

# WHITEPAPER

## Connect Everything

Achieving a Productive,  
Compliant, and  
Successful Lab

Modern laboratories are often overwhelmed with rapidly scaling operations, strict compliance restrictions, and process improvement challenges. With critical manufacturing processes, labs face enormous pressure to manage operational efficiency while adhering to stringent quality guidelines. Among the challenges, data governance and integrity are at the top. Quality data is crucial to ensure a product's safety, quality, and efficacy.

### Consistent Quality Across Operations

Companies are focusing on producing high quality products with limited regulatory oversight. In addition, scalability in operations is imperative for steady market growth. But, when aligning consistency with scalability, quality is at a greater risk of getting compromised. Manufacturers are promising faster turn-around times which might stress shop floor workers in a manual process-based environment. Manual intervention in data often results in data integrity and compliance risks. This further affects audit results and brand image in the long run.

### Quality inputs deliver quality outcomes

Only accurate data can derive insightful analytics. For example, manual recording of measurements during testing of manufactured goods are prone to integrity issues. The process is lengthy and time-consuming. It may also lead to misrepresentation of data in order to match the expected outcome. Data accuracy and integrity is thus highly compromised.

In today's hyper connected world, technology brings in unimaginable possibilities of bringing material things to life with interconnected systems, artificial intelligence, and machine learning. With smart instruments and devices, accuracy becomes an expected result. Connected systems fetch and record data automatically, leaving practically zero scope for integrity risks. Labs with connected instruments and integrated systems thus perform efficiently.

### Avoiding Unnecessary Complexities

Many laboratories and pharma manufacturers refrain from extracting the benefits of technology. Despite innumerable, result-driven capabilities of the automated systems, there is resistance for acceptance. There are labs that have obtained 100% paperless functioning with integrated systems. Instrument connectivity is just the beginning. With automated data entry through connected instruments, data manipulation is eliminated and insightful analytics for impactful decision-making is possible.

Putting a system in place that has interconnected and interdependent units is the best way to achieve operational lab excellence.

## The Perfect, Efficient Lab

A connected lab is an efficient lab. In an ideal lab scenario, data is collected automatically from the integrated equipment, instruments, and other lab systems into the LIMS system. The collected and cleaned data is used by a reporting engine for further preparation of trends and charts. The data is also used for deriving quality metrics, critical quality attributes, predictive analytics, and more ready-to-use insights for decision-making. Results are documented automatically without the manual involvement of a lab manager, analyst, or scientist. In this scenario, lab productivity is at its highest with scientists being more focused on testing rather than documenting.

When systems, instruments, and equipment talk to each other and pass on information automatically, productivity and efficiency skyrocket. Labs are fully compliant and audit-ready at all times. This ideal lab scenario demands a flexible system that integrates with the rest of the lab and also supports complex regulatory requirements.

FDA expectations like Continued Process Verification, visual inspections, and reference standards are also met effortlessly through complete integration.

***The future-proof lab is already becoming a reality. Digital connectivity brings enormous benefits to users, and ultimately to patients.***

## Building a Realistic Roadmap to a Fully Integrated Lab

A fully connected lab is an optimal solution to get the best benefits of a wide range of platforms. Digital lab tools like analytical instruments, weighing machines, ERP, QMS, etc. help organizations to digitalize their lab processes. Integrating these tools with a powerful LIMS helps fetch the data automatically to the system.

The collected data from a robust LIMS system can be used for deriving further analytics that helps in evaluating the current lab processes and further channelizing and improving processes.

## Exploring lab possibilities with integrated LIMS

In today's data-sharing and informatics environment, almost any instrument or system can be integrated with LIMS. Organizations must use a LIMS system that focuses on data reusability, quality, and accessibility. It is the most efficient solution to overcome data silos.

An efficient LIMS like CaliberLIMS supports the integration of lab tools, equipment, instruments, and other business systems of manufacturing, and quality management departments. However, what needs to be integrated and the order of integration is unique to a specific lab situation. Evaluating the complexity of the level of integration helps in prioritizing lab integrations.

Lately, regulatory authorities have been asking for more error-free lab metrics to ensure overall lab quality, efficiency, and compliance. Providing lab metrics and other required data is possible with the availability of a LIMS system with integration capabilities. To achieve more, pharma companies must look toward lab integration prospects to avoid data silos.

Lab integration will help resolve issues caused by data silos, collate data in the LIMS system for analytics, and empower the management to make informed decisions.

## The Art of Pulling Data Together - Integration



Integrating external and internal applications with the LIMS platform leads to data collection in real time. This data is crucial for leveling up the game with industry peers and moving ahead. Pharma companies must look for a platform that seamlessly integrates multiple systems.

Further, with an integrated LIMS system, labs can save and manage huge sets of data collected from multiple facilities using a cloud-based platform. This data can be accessed in real time across the facilities to address company-wide quality issues.

