



4Cell[®] CHO Platform

Cell Line Development
Service

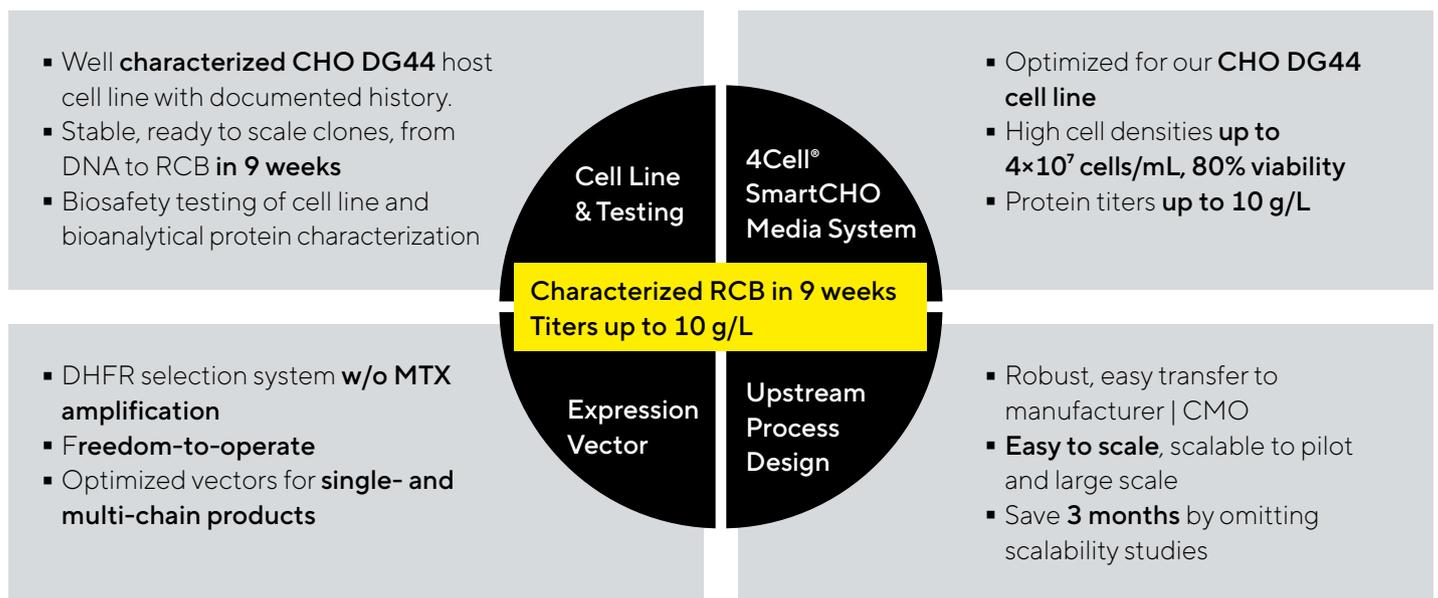
Simplifying Progress

SARTORIUS

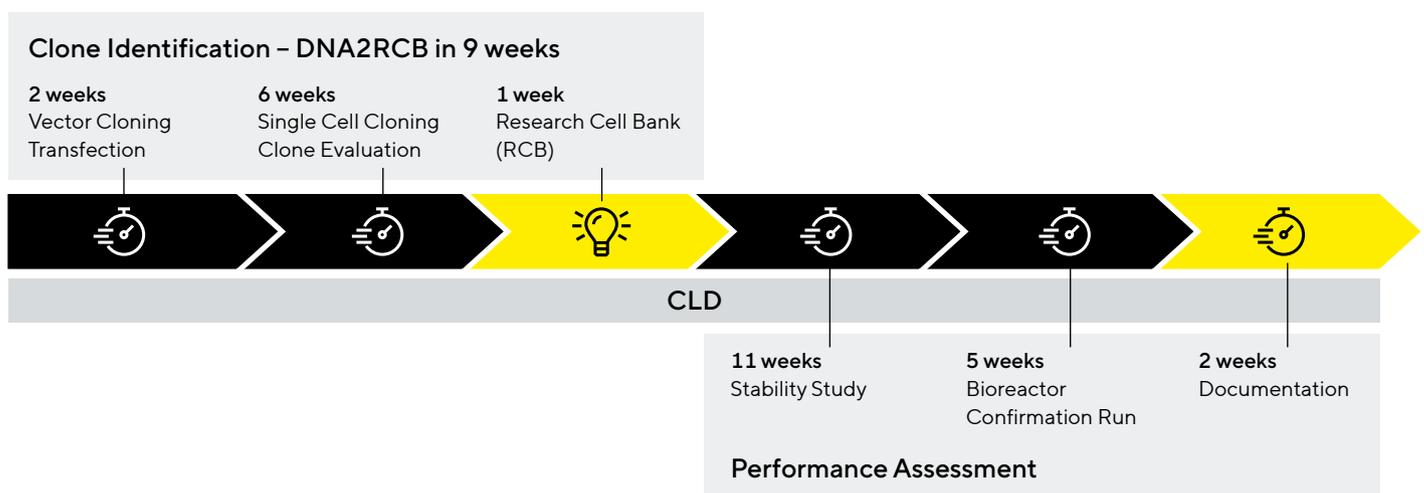
Cell Line Development Service

Sartorius is a leading provider of cell line development services allowing customers easy open access to a cost effective reliable technology platform. The Cell Line Development platform consistently delivers stable research clones from DNA to Research Cell Bank (RCB) in just 9 weeks with monoclonal antibody titers of up to 10 g/L in an easily scalable fed batch process.

