

BOOST QUALITY MANAGEMENT

Why food and beverage labs are leaning into enhanced LIMS platforms for quality and compliance

uality management is essential for food and beverage labs to deliver high-quality results and comply with the latest regulatory standards. Food safety testing is crucial to safeguarding public health, minimizing economic losses, and ensuring a sustainable and safe food supply. Labs face evolving requirements from diverse stakeholders and need flexible, cost-effective solutions to support their role in ensuring the quality of all output from testing and analyzing food materials, identifying contaminants, ensuring ingredient stability, checking cross-contamination, and investigating package materials and production processes.

Lab digitalization creates a dynamic, connected lab environment enriched with advanced intelligence. Its goal maximizing throughput and precision—allows food and beverage labs to enhance their processes for ensuring product safety and compliance and enabling innovation. By streamlining workflows and data management, lab staff can focus on solving complex challenges and driving innovation in the food and beverage industry.

Harnessing information from enhanced informatics systems like an advanced LIMS can strengthen quality management systems (QMS) and help labs maximize their return on investment. These tools and applications help drive efficiencies that address key industry challenges, enabling growth, streamlining operations, improving data integrity, centralizing recordkeeping, and supporting continuous improvement. Enhancing data integrity and reliability establishes the framework for implementing advanced predictive analytics, empowering labs with improved forecasting.

#### CHALLENGE: KEEPING PACE WITH **CHANGE**

Labs must continuously adapt to health concerns, quality standards, and market demands in the regulated food and beverage industry. New test protocols are often required to respond to international and domestic regulatory changes, for example, decreasing maximum residue limits from the European Food Safety Authority, or new market trends like plant-based or CBD-infused products. Innovative food products can require extensive protocol development and validation to assess, for example, product stability. To remain competitive and ensure a positive customer experience, labs also need to be able to quickly scale operations to meet demand fluctuations and adapt reporting format and accessibility according to changing expectations.

Testing labs need flexible software systems to accommodate growth and operational changes without service disruptions or added costs while ensuring their OMS remains effective.

## Solution: Seizing control with modular

Enhanced LIMS with configurable workflows and modular design provide the flexibility to meet dynamic regulatory, client, and operational needs, allowing labs to respond quickly and efficiently to changes. Full control over digital workflows empowers labs to adapt processes or create new workflows as needed. Modular systems allow labs to expand into new service areas without changing platforms. Cloud-based software-asa-service (SaaS) deployment models offer maximum scalability, performance, and security, providing ongoing support for resilient, cost-effective solutions.

#### **CHALLENGE: REMOVING DIGITAL BOTTLENECKS**

Quality and compliance are intertwined, requiring consistency and thorough documentation of processes and process controls. Inefficiencies or gaps in data capture and digital workflows undermine quality and compliance efforts and create bottlenecks, especially the need for manual intervention in data entry or transfer. In addition to impacting speed and throughput of testing, manual tasks introduce variability and potential for human error. Reporting workflows can be particularly challenging due to the complexity introduced by diverse stakeholder needs.

#### Solution: Integrated and automated workflows

Informatics platforms that fully integrate with instrumentation and automate routine tasks or workflows dramatically improve operational consistency, reliability, and efficiency end-to-end. Enhanced systems can help ensure processes follow defined SOPs, reduce risk of human error with increased automation, and improve documentation and reporting.

Complete electronic records and signatures for all testing activities—including sample tracking, test results, chain of custody, and process documentation—support traceability and accountability, both of which are essential to a QMS.

Testing labs benefit from robust reporting capabilities with customizable templates to meet the needs of different stakeholders. Platforms with automated reporting pipelines that support client access for self-service, regulatory audits, and quality management reduce in focus | Clinisys

the administrative workload considerably. Enhanced automation and documentation also help labs meet demands for greater transparency and faster results.

### CHALLENGE: PRESERVING DATA INTEGRITY AND SECURITY

Data integrity and security are crucial for regulated testing labs to comply with regulations and industry standards like ISO/IEC 17025 and protect proprietary or confidential information. To support compliance with regulatory guidance such as 21 CFR Part 11, software needs specific features, including controlled user access, secure integrations, electronic signatures, and complete audit trails. Further, labs must protect test data and client information from unauthorized access.

#### Solution: Compliant, controlled role-based user access

Regulated labs need compliance-ready software that meets core requirements for data integrity. Due to the central role of informatics software in operations and data management, advanced features that elevate data integrity and security are particularly impactful. Digital workstreams that facilitate comprehensive electronic records, capturing all actions and changes to data, are essential to maintaining detailed audit trails to facilitate both internal and external audits.

Controlled user access is important to compliance, chain of custody, and security, ensuring tasks are performed by qualified personnel and preventing unauthorized access to data. Adding to role-based access controls, LIMS that incorporate certification dates in user profiles enable labs to restrict test or method activity to only analysts with valid certifications. This allows access to be controlled dynamically, with alerts that prevent a user from continuing if relevant certifications are expired.

Robust data security measures are required to protect proprietary and confidential information against data breaches. SaaS platforms are an ideal solution, as providers can ensure relevant systems and back-end data storage and handling align with industry best practices and regulatory standards.

