



THE DIGITAL LAB ADVANTAGE:

Transforming Biologics
from Development to Manufacturing



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INTRODUCTION: DIGITALIZING THE LAB TO TRANSFORM BIOLOGICS DEVELOPMENT

Biologics development is a race against time. It demands precision, consistency, and adaptability. Yet, many labs still rely on fragmented, outdated processes that slow innovation and introduce costly inefficiencies. Paper-based documentation, disconnected data, and manual workflows make it difficult to maintain traceability, manage variability, and ensure compliance.

Lab digitalization transforms biologics development by integrating data, automating workflows, and enabling seamless collaboration. A fully digital lab environment eliminates inefficiencies, accelerates decision-making, and ensures process consistency—critical for scaling production and maintaining regulatory compliance.

This E-Book explores how lab digitalization accelerates drug product and process development, offering a connected approach to improve efficiency, scalability, and regulatory readiness. Through three key steps, we'll show how organizations can reduce tech transfer time, optimize process management, and accelerate measurement of critical quality attributes, ultimately bringing high-quality biologics to market faster.

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CHALLENGES IN BIOLOGICS DEVELOPMENT

Biologics development is a complex, multi-stage process requiring precise coordination.

Unlike small molecules, biologics are structurally complex and highly sensitive to their environment, making development more challenging. Without a unified approach inefficiencies arise, leading to delays, inconsistencies, and increased costs.

The key challenges in biologics development include:

1. Managing Process Variability and Complexity

Biologics are highly sensitive to experimental conditions, material attributes, and process parameters, making it difficult to track and control variations. Unpredictable process changes can lead to inconsistencies, delays, and manufacturing instability. Without a centralized system, teams struggle to manage these interdependencies efficiently.

2. Ensuring Traceability and Compliance

Maintaining real-time tracking across development stages is often time-intensive and error-prone, requiring significant effort to ensure data accuracy. Regulatory compliance depends on complete, audit-ready documentation, but without robust systems in place, meeting these standards is challenging.

3. Standardizing Recipes and Methods for Efficiency

Biologic formulations and production methods evolve through multiple development stages. Manually tracking updates and ensuring consistency is difficult, increasing the risk of errors and inefficiencies. A lack of standardized workflows slows down knowledge transfer, making scale-up to manufacturing more complex and time-consuming.



OPTIMIZING BIOLOGICS DEVELOPMENT WITH BIOVIA ONE LAB

Bringing a biologic drug from development to manufacturing requires precise coordination across multiple teams, workflows, and data sources. However, disconnected processes and fragmented data often lead to inefficiencies, delays, and increased costs. Lab digitalization streamlines biologics development by standardizing workflows, improving traceability, and ensuring seamless process continuity.

BIOVIA ONE Lab: A Digital Solution for Seamless Integration

BIOVIA ONE Lab transforms biologics development by unifying fragmented workflows into a single digital environment. By replacing manual processes with structured automation, it optimizes bioprocess development, drug formulation, and analytical testing—reducing delays, improving resource allocation, and ensuring regulatory readiness.

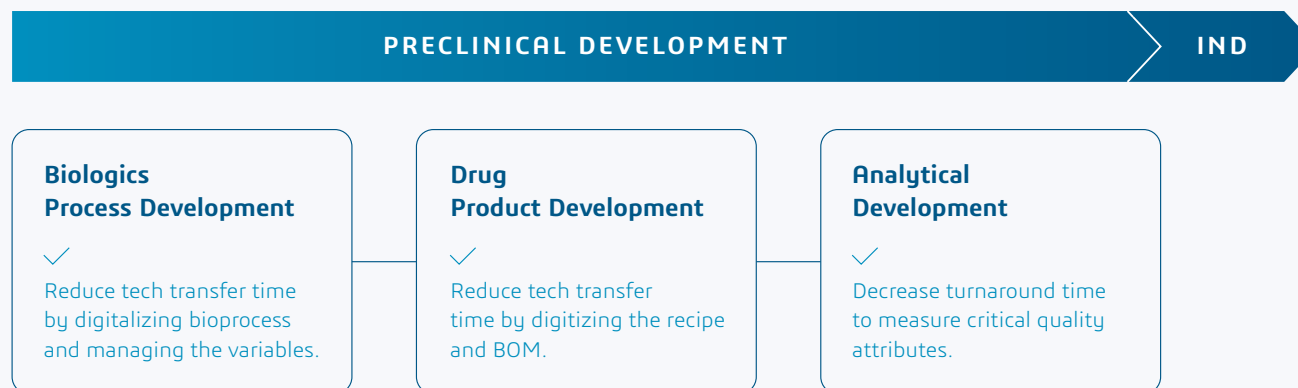
BIOVIA ONE Lab allows companies to:

- **Ensure end-to-end process continuity** by connecting lab workflows, from development to manufacturing.
- **Increase operational efficiency** by eliminating manual record-keeping and automating data capture.
- **Ensure traceability and compliance** with automated data capture and audit-ready records.
- **Improve collaboration** by centralizing data for real-time access across teams.