Key Components



CLD: Cell Line Development, RTU: Ready to Use, RCB: Research Cell Bank, MCB: Master Cell Bank



Key Benefits

Track Record

- More than 240 projects using the Sartorius Cell Line Development Technology

Performance

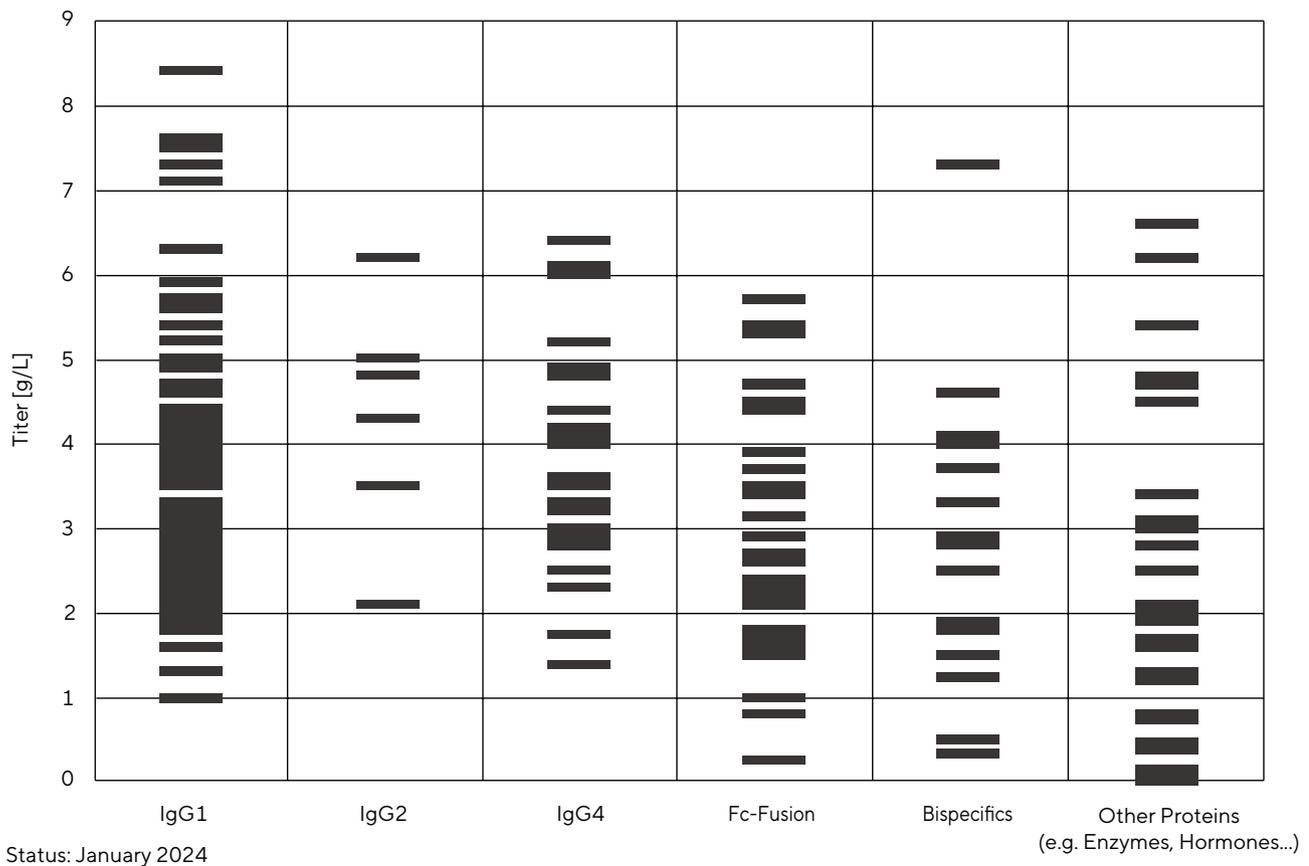
- Proven results across a range of molecules including non-mAbs and “difficult to express” molecules

Regulatory-compliant

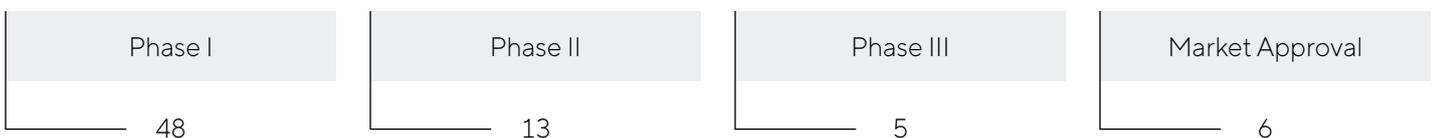
- 2 products achieved market approval, 5 products in phase III studies

