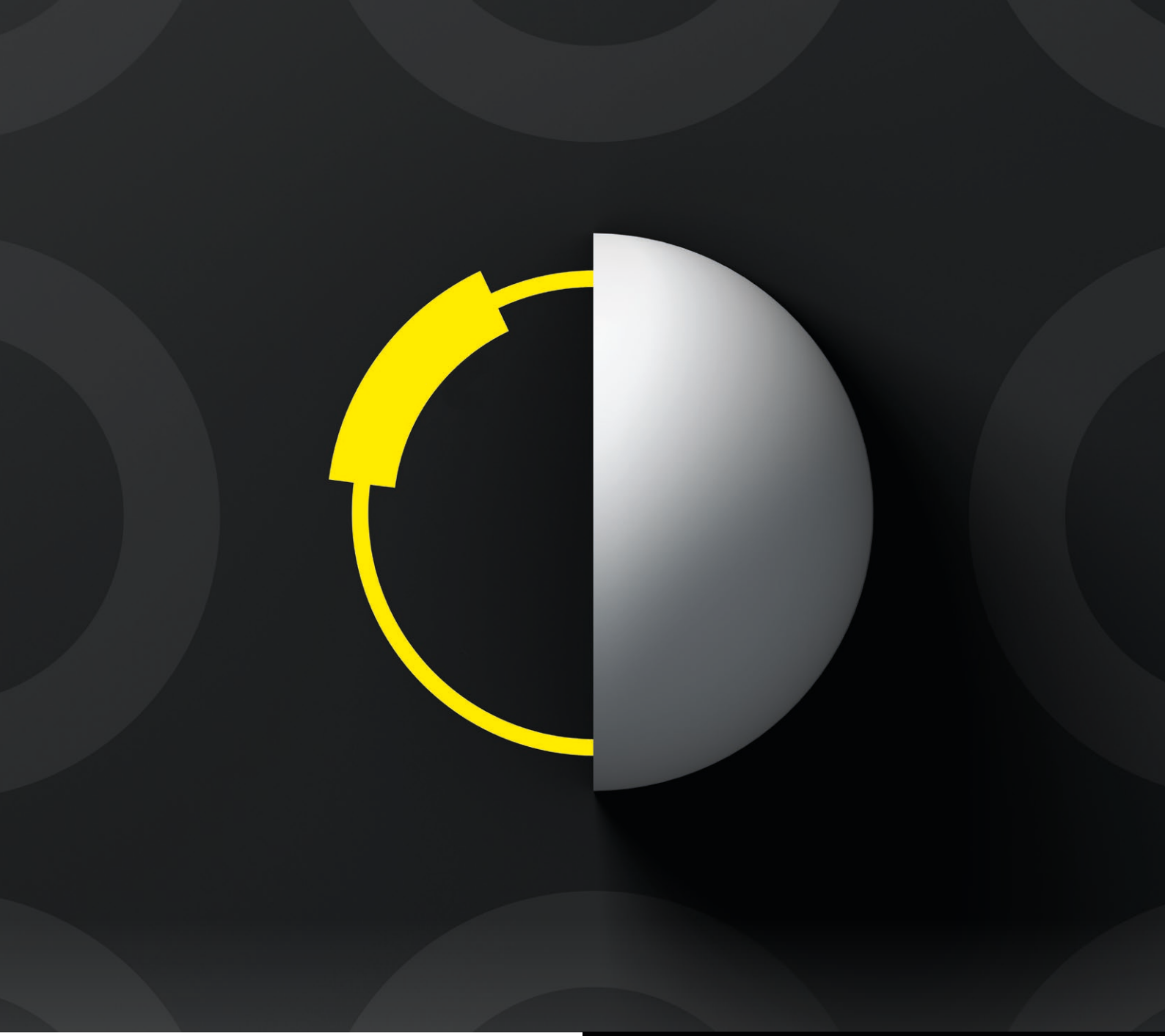


CHO Cell Line Development

Solutions and services for therapeutic protein development

Simplifying Progress

SARTORIUS

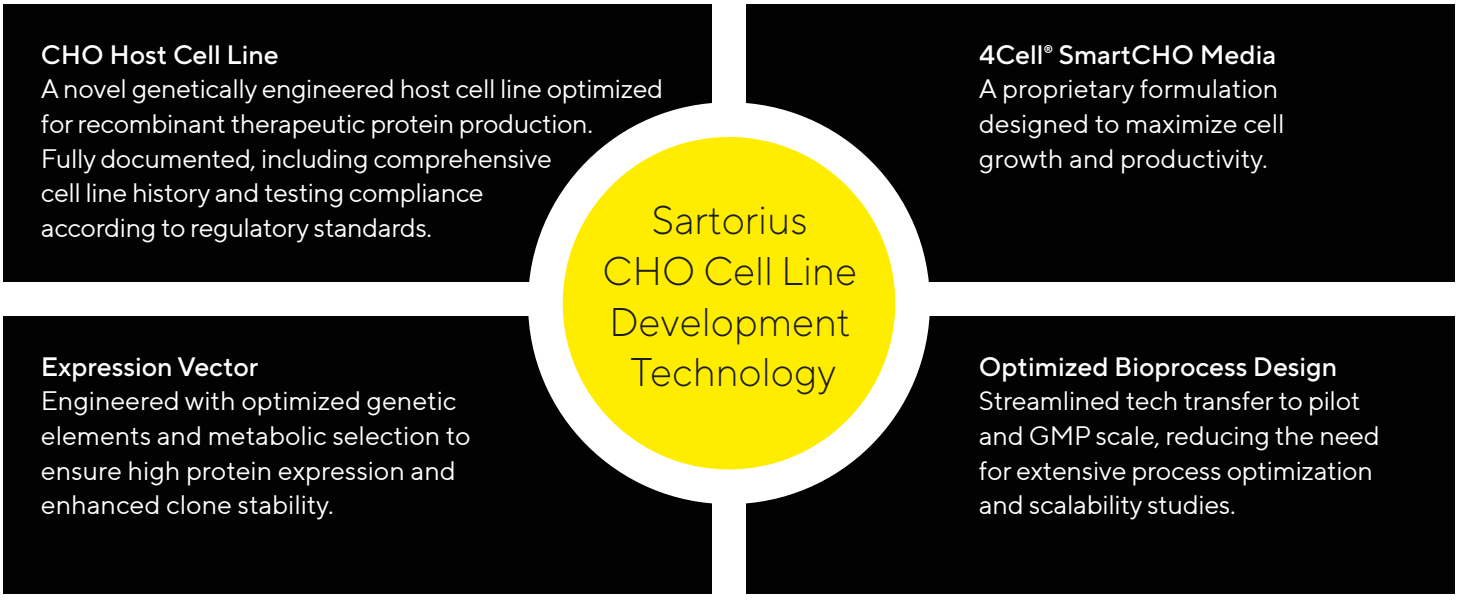
From DNA to IND-Ready With Confidence

Sartorius' CHO Cell Line Development Service provides drug developers with a high-yielding, stable CHO cell line for the production of CHO Cell Line Development Solutions and services for therapeutic protein development.

Our services are built on a foundation of expert knowledge and cutting-edge technology, and reflect decades of innovation. In 2025, we proudly mark two milestones: 10 years since Cellca — an industry leader in cell line development — joined Sartorius, and 20 years since Cellca's founding. This legacy equips us to deliver customized, effective solutions for your bioprocess.

Our platform enables rapid delivery timelines, providing research cell banks (RCBs) within 9 weeks and completing master cell bank (MCB) manufacturing and release in 9 months.

Key Components of Our CHO Cell Line Development Technology



Successful Track Record

- Over 16 years of experience and more than 330 successfully completed cell line development projects
- 85+ molecules currently in clinical stages, with 10 molecules approved for market use
- Strong client loyalty, with many returning for over 15 collaborative projects

"We are very satisfied with the outcome of the project. The initial timeline was precisely met and the titer was better than expected for a very difficult molecule. The team at Sartorius was also responsive, capable, and easy to work with."

