



# 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® SmartCHO cell culture media, 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.

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## 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.

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## 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.

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## 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.

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## 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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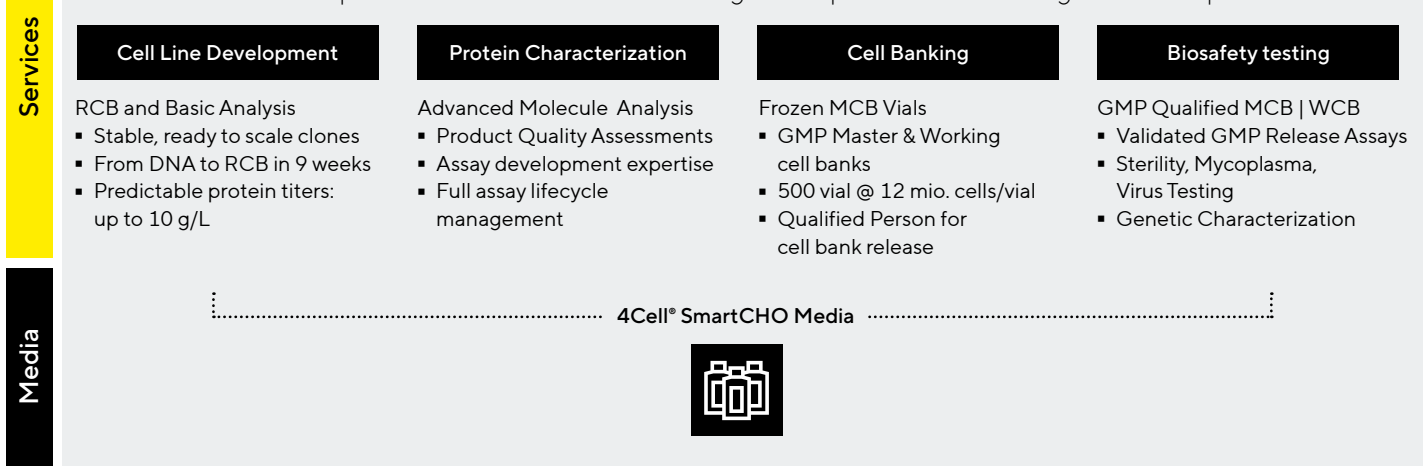




# The 4Cell® CHO Platform: Integrated Service Package from DNA to Cell Banks

## DNA to Cell Banks

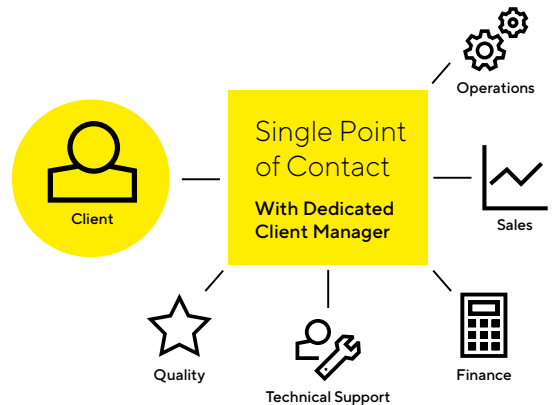
Predictable performance and accelerated drug development with our integrated CHO platform



## Excellent Customer Service

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.

- Over 80% of customers return to Sartorius for their next CLD project
- One point of contact with regular updates on your project
- Expert technical assistance and guidance throughout early-stage development to lot release.



