Benchling
Bioprocess

Product Brief

Reduce time to milestone with an end-to-end process development platform

Perform high-throughput process development using a visual process designer, centralized data capture, and connected instruments.

Benchling

Are your process development teams looking for ways to reach milestones faster, increase throughput, and generate data-driven insights?

Still relying on spreadsheets, point solutions, and internally-built systems for your process development?

Benchling Bioprocess is the only cloud-native solution that provides an end-to-end solution for modern, high-throughput process development. It helps development teams accelerate their path to critical milestones, while increasing operational efficiency and simplifying technology transfers into manufacturing.

Learn more about...

"At Benchling, our mission is to unlock the power of biotechnology for our customers. We want to provide connected workflows and data across the R&D lifecycle to bring innovative discoveries to market. Process development is a critical phase en route to filing and clinical milestones, where speed, quality, and safety are all paramount.

We've worked extensively with process development teams at some of the world's leading biopharmaceutical organizations. Benchling Bioprocess reflects the needs that we've consistently heard from our customers. We've put the process scientists, operators, IT teams, and data scientists at the center of our design process, and produced a unified solution that will accelerate process development cycles with faster, higher throughput experimentation. We remain committed to FAIR data principles, with process data being centralized, traceable, and ready for the next generation of advanced analytics and machine learning.

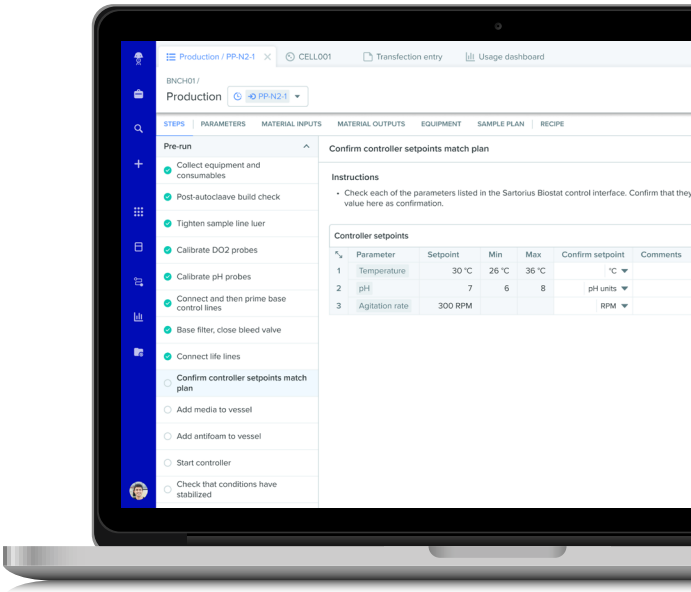
We're truly excited to continue our support for process development with Benchling Bioprocess and remain committed, with an innovative roadmap, to help our customers stay prepared for what's next."

Shawna Wolverton
Chief Product Officer, Benchling

Benchling

Get to know Benchling Bioprocess

Benchling Bioprocess is the only cloud-native solution that provides an end-to-end solution for modern, high-throughput process development. It helps development teams accelerate their path to critical milestones, while increasing operational efficiency and simplifying technology transfers into manufacturing. Bioprocess includes essential capabilities such as a visual process designer, guided process execution, and pre-built instrument integrations, all with a modern, easy-to-use interface that promotes fast and accurate data collection. Highly-structured process data from Bioprocess, supported by an ISA88-compatible data model, feeds into data science and machine learning platforms, helping users gain new process insights. Bioprocess is part of the Benchling R&D Cloud, in use by over 1,200 biotechnology companies, and for the first time, provides purpose-built solutions for both research and process development scientists residing on a unified platform.



Who is it for?

Benchling Bioprocess is for any biopharmaceutical R&D team that designs and executes processes across early and late stages of development.

