New Biological Entity

Product Characterization Services
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 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.

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

- +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
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.

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

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

- 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

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

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

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

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

Our assays have been qualified with commercially available innovator mAbs such as Humira, Rituxan, Herceptin, Avastin etc. – Ask for our qualification reports today.

Don’t see your target? Don’t worry. Contact us today to discover our possibilities.
For further information please refer to the individual brochures for each service area.
Cell Line Development

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

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
- DHFR selection system w/o MTX amplification
- Freedom-to-operate
- Optimized for our CHO DG44 cell line
- High cell densities 4 × 10⁷ cells/mL, 80% viability
- Protein titers up to 10 g/L
- 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
- 5 weeks Single Cell Cloning Clonbe Evaluation
- 2 weeks 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 characterized, well-documented, homogeneous master cell bank (MCB) and working cell bank (WCB). We offer comprehensive biosafety testing services, including cell bank characterization and genetic stability assessments of final producer cell lines.

Key points to note:
- Closed, single-use manufacturing system with in line 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 characterization requirements.
Global Facilities of Sartorius for Cell Line Development, Cell Bank Manufacturing and Testing

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