BIOVIA

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MOVING BEYOND LIMS
FULL DIGITAL TRANSFORMATION REQUIRES A PARADIGM SHIFT

Whitepaper

In the rapidly evolving life sciences landscapes, quality control (QC) laboratories are at the forefront of ensuring compliance, accuracy, and efficiency. However, as labs strive to keep pace with technological advancements, the need for a complete digital transformation becomes increasingly crucial. This white paper explores the steps required to achieve this transformation and highlights the unique strengths of BIOVIA solutions in facilitating this process.

DASSAULT SYSTEMES

THE NEED FOR FULL DIGITAL TRANSFORMATION

While many labs have adopted Laboratory Information Management Systems (LIMS) to streamline data management, **relying solely on LIMS is insufficient for true digital transformation.**

Most LIMS have specific gaps that prevent full lab digitalization:

LACK OF TRUE INSTRUMENT INTEGRATION

One of the significant limitations of traditional LIMS is their inadequate instrument integration capabilities. Many LIMS solutions are designed to manage data and samples rather than facilitate seamless communication between various laboratory instruments. This lack of true integration results in siloed data, requiring manual data entry and increasing the risk of errors. Consequently, scientists spend valuable time transferring information between systems, which detracts from their ability to focus on critical analysis and decision-making. Effective digital transformation demands a unified approach that enables real-time data exchange between instruments and LIMS, enhancing workflow efficiency and ensuring data integrity across the laboratory environment.

INABILITY TO TRACK CONSUMABLES AND MANAGE CHEMICAL INVENTORY

A prominent limitation of many LIMS is their inability to track consumables and manage chemical inventory effectively. Traditional LIMS often lack the comprehensive functionality to monitor stock levels, track expiration dates, and manage reordering processes. As a result, laboratories face challenges such as stockouts or excess inventory, which can lead to project delays and increased operational costs. This oversight not only hampers lab efficiency but also compromises compliance with regulatory requirements related to chemical management. To truly embrace digital transformation, laboratories must implement systems that provide robust inventory management capabilities. These systems should enable real-time visibility of chemical stock, ensure traceability of materials, and facilitate timely replenishment, thereby streamlining laboratory operations and contributing to improved safety and compliance in the life sciences environment.

LACK OF TRUE GUIDED PROCEDURE EXECUTION

Another critical shortcoming of many is their inability to provide accurate guided procedure execution. While LIMS can help document processes, they often fail to deliver interactive, step-by-step guidance for laboratory workflows. This deficiency can lead to inconsistencies in procedure execution, as operators may not follow established protocols precisely without clear, enforced instructions.

Furthermore, without integrated guidance, training new staff can become cumbersome, increasing the potential for human error and impacting overall lab productivity. To achieve meaningful digital transformation, laboratories require solutions that manage data and promote adherence to standard operating procedures (SOPs) through automated, guided execution. Such capabilities ensure compliance, enhance reproducibility, and ultimately contribute to higher quality results within the life sciences sector.

To fully modernize quality control operations in laboratories, it is essential to eliminate all paper-based processes, which reduces manual errors and enhances data integrity. Laboratories must digitalize and standardize all data and procedural records to ensure consistency and accessibility. Integrating all laboratory instruments is crucial for real-time data capture and analysis. Lastly, efficient management of inventory and consumables through digital solutions will significantly reduce waste and improve resource allocation, ultimately optimizing laboratory efficiency and compliance in the life sciences sector.

ACHIEVING DIGITAL TRANSFORMATION IN QC

To achieve full digital transformation and enable a step-change in QC productivity, the following areas must be addressed:

- Full integration of all instruments
- Full integration of inventory/consumables
- Removal of all paper in the lab, including equipment logbooks and any static / PDF-based SOPs
- Standardization of all data and procedures
- Digitalized management of QC documents for compliance and auditing

FULL INTEGRATION OF LAB INSTRUMENTS

Integrating all laboratory instruments with a digital lab solution facilitates real-time data capture, allowing laboratory personnel to promptly analyze and respond to results. This immediacy speeds up decision-making and helps identify trends and anomalies that can influence research outcomes or quality control processes. Secondly, integrated systems dramatically reduce the potential for human error associated with manual data entry, ensuring higher data accuracy and reliability. Improved data integrity is vital for compliance with stringent regulations in the life sciences sector.

Full integration allows for seamless workflows, as data flows effortlessly between instruments and the digital lab solution. This interconnectedness minimizes downtime and operational bottlenecks, thereby increasing productivity. Further, it enables comprehensive data analytics, allowing laboratories to harness the power of advanced analytics tools for deeper insights into processes and results.

