



Cell Bank
Manufacturing &
Characterization

Simplifying Progress

SARTORIUS



The Next Generation of GMP Cell Banking

Fully characterized, well-documented, homogeneous master cell banks (MCB) and working cell banks (WCB) are critical attributes to mitigate risk and ensure safety and product quality of any biological product.

Manufacturing in Closed System

Closed manufacturing system achieved by using sterile single use solutions. Including options for shake flask manufacturing utilizing the Sartorius Mycap® fluid transfer system, cell culture fermentation in the Biostat® RM, aseptic transfers via Biowelder® and Biosealing® and culminating in automated vial filling in the Fill-It and controlled rate freezing.

Integrated in Cell Line Development and Biosafety Services

Cell banking services integrated in our Cell Banking Characterization services and can be offered as integral part of the Sartorius 4Cell® CHO Platform Service Package.

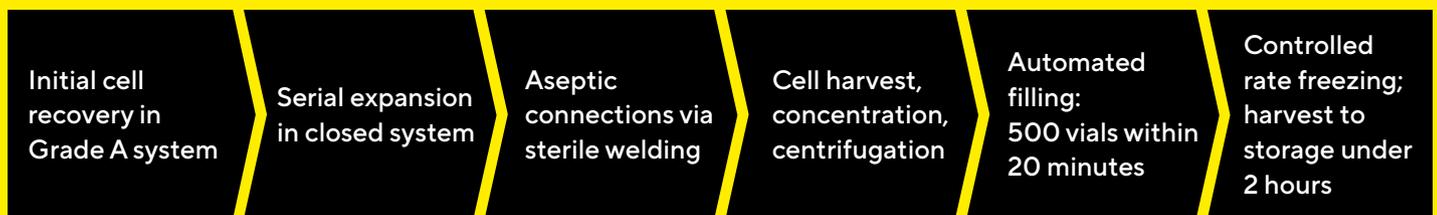
Quality Assurance

Sartorius offer this as a fully broth qualified manufacturing platform for added process safety and sterility assurance. The custom built 260 m² GMP cleanroom facility is fully dedicated to mammalian cell lines in suspension, manufactured using serum-free, animal component free media.

For Your Applications: from mAbs to Vaccines

GMP cell banking services for CHO cell lines, HeLa, HEK293, and further mammalian suspension cell lines. Service options include transfer of the client's shake flask or bioreactor process.

Cell Bank Manufacturing Process Flow



Biostat® RM

Mycap®



Biowelder®



Biosealer®



Fill-It



Our Cell Banking Service

Safety

Regulatory

Deliverables

Ultimate Safety Standards

- Closed & automated system
- Automated filling (Fill-It)
- Dedicated facility for mammalian, suspension cell banks using serum-free & animal component free media
- Extensive environmental monitoring programme supporting manufacturing platform
- Manufacturing process broth qualified for sterility assurance

