



# New Biological Entity

Product Characterization  
Services

Simplifying Progress

**SARTORIUS**

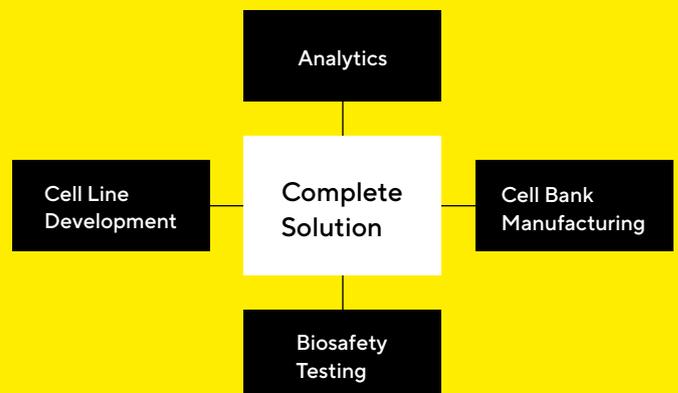
# Leading Service Provider

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

<b>Speed</b>	Faster assay development to shorten your timeline IND submission
<b>Flexibility</b>	Tailored testing packages
<b>Expertise</b>	Extensive experience & full range of platform methodologies
<b>Compliant</b>	Fully cGMP compliant laboratories
<b>Integrated</b>	Full service package available



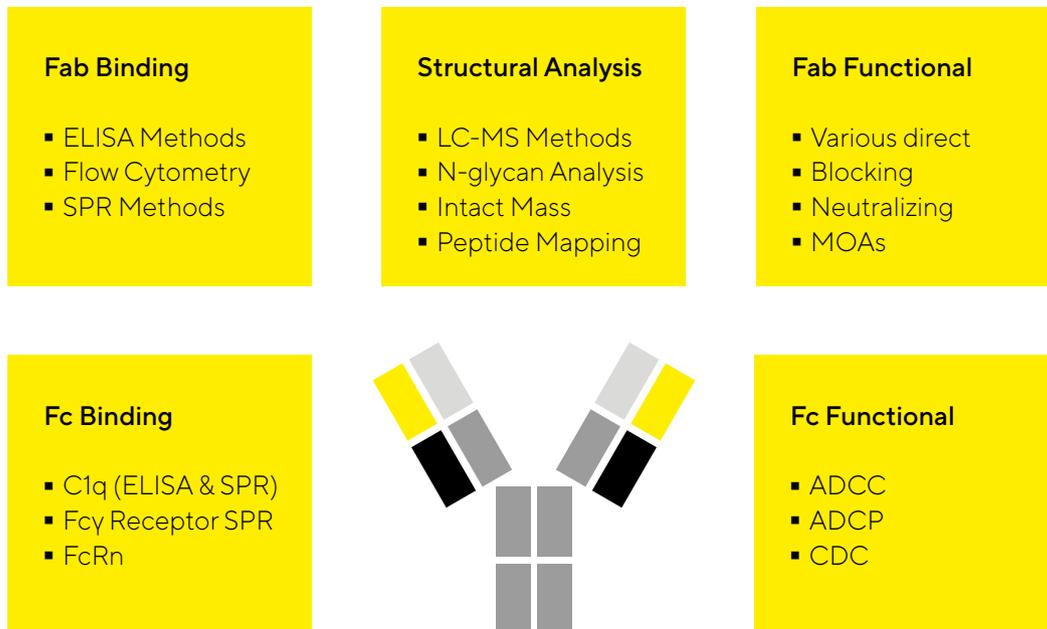
Our method lifecycle approach takes you from pre-clinical development through to phase III validation and commercial lot release, with a smooth transition to cGMP services from our fully compliant laboratories.