Integration of lab instruments should be native to your digital lab solution rather than a third-party add-on to minimize custom integrations and data transformations.

FULL INTEGRATION OF INVENTORY AND CONSUMABLES

Integrating chemical inventory with a digital lab solution enables automatic tracking of consumable levels based on the amounts used in analytical tests. This provides real-time visibility into stock levels, allowing laboratory personnel to monitor inventory effectively and make informed decisions regarding reordering processes. This capability significantly reduces the likelihood of stockouts, which can disrupt research and testing workflows, and also mitigates the cost implications of excess inventory that can lead to waste.

Moreover, an integrated inventory management system streamlines chemical tracking, ensuring that expiration dates are adhered to and that materials can be traced throughout their lifecycle. This level of oversight is crucial for maintaining compliance with regulatory standards, as it contributes to the safety and integrity of laboratory operations. Centralizing inventory data within a digital solution enhances team collaboration, as all personnel have access to consistent and up-to-date information.

Environmental health and safety (EHS) information can also be integrated, which is essential for promoting a safety-first culture in laboratories. Such integration allows for comprehensive management of all chemical-related data, including safety data sheets (SDS), risk assessments, and regulatory compliance information. By consolidating EHS data alongside inventory management, lab personnel can quickly access critical safety information directly connected to specific chemicals used in experiments or processes.

This centralized approach enhances risk management by providing real-time access to essential safety protocols, exposure limits, and hazard classifications, ensuring that laboratory staff can make informed decisions regarding safe handling, storage, and disposal of chemicals. Furthermore, implementing automated alerts for expiration dates or safety reviews facilitates proactive compliance with evolving regulations and standards. The availability of integrated EHS information empowers laboratories to respond swiftly to safety incidents, mitigating risks and ensuring that safety measures are consistently followed across all operations. Ultimately, this holistic management of EHS data and efficient chemical inventory practices leads to a safer, more compliant, and more efficient laboratory environment in the life sciences sector.

ELIMINATING ALL PAPER IN THE LAB

Many sources of paper have been removed from the lab following the first waves of digitalization. However, paper persists in places like equipment logbooks and PDF records of Standard Operating Procedures etc. To fully embrace digital transformation, eliminating all paper records is essential. This includes transitioning from PDF-based SOPs to dynamic, interactive procedures that can be accessed and executed directly within the digital lab solution. Such an approach enables streamlined execution of procedures, as well as real-time data capture and analysis throughout the workflow. Additionally, integrating lab equipment directly with a digital lab solution can replace equipment logbooks with electronic versions, allowing for automated logging of maintenance and metrology into the digital lab solution.

Removing paper from laboratory processes reduces manual errors, improves data integrity, and enhances compliance with regulatory requirements related to record-keeping. By eliminating static records and introducing dynamic ones,

laboratories can ensure consistency in procedure execution and enhance productivity

ACHIEVING AUTOMATION AND STANDARDIZATION

By addressing these key areas, labs can finally digitalize areas that have lagged behind the first waves of digitalization. The benefit is that more tedious manual activities can be automated, driving substantial efficiency gains. Digitalizing instrument data capture and consumables tracking enables true digital procedure execution, streamlining workflows and reducing the potential for errors.

Moreover, with lab instruments integrated into digital solutions, data can be automatically captured and standardized, improving data accuracy and consistency. With all of these processes connected within a digital environment, laboratories are better equipped to handle complex workflows and streamline operations. Automation also supports proactive monitoring of quality control processes by providing real-time visibility into performance metrics, allowing labs to identify trends or issues that require attention quickly.

ACCELERATE TEST REVIEW CYCLES WITH REVIEW-BY-EXCEPTION

Implementing a review-by-exception approach for test results that comply with expected specifications offers significant advantages in laboratory quality control processes. This method enables laboratories to focus their resources on results deviating from established norms, optimizing the review process. By automating the approval of standard results, scientists can redirect their attention towards investigating anomalies, which is crucial for identifying potential issues that may warrant further inquiry.

Additionally, review-by-exception enhances operational efficiency by reducing the time spent on routine data evaluations. This streamlining allows for faster turnaround times, contributing to more timely decision-making in testing and quality control. Moreover, it promotes a higher confidence level in the quality of data output since results are consistently validated against predefined specifications. This approach fortifies compliance with regulatory expectations and supports Continuous Quality Improvement (CQI) initiatives, as laboratories can quickly adapt to benefit from insights gained through focused analyses of exceptional results.

