



Biosafety Testing for Biologics and Viral Vaccines

Simplifying Progress

SARTORIUS

Experience

All biopharmaceutical and biotechnology products must undergo stringent safety testing throughout development and manufacture to ensure the products and host cell lines are characterized and free from contamination.

Excellent Technical Expertise

Industry leading expertise in biosafety testing of biologics and viral vaccines

Extensive Regulatory Knowledge

Knowledge of testing requirements for release in Europe, USA, Japan and South Korea

Industry Leader

Biosafety testing of biologics and viral vaccines

Fast Turnaround Times

Industry leading assay turnaround times

Greater Quality Assurance

Quality driven results. Fully compliant GMP, GLP and GCP facilities

Biosafety testing within the manufacturing process should be established in the early stages of drug development. Before clinical trials the following cell banks require complete testing as well as demonstrating that the process samples are free from contamination:

- Master Cell Bank (MCB)
- Working Cell Bank (WCB)
- End of Production Cell Bank (EPC)

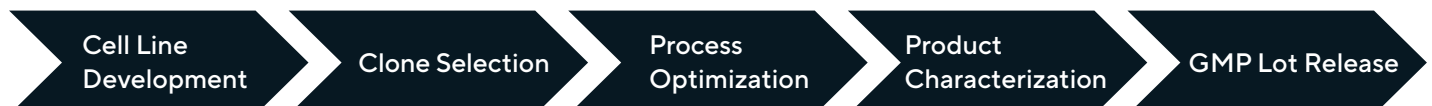
BioOutsource also supports the testing of:

- Bulk harvest
- Genetic stability and identity of cell banks
- Final product lot release

We have developed and validated a range of assays to characterize cell banks originating from different species including murine, hamster, human and primate and have experience working with the following products:

- Biosimilar monoclonal antibodies
- Monoclonal antibodies
- Recombinant proteins
- Vaccines
- Gene therapy vectors
- Regenerative medicine

BioOutsource partner with clients from early stage development through to commercialisation of the product:



Complete Solution



Germany

Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen
Phone +49 551 308 0


USA

Sartorius Stedim North America Inc.
565 Johnson Avenue
Bohemia, NY 11716
Toll-Free +1 800 368 7178

245 First St
Cambridge, Boston MA02142
Toll-Free +1 857 209 3414

UK

Sartorius Stedim BioOutsource Ltd.
1 Technology Terrace, Todd Campus,
West of Scotland Science Park
Glasgow, G20 0XA,
Toll-Free +44 141 946 4222

 For further contacts, visit
www.sartorius.com

Specifications subject to change without notice.

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