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ASIA EDITION

Accelerating Digitalization in the Life Sciences Industry

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BIOVIA ONE Lab boosts R&D operational excellence and enhances collaboration

Growing trends in laboratory digitalization are continuously transforming execution and practices in the biopharma and clinical industries. Bioscience R&D is constantly evolving with digital enhancements as novel tools empower scientists to simplify the multiple stages of clinical trials and the R&D life cycle, such as integrating and standardizing lab data, resources, and processes through the use of unified environments like BIOVIA. BIOVIA ONE Lab is a unified software solution that streamlines research and laboratory processes to bring therapies to market faster for an enhanced patient experience.

Medidata's proprietary platform solutions, in conjunction with BIOVIA, aim to improve research outcomes and for products to make trial delivery timelines shorter. **Automatic digital capture** of experimental data without manual intervention can offer demonstrable operational benefits like enhanced productivity, improved compliance, and better collaboration within and across teams. Moreover, BIOVIA provides real-time results and informed decisions all in one platform.

In an effort to bring increased efficiency, security, and accessibility to clinical research programs, the global firm Medidata, a wholly-owned subsidiary of Dassault Systèmes redefines end-to-end solutions for sponsors (drug, vaccine, and medical device developers) and CROs to cross the crucial benchmarks of clinical trials.

Edwin Ng, Senior Vice President, General Manager (Asia Pacific) at Life Science, Dassault Systèmes explains, “By addressing challenges of product lifecycle management in the life sciences industry, BIOVIA in conjunction with Medidata’s suite of solutions allows innovators and collaborators to access data faster and tap on powerful insights to shorten time-to-market. It enables pharma and life sciences companies to have a better understanding of how their product does in a physical environment which essentially reduces physical testing and risks. With the life sciences industry adopting digital approaches for process and product management more than ever, BIOVIA and Medidata drive operational excellence and support collaboration across various partners in the same ecosystem.”

Adopting modern digitalized R&D practices and advanced automated clinical trial models in pharmacovigilance can address the critical reasons responsible for setbacks in development and clinical operations, by enhancing the capabilities of researchers and drug developers.

Elevating lab technologies for next-gen R&D solutions

Typical experimental procedures and lab operations generate a substantial amount of data from a plethora of different data

sources. A large number of R&D laboratories use manual data handling to record critical observations during development procedures, resulting in scattered data and unorganized records. Effective management of experimental data is crucial for organizations to ensure optimal lab efficiency, assist in decision-making, and avoid unessential record duplication.

In conventional approaches, these experimental records, captured data, and scientific results were stored in multiple Excel files, scanned PDF documents, and siloed lab solutions. In other words, collaboration across departments was solely dependent on ad hoc and informal channels, which leads to uncontrolled and often long-delayed workflows.

BIOVIA ONE Lab allows for **automatic digital capture** of experimental data without manual efforts, offering demonstrable operational benefits like enhanced productivity, improved compliance, and better collaboration within and across teams. BIOVIA's modeling and simulation software also allow for scientists to perform computations of chemical, biological, and materials properties to simulate, visualize and analyze chemical and biological systems among the research organizations and to communicate the results to other scientists. It not only accelerates isolated workflows but also eliminates transient disruptions of workflows along the value chain, specifically between R&D and manufacturing. Moreover, BIOVIA provides real-time results and informed decisions all in one platform.

BIOVIA, the unified and secure R&D optimization solution

- **Accelerating the digitalization journey**

BIOVIA's objectives are to realize operational benefits through automation across the entire research-development-manufacturing continuum. In addition to eliminating paper-dependent data management, BIOVIA helps organizations reduce inefficiencies and compliance risks, thereby improving productivity and reducing cycle times. The raw data generated can be collected, compiled, and analyzed for further interpretation through advanced data science techniques. The fully paperless environment enabled by automating data capture is a critical step in a company's **digital transformation journey.**

BIOVIA's solution summarizes all recorded data with process parameters in an experimental protocol, along with associated calculations for further review and approval, which can be made available in a consolidated format for all users involved in the process. The exchange of data captured throughout the product lifecycle creates enterprise-wide intelligence that accelerates product development cycle times. With this unparalleled solution, R&D, analytical, quality assurance, and quality control laboratory workflows can all be improved, replacing cumbersome manual workflows.