By fully digitalizing lab environments, teams eliminate inefficiencies and accelerate biologics development.

The following sections explore the three key steps enabled by BIOVIA ONE Lab.

THE BIOLOGICS DEVELOPMENT JOURNEY



Together, these steps streamline the development of biologics, enabling researchers to optimize processes, ensure scalability, and accelerate the path to manufacturing—resulting in safer, high-quality treatments brought to market more efficiently.

STEP 1

REDUCE TECH TRANSFER TIME BY DIGITALIZING BIOPROCESS AND MANAGING VARIABLES

Optimizing biologics process development requires a structured, digital approach to efficiently design, document, and transfer processes from development to manufacturing. **Biologics Process Development** with BIOVIA ONE Lab provides an end-to-end digital approach that enables organizations to manage upstream and downstream processes, ensuring accurate tracking, improved scalability, and faster tech transfer.

With BIOVIA ONE Lab, organizations can:

- Digitalize bioprocess workflows to integrate cell line management, media selection, equipment tracking, and experimental conditions into a unified system.
- Standardize method and recipe development using structured documentation for consistency across development and manufacturing.
- Enable seamless digital continuity to transfer the manufacturing Bill of Materials (BOM), recipes, and methods into production efficiently.
- Develop and optimize biologic drug substance manufacturing and characterization processes using the industry-standard S88 process model to enhance reproducibility and regulatory compliance.

Key Benefits of Lab Digitalization in Bioprocess Development

Digitalized process tracking reduces manual effort and improves accuracy.

Standardized workflows enhance scalability and regulatory compliance.

Accelerated tech transfer minimizes delays and ensures manufacturing readiness.



STEP 2

REDUCE TECH TRANSFER TIME BY DIGITALIZING THE RECIPE & BOM

Precise control over recipes, compositions, and process parameters is essential for seamless scale-up and manufacturing readiness. For **Drug Product Development**, BIOVIA ONE Lab provides an end-to-end digital capability to define the final drug product composition and establish a scalable manufacturing process aligned with the Target Product Profile (TPP).

With BIOVIA ONE Lab, organizations can:

- Develop and refine drug product formulas to optimize efficacy, safety, and cost performance in line with TPP requirements.
- Digitalize recipe and Bill of Materials (BOM) management for drug product formulation, ensuring consistency across all development stages.
- Automate and streamline data capture and lab workflows, reducing manual effort and improving efficiency.
- Leverage the industry-standard S88 process model, enabling seamless tech transfer from lab-scale development to full-scale production.
- Verify formulation outcomes with integrated lab testing, ensuring product quality and process optimization.

By digitalizing drug product development, organizations can accelerate scale-up, improve formulation consistency, and enhance regulatory compliance—ensuring a smooth transition from formulation to manufacturing.

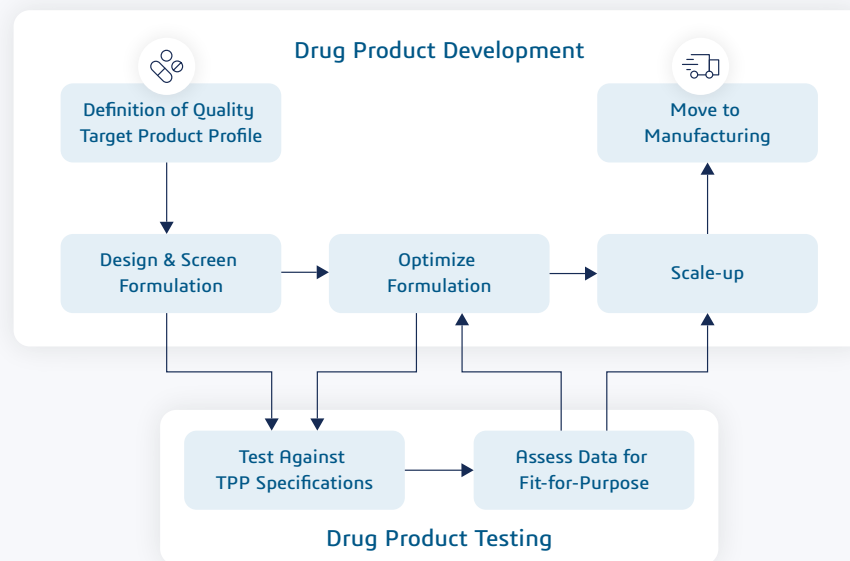
Key Benefits of Lab Digitalization in Drug Product Development

Optimized formulation design ensures efficacy, safety, and cost efficiency.

Seamless tech transfer supports efficient scale-up and production readiness through cross-functional collaboration.

Increased "right-first-time" outcomes through standardization and enhanced regulatory compliance, reducing rework and delays.

Digital Drug Product Development Process





STEP 3

DECREASE TURNAROUND TIME TO MEASURE CRITICAL QUALITY ATTRIBUTES

Accurate measurement of critical quality attributes (CQAs) ensures biologics meet safety, efficacy, and regulatory standards.