# 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).

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



## 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

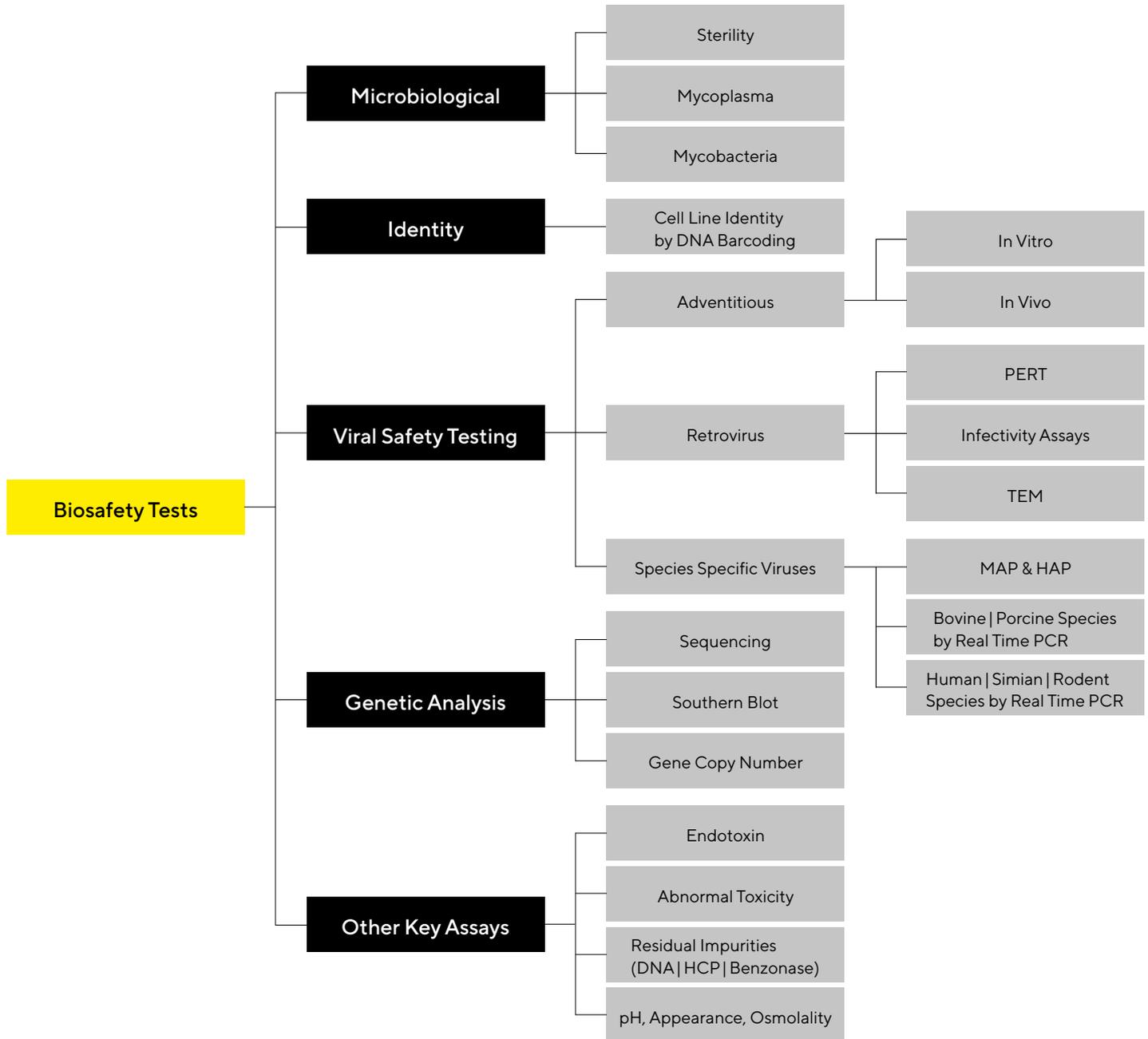


Don't see your target? Don't worry. Contact us today to discover our possibilities.