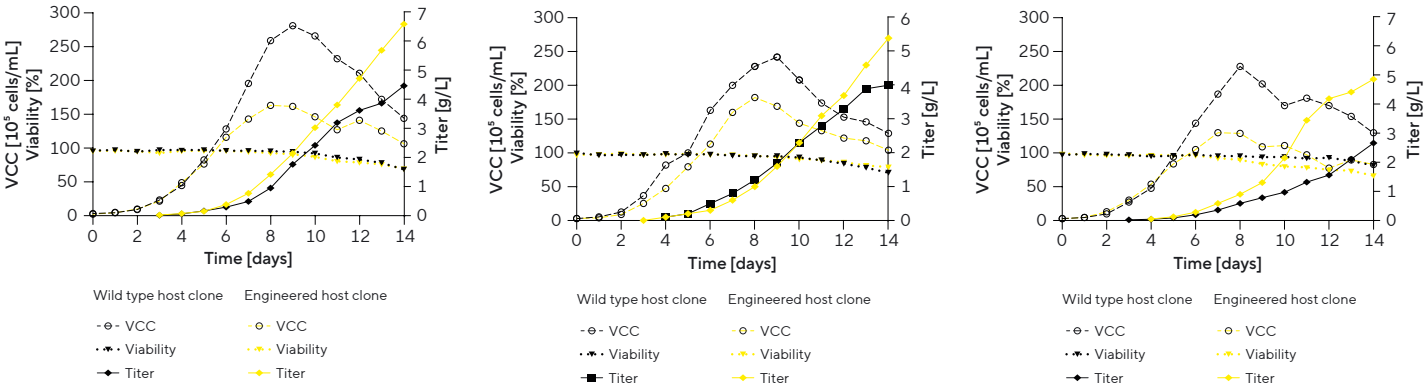
Biotech Customer
California, USA

A Novel Genetically Engineered CHO Host Cell Line with Superior Performance

In 2026, we continue our commitment to innovation, leveraging our in-depth knowledge in recombinant protein expression and cellular machinery to launch a novel genetically engineered CHO host cell line* that more effectively supports biopharmaceutical development.

- Through proteomic profiling, we mapped our host cell and identified 67 endogenous proteins which are energy intensive
- Using CRISPR-mediated gene editing, we performed a comprehensive knock-out study to identify a target which significantly increased expression titers and productivity
- We developed a novel genetically engineered host cell line with significant productivity gains — **up to an 80% increase in titer and up to 280% higher cell-specific productivity (Qp)** — while maintaining high and consistent product quality across different protein types..

mAb (IgG4)		mAb (IgG1)		Fc-Fusion	
Titer **+50%**	Qp **+220%**	Titer **+40%**	Qp **+170%**	Titer **+80%**	Qp **+280%**



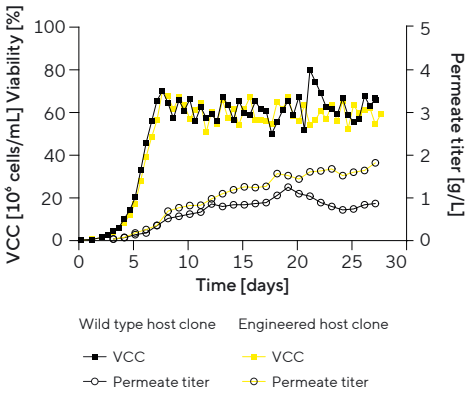
VCC = Viable Cell Concentration

Results from the final evaluation of the new engineered host cell line relative to the wild type CHO host across different cell line development campaigns in which cells expressed IgG1, IgG4 and Fc-fusion proteins. Data were derived from a 14-day non-optimized fed-batch study conducted in a 5 L bioreactor using 4Cell® SmartCHO culture media.

The new host cell line also demonstrates improved phenotypic and genetic stability ensuring our platform maintains robust performance.

Beyond, traditional fed-batch processes, the engineered host cell line is also ideally suited for intensified processes, demonstrating up to a **twofold increase in titer during a 28-day perfusion run**. This performance enables efficient manufacturing using next generation processes.

Combining this rationally engineered host with a data-driven workflow strengthens our cell line development platform and delivers higher productivity, greater stability, and broader process versatility, helping developers reduce risk and improve overall manufacturing efficiency and cost per dose.