## CHALLENGE: LARGE VOLUMES OF DIVERSE OPERATIONAL RECORDS

Testing labs record, process, archive, and retrieve large volumes of data. Thorough recordkeeping, including instrument, personnel, and inventory records,

is critical to supporting operations, but adds volume and complexity to data management needs. Lab managers need convenient access to this breadth of data to effectively manage a variety of tasks, including resource planning, continuous process improvement, and corrective and preventative actions (CAPA).

## Solutions: Unified system for operational and test data

Using an enhanced LIMS platform to centralize management of operational data offers greater convenience and ROI. These platforms support extensive recordkeeping—including data collection, storage, reporting, and analysis—for more effective resource management boosting productivity. Comprehensive data and reporting tools facilitate root cause analysis and CAPA. Prompt identification and documentation of underlying issues, deviations, or non-conformances enable rapid and effective response, which can be further enhanced with built-in CAPA functionality.

Incorporating instrument records, such as installation, maintenance, and calibration, prompts timely calibration and validation, maintaining experimental accuracy and reliability of results.

Personnel records, including training, certification, and proficiency testing, ensure tests are conducted by qualified analysts with supporting documentation. They can also aid in scheduling and long-term operational planning.

LIMS that aid materials tracking, including stock and expiration dates, support efficient inventory management tied to real-time operational needs. This helps avoid inventory-related downtime and minimize waste.

# CHALLENGE: DISTILLING INSIGHT FROM DATA

Informed decision-making relies on easy access to integrated, well-organized data to form a comprehensive view. While large volumes of data are an essential resource for laboratories, leveraging them is cumbersome without advanced tools. Structure with contextual metadata and analytical support is critical.

#### Solution: Structuring for success

Enhanced LIMS platforms improve data capture and storage by associating structured data with the right metadata, enabling easy retrieval for confident processing and analysis. Real-time data capture and reporting provide up-to-date operational information and results, supporting proactive quality management. Centralized data storage offers easy access to historical data for trend analysis, informing quality improvement initiatives and supporting predictive decision-making. Integrating multiple datasets enables analytics to answer complex questions and extract insights for informed strategic decisions. These platforms can also help managers monitor KPIs related to quality, such as test accuracy, turnaround times, and compliance rates, to identify areas for improvement and track progress.

# ADVANCED LIMS FOR FUTURE-READY LABS

The Clinisys Laboratory Solution<sup>TM</sup> (CLS) is an advanced LIMS, cloud-based SaaS deployment model, which offers maximum scalability, performance, and security to future-proof lab informatics. Adaptable, discipline-specific LIMS configurations ensure labs are well-supported with tailored solutions that maximize ROI across industries and sectors. CLS can handle large volumes of data, support multiple users, sites, and regions, and integrate with different lab instruments seamlessly. CLS ensures data protection, backup, and recovery, as well as compliance with the latest regulatory standards. This flexibility and modularity accommodate evolving processes and service offerings for long-term growth, supporting single and multi-site locations and teamwork both on-site and from home.

Clinisys Food and Beverage Laboratory<sup>TM</sup>—one of the many discipline-specific offerings within CLS—has established workflows to meet wide-ranging industry needs, such as identifying contaminants, ensuring ingredient stability, and investigating packaging materials. The LIMS also enables rapid creation of unique workflows and access to data via a client self-service portal. Labs see efficiency improvements through unlimited connectivity with instrumentation, databases and registries, and API support, as well as automated workflows from sample login to reporting and billing.

Leveraging deep industry experience and proven solutions, Clinisys helps labs satisfy the needs of diverse stakeholders with enhanced visibility and control. CLS supports compliance with various regulations, including ISO/IEC 17025, FSMA, GMP, HACCP, 21 CFR Part 11, and many other national and international standards.

By using Clinisys Laboratory Solution LIMS to support QMS, labs gain powerful tools for high-quality results, regulatory compliance, and continuous improvement, boosting ROI through improved productivity



and efficiency, faster turnaround, and better decision-making. Squeezing added functionality from existing systems like LIMS enables labs to consolidate efforts, reduce complexity, and overcome technology deficits.

Clinisys's customer-centric approach enables delivery of tailored solutions that meet the specific needs and challenges of each laboratory. Clinisys helps its customers provide excellent service to their end-users, whether they are patients, physicians, researchers, or regulators. By leveraging advanced technologies, such as cloud computing, artificial intelligence, and automation, Clinisys ensures its customers can operate efficient, reliable, and secure labs, 24x7, with minimal downtime. Clinisys also offers extensive support and training services, as well as continuous updates and enhancements, to help its customers stay ahead of the evolving demands and standards of the laboratory industry.

Every enhancement in quality and transparency within food and beverage testing labs resonates beyond the lab. These improvements ensure that the food and drinks we consume are safe, healthy, and reliable, fostering greater consumer trust and public health. Clinisys informatics solutions empower your lab as a cornerstone of food safety and quality. Together, we can build a healthier, safer, and more transparent food supply chain for the global community.





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