Typical teams that use Benchling Bioprocess

- Cell line development
- Upstream processing
- Downstream processing
- Formulation
- Analytical

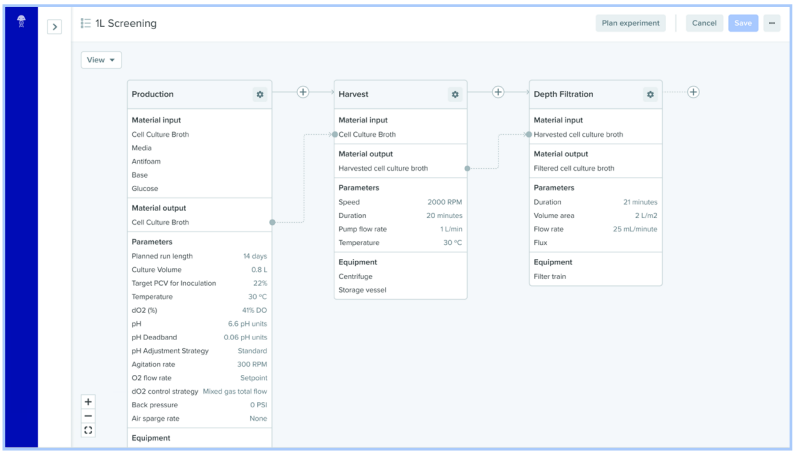
What can Benchling Bioprocess do for my R&D organization?

- Accelerate process development cycles by harnessing data at scale
- Simplify tech transfer for cutting-edge products with structured, traceable process design
- Enable data science with a centralized and open data platform

What can you do with Benchling Bioprocess?

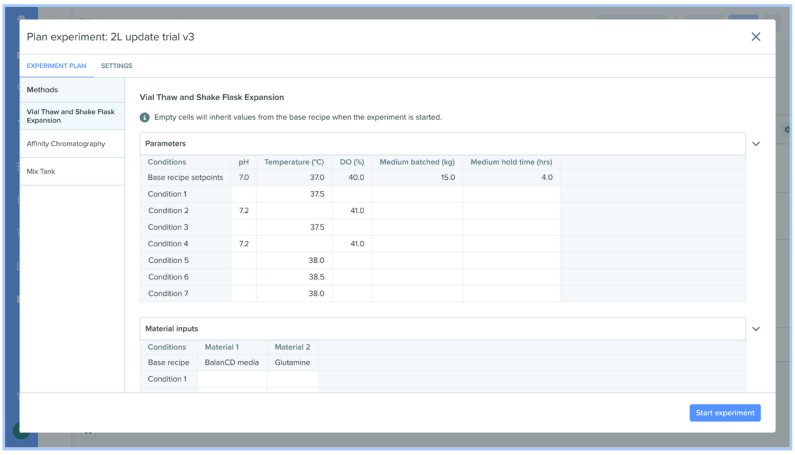
Recipe design

Create recipes using an intuitive, visual designer. Sequence the order of unit operations using a drag-and-drop interface, and define the process parameters, material inputs/outputs, and equipment.



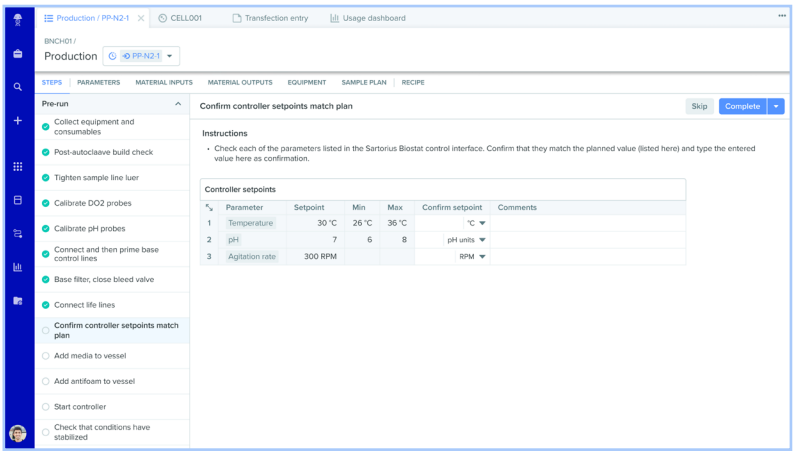
Experiment planning

Flexibly design experiments that cover the process design space with variations across process parameters and materials.



Batch execution

Quickly move your recipe designs and experiments into guided batch execution, with instructions dynamically populated from the recipe definition. Run experiments in parallel, collect data at each process step, collaborate across teams, and track overall progress, while saving time from not having to configure batch instructions.

