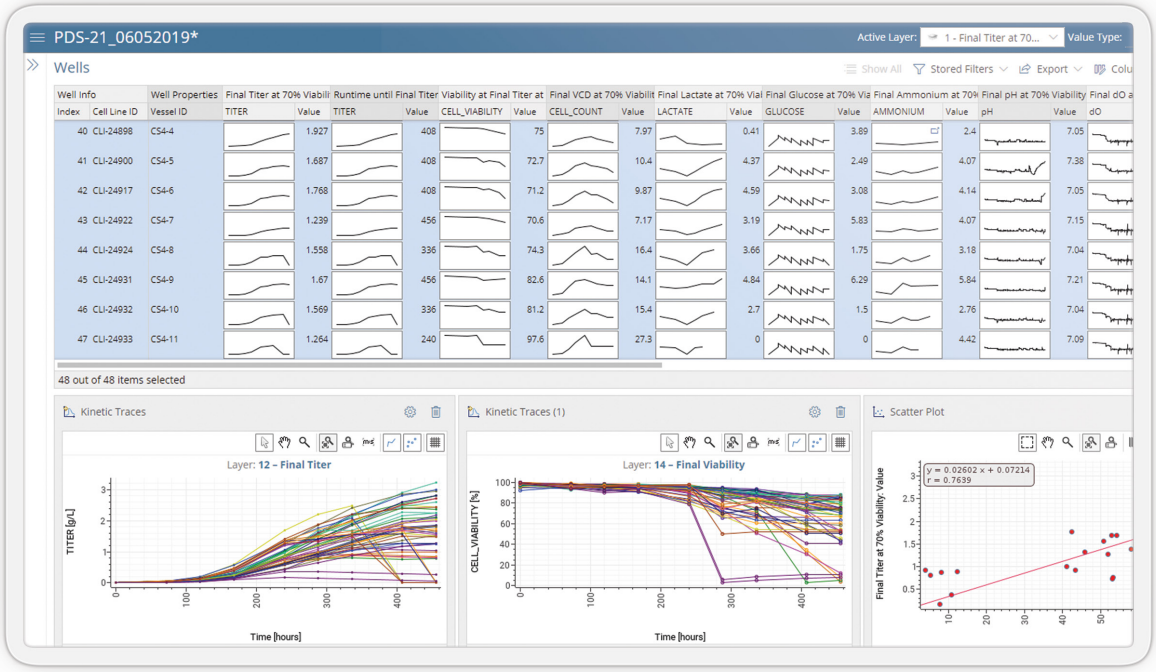
Genedata

# Bioprocess Development. Next-Generation.

## BIOPROCESS



# Why Genedata Bioprocess?

## End-to-End Platform for Highest Data Volumes

Genedata Bioprocess® designs next-generation bio-manufacturing processes across CLD, USP and DSP, formulation, and analytics development. It enforces data integrity and compliance, streamlining development of originator drugs and biosimilars. The only platform uniquely designed from the start for the development of biotherapeutic drugs, Genedata Bioprocess acts as an integrated data backbone to ensure maximum efficiency along the whole end-to-end workflow and supports cutting-edge technologies, such as highly parallel scale-down bioreactor panels, as well as complex DSP unit operations and sophisticated analytical techniques. The intuitive user interface allows flexible and interactive data registration, analysis, and reporting. The platform can be configured to support corporate-specific variants of bioprocess development workflows and can be used to develop manufacturing processes for all biotherapeutic modalities (e.g., therapeutic proteins, RNAs, AAVs).

## Improves Productivity & Quality

Pharmaceutical giants as well as renowned CRDMOs around the world use Genedata Bioprocess to increase the efficiency of their development processes. Scaling with highest data volumes, the platform integrates and harmonizes overall bioprocess development and CMC workflows, streamlines communication and handovers, and provides central and transparent real-time access to all process information. Within a single system, Genedata Bioprocess enables lineage tracking of candidates, cell lines, samples, and unit operations, together with process performance and analytical data, enabling the systematic identification of Critical Process Parameters (CPPs) and Critical Quality Attributes (CQAs). This ensures data integrity and dramatically improves the quality of results.