- **Dynamic infrastructure with Integrated Unified Workflow**

By optimizing innovation processes, BIOVIA provides a scalable framework necessary to transform a lab into an intelligent, data-centric machine and to **increase operational efficiency**. By integrating workflows and a homogenized execution system, BIOVIA enables automated data harvesting and data standardization for collaborative innovation across clinical and biosciences ecosystems.

Commenting on BIOVIA's dynamic infrastructure for laboratory informatics Edwin Ng says, "By integrating a unified solution like BIOVIA ONE Lab in their workflows, organizations can accelerate the product development cycle and increase collaboration to address real-world patient concerns, essentially supporting the growth of the industry in the region."

For instance, in many bioprocessing designs, upstream process design does not always reflect the needs of downstream manufacturing. As well, knowledge accumulated downstream was not fed back into R&D. These disconnects resulted in additional lab work at late stages, inefficient workflow, long review times, late decisions, and excessive effort. Managing workflow efficiency with such poorly integrated lab systems can be challenging.

The reporting and analysis of BIOVIA's solution enable comparison of new results with previous batches to understand the progressing development process. It also assists in making informed decisions on the next development cycle. The software solution ensures that sponsors and CROs are equipped with a robust end-to-end, unified, and secured environment for R&D labs. Such a systematic approach to Quality by Design (QbD) in pharma and clinical development with predefined objectives can emphasize process control, based on scientific rationale. As and when the solution is expanded to more sites of an organization in an incremental and controlled manner, risk management improves in the operation.

- **A secured validation-ready laboratory informatics solution**

BIOVIA ONE Lab offers process-driven solutions for effective recording and processing of experimental data by streamlining tedious processes into faster and more cost-effective operations. By integrating and consolidating informatics components

across research, development, QA/QC, clinical innovations, and manufacturing, BIOVIA is accelerating the product development process across the lab to plant continuum promoting quality operations.

Through cloud deployment of the ONE Lab, BIOVIA provides a secure, validation-ready laboratory informatics solution. Improving lab operation compliance with regulatory requirements drives innovation coupled with strategic resource management. BIOVIA's cloud configuration eliminates the need for internal IT staff to manage the applications and servers, keep track of upgrades, maintain performance, and manage security concerns.

Secure access is delivered via SSL encryption, ensuring system security regardless of user location. Authorized users anywhere in the company, anywhere in the world can access the organization's secure laboratory informatics solutions any time they want. Thus, A common digitized and automated solution across the laboratory continuum can lay a solid foundation to implement a common solution across all therapeutic modalities.

In brief, BIOVIA leverages a dynamic infrastructure for laboratory informatics, enhancing collaboration, and reducing regulatory compliance and safety risks, while also decreasing overhead expenditure for IT management.

BIOVIA ONE Lab also assists in material identification, regulatory list management, biological materials management, and safety data sheet (SDS) management to enable an organization to comply with the environmental, chemical safety, and biological safety regulatory reporting requirements. The solution is the one-step answer to quickly and efficiently transfer new product development processes and analytical methods into reliable and repeatable procedures. Implementing these methods and frameworks early in the development process results in a standard approach for product development and scaling up.

Leading Futuristic Trends

With its potential to improve efficiency, and productivity, and increase collaborations to propel future innovations, BIOVIA drives synergy in biopharma R&D operations. It establishes how digital transformation can allow companies to harness the power of a common software environment that manages most aspects of today's laboratories, while also integrating with other existing lab informatics systems.

However, harmonization and business transformation can only be successful with the active involvement of all organizational levels and management lines. If you're keen to learn more, read more about BIOVIA's solutions **here**, and **hear from experts** on how digital continuity and technologies can be leveraged to improve efficiencies in the life sciences industry today.