# 4Cell<sup>®</sup> CHO Platform Cell Line Development Experience and Track Record



~ 240  
CLD projects

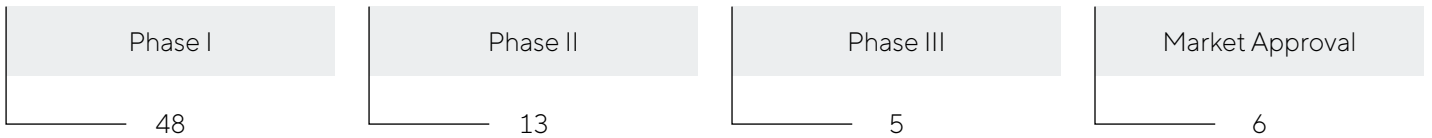
Capacity for ~50 CLD  
projects per year

Proven regulatory  
compliance

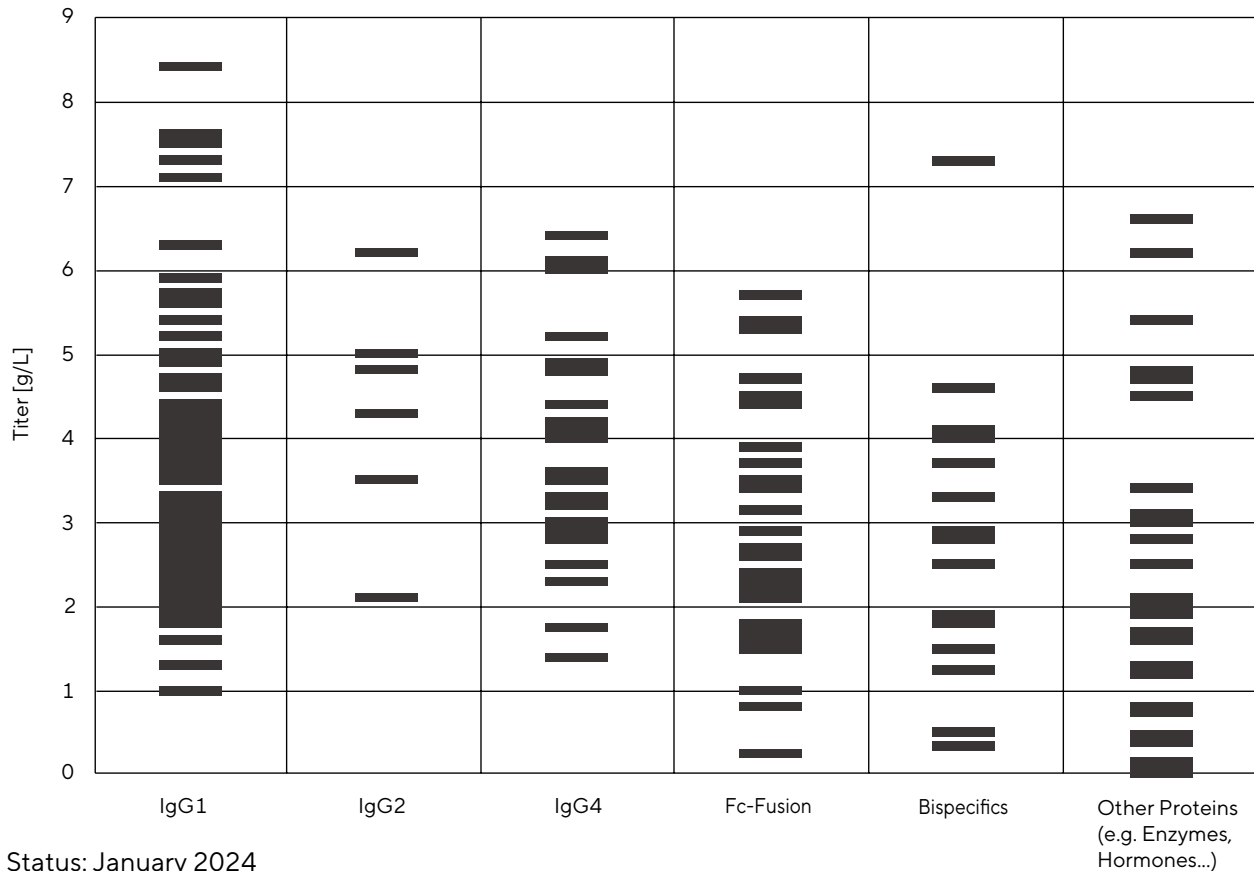
Continuous  
improvements &  
innovation