Regulatory Acceptance

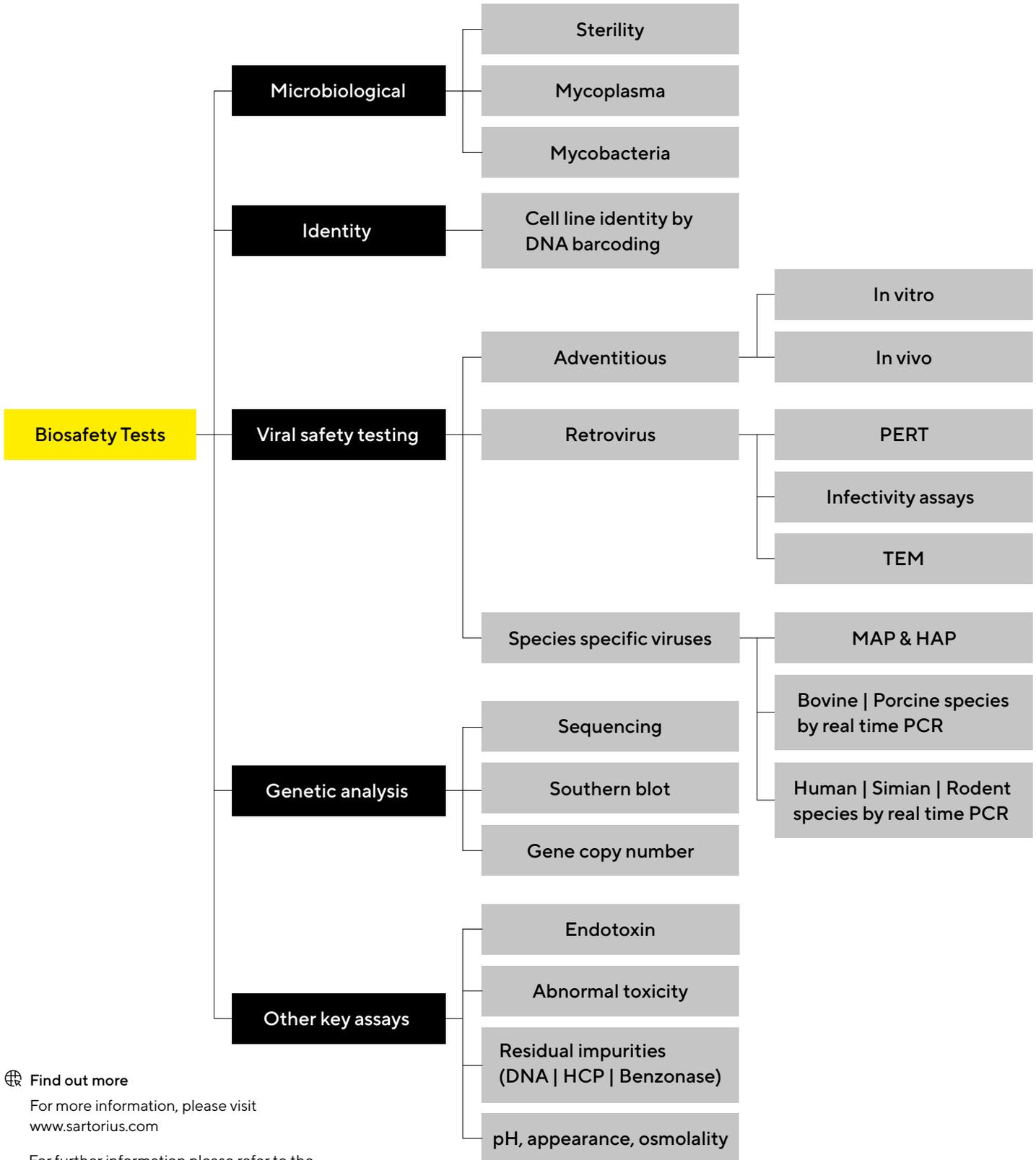
- MHRA IMP (MIA) licenced manufacturing facility
- MHRA GMP Licenced Testing Facility
- Facilities and equipment validated to VMP
- Cell bank testing to global regulatory standards

Deliverables

- >500 vial bank ~ 1×10^7 viable cells | vial: verified >80% viability on thaw
- Manufacturing Summary Report
- Certificate of GMP Compliance
- TSE | BSE Batch Certification
- Certificate of Analysis for each Release and Characterization Assay
- Storage of filled vials in vapor phase LN2

Integrated GMP Cell Bank Characterization

As part of our integrated service offering for a complete solution, we also offer comprehensive biosafety testing services, including cell bank characterization and genetic stability assessments of the final producer cell lines.



Find out more
 For more information, please visit
www.sartorius.com

For further information please refer to the individual brochures for each service area.