For **Analytical Development**, BIOVIA ONE Lab enables organizations to develop and validate analytical methods in a fully digital environment. By streamlining everyday lab operations, this solution improves access to materials and equipment, enhances knowledge reuse, and facilitates collaboration and data sharing. Automating documentation and standardizing quality assessments strengthens compliance, reduces errors, and accelerates biologics manufacturing.

With BIOVIA ONE Lab, organizations can:

- Develop and validate analytical methods in a fully digital environment, ensuring accuracy and compliance.
- Measure critical quality attributes (CQAs) for raw materials, in-process samples, finished products, and stability testing.
- Automate data capture from lab equipment, eliminating manual transcription errors and ensuring data integrity.
- Standardize and document analytical methods using the industry-standard S88 model to ensure consistency.
- Enable seamless digital tech transfer, ensuring validated analytical methods are efficiently transferred from development to manufacturing.

By digitalizing analytical development, organizations reduce delays, improve regulatory compliance, and accelerate time-to-market for biologics.

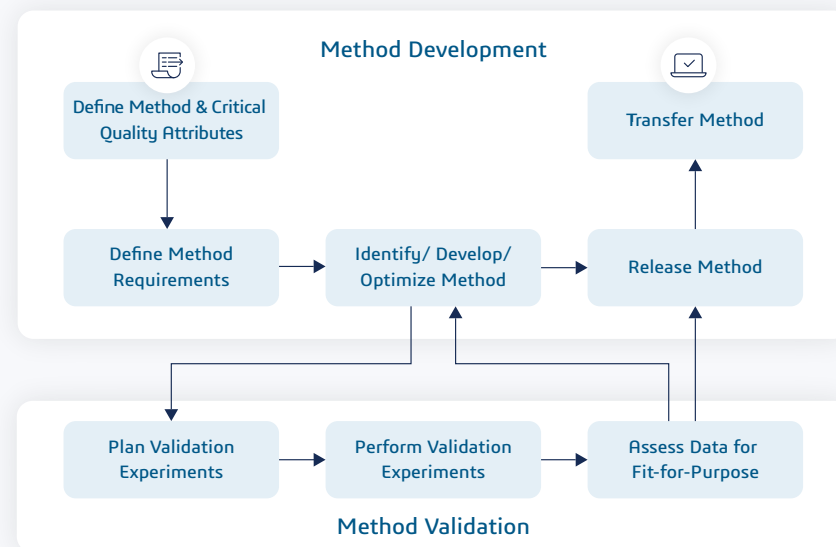
Key Benefits of Lab Digitalization in Analytical Development

Automated method validation reduces errors and ensures accuracy.

Standardized workflows improve data integrity and regulatory readiness.

Seamless digital tech transfer ensures validated analytical methods move efficiently to manufacturing.

Digital Analytical Development Process



THE TRANSFORMATIONAL IMPACT OF LAB DIGITALIZATION

By digitalizing biologics, formulations, and analytical labs, organizations can accurately track interdependencies, streamline processes, and preserve knowledge for scalable manufacturing. This integrated approach improves efficiency, compliance, and data integrity, enabling teams to optimize every stage of development.

With BIOVIA ONE Lab, companies can:

- Manage variables and interdependencies across materials, equipment, and processes to improve consistency.
- Identify and track equipment use, sample genealogy, team involvement, and chain of custody for full traceability.
- Reduce deviations and compliance risks by ensuring structured, standardized workflows.
- Optimize test methods and specifications to shorten R&D cycle times and accelerate decision-making.
- Enable a digital representation of SOPs in quality control labs to simplify experiments and minimize transcription errors.

By implementing BIOVIA ONE Lab, companies enhance process efficiency, accelerate R&D timelines, and improve biologics manufacturing reliability—ensuring faster, scalable innovation.



Real-World Results with Lab Digitalization

Organizations leveraging BIOVIA ONE Lab for biologics development have seen:

50% reduction in time spent on quality review processes through digitalized lab experiments.

50% faster turnaround time with digitalized data and workflows.

80% of lab experiments reused throughout the product lifecycle, reducing experimental costs by up to 50%.

85% improvement in data traceability through a fully digitalized chain of evidence.

87% reduction in material usage by digitalizing development laboratories.

Source: BIOVIA internal analysis

THE DIGITAL LAB ADVANTAGE

As the demand for biologics grows, organizations must streamline development, scale production, and ensure regulatory compliance—all while maintaining scientific precision. BIOVIA, a Dassault Systèmes brand, empowers biopharma companies to accelerate drug development with a fully integrated digital lab environment.

BIOVIA ONE Lab unifies bioprocess development, drug product formulation, and analytical testing into a seamless, data-driven approach. By replacing fragmented workflows with structured, automated processes, organizations gain end-to-end traceability, improve collaboration, and reduce inefficiencies—accelerating the path from development to manufacturing.

For more information, visit www.3ds.com/products/biovia/one-lab.



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