# 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.

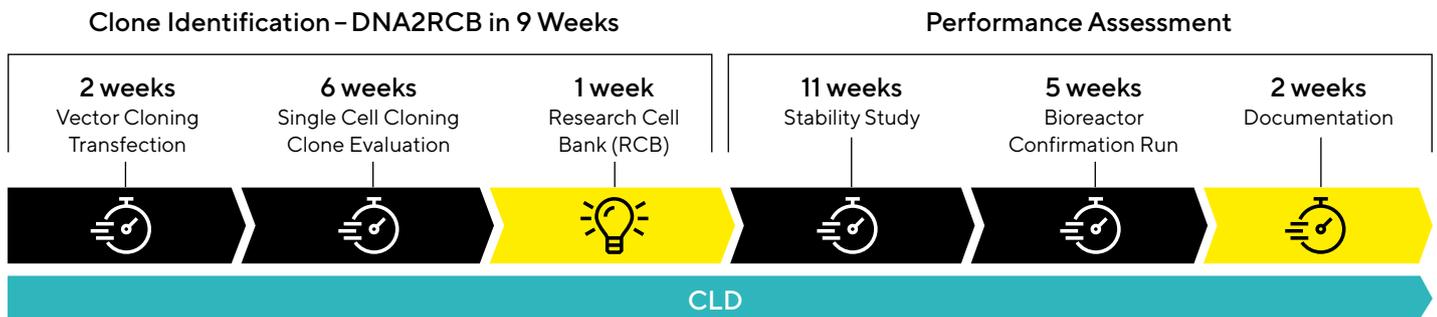
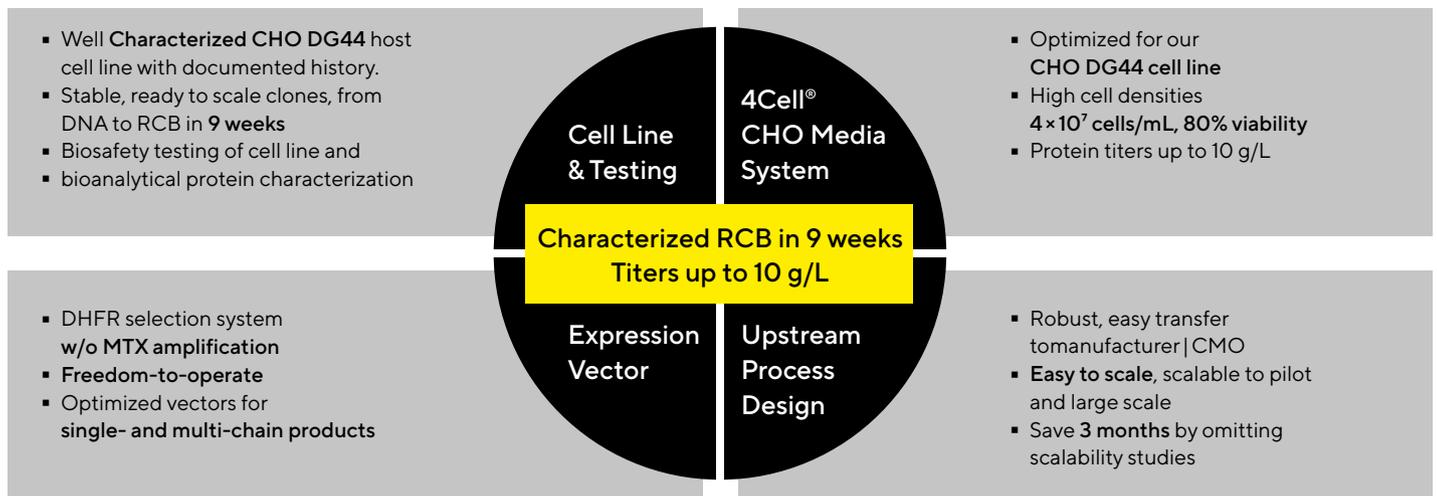


For further information please refer to the individual brochures for each service area.

# 4Cell<sup>®</sup> 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<sup>®</sup> CHO Platform, we offer a de-risked and time-saving approach from DNA2MCB in less than 10 months.

## Key Components



## 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 in line monitoring and control
- Animal product free production
- Up to 500 vial cell banks at 4 × 10<sup>7</sup> at 12 million cells per vial
- Automatic vial filling system and controlled rate cryopreservation
- Storage of filled vials in vapor phase LN<sub>2</sub>

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



## Germany

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[www.sartorius.com](http://www.sartorius.com)

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