VCC = Viable Cell Concentration

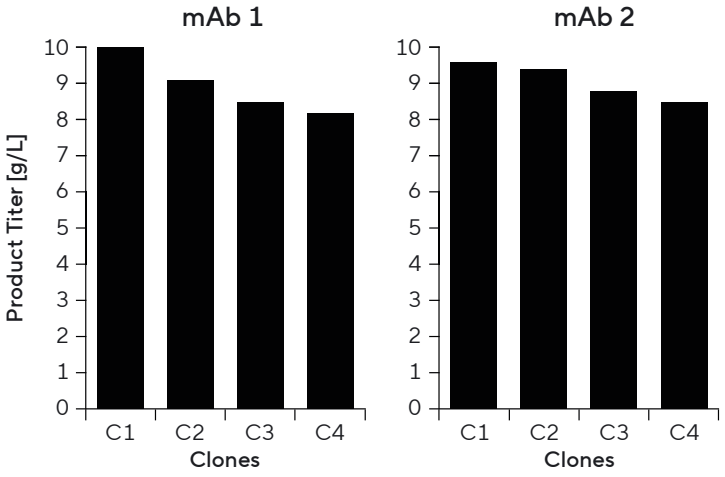
Results from the evaluation of the new engineered host cell line relative to the wild type CHO host expressing a monoclonal antibody during a 28-day perfusion process in Ambr®250.

*This new host cell line has freedom-to-operate and has no associated license fees.

Expertise Across Diverse Modalities—From Monoclonal Antibodies to Complex Proteins

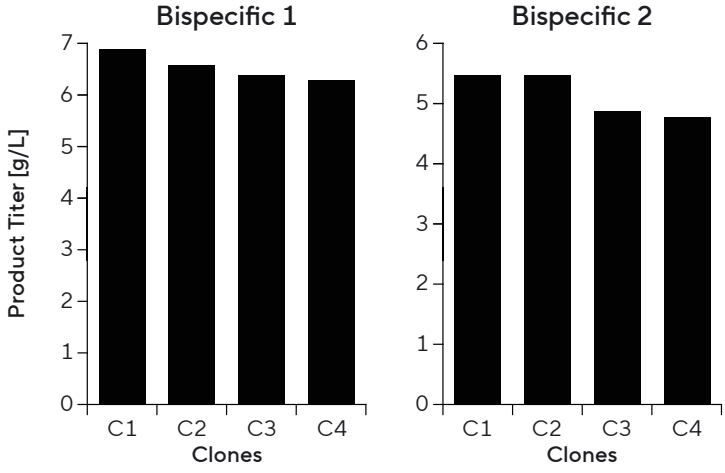
Our CHO Cell Line Development Service team possesses a comprehensive skillset that extends to complex and challenging biomolecules, whether they are new biological entities or biosimilars, including:

Conventional mAbs: 180+ projects completed, 55+ in clinical stages, including 10 in commercial manufacturing and approved for market use. Titers reaching up to 10 g/L.



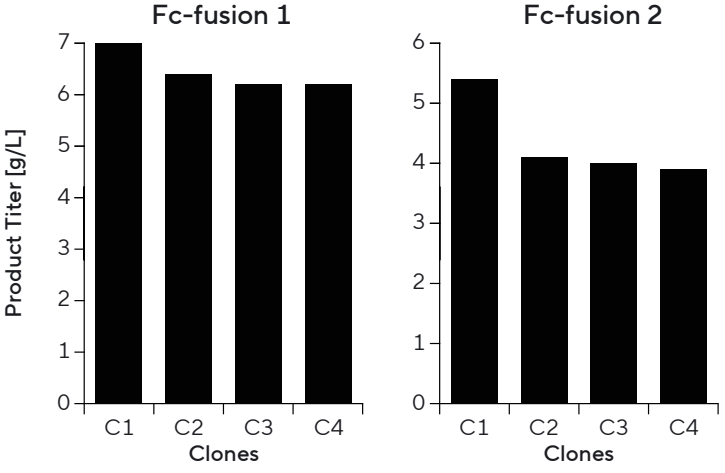
Results from two cell line development campaigns (mAb 1, left and mAb 2, right), showing the titer of the top four clones cultured in the Ambr® 15 system under standard fed-batch conditions (unoptimized).

Bi- and Multispecific Antibodies: Almost 40 projects completed, 12+ in clinical stages. Titers reaching above 7 g/L.