Versatility  
(IgG1, IgG2, IgG4,  
Fc-Fusion,  
Bi-specifics  
and more)

## Clinical Track Record

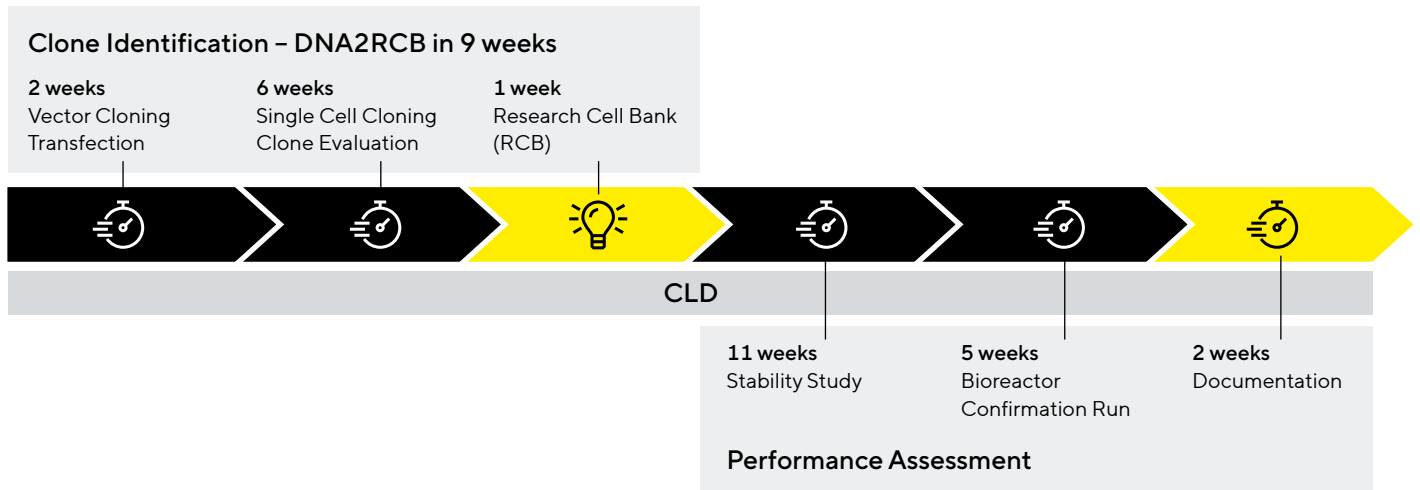


Unoptimised yields in a 12-14 days fed-batch process with minimum 70% viability



Status: January 2024





## Cell Line Development (CLD)

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® SmartCHO Media, and upstream process design.

- Ready-to-use CLD platform with integrated testing & cell banking services—all from Sartorius
- DNA to RCB in just 9 weeks
- 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
- Proven results across a range of molecules (IgG1, IgG2, IgG4, Fc-Fusion, Bi-specifics and more)
- Our CLD platform works with non-mAbs and “difficult to express” molecules



## Protein Characterization

We have extensive expert knowledge to support your New Biological Entity (NBE) or Biosimilar development with our off-the-shelf & custom assays, as well as regulatory compliant biosafety testing in the following areas:

- Bioassays
- Cell-based Potency Assays
- Binding Assays
- Physicochemical & Structural Analyses
- Qualification & Validation

### Fab Binding

- ELISA Methods
- Flow Cytometry
- SPR Methods

### Structural Analysis

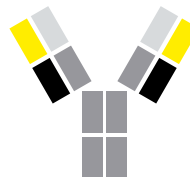
- LC-MS Methods
- N-glycan Analysis
- Intact Mass
- Peptide Mapping