## Automates & Industrializes

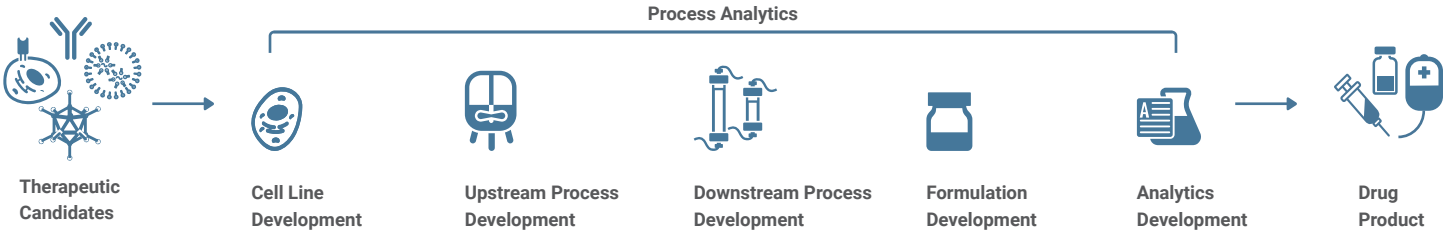
By directly integrating with all laboratory instruments, such as bioreactors, downstream processing equipment, and analytics devices, Genedata Bioprocess automates data capture, which simplifies and streamlines complex workflows, significantly improves overall productivity, and reduces manual errors. Dedicated instrument adapters enable seamless integration with all major lab instruments on the market (e.g., liquid handling robots, colony pickers, or chromatography skids). The platform supports fully automated and barcoded processes, which eliminates laborious and error-prone manual data handling. Transparent and flexible application interfaces (e.g., RESTful web services and Java APIs) allow for straightforward integration with existing laboratory and corporate IT systems, such as LIMS or data warehouses.

## Enables QbD & Data-Driven Decision Making

With Genedata Bioprocess, data is centrally captured, structured, and stored, which makes it possible, for the first time, to fully exploit its value by analyzing all data both within and across projects. This provides a thorough understanding of the process, its variables, and risks, which facilitates an efficient and systematic Quality-by-Design (QbD) approach to development and reduces costs and process downtime. A Quality-by-Design-oriented platform identifies and monitors product-critical quality attributes (CQAs) and correlates these with critical process parameters (CPPs). Cross-project data investigations increase real-time understanding of the impact of process parameters and guide process and technology enhancements to eliminate workflow bottlenecks.

## Assesses Developability & Manufacturability Risks

Genedata Bioprocess systematically analyzes product quality, developability, and manufacturability of drug candidates. The system captures heterogeneous types of product quality and developability test data, including stability, degradation, viscosity, solubility, glycosylation, and immunogenicity. It provides a structured compilation of product quality attributes and associated assay results from various technologies and multiple laboratories in one integrated view. This is of critical importance for making an informed decision on the developability and manufacturability risk profile of each drug candidate. The system assesses all critical quality attributes to identify potential problems, including aggregation, formulation instability, and reduced pharmacological activity, resulting in a developability risk scoring matrix that provides the basis for the selection of cell lines as well as USP and DSP parameters.




# End-to-End Workflow

## Cell Line Development

The platform streamlines the generation of manufacturing cell lines with optimal titer, stability, and critical product quality attributes, making their development faster and more cost-efficient. Genedata Bioprocess greatly increases the efficiency of the entire clone selection process — from initial transfection of the host cell line all the way to final clone assessment and cell banking. The platform allows for systematic integration and interpretation of all relevant information, such as productivity and quality data, throughout the entire process. It is designed to enable ultra-high throughput and fully automated cell line selection to create robust, clonal, and highly productive cell lines for manufacturing.