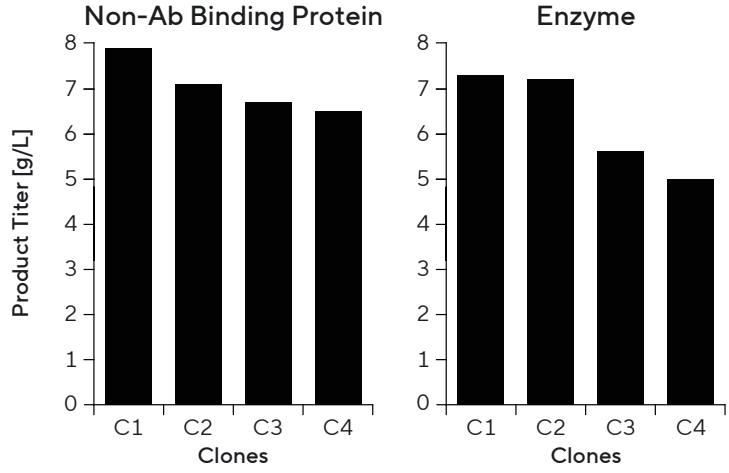
Results from two cell line development campaigns (Bispecific 1, left and Bispecific 2, right), showing the titer of the top four clones cultured in the Ambr® 15 system under standard fed-batch conditions (unoptimized).

Fc-Fusion Proteins: 50+ projects completed, 12+ in clinical stages. Titers reaching above 7 g/L.



Results from two cell line development campaigns (Fc-fusion 1, left and Fc-fusion 2, right), showing the titer of the top four clones cultured in the Ambr® 15 system under standard fed-batch conditions (unoptimized).

Non-Antibody Proteins: 40+ projects completed, 10+ in clinical stages. Titers up to 8 g/L.



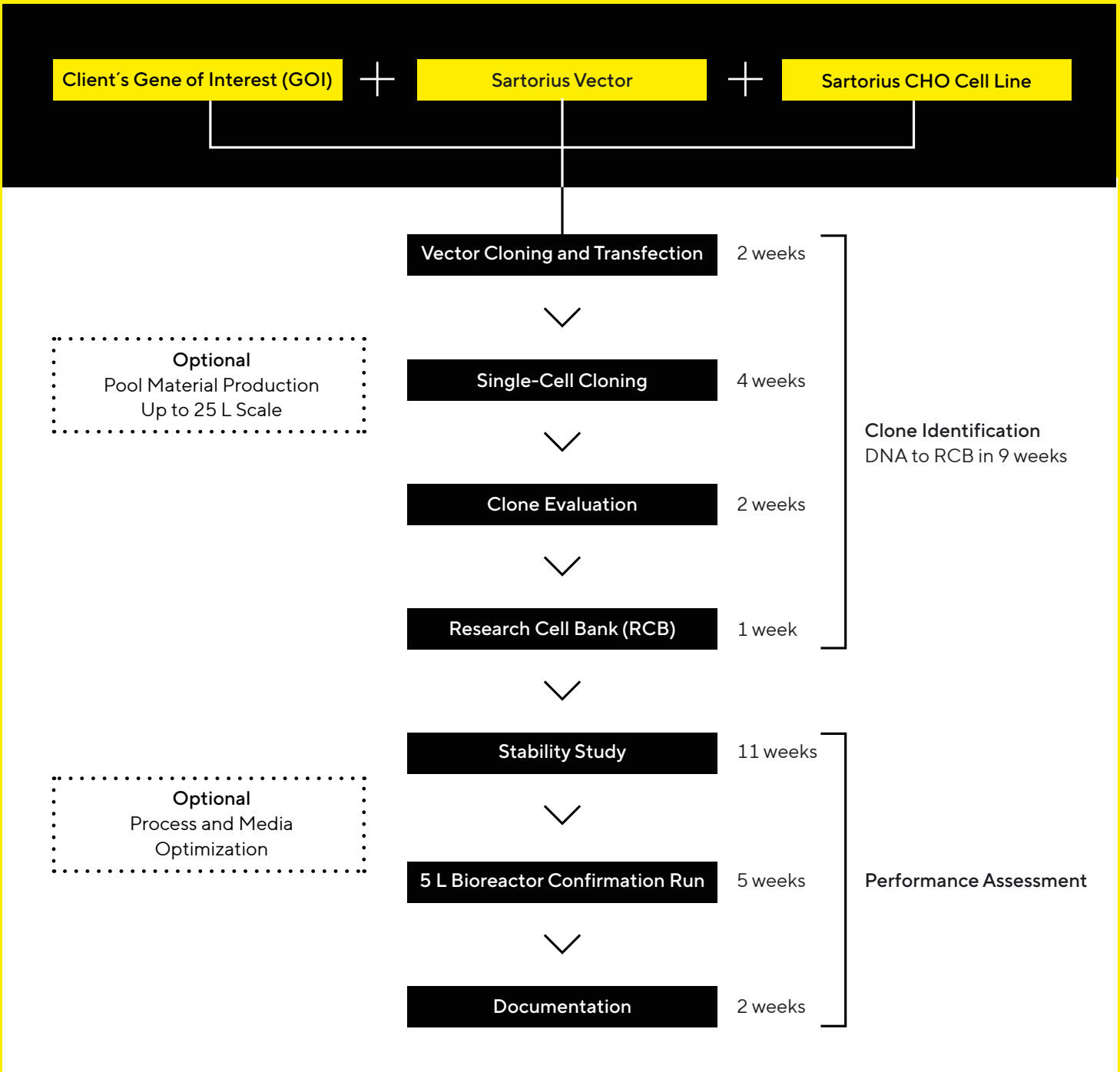
Results from two cell line development campaigns (a non-antibody binding protein, left and an enzyme, right), showing the titer of the top four clones cultured in the Ambr® 15 system under standard fed-batch conditions (unoptimized).