Track Record 4Cell® CHO Platform | Cell Line Development

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



Clinical Track Record



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

Services	Cell Line Development	Protein Characterization	Cell Banking	Biosafety testing
Media	<p>RCB and Basic Analysis</p> <ul style="list-style-type: none"> ▪ Stable, ready to scale clones ▪ From DNA to RCB in 9 weeks ▪ Predictable protein titers: up to 10 g/L 	<p>Advanced Molecule Analysis</p> <ul style="list-style-type: none"> ▪ Product Quality Assessments ▪ Assay development expertise ▪ Full assay lifecycle management 	<p>Frozen MCB Vials</p> <ul style="list-style-type: none"> ▪ GMP Master & Working cell banks ▪ 500 vial @ 12 mio. cells/vial ▪ Qualified Person for cell bank release 	<p>GMP Qualified MCB WCB</p> <ul style="list-style-type: none"> ▪ Validated GMP Release Assays ▪ Sterility, Mycoplasma, Virus Testing ▪ Genetic Characterization
	<p>..... 4Cell® SmartCHO Media</p> 			

4Cell® CHO Platform | Fee-for-Service Products

Smoothen the path from development to IND submission with high-performance clones, well-documented characterization, and regulatory support

DNA2Pool Feasibility Track The Trail	DNA2RCB Cell Line Development The Pure	DNA2MCB One-Stop-Shop The Complete
 <p>~6 weeks: DNA to Pool Material</p>	 <p>~9 weeks*: DNA to RCB</p>	 <p>~10 months*: DNA to MCB</p>
<div style="display: flex; justify-content: space-around;"> <div style="text-align: center;">  <p>Performance check of molecules in our ready-to-scale CHO platform</p> </div> <div style="text-align: center;">  <p>Candidate evaluation & screening</p> </div> <div style="text-align: center;">  <p>Early protein material supply</p> </div> </div>	<div style="display: flex; justify-content: space-around;"> <div style="text-align: center;">  <p>Core CLD: DNA2RCB of top 4 clones</p> </div> <div style="text-align: center;">  <p>Optional RCB2USP: top 4 clones' stability study & 5 L fed-batch process</p> </div> <div style="text-align: center;">  <p>Best-in-class cell lines for robust and scalable bioprocesses</p> </div> </div>	<div style="display: flex; justify-content: space-around;"> <div style="text-align: center;">  <p>DNA2MCB including basic protein characterization</p> </div> <div style="text-align: center;">  <p>Optional in-depth protein characterization upon request</p> </div> <div style="text-align: center;">  <p>Seamless support to IND submission for accelerated drug development</p> </div> </div>

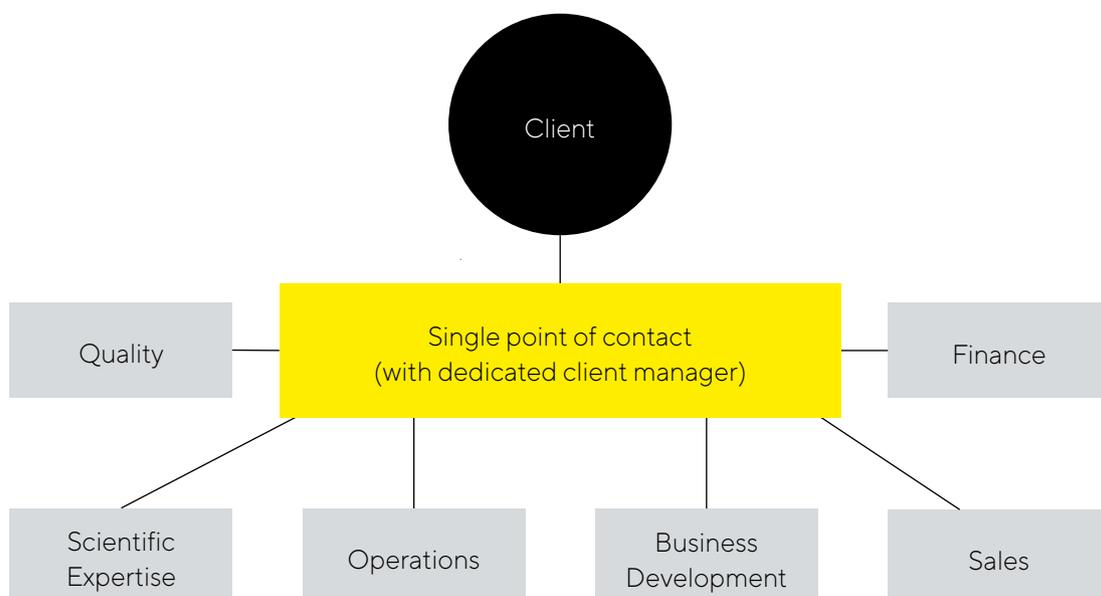
*Timeline is for a standard IgG1 NBE - scope & timeline can be adapted depending on molecule & client's needs

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



Customer Focus

Single point of contact throughout the whole process from DNA to fully characterized RCB.



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Specifications subject to change without notice.

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