## Upstream Process Development

Genedata Bioprocess enables systematic testing of different growth parameters (e.g., culture conditions, feeding strategies) for best expression in bioreactors. New bioreactors, in particular scale-down systems such as ambr®, as well as process analytical technologies (PAT), have led to more readout data (online, offline, and at-line) that need to be captured, processed, and analyzed in the context of applied process parameters. The platform tracks bioreactor production runs, process and analytical data, and includes capabilities for serial sub-cultivation workflows in both seed train expansion and clone stability assessment. Both fed-batch and perfusion upstream processes are supported along their entire workflows as well as production runs of any scale. Genedata Bioprocess enables an integrated, parallel assessment of large panels of bioreactor experiments based on multiparameter decision criteria. The system analyzes growth characteristics, such as specific productivity (qP) and integrated viable cell density (IVCD). The platform helps to significantly reduce timelines and costs for new upstream processes that can be scaled up for large-scale production of biotherapeutics.

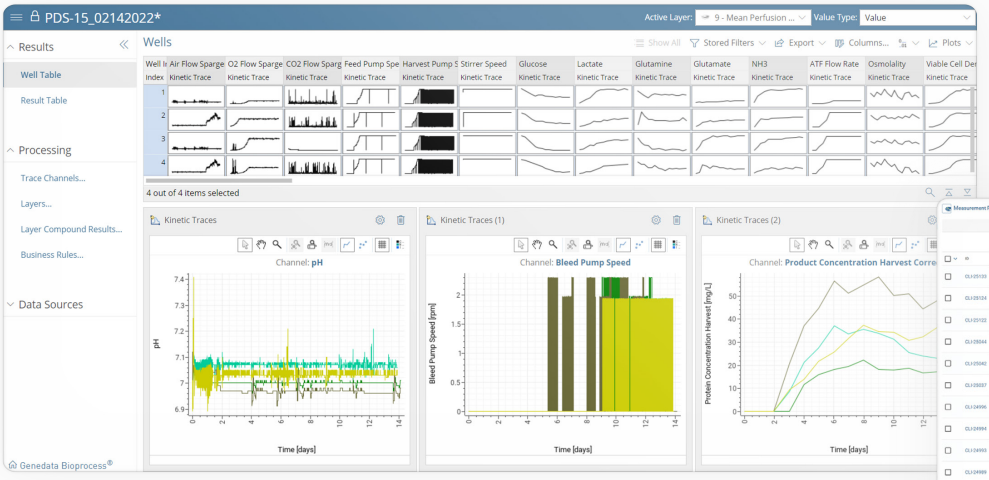



**Figure 1.** A cell line development hit selection table integrating diverse data types (e.g., genealogy, Clone-Select Imager and Octet data) for comprehensive screening and selection of single cell-derived clones that produce high levels of the target therapeutic protein.

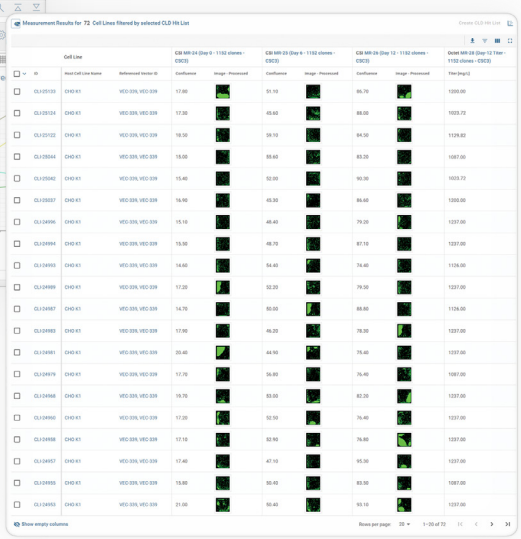


**Figure 2.** A The flexibility of the system allows tracking of the specific parameters required for perfusion production processes. The aggregation of online, offline, and at-line data leads to the identification and selection of the best-producing clones under perfusion process conditions. This subset of data is relevant for decision-making and users can easily access the complete dataset of online, offline, and at-line data and calculations in just a few clicks.