Biosimilars

We have successfully completed around 30 biosimilar projects, with three approved for market use and titers up to 9 g/L.

Inside Sartorius' CHO Cell Line Development Service

Sartorius' CHO Cell Line Development Workflow



Vector Cloning and Transfection

The expression vector system employed within our CHO Cell Line Development Service has been extensively developed to work synergistically with our host cell line for optimal and high expression of recombinant proteins. This includes:

- A suite of optimized vector elements (promoters, 5′ and 3′ UTRs, signal sequence peptide, and S/MAR elements) to ensure optimal and stable gene expression
- Maintaining high stringency in metabolic selection using innovative genetic elements to identify high-producing clones exhibiting low copy numbers, without the need for inhibitory agents
- An optimized vector topology and gene cassettes for single- and double-gene constructs to ensure efficient expression of the therapeutic protein

By combining an optimized expression vector with effective gene delivery methodology via electroporation-mediated transfection, we can successfully generate cell lines exhibiting competitive titers for different modalities.

Vector Cloning and Transfection

Single-Cell Cloning

Clone Evaluation

Research Cell Bank (RCB)

Stability Study

5 L Bioreactor Confirmation Run

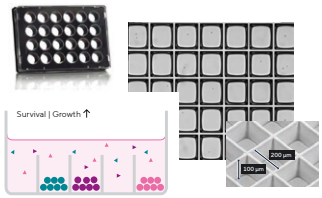
Documentation

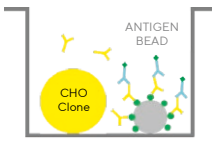
Single-Cell Cloning

Single-cell cloning is performed using the high-throughput automation capabilities of the Sartorius CellCelector™. Cells from established stable pools are inoculated and cultured in a 24-well plate, with each well consisting of 4,300 nanowells.

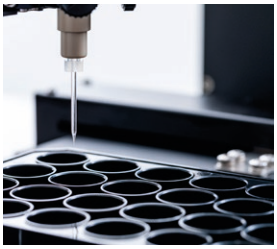
Monoclonality is assured by automated image-based verification using the integrated software, with a probability of 99.7%. Our proprietary Protein A bead productivity assay leverages the fluorescent detection capabilities of the CellCelector™ to identify high-producing clones only four days after single-cell cloning.

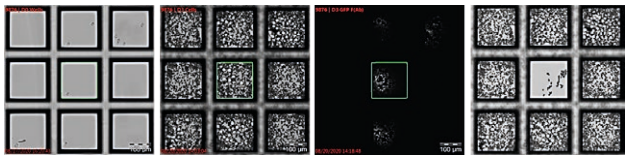
Combining the vast number of cell and expression parameters captured by the CellCelector™, with our proprietary multivariate data analysis (MVDA) tool powered by advanced artificial intelligence and machine learning algorithms, we can effectively differentiate and select high-producing clones to progress to clone expansion and evaluation. Through high-throughput automated screening of thousands of clones and advanced digital solutions, we enhance and de-risk our clone selection strategy to ensure the identification of high-producing clones as early as possible.





