



4Cell[®] CHO Platform Service Package: The Fast Track to IND

Uncompromised Quality
and Robust Scalability
for Biopharmaceutical
Cell Line Development

Simplifying Progress

SARTORIUS

Simplify From DNA to GMP Master Cell Bank With One Provider

Development of new protein therapeutics is a complex process, with technical and regulatory hurdles to overcome in the path to commercial success. With increasing competition and the progress of biosimilars, drug developers need to focus on speed, predictability, and quality.

The 4Cell® CHO Platform service package brings together cell line development (CLD) including the fully optimized 4Cell® cell culture media system, protein characterization, cell banking, and biosafety testing to accelerate your program and puts your molecule on the path to success.

The package offers reduced costs and proven results while maintaining an exceptional degree of flexibility. With the freedom to use the CMO of your choice, you can rapidly progress from DNA to GMP cell bank (MCB | WCB) and overcome typical obstacles that can delay a first commercial manufacturing batch.



Predictable Productivity

Our superior, scalable technology leads to high productivity (protein titers of up to 10 g/L) and high product quality.



Reliability

With the experience of more than 240 cell line development projects in our portfolio and 14 years of technical and regulatory expertise, we can help you get it right the first time.



Reduced Time-to-Market

A proven platform enables a research cell bank in just 9 weeks and a released master cell bank in less than five months, with no need for media, process optimization and scalability studies.



Reduced Risk

With one seamless process, from DNA to GMP master cell bank, it's much easier to mitigate the risk of a cell line not meeting productivity or quality goals.



Financial Advantages

Save money with our bundled offering. With the Cell Line Development service, you pay no royalties or milestone-dependent fees, removing licensing or partnering barriers.

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ASUS

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Cell Line Development
RCB and Basic
Analysis



Protein Characterization
Advanced Molecule
Analysis



Cell Banking
Frozen MCB Vials



Biosafety Testing
GMP Qualified
MCB | WCB



4Cell® Media System



The 4Cell® CHO Platform Service Package

Cell Line Development

The Sartorius Cell Line Development technology is an accessible, scalable, and robust system that delivers a product from DNA to research cell bank in just 9 weeks. It combines four proprietary components – expression vector, CHO DG44 host cell line, 4Cell® Media System, and upstream process design.

- Predictably high protein productivity of up to 10 g/L
- 3 or 4 stable clones for steadily high-performing cell line from each single project
- Experience of more than 240 CLD projects

4Cell® Media System

The 4Cell® Media System is a high-quality and high-performing cell culture formulation for CHO cell lines. It is chemically defined, serum-free and free of animal components.

- Designed for high cell densities, up to 4×10^7 cells/mL

Protein Characterization

Sartorius' protein characterization services are scaled to each phase of drug development. These services include:

- Development
- Qualification
- Validation of product characterization of:
 - Off-the-shelf assays
 - Custom assays

Our panel of assays have been pre-qualified with commercial monoclonal antibodies and can shorten clone selection timelines.



Cell Banking

The CHO cell banking service ensures secure cell bank manufacturing with sterile, single-use solutions. The seamless transition from CLD to master cell bank (MCB) and working cell bank (WCB) manufacturing occurs via an integrated service approach. By combining cell banking with CLD services, a project can move from DNA to final released MCB in less than 10 months.

- Rapid filling of 500 vials @ 12 M cells/vial for MCB manufacturing
- Fully GMP-compliant closed cell banking platform
- Qualified Person (QP)* for MCB | WCB release

