



Physicochemical and
Biological Analytical
Comparability for
Biosimilars

Simplifying Progress

SARTORIUS

Complete Solution

Industry Leader

Characterisation and comparability of biosimilar monoclonal antibodies

Expertise

Industry leading experience working with over 12 biosimilar molecules and 30+ biosimilar developers

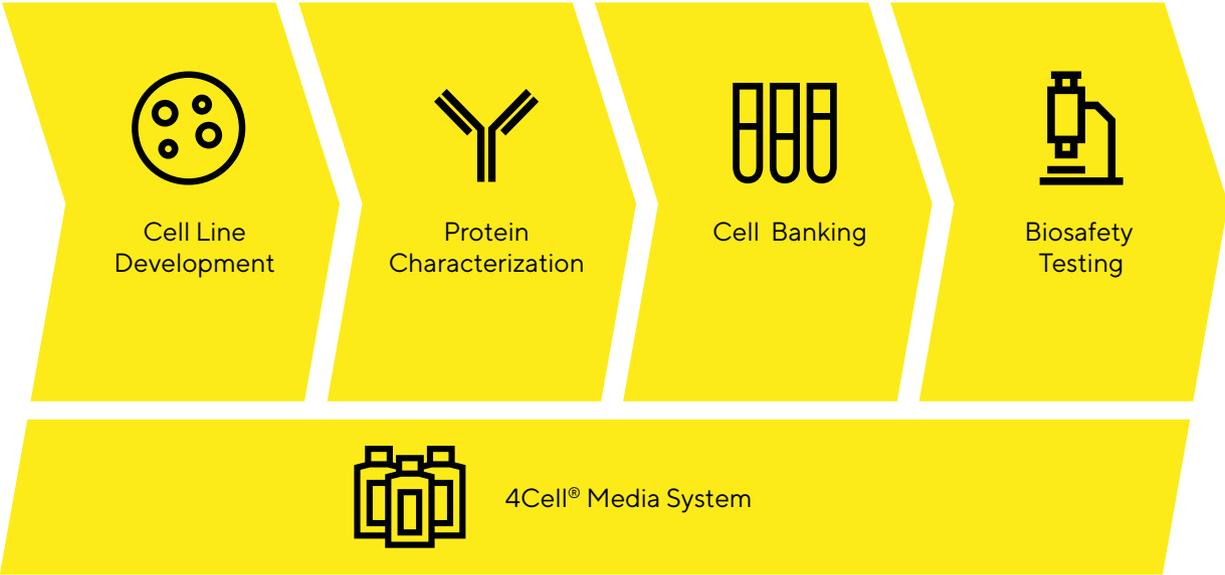
Speed to Market

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

Greater Quality Assurance

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

The 4Cell[®] CHO Platform: Integrated Service Package from DNA to Cell Banks





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:

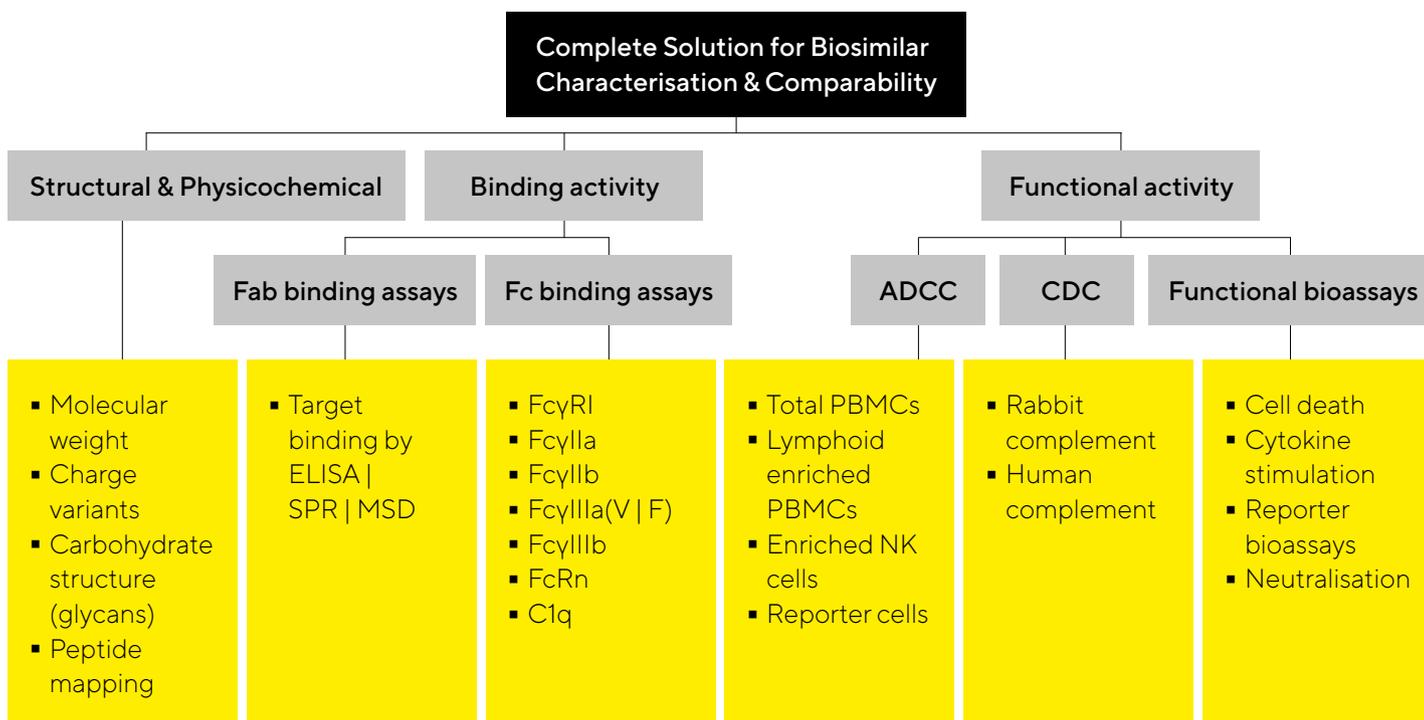
- Erbitux (cetuximab) target – EGFR
- Opdivo (nivolumab) target – PD-1
- Imfinzi (durvalumab) target – PD-L1
- Tecentriq (atezolizumab) target – PD-L1
- Keytruda (pembrolizumab) Target PD-1