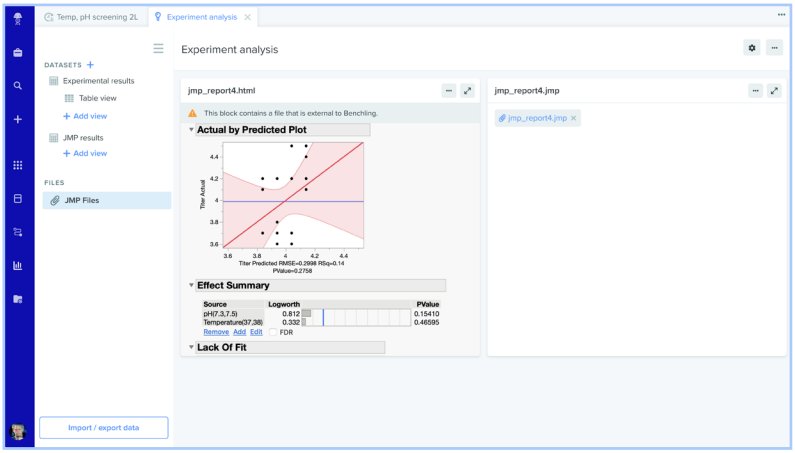


Process insights

Visualize process data with full experimental context and traceability within the platform. Move structured data from Bioprocess right into 3rd party analysis tools using out-of-the-box connectors (e.g. JMP, Pluto, Watershed), as well as feed into data lakes and AI/ML pipelines using APIs.

Platform and data integration

Connect, manage, and analyze high-throughput R&D data across your organization. Bioprocess is built on a unified platform with Bioresearch, allowing R&D teams and their IT partners to consolidate onto a common technology stack with shared ontologies, data structure, user provisioning, and data access.



Why the industry needs a new solution for process development

Process development teams face increased market pressure to move promising discoveries into manufacturable products. The pace of drug development has increased in recent years, with the number of novel drugs launched annually rising to almost twice the level as the early 2000's[1]. Biopharmaceutical companies have broadly shifted towards new drug modalities, such as cell and gene therapies, RNA, and complex drug conjugates to address unmet patient needs, and are utilizing accelerated regulatory pathways 74% of the time to bring these drugs to market faster than ever before[2].

Process science has evolved considerably to support these aims, with new innovation and instruments to support process intensification, automation, and sustainability. But the software applications available to process teams remains a siloed array of rigid point solutions, legacy ELN and LIMS applications, custom integrations, and internally-built systems. All of these software applications contribute to siloed data, poor user experience, and high cost of ownership, forcing scientists to spend as much as 20-35%[3] of their time searching for and aligning their data for analysis.

A new digital approach is required for process teams to thrive in the modern era of biopharmaceutical development.

Newer, Complex Modalities

21%

of biopharma pipeline are complex, next-generation therapies[4]

New modalities such as cell therapies, gene therapies, bispecifics, antibody-drug conjugates, mRNAs, and RNA therapeutics are forcing bioprocessing practices to evolve.

Bioprocess Intensification

1 to 10

fold average boost in bioprocessing productivity due to process intensification[5]

Innovations in equipment, processes, and materials are leading to novel bioprocess intensification practices with increased productivity and savings in time, volume, and cost.

Process Analytical Technology (PAT)

3X

projected growth in PAT market size over the next 10 years[6]

Adoption of PAT to ensure high quality products with real-time monitoring and control is creating new in-line, on-line, at-line, and off-line data sets for process optimization.

Bioprocessing 4.0 Technologies

18.4%

CAGR projected for the global bioprocessing automation market by 2030[7]

Smart technologies such as automation, internet of things, artificial intelligence, machine learning, robotics, and digital twins are causing unprecedented digitization of bioprocessing.

1) IQVIA Institute, 2023
2) Regulatory Focus, 2022
3) Source: Blinded survey of process development professionals, conducted by third party research firm, 2023
4) GlobalData, assessed May 2023
5) https://doi.org/10.1016/j.cep.2022.108793; https://doi.org/10.1016/j.cep.2021.108727
6) https://www.globenewswire.com/news-release/2023/04/18/2649029/0/en/Process-Analytical-Technology-Market-Predicted-to-Grow-at-a-CAGR-of-13-8-between-2023-and-2032-Market-us.html
7) https://www.einpresswire.com/article/589518481/global-bioprocessing-automation-market-is-projected-to-reach-usd-5-7-billion-by-2030-growing-at-a-cagr-of-18-4

What Benchling Bioprocess can do for your organization

Accelerate process development cycles by harnessing data at scale

Shorten process development timelines by running high-throughput experiments on a centralized platform. Benchling Bioprocess brings together capabilities for process design, execution, and analysis to help teams reach milestones faster.