## CaliberLIMS Integration Possibilities

An integrated LIMS platform such as CaliberLIMS increases efficiency, streamlines production processes, and amplifies operations. It collects data directly from instruments, Manufacturing Execution Systems (MES), Electronic Batch Records, Enterprise Resource Planning Systems (ERPS), Chromatography Data Systems (CDS), and other sources. It results in excellent collaboration enterprise wide.

### 1. Integration with Instruments & Equipment

Instrument integration must be prioritized during phase 1 of the LIMS adoption process. This helps in identifying data elements that need to be added to LIMS and eliminates re-visiting integration requirements at a later stage. CaliberLIMS provides advanced instrument interpretation algorithm for easy onboarding of instruments. This automates parser creation and saves up 80% time & efforts.

#### Benefits

- Regular activities like tracking instrument and equipment calibration schedules and keeping consumable records are automated to speed up the analysis work.
- Integrating instruments and equipment with CaliberLIMS eliminates manual noting of data and reduces transcriptional errors.
- Complete access to control the calibration schedules ensures that no delays occur.
- Identify and address issues before they impact production.
- Facing audit for a lab that has integrated instruments and equipment is easy to manage.

#### How CaliberLIMS Integrates

Caliber's External Data Aggregation Processor Engine (EDAP) facilitates integration between the instruments and the LIMS in three different modes of data collection.

CaliberLIMS integrates with heterogeneous instruments with file-based or port-based output, and with multi-vendor CDS systems. Users can track end-to-end asset management along with instrument usage logs, instrument calibration schedules, consumable records maintenance records etc., which speeds up analysis. With the enhanced instrument interface features, CaliberLIMS can facilitate speedy configuration based on AI & ML. The interface allows for quicker implementation, self serviceability, and lower cost of ownership.

Seamless bi-directional interface for work list posting and transfer of results automatically from equipment. . CaliberLIMS seamlessly integrates with equipment management software like LabX to boost efficiency.

## 2. Integration with ERP Systems

Connecting LIMS and ERP systems is crucial to leverage the full benefits of modern ERP solutions and laboratory automation, ultimately enhancing supply-chain management. LIMS provides summarized data to the ERP system from a large volume of laboratory operational data. ERP systems typically maintain quality test specifications during production.

These specifications have a valid range of test results to determine the disposition of the product. By pushing this data to LIMS, quality assessments can be made to ensure quality and regulatory compliance for products.

### Benefits

- Efficient use of resources by reducing the time and manual effort on data entry and calculations.
- Eliminates data transcription errors.
- Presents a clear view of the work-in-progress status of the laboratory processes that helps in identifying bottlenecks.
- Improves turnaround time.
- Streamlines business processes such as COA generation and delivery and quality sample storage/disposal.

### How CaliberLIMS Integrates

The ERP interface engine of the CaliberLIMS platform enables the integration of SAP or any ERP system. This integration helps derive specific benefits.

- Fetches step-by-step details of specifications of quality tests performed on a batch or lot from the ERP systems and sends them to QA.
- During a project, it facilitates the transfer of data from one department to another, which can otherwise be time-consuming.
- Enables organizations to find a valid range of test results and find the position of the product.
- Helps the QC assign standard or specific tests in CaliberLIMS.

## 3. Integration with Quality Management Systems (QMS)

An effective laboratory management system must have an integrated quality management system. This ensures continuous quality efforts throughout the production and design lifecycle. It results in a quality ecosystem of data that proactively manages the enterprise's quality efforts.

### How CaliberLIMS Integrates

CaliberLIMS automatically links critical data from other supportive quality modules to the LIMS module.

- Ensures adherence to guidelines, protocols, processes with easy reference to standard documentation.
- OOS can be easily managed and tracked
- Quality events can be managed
- Create or modify lab processes with easy reviews and approvals

## 4. Integration with Analysis and Reporting Tools

Having ready-to-use business intelligence in the laboratory unlocks more insights from the available data. Robust analytics tools help in generating detailed insights from captured laboratory data.

Integration of real-time analysis and reporting of laboratory data can eliminate quality issues at an early stage. Meaningful lab-specific reports and trend analysis can help you make better decisions.

- Smart analytics boost innovation lifecycle.
- Data-driven insights from the internal and external lab data add value to the QC process.
- Ensure high product standards.
- Improve operational lab efficiencies and the effectiveness of lab networks.
- Maintain process parameters within regulatory safety and product standards.
- Boost the efficiency of KPI reporting of labs.
- Quality metrics can be easily drawn and used

### How CaliberLIMS Integrates

CaliberLIMS includes a dedicated reporting module with an easy-to-use interface. CaliberLIMS captures and organizes lab data to support on-demand analysis. The reporting functionality is customizable and can be integrated into existing operations. Reports such as material usage logs, instrument usage logs, training and certification reports, etc. are available in the module.

## 5. Integration with Other Caliber Applications

Integrating corporate, production, and quality systems helps in leveraging critical data across platforms. Integration of CaliberLIMS with CaliberBRM, QMS platform - EPIQ, and statistical tools like Anytime PQR plays a significant role in having all the data stored in one data lake. The accumulated data can be used to fine-tune lab, quality, and production processes across the organization.

