BIOVIA

3DEXPERIENCE®

BIOPHARMA ACCELERATES LAB DIGITALIZATION WITH BIOVIA ONE LAB

STREAMLINING LAB EXECUTION WITH BIOVIA

Use Case

DASSAULT SYSTEMES

Challenge:
Manual data handling; data not available for planning/decisions; information buried in scattered documents; knowledge kept at individual level; excessive late-stage lab work.

Solution:
A single CMC lab informatics solution based on BIOVIA ONE Lab.

Results:
- Enable growth through scalable collaboration processes
- Create foundation for systematic knowledge management
- Reduce risk with better informed decisions
- Remove bottlenecks to growth
- Eliminate redundant work
- Accelerate time to market

CUSTOMER: A GLOBAL LEADER IN HEALTHCARE

This BIOVIA customer is one of the world's largest companies engaged in the research, production and distribution of pharmaceutical, consumer healthcare and vaccine products. The company is currently developing a broad offering of biologics products in addition to their sizeable small molecule portfolio. The growing complexity and diversity of their expanding product lines, as well as the acceleration of clinical trial processes, has put their Chemistry, Manufacturing and Controls (CMC) organization on the critical path for commercial product launches.

CHALLENGE: POORLY INTEGRATED LAB SYSTEMS, WORKFLOW INEFFICIENCIES

This biopharma company's primary challenge is to accelerate innovative drugs to market. They realized that this would require a transformation of CMC processes that would not only accelerate isolated workflows but also eliminate transient disruptions of workflows along the value chain, specifically between R&D and Manufacturing. In many cases, experimental records, recipes and scientific results were stored in multiple Excel files, scanned PDF documents and siloed lab solutions, many of which did not use the same conventions from lab to lab or scientist to scientist. Collaboration depended on ad hoc and informal channels such as e-mail, which led to uncontrolled and often long-delayed workflows across departments. Upstream process design did not reflect the needs of downstream manufacturing. Likewise, knowledge accumulated downstream did not flow back to R&D. These disconnects were leading to additional lab work at late stages, workflow inefficiencies, long review times, delayed decisions, excessive effort and wasted material.

SOLUTION: A SOLID FOUNDATION FOR LAB DIGITALIZATION AND AUTOMATION

The company accepted the challenge to implement a common solution across all CMC labs and for all therapeutic modalities—both small molecules and biologics. Built with BIOVIA Dassault Systèmes' ONE Lab solution, the project provides a common platform for use across all drug substance, drug product and analytical development labs worldwide. With this single lab informatics solution, the company is now in a better position to:

- **Accelerate tech transfer:** S88-compliant procedures replace inefficient paper-based processes for capturing, managing and executing recipes, processes and methods. The S88 ISA standard manages methods and procedures from method development to sample analysis, enabling the accurate, uniform storage of enterprise data in a single centralized database.
- **Automate lab processes:** The digital platform enables scientists to capture and secure IP and streamline data acquisition, consolidation, interpretation and reporting, while reducing risks resulting from human errors.
- **Structure products and processes:** A common product and process reference-base allows the company to collaborate using a collective understanding of process maturity and detailed product dependencies.

Their new CMC lab informatics environment leverages BIOVIA ONE Lab as a central hub for workflow execution and access to scientific information, providing scientists and technicians with more efficient and better integrated workflows for drug substance development. For example, working in a paperless environment with automated data capture from equipment and instruments, chemists can use the flexible capabilities of the new CMC solution to make a new antibody-drug conjugate (ADC). They can plan and execute a purification protocol following a step-by-step recipe designed in the CMC solution and subsequently extract samples for analysis in the same system. When the purification protocol is complete, the system provides a summary of all process parameters, along with associated calculations. Finally, the purified ADC progresses to the review stage for approval with all data and results consolidated and available for use by others with a need to know in the organization.

Figure 1: In the lab, the operator has opened the purification recipe on his iPad and is ready to follow the step-by-step guidance on the screen.

In another example, the chemist has taken a sample of his purified product and wants it analyzed by HPLC. The chemist browses the list of available HPLC tests, selects the desired test, applies it to the sample and submits the request to the analytical department, all from within their new CMC lab informatics environment. The assigned analyst prepares the samples by following the specified HPLC method, connecting to inventory and equipment as necessary. The analyst imports the samples into an Empower CDS sequence and completes the analysis. The sample results and all associated report files are then exported back to the CMC lab solution where they appear in the execution record. The requesting chemist pulls the analytical results into the electronic lab notebook (ELN) experiment where there is now a full record of the new batch. The chemist can then compare this result with data for the designated reference batch to understand the effectiveness of the process. Finally, the chemist uses the system reporting and analysis tool to compare the new results with historical batches to understand how the development process is trending and make an informed decision on the next development cycle.

> "Our single lab informatics solution for CMC is giving time back to our scientists so that they can focus on science, ultimately benefiting our growing product portfolio, and our patients."
>
> — Project Manager, Biologics
> Leading Biopharmaceutical Company

The company also benefits from BIOVIA's long-term partnership with the Allotrope Foundation to help develop a standardized data format for the acquisition, sharing and management of structured procedural methodology and all experimental, analytical and process data. The goal is to enable more compliant data tracking and better data integrity; to do away with data silos; and simplify the laboratory operational landscape.