23%

of time is spent collecting and structuring data for analysis[1]

Simplify tech transfer for cutting-edge products with structured, traceable process design

Partner more effectively with MSAT, RA, and QA teams to move processes into manufacturing, and to be more responsive to quality and regulatory inquiries. Benchling Bioprocess ensures efficient collaboration using a structured, ISA88-compatible recipe data model.

87%

of PD scientists consider data errors an issue for their organization[1]

Enable data science with a centralized and open data platform

Gain a competitive edge with a platform that fuels your digital strategy. Benchling Bioprocess sends highly structured process data into your data science and machine learning platforms, so you can ask new questions and generate predictive insights.

The largest hurdle to use of digital and analytics is lack of integrated data sources[2]

1) Blinded survey of process development professionals, conducted by third party research firm, 2023
2) McKinsey survey of 100 digital and analytics leaders in life science functional areas, November 2022

"At Gilead, we're committed to creating a healthier world for everyone by discovering, developing, and delivering medicines for life-threatening diseases. This work requires managing highly complex, multi-dimensional data and necessitates technology partners that can support the scale and complexity of the data created by high-throughput biology.

We selected Benchling as a partner because it's built for biology. By capturing structured data in Benchling, our scientists are empowered to ask challenging questions and uncover new insights."

Peter Huang
Executive Director, Pharmaceutical Development & Manufacturing Information Systems

GILEAD

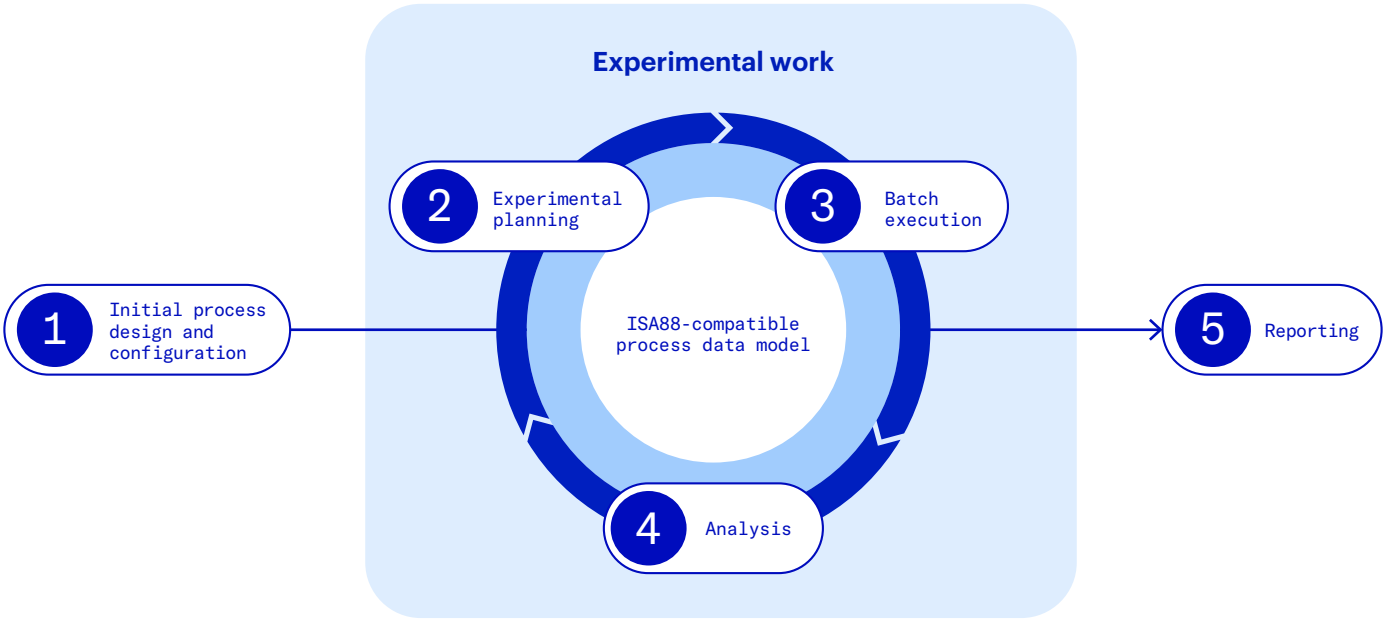
Benchling Bioprocess supports teams across all phases of process development