### Fab Functional

- Various direct
- Blocking
- Neutralizing
- MOAs

### Fc Binding

- C1q (ELISA & SPR)
- Fcγ Receptor SPR
- FcRn



### Fc Functional

- ADCC
- ADCP
- CDC

## Dedicated Analytical Packages within CLD

### Recommended Protein Characterization Packages

Top 4 Clones

Standard IgG  
STD  
EXT

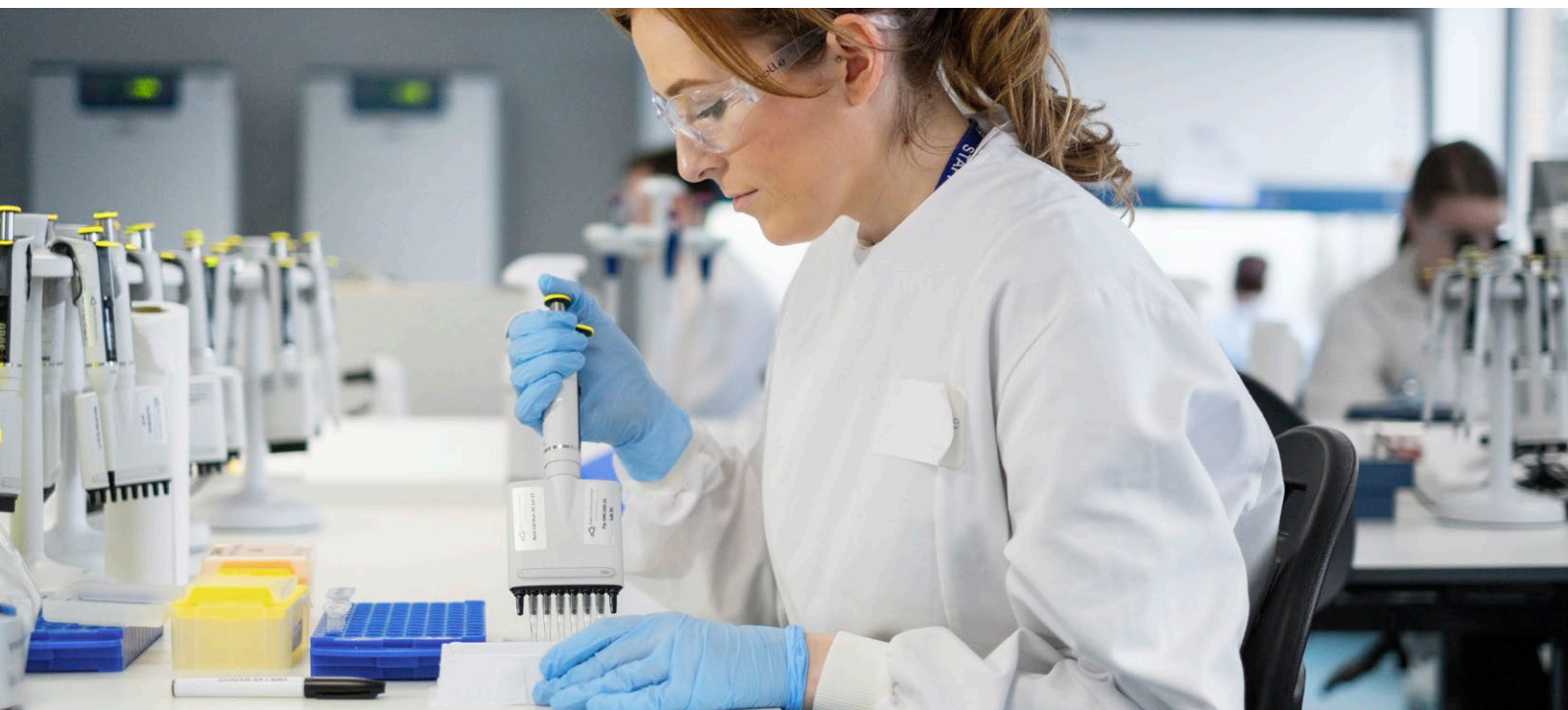
Appended IgG  
STD  
EXT

Lead Clones

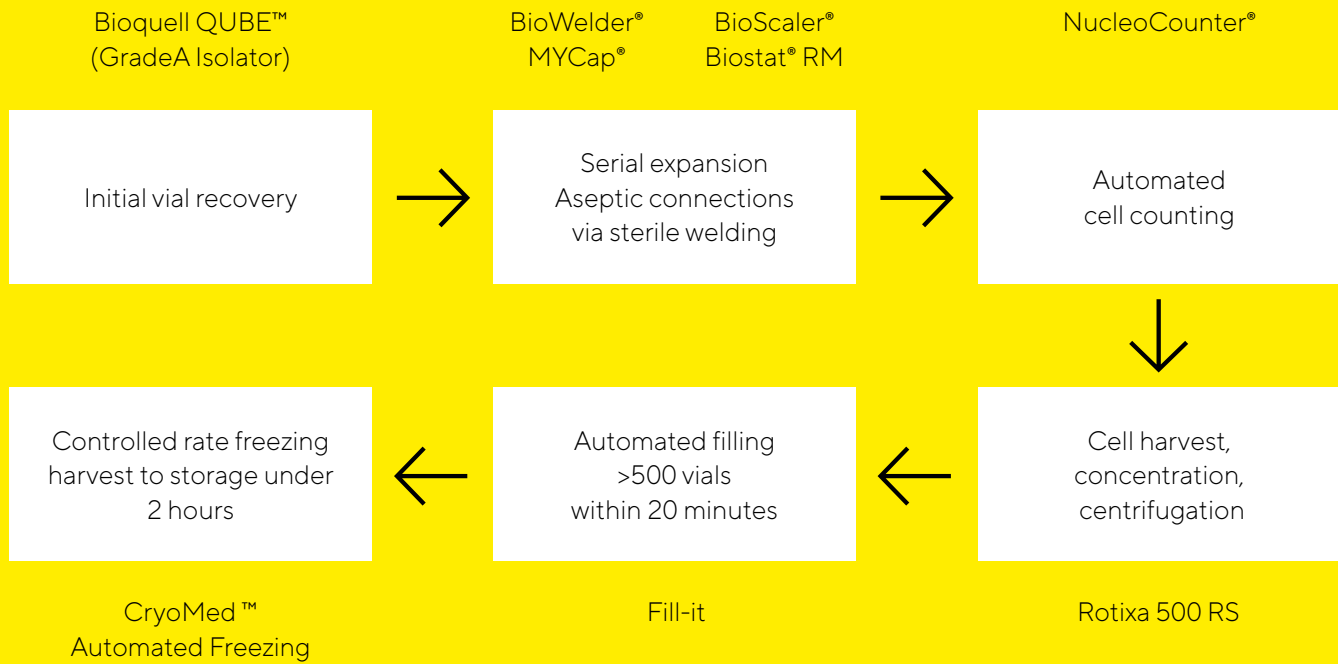
Standard IgG  
STD  
EXT

Appended IgG  
STD  
EXT

- Recommended selling price
  - Discount rules available
  - STD=standard
  - EXT=extended
- Can still be customized upon request if package not adequate (assays can be added and/or removed)



# Closed Manufacturing System, Both Qualified for Sterility Assurance



## 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.

Packages available for:

- Master Cell Bank
- Working Cell Bank
- Pilot Study
- Engineering Run



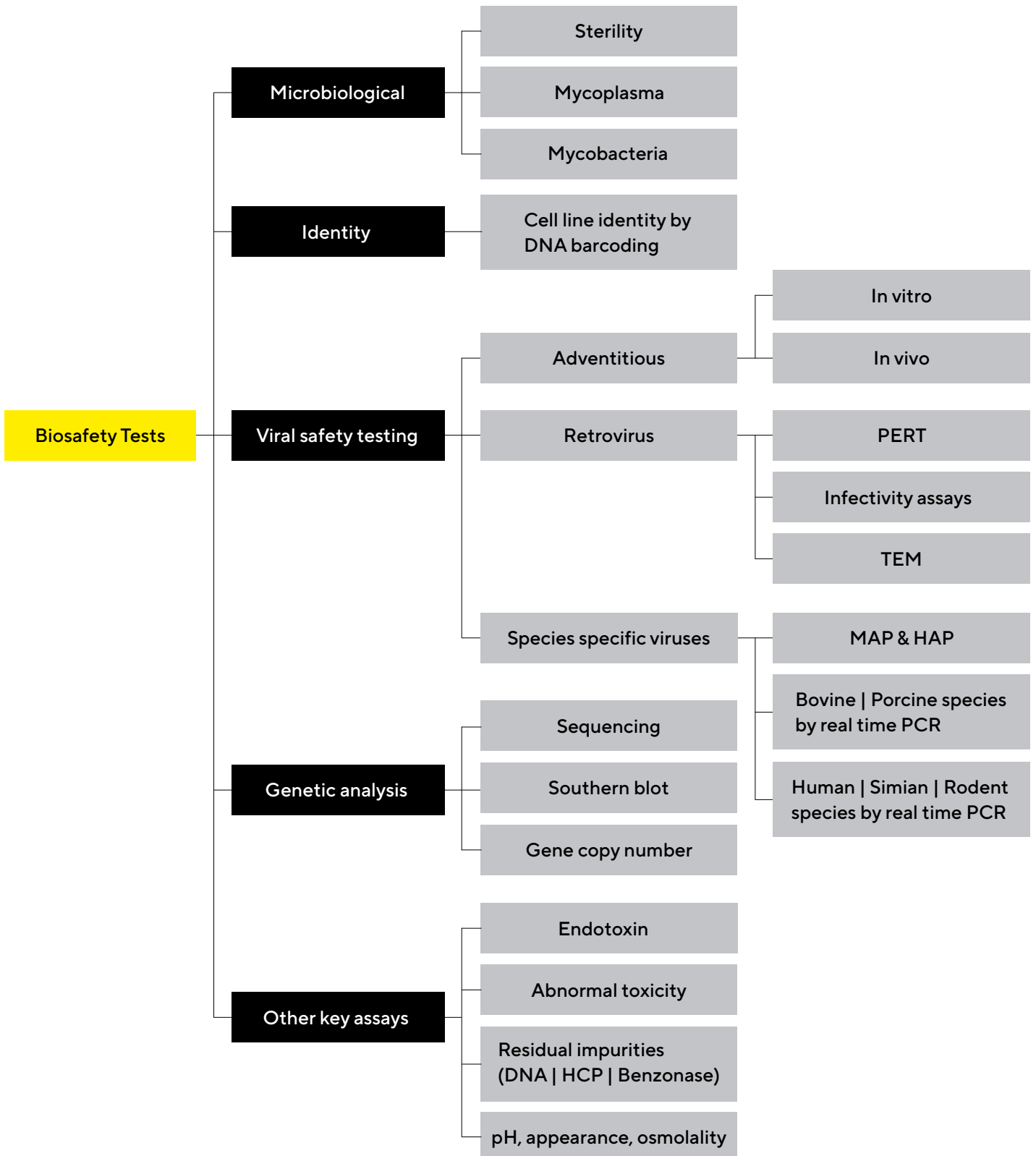


# Biosafety Testing

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.

Packages available for:

- Master Cell Bank Biosafety
- Working Cell Bank Biosafety
- End of Production Cell Bank Biosafety





## 4Cell® SmartCHO Media

The 4Cell® SmartCHO Media is a high-quality and high-performing cell culture formulation designed for our CHO DG44 cell line. It is a chemically defined, non-animal origin, growth media formulated to maximize the product titer in CHO cell lines. It provides robust performance in production systems of small and large scale, e.g. flask, Ambr® 15 | 250 and bioreactors. 4Cell® SmartCHO Media and Feeds are optimized for high filterability and solubility performances.