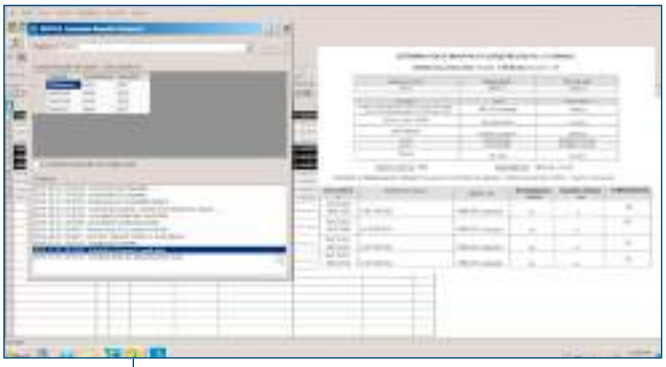
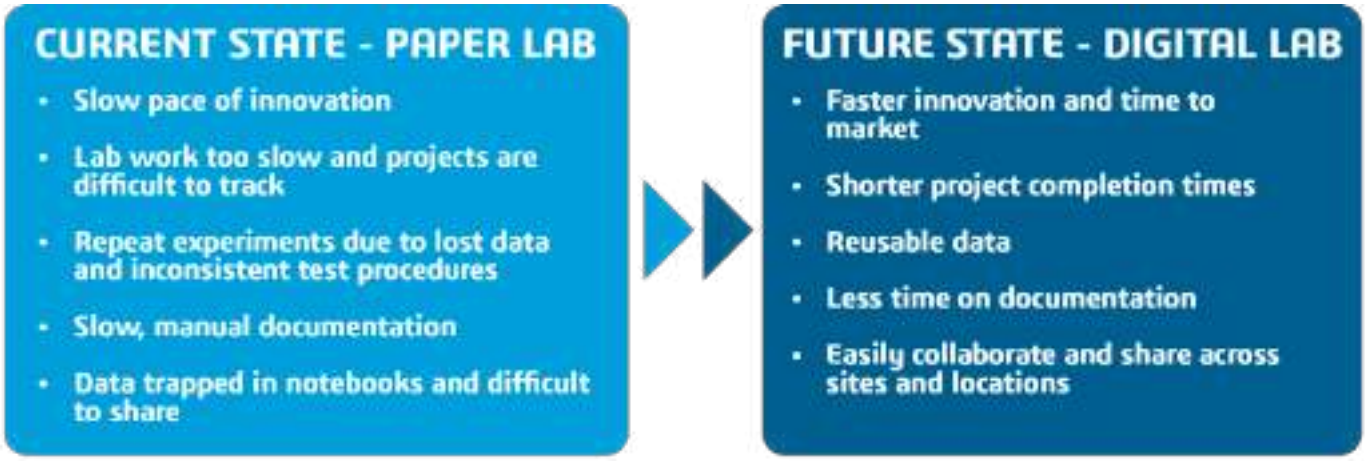


Figure 2: Once the HPLC analysis is complete, the sample results and all associated report files are exported directly to the new CMC lab informatics solution where they appear in the execution record.

RESULTS: IMPROVED CAPABILITY, COORDINATION AND COLLABORATION

By laying the foundation for seamless and fast access to relevant product and process data throughout the development and manufacturing lifecycle, this company's CMC lab informatics project has become a critical destination on the company's digital transformation journey. The project enables scientists to work in a paperless lab environment by automating data capture from equipment and instruments, by managing the flow of samples, requests and tests through the labs and by making the data collected available to others.



The company's deployment strategy hinges on three key principles: (1) value-based prioritization of CMC labs and capabilities, (2) phased incremental development of the core CMC lab informatics environment and (3) a Lighthouse pilot approach to deployment. The Lighthouse approach means deploying each release first at a single site where project managers can focus on a small-scope implementation. Here they can test and verify selected processes in the new environment and learn how best to scale the system up to additional sites in an incremental and controlled manner.

The company's key takeaways after one year of experience with the new lab informatics solution are:

- CMC has already achieved considerable value from connecting lab instruments and equipment to automate data acquisition and reduce manual data handling.
- Lab workflow digitalization has improved collaboration within and across labs.
- To harmonize workflows across different labs, first agree on a master list of methods that will serve most labs. Business analysts can play a critical role in helping to drive successful harmonization and business transformation.
- Change Management is key for successful deployment and adoption. Moving from paper notebooks and PDF procedurals to digital workflows can be a learning step for lab technicians.
- Digital change agents at each site can help drive a successful deployment. The active involvement of all organizational levels and management lines is key to success.

This ambitious CMC lab informatics project, built on the BIOVIA ONE Lab solution, is enabling this company to leverage the knowledge accumulated across their CMC/R&D organization. With this new lab digitalization solution, they are on their way to improving efficiency, productivity and collaboration, while also accelerating successful new therapies to patients.

LEARN MORE

Our **3D**EXPERIENCE® platform powers our brand applications, serving 11 industries, and provides a rich portfolio of industry solution experiences.

Dassault Systèmes, the **3D**EXPERIENCE Company, is a catalyst for human progress. We provide business and people with collaborative virtual environments to imagine sustainable innovations. By creating 'virtual experience twins' of the real world with our **3D**EXPERIENCE platform and applications, our customers push the boundaries of innovation, learning and production.

Dassault Systèmes' 20,000 employees are bringing value to more than 270,000 customers of all sizes, in all industries, in more than 140 countries. For more information, visit **www.3ds.com**.

3DEXPERIENCE®

DASSAULT SYSTEMES | The 3DEXPERIENCE® Company

Americas
Dassault Systèmes
175 Wyman Street
Waltham, Massachusetts
02451-1223
USA

Europe/Middle East/Africa
Dassault Systèmes
10, rue Marcel Dassault
CS 40501
78946 Vélizy-Villacoublay Cedex
France

Asia-Pacific
Dassault Systèmes K.K.
ThinkPark Tower
2-1-1 Osaki, Shinagawa-ku,
Tokyo 141-6020
Japan