



cGMP Cell Bank
Manufacturing and
Characterization

Simplifying Progress

SARTORIUS



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

- RCB and Basic Analysis
- Stable, ready to scale clones
 - From DNA to RCB in 9 weeks
 - Predictable protein titers: up to 10 g/L

Protein Characterization

- Advanced Molecule Analysis
- Product Quality Assessments
 - Assay development expertise
 - Full assay lifecycle management

Cell Banking

- Frozen MCB Vials
- GMP Master & Working cell banks
 - 500 vial @ 12 mio. cells/vial
 - Qualified Person for cell bank release

Biosafety testing

- GMP Qualified MCB | WCB
- Validated GMP Release Assays
 - Sterility, Mycoplasma, Virus Testing
 - Genetic Characterization

Media

4Cell[®] SmartCHO Media



Excellent Customer Service

A dedicated team of Client Managers provides a single point of contact to the client throughout the Cell Line Development (CLD) process, from DNA to released Master Cell Bank (MCB) | Working Cell Bank (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 Investigational New Drug (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.



Cell Bank Manufacturing Process Flow



Biostat® RM



Mycap®



Biowelder®



Biosealer®



Fill-It

The Next Generation of cGMP 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 Biowelding® 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 Cell Line Development service.

Cell Banking

- Packages available for:
 - Master Cell Bank
 - Working Cell Bank
 - Pilot Study
 - Engineering Run
- Available in either shake flask or Biostat® RM
- Bundles contain full service & bill of materials

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

cGMP 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.

FILL-IT

Busy Dispensing

Push STOP to halt

FUNCTION



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

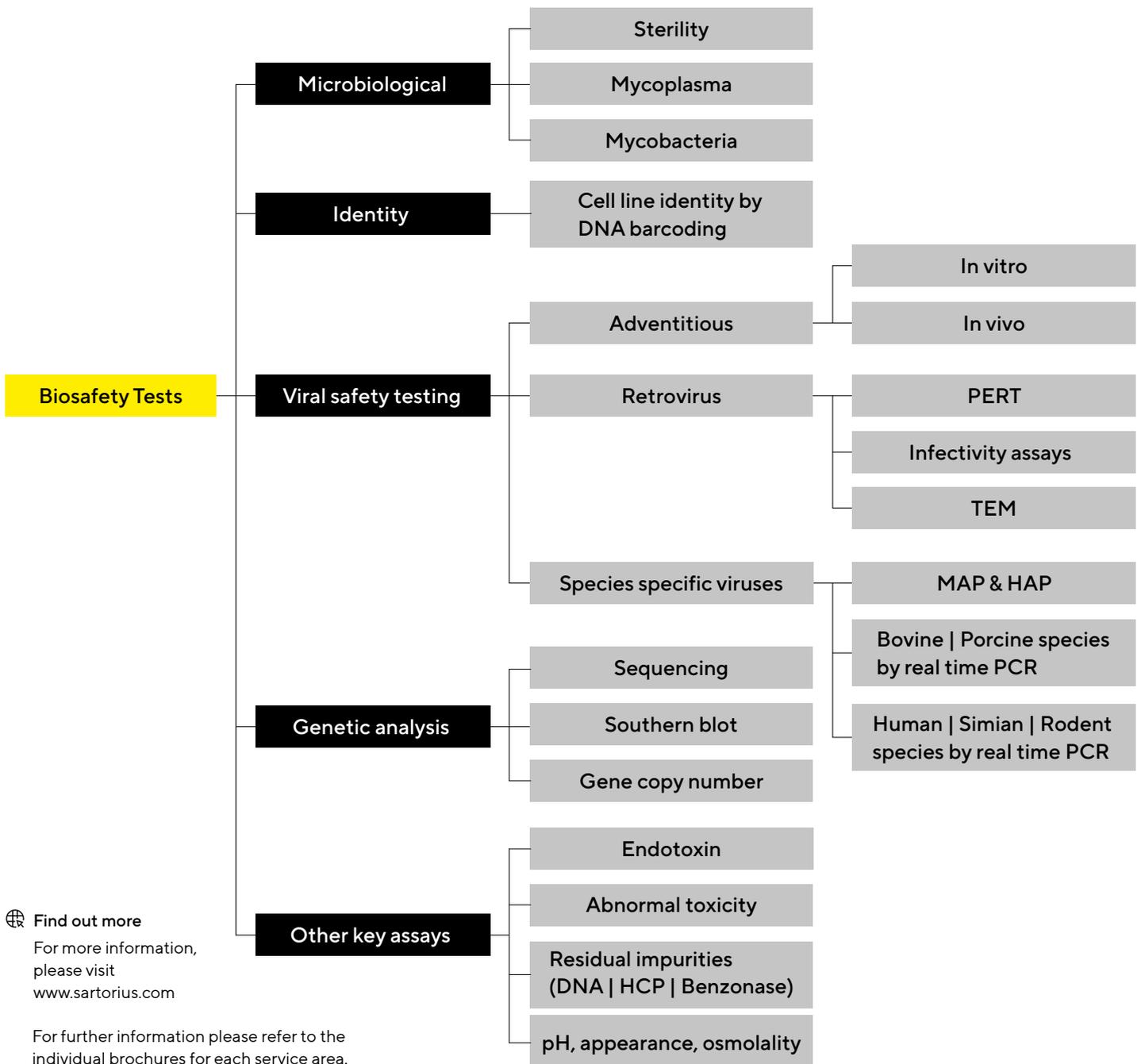
Integrated cGMP Cell Bank Characterization

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 to assess the safety of biologics throughout the drug development pathway.

Our scientists have a wealth of knowledge and experience in biosafety testing, coupled with a thorough understanding of the regulatory requirements for the release of cell banks, molecules, and the cell lines used to manufacture these products.

Biosafety Testing

- Packages available for:
 - Master Cell Bank Biosafety
 - Working Cell Bank Biosafety
 - End of Production Cell Bank Biosafety
- Contain all necessary assays to satisfy regulatory requirements for biosafety testing and release of cell banks.
- One single price for all of your biosafety testing requirements.



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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