BIOVIA

3DEXPERIENCE®

ACCELERATING BATCH RELEASE WITH BIOVIA ONE LAB

Customer Story

Transforming QC labs with Digitalized Procedure Execution

Many life science companies struggle with lengthy batch release processes. However, implementing a comprehensive laboratory informatics solution like BIOVIA ONE Lab can significantly shorten batch release times. By streamlining procedures, data management, and equipment/inventory management, organizations can achieve same-day batch release and enhance their overall operational efficiency and accuracy.

DASSAULT SYSTEMES

Challenge:

- Lengthy batch release processes - up to 30 days.
- Inefficiencies in Quality Control (QC) labs leading to extensive review times.
- Non-standardized procedures contributing to inaccuracies and delays.
- Disparate data sources complicating data management.
- Manual workflows increasing the risk of human error.

Solution:

- BIOVIA ONE Lab for Procedure Execution

Benefits:

- Reduction of batch release time from 30 days to 15 days within the first year.
- 50% decrease in review times due to automated workflows.
- Streamlined test release through unique "Review-by-Exception" technology

THE CUSTOMER

This BIOVIA customer is at the forefront of the pharmaceutical industry, producing high-quality clinical and commercial products. Renowned for their commitment to innovation and precision, they continually strive to enhance their manufacturing processes. However, the lengthy batch release times hindered their objective of delivering life-saving therapies quickly to patients. They sought to shorten their batch release time from over 30 days to just 10 days by 2025 and achieve same-day release by 2030. By implementing BIOVIA ONE Lab in a GMP environment, this customer successfully standardized procedures, increased accuracy, and significantly reduced review times in their Quality Control (QC) labs.

THE CHALLENGE

Our customer set out on an ambitious journey to transform their batch release process, which could take up to 30 days. Their goal was not just to reduce the batch release process to 10 days in the interim, but to achieve same-day batch release within the next 7 years. The primary challenges they faced were the inefficiencies of their QC labs, where extensive review times and re-tests were common. These inefficiencies were due to non-standardized procedures, disparate data sources, and manual workflows, all contributing to inaccuracies and delays. The customer recognized that to achieve their goals, they needed a technology solution that could address these challenges.

SOLUTION

After an in-depth consultation with BIOVIA solution experts, the customer implemented BIOVIA ONE Lab, an innovative laboratory informatics platform explicitly designed for GMP environments. This deployment required validation to meet stringent regulatory standards.

The customer integrated ONE Lab for Procedure Execution with their existing Laboratory Information Management System (LIMS), so that ONE Lab became the core software environment for analysts working in the lab. With its unified workflows and data management capabilities, this solution enables the standardization of procedures, data capture, and analysis in a regulated QC environment. By leveraging ONE Lab in their QC labs, the customer gained real-time visibility into all lab activities and streamlines review processes.

Additionally, ONE Lab integrates equipment management and materials/inventory management into the same solution, for a truly holistic lab informatics environment. Integrated equipment management lets the customer capture and standardize data directly from lab instruments, while also tracking and managing metrology, all without the need for a 3rd party system. Materials and inventory managment similarly enables automatic tracking of consumables use, along with integrated EH&S data available at a global level.

RESULTS

Implementing BIOVIA ONE Lab completely transformed the customer's QC labs. Manual processes and paper-based documentation were replaced with automated workflows and electronic records, significantly reducing the risk of human error and improving overall efficiency. The solution also provided real-time data analysis and reporting, allowing quicker decision-making and improved quality control.

> "BIOVIA ONE Lab has been a game-changer for our Quality Control processes. Focusing on non-compliant samples with the 'Review-by-Exception' has both improved our accuracy and enhanced overall productivity."
>
> — Head of QC, Global Biopharma Company

The benefits of using BIOVIA ONE Lab were evident from the beginning. BIOVIA's "Review-by-Exception" technology allowed test results that were within specifications to be automatically released, enabling scientists to focus attention only on samples which were out of spec. This led to more accurate data analysis and increased overall test release rates.

The customer reported a reduction in review times, while the overall batch release process dropped from an average of 30 days to 15 within the first year, keeping them on track for their 2025 and 2030 targets.

Implementing BIOVIA ONE Lab for Procedure Execution has greatly benefited our customer's QC labs. By streamlining review processes and providing guided procedure execution, BIOVIA ONE Lab resulted in remarkable improvements in the batch release process. Digitalizing all parts of the lab workflow, including inventory tracking and equipment management was a key aspect to achieving the customer's goals.

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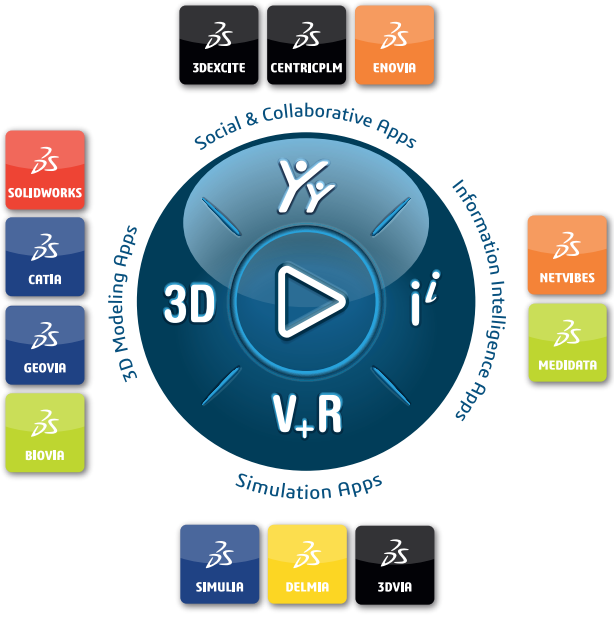

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