- Antigen protein A/G
- Secreted Ab
- Fluorescently labelled Ab





Day 0: detection of monoclonality

Day 4: detection of outgrowth

Day 4: detection of highly secreting clone

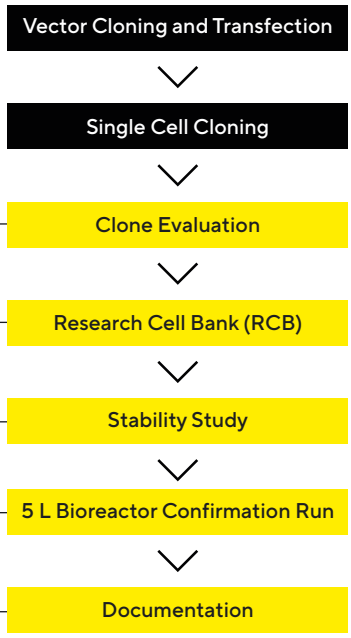
Day 4: Transfer of high performing clone to 96- or 384 well plate

Clone Evaluation and RCB Generation

Once a subset of clones is selected from the single-cell cloning process, they are expanded and further characterized in two stages:

- **Stage 1:** Clones are evaluated within a high-throughput small-scale fed-batch system where they are cultured in a 96-deep well plate. This assay mimics the larger-scale fed-batch process, employs 4Cell® SmartCHO media and feeds, and yields indicate the performance of the individual clones.
- **Stage 2:** A subset of clones ranked during stage 1 are further evaluated in the Ambr® 15 and | or Ambr® 250 for features such as growth and titer profiles. Material generated from this evaluation can also be used to perform a range of product quality analyses, including but not limited to N-glycan, charge variant, and monomer profiles (depending on the client's requirements).

This evaluation will comprehensively identify the top four clones, which are cryopreserved to manufacture an RCB.



Clone Stability, Bioreactor Run, and Documentation

Stability

- The stability of the top four clones is evaluated using an 8-week stability study that mimics the culture duration from establishing an MCB to the completion of a production run.
- Phenotypic clone stability is determined by ± 20% deviation in fed-batch titers and specific productivity (Qp) between the start and end of the culture duration.
- The clones generated exhibit high and robust long-term stability (on average >80% over >70 generations).

Bioreactor Run

- A lead clone is selected and further evaluated for scalability by performing a 5 L proof-of-concept bioreactor run using Sartorius' optimized upstream process,with demonstrated scalability up to 2000 L.
- A transfer protocol from the 5 L run is provided to the client or their CDMO for continuation to process development.

Documentation

- Upon completion of all activities, a comprehensive project report will be provided, including all data generated during the program.
- This project report is adherent to future IND filing submissions.

"The cell line titer is well above our target. We are very pleased with Sartorius´ performance, working with Parvus to deliver a highly productive clone."

Louis Demers
Parvus Therapeutics, USA

Customization Options

Explore some of the customization options that we offer to secure your success and future-proof your process.

Pool Generation
Our DNA to Pool service enables fast, parallel candidate screening in-house or at Sartorius to evaluate the manufacturability of the molecule. We also offer a mini-pool approach that ensures the lead clone meets the targeted quality profile, reducing risks in cell line development.

Engineered Cell Lines
We offer additional cell line engineering to improve host cell and | or bioprocessing performances. This includes an FUT8 knock-out service to enhance antibody-dependent cellular cytotoxicity, and other custom gene knock-out services to boost growth, yield, and quality.

Intensified Processing
We can implement a range of Ambr® 15 and Ambr® 250 scale-down tools to directly select the best clones for perfusion or high-inoculation fed-batch (HIFB) during cell line development. These tools also guide the selection of the optimal manufacturing mode for specific molecules.

Seamless Tech Transfer
By prioritizing long-term performance, scalability, and regulatory compliance during the early stages, we minimize risks during the transition to clinical and commercial phases. Our cell lines are fully transferable to any CDMO—successfully executed with 25+ global partners.

"We are satisfied with the whole project, project lead, and communication. The titer is amazing and gives us enough space to optimize the quality of our biosimilar. The challenge of achieving monoclonality of one clone was handled correctly and is therefore seen as positive."

Gedeon Richter
Plc, Hungary

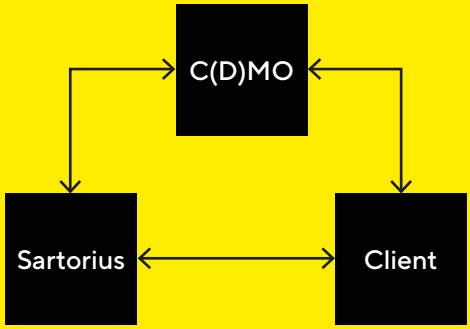
Flexible Outsourcing Packages

Outsourced Cell Line Development
Outsource your cell line development process (partially or entirely) to Sartorius as your extended laboratory bench and trusted drug development partner.

