Simplifying Progress

New Biological Entity

Product Characterization Services

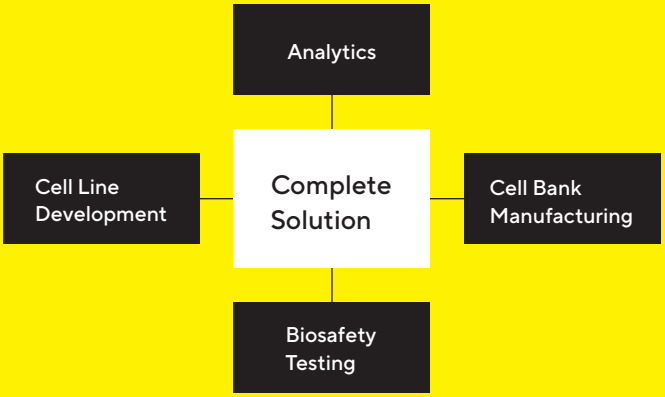
SARTORIUS

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 BioOutsource 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 Sartorius portfolio, Sartorius Stedim BioOutsource 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) BioOutsource, the team has been knowledgeable, engaged, and proactive.
They consistently and professionally deliver on promise with no surprises.
A truly pleasant experience."

Client Quote

- 10+ 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

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

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.

Early Assay Development & Screening

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

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

Fab Binding

- ELISA Methods
- Flow Cytometry
- SPR Methods

Structural Analysis

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

Fab Functional

- Various direct
- Blocking
- Neutralizing
- MOAs

Fc Binding

- C1q (ELISA & SPR)
- Fcγ Receptor SPR
- FcRn

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

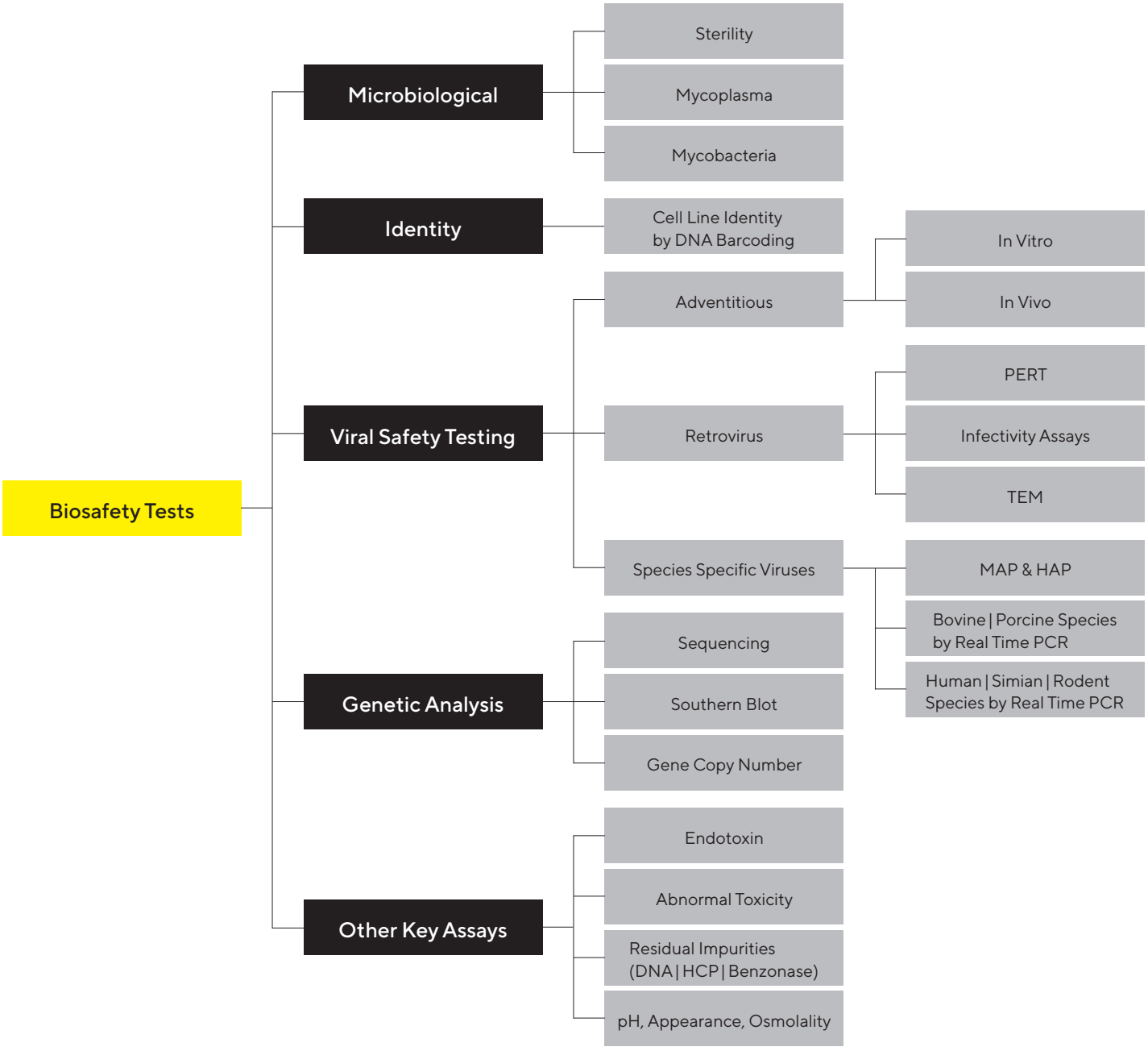
- Product specific validation supporting stability studies & lot release
- USP1033, Ph. Eur. & ICH Q2B specifications