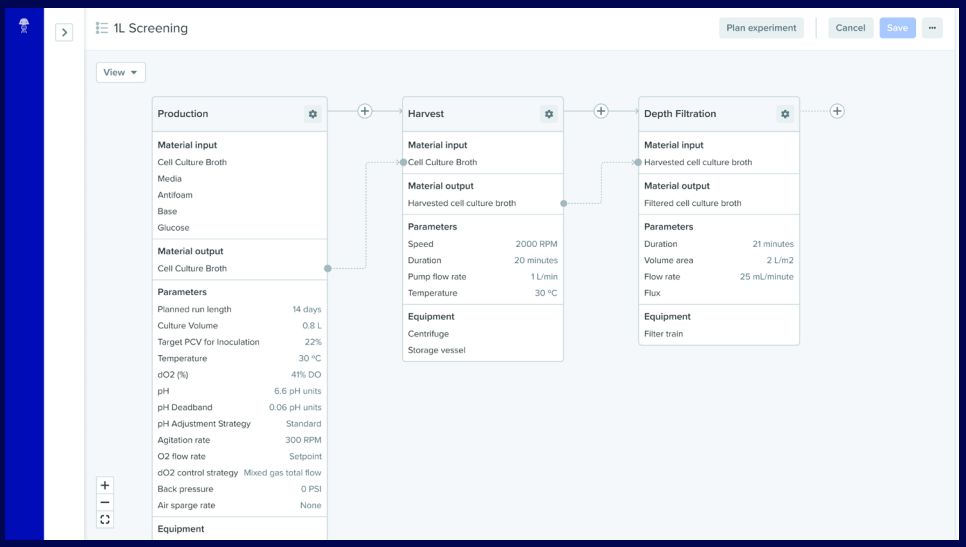
Cell line development	• Screen cell lines more efficiently with integrated in silico design and experimentation. • Identify optimal clones with high production and stable expression using structured data analysis across studies. • Manage and transfer inventory of cell lines with their full lineage and experimental history.
Upstream process development	• Scale up from bench-scale to pilot-scale bioproduction using a visual process designer and a guided process development execution interface. • Centralize on-line, at-line, and off-line bioreactor data into a structured, searchable repository. • Analyze and optimize process conditions with clear alignment between process inputs and outputs.
Downstream process development	• Develop stable formulations using optimal combinations of buffers, excipients, and processing conditions. • Manage all reagents, materials, and final formulations with full traceability and results. • Coordinate material and workflow handoffs between purification teams, analytical studies, and other formulation recipients.
Formulation	• Use pre-populated templates for development and execution of analytical methods across a range of frequently-used assay types. • Orchestrate requests coming in from other process development teams, and return offline results back with full analytical context. • Centralize assay results to increase data accessibility across teams, and utilize operational metrics to identify opportunities to increase productivity.
Analytical development	• Use pre-populated templates for development and execution of analytical methods across a range of frequently-used assay types. • Orchestrate requests coming in from other process development teams, and return offline results back with full analytical context. • Centralize assay results to increase data accessibility across teams, and utilize operational metrics to identify opportunities to increase productivity.
R&D IT	• Consolidate multiple software applications down to a unified solution spanning both research and development functions. • Take advantage of purpose-built process development capabilities, instrument connectors, and codeless configuration to recognize fast time to value. • Build on an extensible, secure cloud platform that scales with your organization and prepares your data for advanced analytics and machine learning.
Quality	• Leverage native platform capabilities to ensure 21 CFR Part 11 compliance. • Receive validation process support, including supporting documentation (IQ/OQ/PQ/UAT) to align with GLP/GMP requirements. • Track engagement and changes throughout the system using audit trail and granular user permissions.

How Benchling Bioprocess works

Benchling Bioprocess supports the entire process development lifecycle, from early process definition through later phases of optimization, all on a centralized platform. An easy-to-use interface guides you through process design, execution, and analysis, while critical process data is captured, structured, and ready for analysis.

Process development is an iterative process. Bioprocess ensures that results from each cycle can be readily accessed, with process inputs aligned to process outputs, to minimize time between iterations. Historical data is retained in a searchable, relational database, so you can understand the experimental context even over long development horizons.

