



Protein
Characterization
and Biosafety
Testing Services

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

4Cell[®] SmartCHO Media

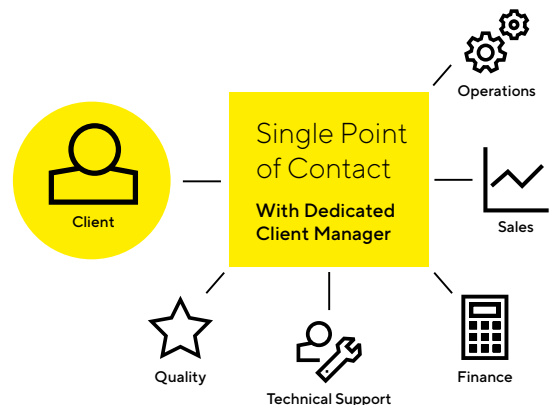


Media

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 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



Leading Service Provider

The foundation for approval of new biological entities is built on a robust analytical data package that proves the safety, purity and potency of the product. The Sartorius analytical testing package combines physicochemical and biological analysis for in-depth characterization studies from a single contract partner. Our service offering uses platform methods, off-the-shelf assays and custom developed bioassays to enable rapid data-driven decisions during drug development and is available from pre-clinical through to clinical phases and lot release. Coupled with our extensive options as part of the 4Cell® CHO platform including cell line development, biosafety testing, and cell bank manufacturing, Sartorius is the preferred choice for your program.

Technical Expertise

“Over the 3 years working with Sartorius, the team has been knowledgeable, engaged, and proactive. They consistently and professionally deliver on promise with no surprises. A truly pleasant experience.”

Client Quote

- >15 years' experience
- 99% delivery on time
- Highly experienced & knowledgeable scientists
- Experts in development, optimization & validation of complex cell-based potency bioassays & binding assays
- Full range of off-the-shelf assays for routine characterization of monoclonal antibodies
- Dedicated team of protein characterization experts



Our Services

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

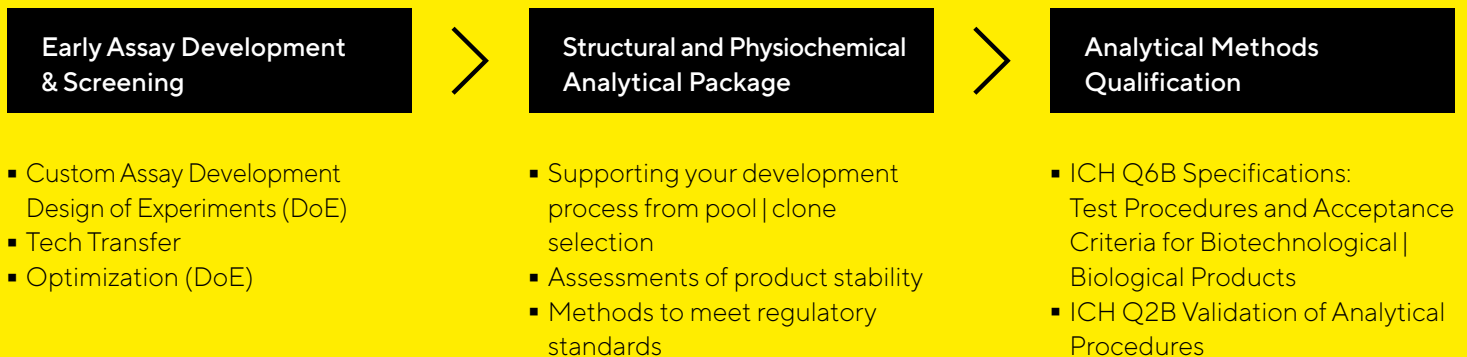
- Bioassays
- Cell-based Potency Assays
- Binding Assays
- Physicochemical & Structural Analyses
- Qualification & Validation

Our Approach = Your Success

Speed	Faster assay development to shorten your timeline to IND submission
Flexibility	Tailored testing packages
Expertise	Extensive experience & full range of platform methodologies
Compliant	Fully current Good Manufacturing Practice (cGMP) compliant laboratories
Integrated	Full service package available



Our method lifecycle approach takes you from pre-clinical development through to phase III validation and commercial lot release, with a smooth transition to cGMP services from our fully compliant laboratories.



