New Biological Entity

Product Characterization Services
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 for biologics safety testing, and the wider portfolio, Sartorius is the leading service provider, and preferred choice for your program.

Industry Leading Integrated Services

Supporting the development and characterization of biologic products from pre-clinical development through to commercialization, we have services to meet your needs.
Client Management Organization

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

"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

- +14 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

Technical Expertise
Our Services

We have extensive expert knowledge to support your New Biological Entity (NBE) 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

Our Approach = Your Success

**Speed**  
Faster assay development to shorten your timeline IND submission

**Flexibility**  
Tailored testing packages

**Expertise**  
Extensive experience & full range of platform methodologies

**Compliant**  
Fully 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.

- Customizable Off-the-Shelf Development Services
- Qualification
- Validation

Early Assay Development & Screening

- Custom Assay Development (DoE)
- Tech Transfer
- Optimization (DoE)

Structural and Physicochemical Analytical Package

- Supporting your development process from pool | clone selection
- Assessments of product stability
- Methods to meet regulatory standards

Analytical Methods Qualification

- ICH Q6B Specifications: Test Procedures and Acceptance Criteria for Biotechnological Biological Products
- ICH Q2B Validation of Analytical Procedures
Our Targets

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.).

- **Fab Binding**
  - ELISA Methods
  - Flow Cytometry
  - SPR Methods

- **Fc Binding**
  - C1q (ELISA & SPR)
  - Fcγ Receptor SPR
  - FcRn

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

- **Fab Functional**
  - Various direct
  - Blocking
  - Neutralizing
  - MOAs

- **Fc Functional**
  - ADCC
  - ADCP
  - CDC

**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

**GMP Method Validation**

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

Don’t see your target? Don’t worry. Contact us today to discover our possibilities.
Biosafety Testing

To complement our expertise in bioanalytical characterization, Sartorius also offers a suite of assays 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 monoclonal antibodies and the cell lines used to manufacture these products.

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

Key Components

- Well Characterized CHO DG44 host cell line with documented history.
- Stable, ready to scale clones, from DNA to RCB in 9 weeks
- Biosafety testing of cell line and bioanalytical protein characterization

- Optimized for our CHO DG44 cell line
- High cell densities 4×10⁷ cells/mL, 80% viability
- Protein titers up to 10 g/L

- DHFR selection system w/o MTX amplification
- Freedom-to-operate
- Optimized vectors for single- and multi-chain products

- Robust, easy transfer to manufacturer | CMO
- Easy to scale, scalable to pilot and large scale
- Save 3 months by omitting scalability studies

Clone Identification – DNA2RCB in 9 Weeks

- 2 weeks Vector Cloning & Transfection
- 6 weeks Single Cell Cloning & Clone Evaluation
- 1 week Research Cell Bank (RCB)

Performance Assessment

- 11 weeks Stability Study
- 5 weeks Bioreactor Confirmation Run
- 2 weeks Documentation

Cell Bank Manufacturing

The Sartorius service portfolio also offers fully cGMP compliant cell bank manufacturing. In order to mitigate risk and ensure the safety and quality of any biological product, it is essential to have a fully characterised, well-documented, homogeneous master cell bank (MCB) and working cell bank (WCB).

We offer comprehensive biosafety testing services, including cell bank characterisation and genetic stability assessments of final producer cell lines.

Key points to note:

- Closed, single-use manufacturing system with inline monitoring and control
- Animal product free production
- Up to 500 vial cell banks at 4×10⁷ at 12 million cells per vial
- Automatic vial filling system and controlled rate cryopreservation
- Storage of filled vials in vapor phase LN₂

Contact our experts to discuss your cell bank manufacturing and cell bank characterisation requirements.
Global Facilities of Sartorius for Cell Line Development, Cell Bank Manufacturing and Testing Services

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