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

Biosafety Testing

To complement our expertize in bioanalytical characterization, BioOutsource 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.



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

Cellca CHO Expression Platform

Cellca is a leading provider of Cell Line Development Services allowing customers easy, open access to a cost effective reliable technology platform. Cellca consistently delivers well characterized stable research clones from DNA to Research Cell Bank (RCB) in 4 months, with titres of at least 3.0 g/L in an easily scalable fed batch process.

Key Components

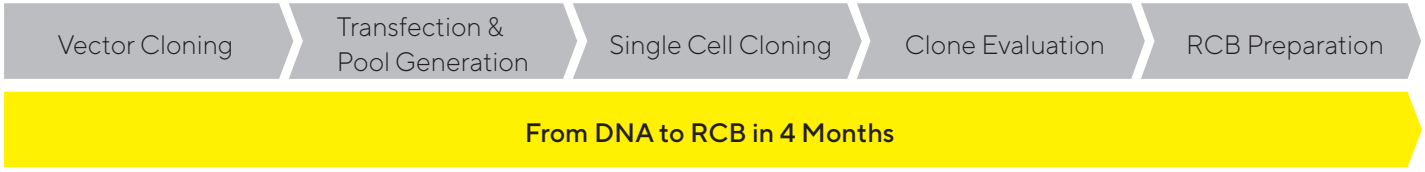
Host Cell Line
- CHO DG44 growth in suspension
- 18 h doubling time
- Long term stability
- Host cell line fully documented & tested according to ICH & WHO

Media System
- Optimized for Cellca cell lines
- Chemically defined, free of animal components and proteins
- High cell densities, viabilities & productivity

DHFR Selection System w|o MTX Amplification

Expression Vector
- Metabolic Selection
- Low DHFR expression
- S/MAR elements
- Optimal signal peptide & promoter
- Freedom-to-operate

Upstream Process Design
- Robust, east to transfer to client/CMO
- Easy to scale, proven performance in various bioreactor systems
- Ready-to-use protocol



Cell Bank Manufacturing

The BioOutsource service portfolio has been expanded and now 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 1–3×107 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.

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