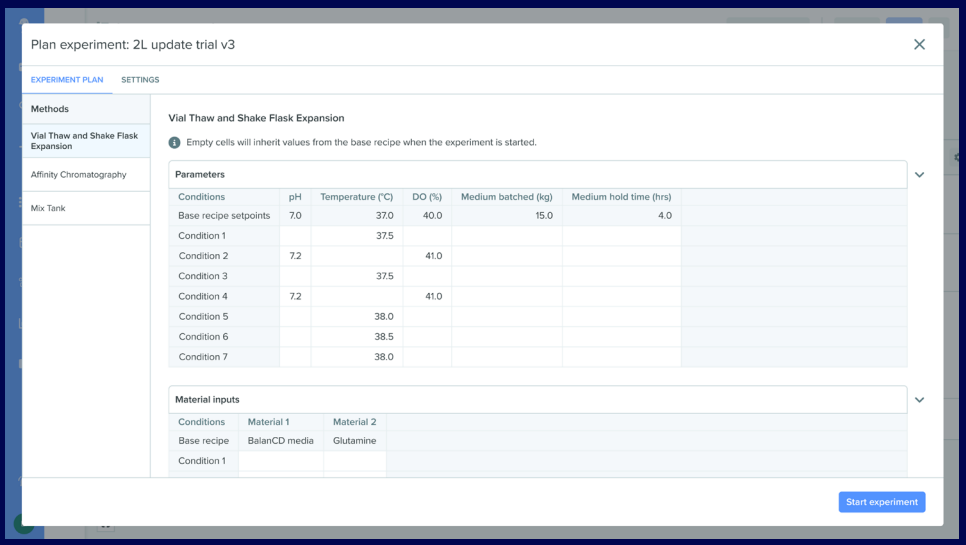




1. Initial process design and configuration

Benchling Bioprocess starts with giving you the ability to easily design and configure your own processes using a drag-and-drop interface, unlike other systems that require extensive IT and vendor resources.

Whether you are starting from a blank slate, or making modifications from a saved template, you can use the visual process designer to sequence the order of unit operations and configure the methods at each step. You can define process parameters (e.g. setpoints, upper/lower limits), material inputs/outputs, and equipment used.

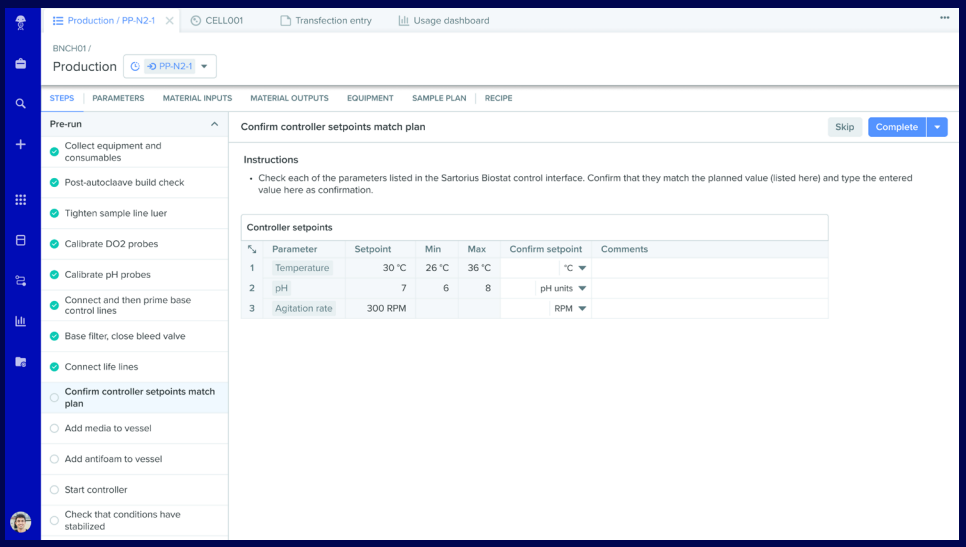


2. Experimental planning

With a single click from any process design, you can bring up the experimental planning interface. Here, you can define a range of experimental conditions to test and enter them in a tabular format.

These conditions can be derived from past experiments, as well as determined from DOE applications.

Once the experiment is defined, these conditions will be carried forward into the run execution with a single click to ‘Start experiment’.