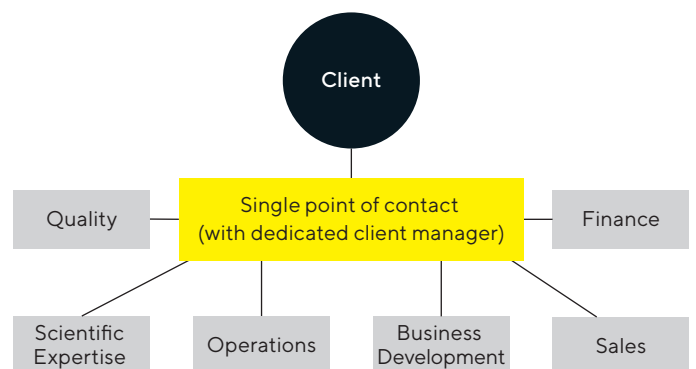
* Annex 16 EU-GMP Guidelines

Biosafety Testing

Sartorius' QC testing plans meet requirements for mammalian cell bank release and are designed to meet ICH Q5A regulations with assays validated to GMP standards. Ready-to-use Quality Control Plans support the full range of biosafety testing at every step, shortening the time it takes to get results.

Customer Focused

A dedicated team of Client Managers provides a single point of contact to the client throughout the CLD process, from DNA to released MCB | WCB, as well as the transfer to the CMO of the client's choice. Our Client Managers facilitate the flow of information, so you can reach IND faster.

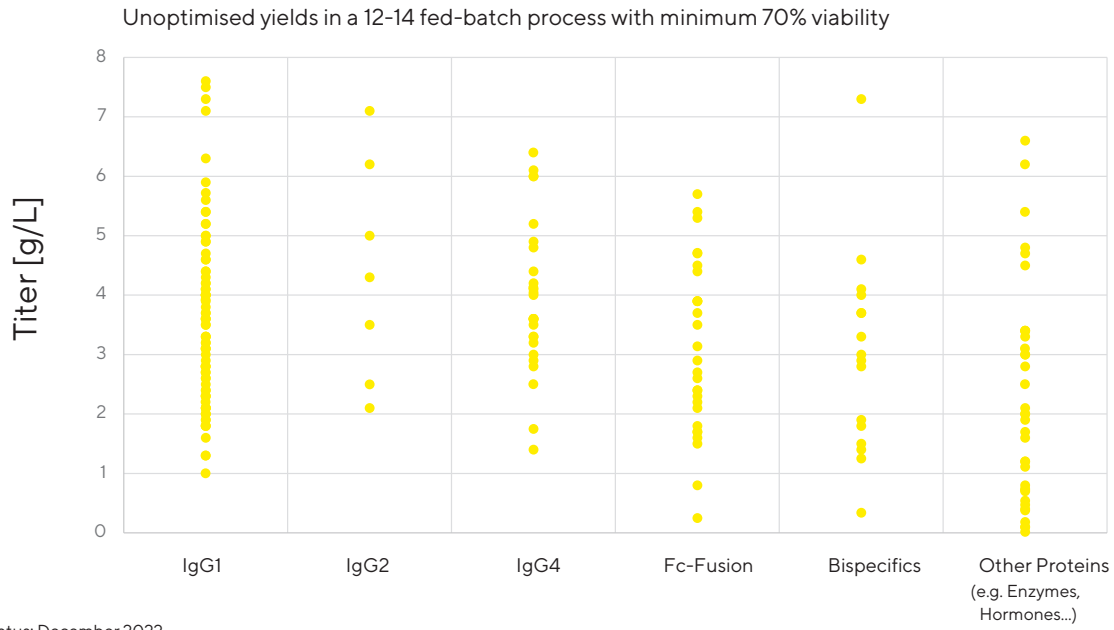


Visit our website:

www.sartorius.com/protein-expression-platform

for more information about the 4Cell® CHO Platform and how you can put your molecule on the path to success.

Track Record Cellca Cell Line Development



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Global Facilities of Sartorius for Cell Line Development, Cell Bank Manufacturing and Testing Services



Germany

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


Sartorius Stedim Cellca GmbH
Marie-Goeppert-Mayer-Str. 9
89081 Ulm-Eselsberg
Phone +49 731 206520

USA

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

UK

Sartorius Stedim BioOutsource Ltd.
1 Technology Terrace, Todd Campus,
West of Scotland Science Park
Glasgow, G20 0XA,
Toll-Free +44 141 946 4222

 For further contacts, visit
www.sartorius.com