The reports derived from such integrated data can be used by management to make informed decisions. Statistics and insights like CPK, PPK, CPV, etc. are a huge contributor of sustained success when data sources are fully linked.

## Multi-faceted Benefits of CaliberLIMS

The most important benefit derived from lab integration is readily available data at any time. The automated data collection process helps get all the essential information for the preparation of reports. Lab equipment, instruments, and LIMS data are collected to identify problems with current procedures. The issues are identified and rectified in the initial stages for better final output. An integrated lab system facilitates the maintenance of lab units across the company using the accumulated data and generated reports. Simply put, it boosts lab efficiency and offers a competitive advantage for the company.

Overall, an integrated LIMS platform like CaliberLIMS provides enterprise-wide data-centric integration capabilities. It helps meet regulatory requirements with ease. The data collected through effective integration of lab tools, equipment, and instruments on one LIMS platform aids in the continuous improvement of quality processes.

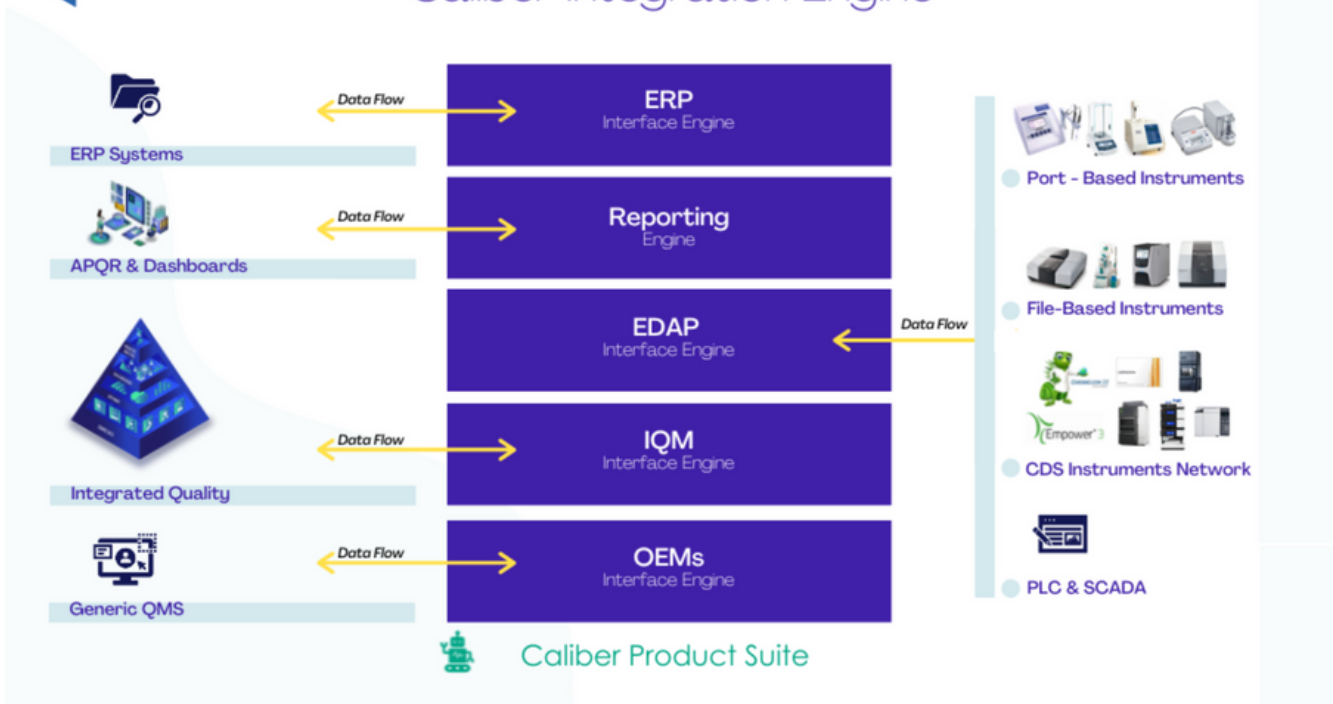
Organizations can use the critical data collected from the LIMS system to derive quality metrics, predictive analyses, and other statistical analyses for lab process optimization. The disciplined testing process and actionable data ultimately contribute to increased quality, efficiency, and profitability. CaliberLIMS assists in streamlining efforts and staying ahead of the competition by producing better products at an accelerated pace.

## A Structured Approach

Integration is essential for any lab that wants to make processes secure, scalable, robust, and error-free. However, integration presents unique challenges in a regulated environment. Therefore, a planned, well-structured approach to lab integration is necessary. Consulting a reliable lab integration solution provider such as Caliber helps establish a robust system while saving time and money in the long run.



## Caliber Integration Engine



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Caliber offers the widest range of solutions for Process Automation, Quality Management, and Regulatory Compliance for highly regulated industries. Our key differentiator is our product suite which gives companies the unique opportunity to achieve Integrated Quality Management with a single suite of products.

**Contact us now for a demo!**



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