3. Batch execution

Once an experiment has been started, a guided process execution interface is created. Here, scientists and operators receive step-by-step instructions on how to carry out the process. These are dynamically populated from the Recipe and experiment design, saving time and ensuring the correct steps are carried forward.

At each step, the user is guided with instructions, set points, material inputs/outputs, sampling plans, and any other details required to complete the operation.

Completing the task automatically triggers the next step in the process, and notifies the appropriate resource assigned to it.

4. Analysis, reporting, and data science

Benchling Bioprocess retains all process data in a structured relational database. Process inputs are coupled to process outputs using an ISA-88 compatible recipe data model.

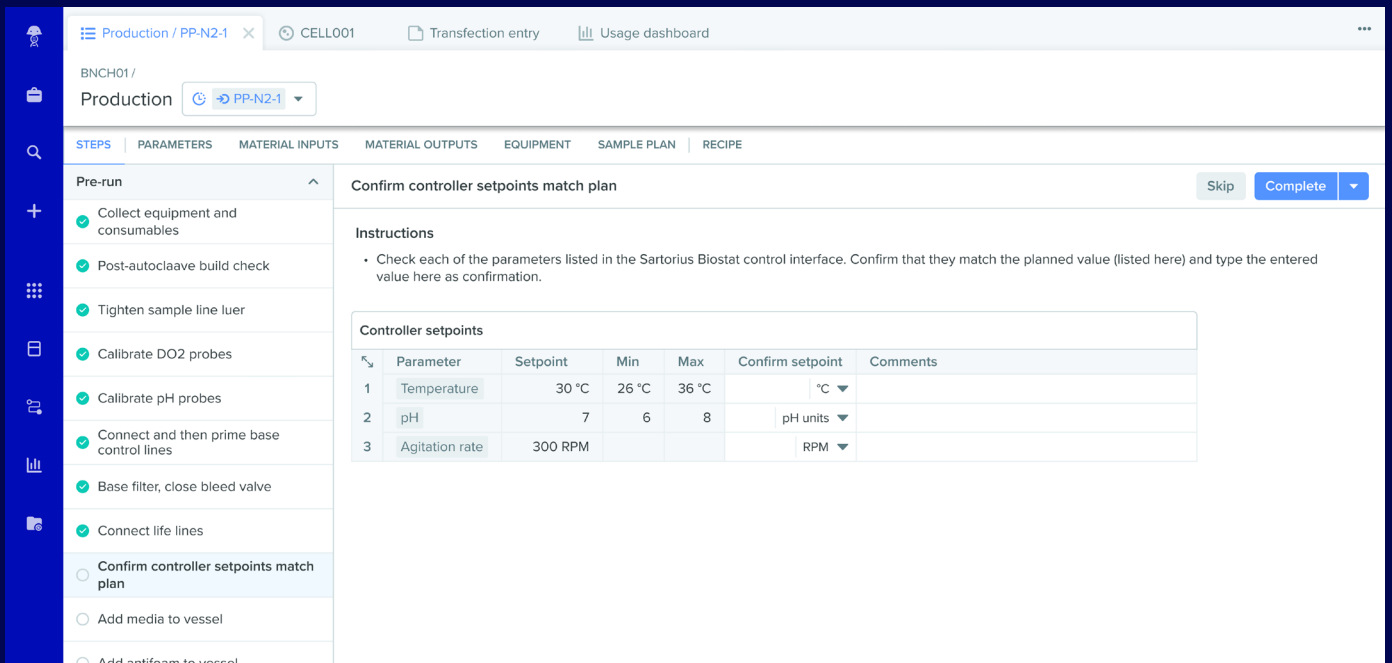
As experiments are being conducted, in-app analytics depict task progress and completion status.

As experimental steps are completed, analytical data can be easily visualized using the included Insights dashboards. These views are fully configurable and provide direct traceability back to the experimental record, unlike standard plots you might find in charting software.

Data can also be moved via API/ETL right into your data warehouse and data science platforms, using interoperable formats aligned to ISA-88 and ASM standards.

What's included with Benchling Bioprocess

Benchling Bioprocess is a purpose-built software application for process development teams, delivered on a fully-managed, secure cloud infrastructure, and accessible by any standard web browser. It is licensed on a per-user basis, with each team member receiving a named login credential. This ensures that granular permissions can be applied at the administrator level, and that actions in the system can be properly attributed. In addition to product licensing, Benchling provides Professional Services to support new implementations, and Success Packages that offer proactive services supporting the long-term success of our customers.



