Physicochemical and Biological Analytical Comparability for Biosimilars
Complete Solution

Greater Quality Assurance
Excellent regulatory and industry insight for generating data required for regulatory submissions

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

Industry Leader
Characterisation and comparability of biosimilar monoclonal antibodies

Greater Quality Assurance
Excellent regulatory and industry insight for generating data required for regulatory submissions
A unique range of integrated early stage development services to support biopharmaceutical drug development.
BioOutsource 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)

Currently, in our R&D pipeline we are developing methods to support assessments of biosimilarity for the following molecules:

- Erbitux (cetuximab)
- Synagis (palivizumab)
- Eylea/Zaltrap (aflibercept)
- Xolair (omalizumab)
- orencia (abatacept)
- Yervoy (ipilimumab)
- Tysabri (natalizumab)

“With 8% of our revenue invested in our R&D programme, we continually add to the molecules we support and extend the range of assays available for molecules already in our service portfolio.”
BioOutsource partners 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.
To complement our expertise in bioanalytical characterisation, 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 biosimilar monoclonal antibodies and the cell lines used to manufacture these products.

For further information please refer to the individual brochures for each service area.
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 characterised stable research clones from DNA to Research Cell Bank (RCB) in 4 months, with titres upwards of 3.0g/litre in an easily scalable fed batch process.

Key Components

- **Host Cell Line**
  - CHO DG44
  - Growth in suspension
  - Long-term stability
  - Fully documented history

- **Expression Vector**
  - DHFR system with high selection stringency
  - Optimal signal peptide
  - Freedom to operate

- **Media System**
  - Chemically defined
  - Free of animal components
  - Free of proteins & peptones
  - Optimised for Cellca cell lines

- **Upstream Process Design**
  - Robust
  - Easy to scale
  - Proven performance in various bioreactor systems

**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 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 1-3x10^7 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.
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For further contacts, visit www.biooutsource.com.