazards is a key part of understanding where the potential hazards occur.

LIMS can help you in the management and risk assessment of your process. First, by mapping the physical locations of your processes, and then by providing detailed records that link to where it came from – using batches, suppliers, dates etc. as a grouping feature.

Preventive Controls Plan

Process and monitor hazards

Preventive controls at each hazard should be documented in a written Preventive Controls Plan. As previously mentioned, the challenge is in capturing data at appropriate areas in your process. Hazards can be introduced through ingredient changes, non-comforming materials, process conditions not being followed, facility malfunctions, or any other critical control point.

Operator competency

Operators need to be competent at the tasks they are carrying out within the process. This includes knowledge of the task, correct execution of the task, and awareness of potential hazards. Training courses, renewal dates, competency assessments can all be managed as a part of the quality data that is collected during the production cycle.

Materials conformance limits

Materials used in the process should be assessed against the quality criteria before they enter the process. The FDA has set minimum guidelines and maximum limits for the materials used in the process, but the system must be in place to know what is entering the process.

An over-arching principle of HACCP is the requirement to maintain records of both the established procedures and the monitoring, and the need to review – and make improvements to - the process on a regular basis.

Materials conformance limits

Materials used in the process should be assessed against the quality criteria before they enter the process. The FDA has set minimum guidelines and maximum limits for the materials used in the process, but the system must be in place to know what is entering the process.

FIGURE 2: Defining input data within LIMS

Materials conformance limits

Materials used in the process should be assessed against the quality criteria before they enter the process. The FDA has set minimum guidelines and maximum limits for the materials used in the process, but the system must be in place to know what is entering the process.

FIGURE 3: Operator training records maintained within LIMS

Materials conformance limits

Materials used in the process should be assessed against the quality criteria before they enter the process. The FDA has set minimum guidelines and maximum limits for the materials used in the process, but the system must be in place to know what is entering the process.

FIGURE 4: Defining output data within LIMS

Materials conformance limits

Materials used in the process should be assessed against the quality criteria before they enter the process. The FDA has set minimum guidelines and maximum limits for the materials used in the process, but the system must be in place to know what is entering the process.

FIGURE 5: Sampling schedule for each sample point maintained within LIMS

Materials conformance limits

Materials used in the process should be assessed against the quality criteria before they enter the process. The FDA has set minimum guidelines and maximum limits for the materials used in the process, but the system must be in place to know what is entering the process.

FIGURE 6: LIMS reporting and data analysis

Materials conformance limits

Materials used in the process should be assessed against the quality criteria before they enter the process. The FDA has set minimum guidelines and maximum limits for the materials used in the process, but the system must be in place to know what is entering the process.

Monitoring Controls & Maintaining Records

Capturing regular and appropriate measurements is an important part of ensuring compliance. LIMS provides the facilities to schedule measurements and alerts for product, shifts, schedule and action taken to other systems to those measurements.

LIMS can help the management and risk assessment of your process. First, by mapping the physical locations of your processes, and then by providing detailed records that link to where it came from – using batches, suppliers, dates etc. as a grouping feature.

FIGURE 7: Incident record keeping feeds back into corrective actions

Maintaining records

Maintaining records in a self-auditing electronic system such as LIMS greatly enhances the capability of the food producer to comply with their regulatory demands. This self-auditing electronic system can help in the identification of trends for training and root cause analysis. Having these facilities to manage the data makes public data simpler to comply with, secure, the system captures and manages all the information that you need to show compliance.

Specifying Corrective Actions

Managing the incidents as they occur

LIMS allows organizations to capture the information associated with any incident, and also evidence a structure to how incidents are managed. Each incident is a record of information that can be traced back to the time it occurred, the location it occurred, the person responsible, and the corrective action taken to mitigate any issues.

FIGURE 6: LIMS reporting and data analysis

Since all the data is collected within a relational database, it is available for reporting and data analysis using business such as statistical quality control charts. Non-conforming data can also be presented in a meaningful and obvious way to a user – for example, on the process maps, or selected highlighted within a list, or in a graph displayed on a screen.

Conclusion

Effective managing product quality assessment, LIMS are powerful applications that are the key to maintaining regulatory compliance. LIMS allow self-auditing electronic systems to be implemented with both tools of managing the process, and a self-auditing system of self-auditing. As we have demonstrated, LIMS holds an organization in order - record and evidence that Preventive Controls Plan is being maintained in each of the required areas.

References