Benchling Bioprocess

Process development capabilities (available Spring 2024)

- Recipe design
- Experimental planning
- Batch execution
- Process insights

ISA-88 compatible process data model

Essential R&D capabilities

- Experiment data capture
- Sample management
- Study management
- Workflows
- Analytics

Cloud-native platform

- Access controls
- Unified data model
- System-wide search
- Codeless configuration
- Best-in-class security

Compliance

- 21 CFR Part 11 compliance
- ISO 27001 certified/aligned with ISO 9001 QMS guidance
- Validation, compliance-ready

Scientific Accelerators

- Cell therapy
- Gene therapy
- Antibodies
- RNA
- Microbial strains

Available services

Professional Services	A full range of implementation services to support companies of any size, from startups to global enterprises. Learn more here.
Success Packages	Every Benchling Bioprocess customer receives foundational success services, such as product support, Help Center, and Benchling Learning Labs, as part of their license. Premier Success Packages are available to extend the level of service and engagement your organization may prefer. Learn more here.

Benchling Bioprocess Scientific Accelerators

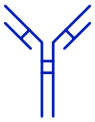
Scientific Accelerators provide a foundational set of data model schemas, configurations, and templates to jump start your implementation. These are based on best practices developed through implementations at over 1,200 customers, and have been shown to be reliable in real-world usage.

When getting started with Benchling Bioprocess for your organization, your Professional Services team will walk you through the Scientific Accelerator that best fits your needs, make any necessary adjustments, then begin the implementation.

Available Bioprocess Scientific Accelerators

Cell therapy

Gene therapy



Antibodies

RNA

Microbial strains

Implementation by Benchling's Professional Services

Benchling's Professional Services team consists of scientifically-trained experts who will understand your R&D and have run thousands of successful implementations for our customers. These range from early startups all the way to the world's largest global enterprises. Professional Services team members work closely with all of our customers to fully understand their R&D requirements and then scope the appropriate implementation work.

95%

post-implementation customer satisfaction

Source: Benchling customer surveys

Our Professional Services team will serve as project managers to ensure steady progress towards a successful implementation. While each project is tailored to your specific needs, these are some of the typical activities in each phase of implementation.

Kickoff and planning

- Pre-project questionnaire
- Align on project scope
- Confirm R&Rs
- Detailed project plan
- Discuss test and training plans
- Set up governance structures
- Initial design workshops
- Access to training content
- Policies and permission setup

Configuration, training, and initial user testing

- Review and understand current process by team
- Configure Benchling to support each team
- Review configurations, capture feedback, update data models and configurations
- Layer in application specific trainings (train the trainer)
- Prepate for UAT

Test and launch

- Complete training delivery
- Execute UAT
- Address Issues
- Plan for post go-live updates
- Execute launch plan
- Launch support/ hypercare
- Celebrate!

Learn more about our Enterprise Implementation Methodology

Customer success with Benchling Bioprocess

Benchling's Customer Success team helps ensure our customers realize continual value from their Benchling implementations. Our Customer Success Managers take a proactive approach with continual assessment, utilization monitoring, and routine communication.

Every Benchling Bioprocess customer receives our foundational Customer Success Program as part of their product license. This entitles you to product support, self-serve Help Center, access to Benchling Learning Labs, and periodic check-ins with our Customer Success team. You can also select one of our Premier Success Packages which extend the level of support with faster response times, optimization services, customized trainings, and a named Technical Account Manager and Customer Success Manager.

99%

Benchling customer retention

Source: Benchling customer surveys

Learn more with our Customer Success Guide

The Benchling R&D Cloud is trusted by leading life science companies

GILEAD · Lyell · Intellia Therapeutics · Beam Therapeutics · CUE Biopharma · editas Medicine · New England BioLabs Inc. · ArsenalBio

New to Benchling?

Learn more on our web site and reach out for an initial call with a product specialist to see how Benchling Bioprocess can help transform your process development organization.

Learn more about Benchling Bioprocess

Request a Demo

Already a Benchling customer?

Reach out to your Account Executive and Customer Success team to learn how Benchling Bioprocess can help your organization, and discuss the optimal transition from your current implementation if needed.

Contact Sales