TOWARDS BATCH RELEASE-BY-EXCEPTION

The review-by-exception methodology not only streamlines the evaluation of test results but also facilitates the concept of release-by-exception in laboratory quality control. Laboratories can significantly enhance operational efficiency by automatically approving batches where all test results conform to specified criteria. This process eliminates the need for extensive manual release procedures when data consistently meets predefined standards.

Automated release-by-exception minimizes delays associated with approving compliant batches, allowing analysts to focus on more critical investigations where results deviate from expected norms. This expedited release process is essential for maintaining workflow continuity and optimizing resource allocation, which ultimately contributes to faster time-to-market for products. Furthermore, the confidence from a robust, automated release system ensures compliance with regulatory requirements while supporting a culture of quality and accountability within the lab environment. By integrating this approach, laboratories can achieve higher operational agility and responsiveness, strengthening their position in the competitive life sciences sector.

A STEP-CHANGE IN QC LAB PRODUCTIVITY

To keep pace with technological advancements in the life sciences industry, full digital transformation is necessary for laboratories. There are critical areas where traditional LIMS may fail to achieve this transformation. Laboratories can modernize their quality control operations by addressing gaps such as instrument integration, paperless processes, inventory management, and automation of review and release procedures. These steps are critical for streamlining workflows, enhancing data integrity, improving compliance with regulatory requirements, and ultimately contributing to higher quality results in the life sciences sector. With a comprehensive digital lab solution that addresses all these areas, laboratories can achieve true digital transformation finally achieve a step-change in lab productivity. So don't wait any longer - start your journey towards full digitalization today!

BIOVIA ONE LAB: THE ONLY COMPREHENSIVE SOLUTION FOR QC LAB TRANSFORMATION

BIOVIA ONE Lab stands out as the premier solution in the market for achieving full digital transformation in quality control laboratories. Unlike traditional LIMS and inventory systems that operate in silos, BIOVIA ONE Lab integrates all essential components—data, instruments, inventory, and procedures—into a unified solution. This holistic approach facilitates seamless data flow across lab functions and enhances real-time decision-making and operational efficiency. It also leverages a single data model, eliminating data silos and enabling comprehensive analytics and business intelligence capabilities.

With BIOVIA ONE Lab, laboratories can eliminate the complexities of managing multiple systems and integrations. The solution's robust architecture allows for the complete automation of workflows, from instrument data capture to chemical inventory management, ensuring that labs adhere to stringent regulatory requirements while maintaining the integrity of their data. Moreover, the system's interactive nature supports dynamic procedure execution, replacing outdated static methods and reducing the risk of human errors.

BIOVIA ONE Lab is not just an alternative to traditional LIMS; it is a transformative solution that empowers laboratories to enhance productivity, improve compliance, and drive quality outcomes. By centralizing all critical functions within a single environment, BIOVIA ONE Lab lays the foundation for a truly digital, integrated, and agile laboratory capable of meeting the evolving demands of the life sciences sector.

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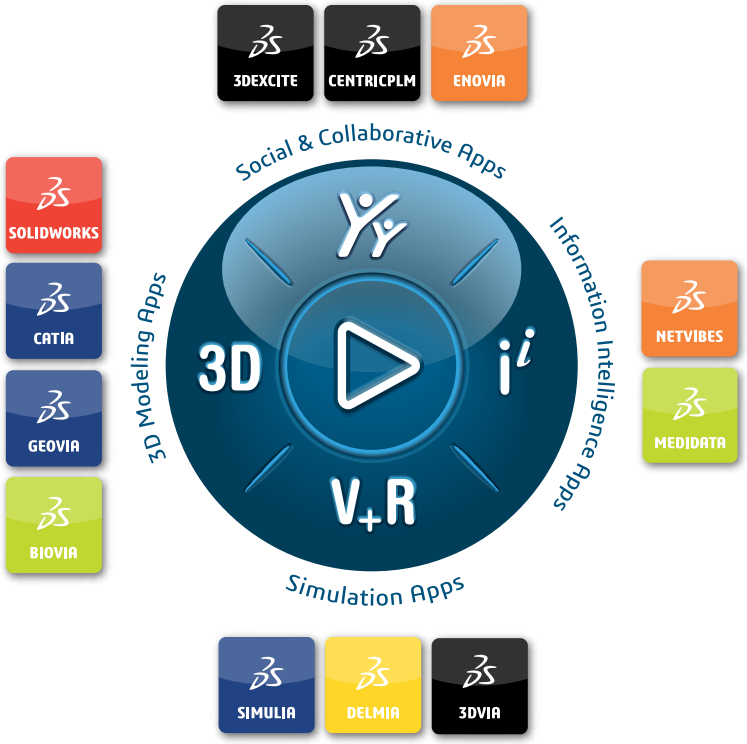

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