Protein Characterization Testing Services

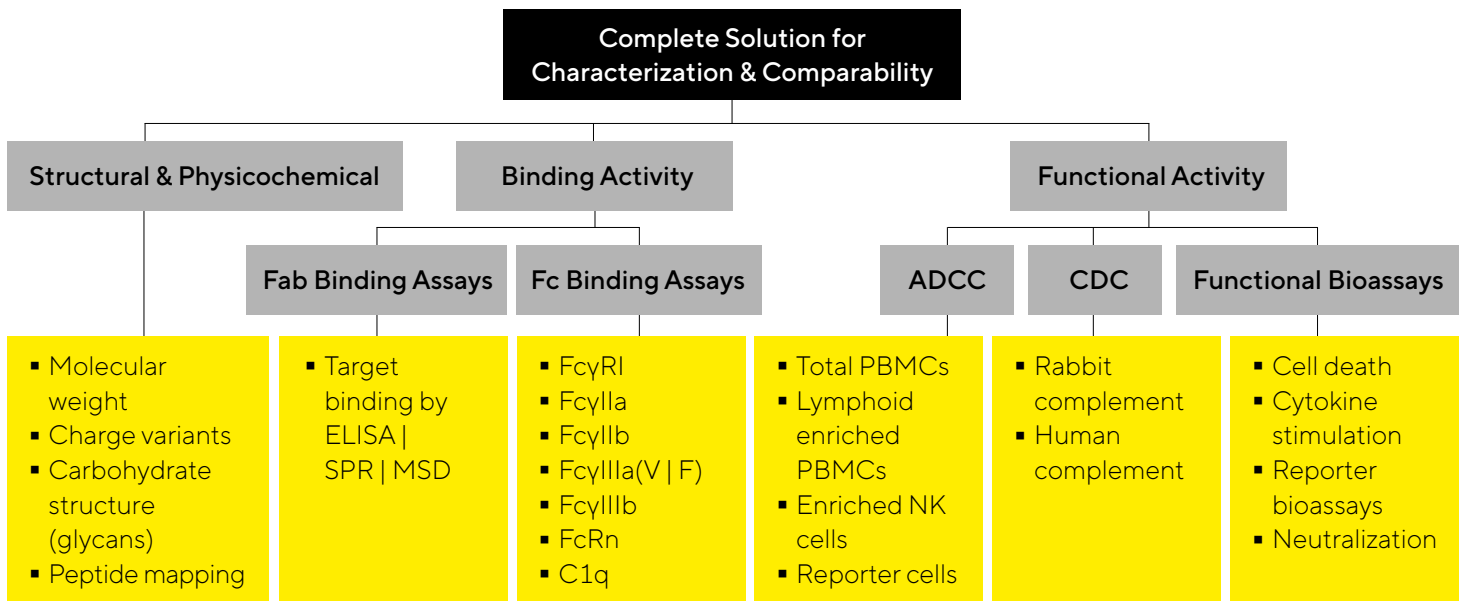
Our panel of off-the-shelf monoclonal antibody characterization assays are ready to go for a range of targets (TNF, CD20, VEGF, HER2, EGFR, PD-1, PD-L1, IgE, IL-12/23, RANKL. etc).

Our assays have been qualified with commercially available innovator mAbs such as Humira, Rituxan, Herceptin, Avastin etc.

Sartorius with clients throughout the molecule development pathway:



Our highly experienced team of scientists have developed methods for molecule characterization in line with regulatory requirements, allowing comprehensive analysis of NBE molecules and comparability of biosimilars to the originator molecule.



Full Range of Fc Effector Binding & Functional Assays

- Protein therapeutics: Characterization of immunological and biological properties
- Experience in Fc characterization assays including binding to C1q, Fc receptors, ADCC & CDC



cGMP Method Validation

- Product specific validation supporting stability studies & lot release
- USP1033, Ph. Eur. & ICH Q2B specifications

 For further information, visit sartorius.com/en/services/biologics-testing

Biosimilars Testing

Industry Leader

Characterization and comparability
of biosimilar monoclonal antibodies

Expertise

Industry leading experience working with over 15 biosimilar molecules and 30+ biosimilar developers

Speed to Market

Comprehensive range of off-the-shelf assays for biosimilar characterization and comparability to ensure cost effective results

Greater Quality Assurance

Excellent regulatory and industry insight for generating data required for regulatory submissions

Experience

Sartorius offer a variety of methods to support the testing of a wide range of biosimilar monoclonal antibodies including:

- Herceptin (trastuzumab)
- Humira (adalimumab)
- Enbrel (etanercept)
- Avastin (bevacizumab)
- Lucentis (ranibizumab)
- Rituxan (rituximab)
- Remicade (infliximab)
- Stelara (ustekinumab)
- Simponi (golimumab)
- Prolia (denosumab)
- Actemra (tocilizumab)
- Synagis (palivizumab)
- Eylea | Zaltrap (aflibercept)
- Xolair (omalizumab)
- Orencia (abatacept)
- Yervoy (ipilimumab)

Currently, in our R&D pipeline we are developing methods to support assessments of biosimilarity for the following molecules:

- Erbitux (cetuximab) target – EGFR
- Opdivo (nivolumab) target – PD-1
- Imfinzi (durvalumab) target – PD-L1
- Tecentriq (atezolizumab) target – PD-L1
- Keytruda (pembrolizumab) Target PD-1



Packages for Testing Services

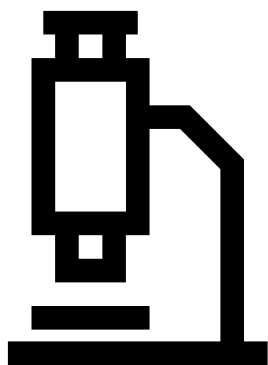
Utilising decades of experience in testing services, we are now offering pre-determined packages for all of your testing needs. These cover full characterization of your molecule, generation of master and working cell banks, and all required biosafety testing. All packages have been carefully assembled with our recommended assays in order to satisfy all regulatory requirements, and accelerate the speed at which your molecule reaches the clinic.

Please speak with us to discuss these packages further, and understand how Sartorius can help you to simplify progress.

Protein Characterization

- Complete protein characterization package of recommended assays for your molecule
- Streamlines processes and accelerates the development of your molecule to the clinic; packages contain sample testing and all method development | feasibility
- Packages are available for protein characterization at either top 4 clone, or lead clone stage

Recommended Protein Characterization Packages



	Top 4 Clones	Lead Clone
Standard IgG		
Standard* package	✓	✓
Extended package	✓	✓
Appended IgG		
Standard* package	✓	✓
Extended package	✓	✓

*The standard package provides the minimum recommended level of testing for protein characterization, whilst the extended package provides a greater number of assays for additional protein characterization work.

🌐 For further information on these packages, visit sartorius.com/en/services/biologics-testing



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



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