## Downstream Process Development

Genedata Bioprocess makes the development of new or optimized downstream processes more efficient by providing a fully integrated application-ready infrastructure that tracks all purification operations (e.g., protein AA capture, centrifugation, low pH virus inactivation, ion-exchange chromatography, small virus retention, ultrafiltration, and diafiltration). This includes their specific process parameters and raw materials, all combinations of unit operations, in-process samples, and process and product analytical data. Users can systematically assess the impact of process parameters on product quality attributes, as measured by various analytical technologies, such as MS, SEC, and SPR. The platform facilitates an integrated, parallel assessment of panels of downstream unit operations, based on multi-parameter decision criteria, to optimize downstream processes. This significantly reduces timelines and costs for new downstream processes that can be scaled up for large-scale production of biotherapeutics. Decision-making is supported by simple and intuitive visualization tools.

## Formulation Development

Genedata Bioprocess improves the effectiveness of formulation development by capturing and analyzing all formulation data to establish stable, easy-to handle formulations with desired characteristics. The platform increases the efficiency by providing a fully integrated tracking and analysis infrastructure for all formulation samples, related formulation parameters, and testing readouts. It enables full automation of lab workflows, such as high-throughput formulation screens, and supports automatic processing and structuring of physico-chemical characterization data. Each molecule's critical quality attributes (CQAs) are monitored and related to the sample's production and formulation history to identify the optimal combination of formulation parameters. By enabling standardization, miniaturization, and full automatization of formulation screens, the platform increases throughput and quality of the data and thereby dramatically reduces costs and timelines.

## Analytical Development & In-Process Control

Genedata Bioprocess enables a fully integrated approach to the analytical characterization of samples across the full biotherapeutic development workflow. All data is centrally captured, managed, analyzed, and made accessible to all involved teams along the process. The analytical data can be correlated with experiment and process details, such as media and raw materials, unit operations, cell lines, molecules, or expression constructs. Automatically generated Certificates of Analysis (CoA) attest that produced materials conform to specified testing standards. Sophisticated request management tools track all handovers between groups and ensure operational excellence and efficient resource allocation within an organization. With its process-centric approach to analytics data management, Genedata Bioprocess significantly shortens timelines and reduces costs, allowing our customers to achieve competitive advantage in process development.

## Vaccine Development

Next-generation bioprocess development is key to create improved, faster, and lower-cost methods for vaccine production. Genedata Bioprocess supports process development for all vaccine types, including mRNA- and AAV-based vaccine technologies. The platform supports in vitro transcription and upstream process development for mRNA-based vaccines as well as their formulation development with lipid nanoparticles. Virus bioprocess development is also supported E2E, including production of recombinant viral vectors (e.g., rAAVs) and their downstream process development spanning purification methods to remove residual plasmids, host cell DNA, and proteins (e.g., chromatography, tangential flow filtration). Genedata Bioprocess also facilitates efficient analytics development for vaccines, including cell-based and molecular assays to quantitate particles and assess potency and efficacy during vaccine development.

## Operational Excellence

Genedata Bioprocess offers an integrated request management system that tracks requests and tasks performed by specialized groups as well as CRDMOs and external collaborators. It streamlines and automates communication of required information and achieved results. The system tracks details of all requests and documents request fulfillment in real time, improving operational efficiency and resource planning.

## Essential for AI/ML

Well-managed data and AI/ML technologies are poised to transform decision-making and drive future innovation in biopharma R&D. Genedata Bioprocess provides built-in structured data architecture across the organization (data as an enterprise level) and prepares data and information for diverse AI/ML pipelines (e.g., AI-driven in silico process optimization). Programmatic access enables efficient data curation and algorithm development for AI/ML tasks.



Genedata BIOPROCESS

Genedata Bioprocess® is part of the Genedata portfolio of advanced software solutions, which digitalize and automate data-rich and complex biopharma R&D processes. From early discovery all the way to the clinic, Genedata solutions maximize the ROI in R&D expenditure.