Sartorius with clients throughout the biosimilar development pathway:



Our highly experienced team of scientists have developed methods for molecule characterisation, in line with regulatory requirements, allowing comprehensive analysis of a biosimilar to the originator molecule.



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.

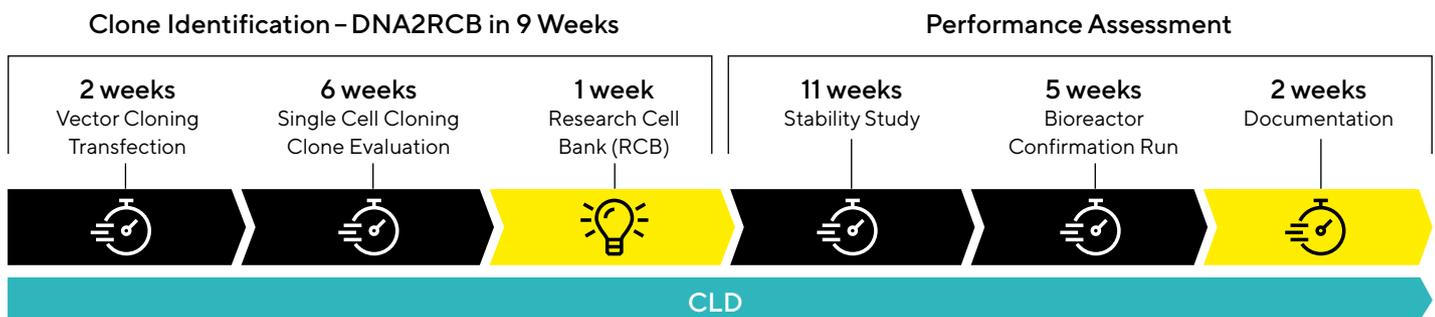
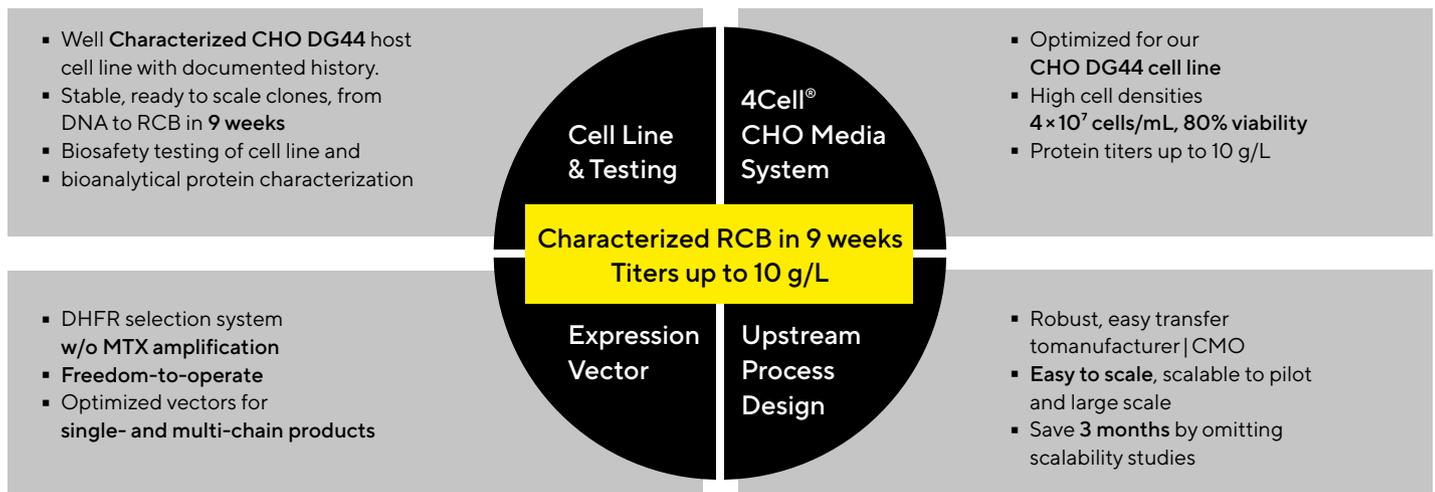
Our scientists have a wealth of knowledge and experience in biosafety testing, coupled with a thorough understanding of the regulatory requirements for biosimilar monoclonal antibodies and the cell lines used to manufacture these products.



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



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 4×10^7 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.

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

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



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