Data Integrity in the Microbiology Laboratory

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1 Abstract

Pharmaceutical quality affects patients on a global scale, consumers expect that each batch of medicines they take will meet quality standards to be safe and effective. In recent years, several data integrity guidance documents have been published by the FDA causing data integrity to become a hot topic in the regulated industry. The Food and Drug Administration (FDA) regulates the quality of pharmaceuticals and the main regulatory standard for ensuring pharmaceutical quality is the Current Good Manufacturing Practice (CGMPs).

CGMPs assure that systems have proper design, monitoring, and control of processes and facilities. Adherence to the CGMP regulations includes establishing strong quality management systems, obtaining quality raw materials, establishing operating procedures, detecting and investigating product quality deviations, and maintaining reliable testing laboratories. This formal system, if adequately put into practice at a pharmaceutical company, helps to prevent instances of contamination, mix-ups, deviations, failures, and errors assuring that drug products meet their quality standards. In recent years there has been an increased focus on data integrity as it poses a large risk to pharmaceutical quality. This presentation explains the innovative use of custom LIMS software in the QC laboratory which significantly improves data integrity.

2 Objective

The use of automated electronic systems such as Biotracker LIMS, a laboratory information management system that provides a platform to capture sample identification findings and organize it in a way that data can be easily accessible and reported against for data acquisition, processing, and reporting is subject to data integrity requirements and cGMP regulation. Charles River has been able to successfully satisfy regulatory compliance regarding data integrity by having a Quality Management System and procedures (SOPs) in place based around the Biotracker LIMS software which also supports the record keeping of CAPAs. CAPAs can be recorded, opened, and managed through Biotracker LIMS to control all needed corrective actions.

Biotracker has several specialty modules that support the QC laboratory with performing DNA sequencing and MALDI-TOF identifications efficiently. This presentation will discuss the use of laboratory information management software in the QC laboratories which can help significantly reduce risk of not complying with regulatory standards.

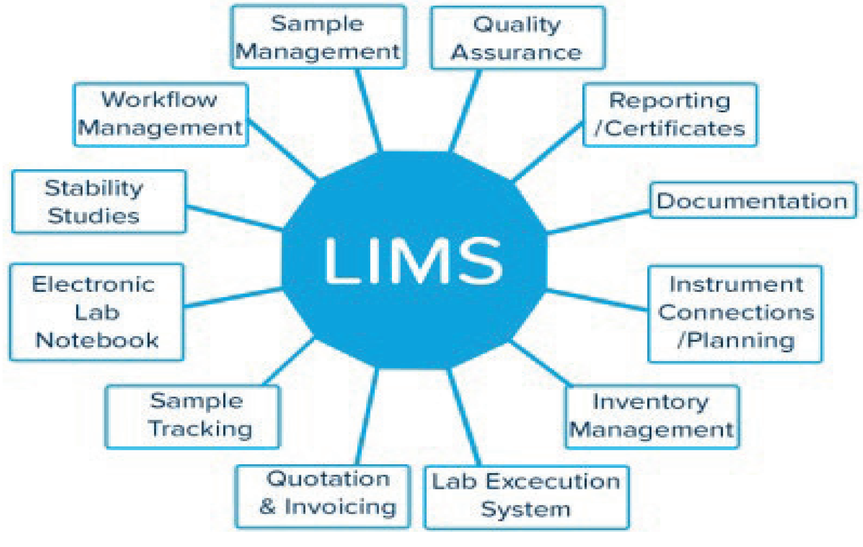
3 Biotracker LIMS

Biotracker offers the following QC laboratory modules to electronically capture data and comply with cGMP regulation:

- *Audit Trail*
- *Electronic Signature*
- *Customer and Supplier Management*
- *Configurable roles and Security*
- *Chain of sample custody*
- *Workflow Management*
- *Equipment/ Inventory Control*
- *Report Release*
- *CAPA/ Deviation Management*
- *Discrepancy Management*
- *Plate Management*

4 Benefits

By having a formal Quality Management System, Biotracker provides a structured electronic approach that ensures consistency against data integrity requirements. Since raw data and test results can be easily falsified, manipulated, changed, and deleted with the strict use of a paper-based data integrity process, Biotracker LIMS provides an electronic assurance that all data integrity gaps are identified, remediated, and closed using a formal Quality Management System and audit trail.



Pictured to the left is the MALDI instrument used in the Charles River laboratories for rapid sample processing that communicates with the Biotracker LIMS application.

Pictured to the right is the genetic analysis used in the Charles River DNA sequencing laboratories that communicates with the Biotracker LIMS application.