The 4Cell® SmartCHO Media is used in our cell line development services and supports the production of RCB and MCB. 4Cell® SmartCHOpe Media, our perfusion media, is compatible with our CLD service and supports clone selection in a perfusion mimic protocol.

### 4Cell® SmartCHO

#### Advanced Formulation

- Designed for CHO DG44 cell line
- Used for Sartorius cell line development services
- Robust performance on other CHO cell lines (e.g. CHO-S, CHO-K1) (up to 6 g/L)
- Valid key product quality sanity checks

#### Improved Performance

- High Protein Yield: increase titer up to 10 g/L
- Simplified Filtration: Formulation supports efficient product harvest
- Improved culture harvestability (+25% harvest volume with same filter area)
- Improved Solubility: Efficient reconstitution of powder without residuals

## The 4Cell® SmartCHO Media consists of four different media:

- 4Cell® SmartCHO Stock & Adaptation Medium (SAM): allows the cultivation or media adaptation of CHO cells. Lacking certain metabolites, the cultivation media exerts a strong selection pressure on cells and shortens the time-consuming adaptation to fed batch culture.
- 4Cell® SmartCHO Production Medium (PM): is a non-selective production medium for batch or for fed batch culture. It can be used for effective cultivation of any CHO cell lines, and helps produce high yield of the active protein.
- 4Cell® SmartCHO Feed Medium A (FMA) and 4Cell® SmartCHO Feed Medium B (FMB): are the ideal companion feeds designed to be used together with 4Cell® SmartCHO Production Medium. Combining those increases fed-batch productivity 3- to 5-fold compared to batch culture conditions.



### 4Cell® SmartCHO Media Kits

Get your ready-to-use media kit and transfer cell line, process and media to your site.

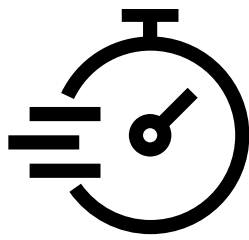
		Units
<b>4Cell® SmartCHO Media</b> [CFP3FB0200]	4Cell® SmartCHO SAM (1 L Bottle)	1
	4Cell® SmartCHO PM (1 L Bottles)	2
	4Cell® SmartCHO FMA (1 L Bottle)	1
	4Cell® SmartCHO FMB (125 mL Bottle)	1
<b>4Cell® SmartCHOpe Media</b> [CQP3FC0100]	4Cell® SmartCHOpe SAM (10 L Powder)	1
	4Cell® SmartCHOpe PM (50 L Powder)	1
	4Cell® SmartCHOpe FMA (3 L Powder)	2
	4Cell® SmartCHOpe FMB (2 L Powder)	1

Further pack sizes and formats are available. Contact us for more information.

<b>CD</b>	Chemically defined   The exact concentration and size of every component is known
<b>ACF</b>	Animal component free   The formulation is entirely made from non-animal   -human origin components
<b>PF</b>	Protein-free   The formulation does not contain any protein

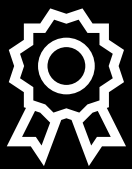
<b>RUO</b> <b>FFM</b>	For Research or Further Manufacturing Use Only*
	Product available in powder format
	Product available in liquid format

\* Study on stability and ageing is on-going; RUO/FFM will be claimed after 6 months of approved stability data



From DNA to  
Research Cell  
Bank (RCB) in  
only 9 weeks

Stable  
expression and  
high titers  
(up to 10 g/L)



Regulatory  
ready package  
of assays



Accelerate  
timelines towards  
commercialization





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



Visit our website:

[www.sartorius.com/protein-expression-platform](http://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.



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[www.sartorius.com](http://www.sartorius.com)