Using LIMS to Maintain Regulatory Compliance in the Food Safety Laboratory

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Overview

Purpose: Demonstrating how LIMS ensures compliance with regulatory demands in the Food Safety Laboratory

Introduction

The Food Safety Modernization Act (FSMA) was signed into law in January 2011 to address the public health burden of 48 million largely preventable illnesses in the US each year (1). The FSMA aims to address some of the structural issues in the food regulatory framework by empowering a single agency to manage regulatory supervision and enforcement across a significant proportion of food production and imports.

Laboratory Information Management Systems (LIMS) have been deployed within organisations to manage laboratory data – collating 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.

This poster will illustrate how LIMS can aggregate the data gathered in the food safety lab and capture information required by regulators – focusing primarily on the FDA and the framework and stipulations of the FSMA.

FSMA Regulatory Framework

Prevention not Reaction

The FSMA places significant emphasis on the prevention of food borne illness rather than reacting to events after consumers have been exposed to potential harm.

All food facilities are required to prepare a written ***Preventive Controls Plan*** (2) which covers the following 5 areas:

- •Evaluating the hazards
- •Specifying preventive steps and controls to minimize/prevent hazards
- •Specifying how the facility will monitor its controls
- •Maintaining records of monitoring
- •Specifying corrective actions to correct problems that arise

Those familiar with the principles of HACCP (Hazard Analysis Critical Control Points) will recognize a consistent theme – and indeed the FSMA specifically requires that HACCP methodology be used by food producers - in ***Section 103 – Hazard Analysis and Risk-Based Preventive Controls*** of the Act.

HACCP is a risk based approach to managing food safety using a program of analysis and control feedback in order to assess and act upon any hazards in the production environment. The principles of HACCP require evaluation of hazards, identification of 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.

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.

Now we will dissect the ***Preventive Controls Plan*** using its 5 constituent parts, and look at how LIMS functionality 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. Potential hazards are often found where materials are added, product is extracted, vessels are opened, final products are packaged, and lastly where operating procedures are not followed. Mapping each of the locations where these product handovers occur, is a step towards being able to identify the potential hazards.

The source of materials used in the process also introduces risk – so being able to track where raw materials came from, and measuring potential hazards is a key part of understanding where the pinch points occur.

LIMS can help you in the management and risk assessment of your process, firstly by mapping the physical locations of your process changes, and then by grouping data according to where it came from – using batches, suppliers, dates etc. as a grouping mechanism to enable trends to be identified. We'll see the real power of this when we look at monitoring controls, but in the initial evaluation phase, a significant part of identifying potential hazards can be accomplished by identifying the physical layout of the process itself.

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

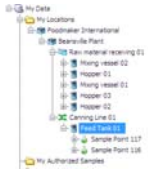
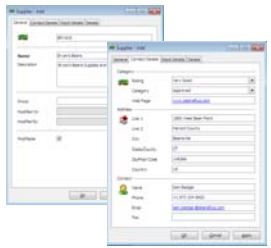


FIGURE 2. Defining Supplier data within LIMS



Preventive Steps & Controls

Minimize/ and prevent hazards

Preventive steps and controls should be documented in a written ***Preventive Controls Plan*** as previously mentioned, but the challenge is in making sure all appropriate areas are covered. Hazards can be introduced through equipment failures, non-conforming materials, process instructions not being followed, human error and so on. Lets take a look at a couple of examples, and demonstrate how LIMS capability enables compliance with the requirements of the organization's plan.

Operator competency

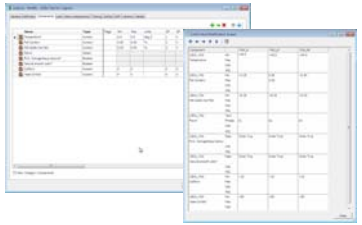
Operators need to be competent at the tasks they are carrying out within the process – so they should be trained to carry out those tasks. In addition competency tests and regular refreshing of training should be included within their job role. As processes evolve, both the requirements of the task assigned to operators and their training assessments also need to be updated. The modern LIMS application can manage the training requirements for users, both inside and outside the laboratory context. Training courses, renewal dates, competency assessments can all be managed as a part of the quality data that is collected during the production cycle, as illustrated below:

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 can be accepted into the production process – this is true for both raw materials as well as in process materials – essentially each step in the process should have a quality stage gate that determines whether the product should move into the next phase of the process. Figure 4 illustrates this concept for yoghurt using an example from the USDA :

FIGURE 4. Materials conformance example – USDA Yoghurt Specification (3) – managed within LIMS



Monitoring Controls & Maintaining Records

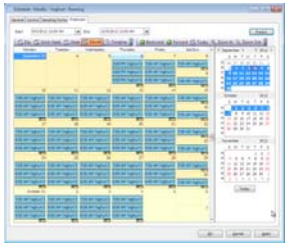
Capturing regular and appropriate measurements

Once appropriate controls have been identified, it is important that measurements are taken at appropriate intervals to ensure conformance. LIMS provides the facilities to schedule measurements and apply control limits, alerts, statistical analysis and interfaces to other systems to those measurements.

LIMS can, for example, be used to manage the sampling process for a production facility, and ensure that environmental samples taken for a production run are grouped together.

Sampling plans to gather measurements for control points can be managed as a group – therefore allowing a consistent protocol to be used for each type of product – which in turn allows comparison between batches.

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



Since all the data is collected within a relational database, it is available for reporting and data analysis using facilities such as statistical quality control charts Non-conforming data can also be presented in a meaningful and obvious way to a user – for example, overlaid on the process map, or color/text highlighted within a list, or via a specific alert message to a user.

FIGURE 6. LIMS reporting and data analysis

Maintaining records

Maintaining records in a secured electronic system such as LIMS greatly enhances the organization's ability to comply with the FSMA requirements. Data is searchable, is secured and authenticated by electronic signatures and audit trails, and can be used for trending and root cause analysis. Having these facilities to manage the data makes audits much simpler to comply with, since 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 enforce a structure to how incidents are managed. Each incident, be it a non-conforming product, or a missing measurement, can be logged, tracked and all actions recorded before the incident is signed off. This means that incidents can be reviewed periodically, and process controls evaluated as a part of a continuous improvement process, leading to better understanding of and minimized risks from potential hazards.

FIGURE 7. Incident record keeping feeds back into corrective actions

Conclusion

Besides managing product quality assessment, LIMS are powerful applications that can markedly improve an organization's ability to meet the requirements of the FSMA, both in terms of supporting the process, and as the system of record for audits. As we have demonstrated, LIMS helps an organization to deliver, record and enforce their ***Preventive Controls Plan*** by managing each of the required five areas:

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

References

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