- DNA to Pool (feasibility | manufacturability assessment)
- DNA to Research Cell Bank (RCB)
- DNA to Master Cell Bank (MCB)

DNA to GMP Services

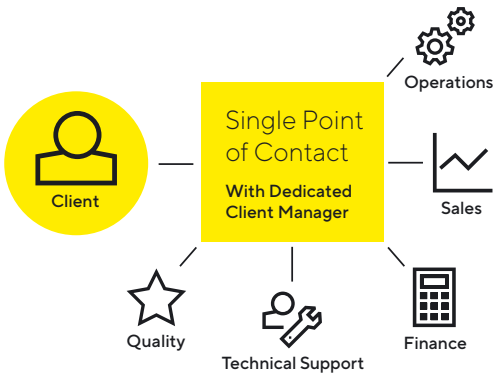
Looking for a "one-stop solution" from cell line development to GMP manufacturing services? We have established strategic collaborations with selected CDMO partners globally to support a seamless, end-to-end development process. Our cell line development services have been integrated into their overall offering to streamline processes and allow our clients to benefit from both companies' expertise.



Excellent Customer Service

A dedicated team of client managers provides a single point of contact throughout the cell line development process, from DNA to released master or working cell bank, as well as the transfer to the CDMO of the client's choice. This streamlines the flow of information, so you can reach IND-readiness more quickly.

- One point of contact with regular updates on your project
- Expert technical assistance and guidance throughout the early stages



Strengthen In-House Cell Line Development Capabilities With Access to Sartorius Technology

If you want to perform cell line development in-house while minimizing risk and avoiding lengthy timelines, you can implement our ready-to-use, industry-recognized, regulatory-compliant platform directly within your own facility.

Benefit from our novel genetically engineered CHO host cell line, optimized expression vector, off-the-shelf media system, ready-to-use protocols, and the expertise of our subject matter experts to ensure efficient and reliable cell line development.

We provide two technology license options to suit your needs:

- A Research License for developability assessment and screening of multiple drug candidates through stable pool evaluation (DNA to Pool)
- A Commercial License to support the generation of stable clonal cell lines (DNA to RCB) for both drug developers and CDMOs

At Sartorius, we are uniquely placed to not only provide access to our cell line development technology but also to the associated single-cell cloning equipment (CellCelector™), protein characterization tools (Octet® BLI systems and iQue® high-throughput screening cytomters), a range of bioreactor technologies from benchtop (Ambr®, and Univessel® systems) to manufacturing scale (Biostat STR®), as well as the required consumables.

Beyond Cell Line Development

Our CHO Cell Line Development Service is enhanced by a suite of additional services designed to support you beyond your cell line development activities. Leverage our extensive expertise to optimize in-house resources and expedite your journey to IND filing.

Process Development

Our experienced team can support your development activities with our Ambr® 250 technology, design of experiment setups, and MVDA, which support the optimization of process conditions, feeding regimes, supplement additions, and scale-up.

Material Generation

We can support initial downstream process trials by providing pool-based material or early material produced by your clone in 50 L rocking-motion bioreactors before the cell line is transferred.

Testing Services

Our assay lifecycle management and GMP-qualified | validated, ready-to-use assay packages and platforms from our GMP testing facility help you meet regulatory requirements and free up in-house resources.

Cell Banking

Our dedicated GMP cell banking facility and expert support team specialize in delivering tested MCBs in four months. Closed-system manufacturing allows our partners to achieve high cell quality with sufficient cell densities and viabilities to transition smoothly to the production phase without delay.

Cell Culture Media Services

We can combine high-throughput cultivation capabilities with our large proprietary library of media and feeds, a broad range of validated media analytics methods, and advanced data analytics approaches for fast and effective media optimization.

Germany
Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen
Phone +49 551 308 0

USA
Sartorius Stedim North America Inc.
565 Johnson Avenue
Bohemia, NY 11716
Toll-Free +1 800 368 7178

For more information, visit
sartorius.com/cld-services

Last modified: 02 | 2026