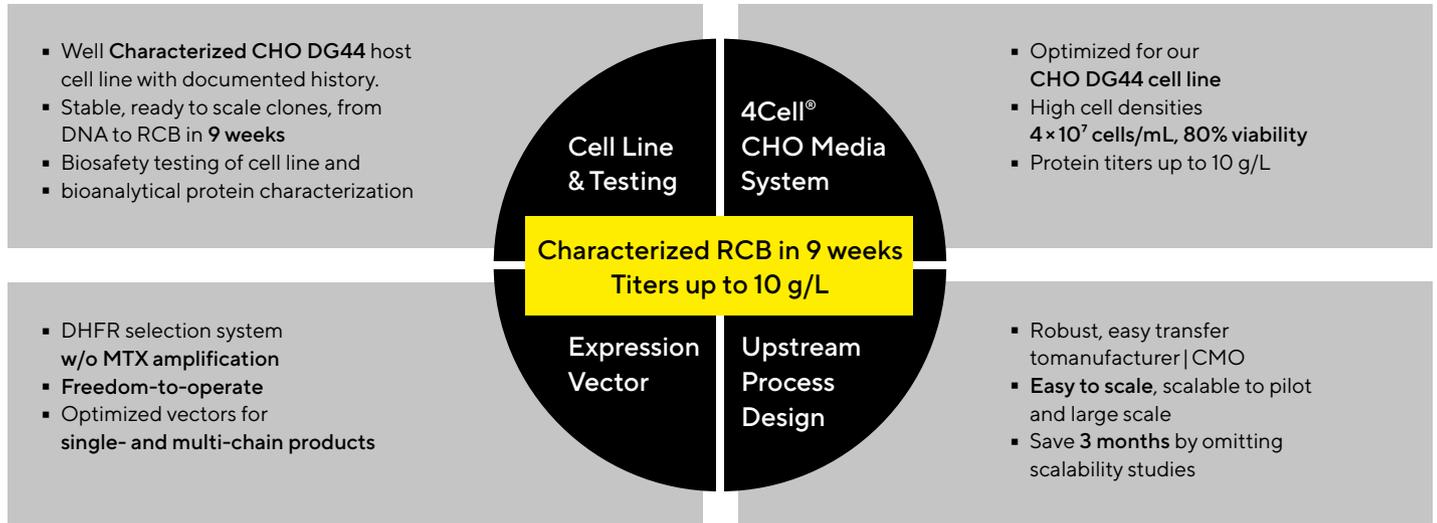


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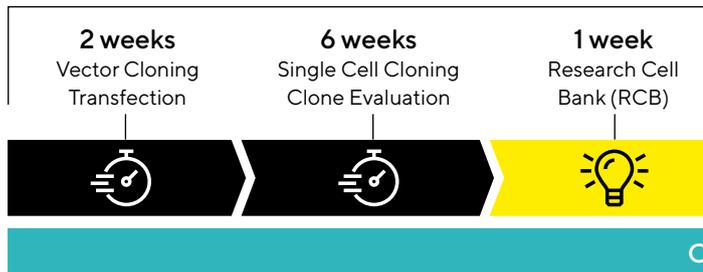
4Cell[®] CHO Platform: Integrated Service Package from DNA to Cell Banks

Sartorius' Cell Line Development service delivers consistently stable clones with titers of up to 10 g/L in easily scalable fed-batch process, from DNA to Research Cell Bank (RCB) in just 9 weeks. Combined with our GMP Banking and Testing Services in our 4Cell[®] CHO Platform we offer a de-risked and time-saving approach from DNA2MCB in less than 10 months.

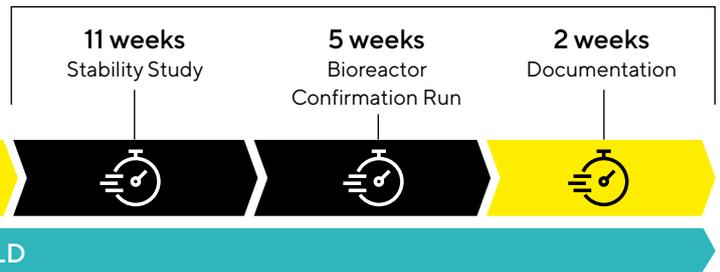
Cell Line Development



Clone Identification - DNA2RCB in 9 Weeks



Performance Assessment



Your Need is Our Mission

Working across a multi-functional team, our client managers provide support, transparency and advice throughout the lifecycle of your projects.

Contact us and we will work together on the solution for your project!



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



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