eurofins | BioPharma Product Testing

Bioassay and cGMP Potency Testing

Bioassays are essential for the development of new biopharmaceuticals. In particular, per regulatory requirement, they are performed to determine the biological activity or potency of the product, a critical quality attribute according to ICH Q6B.

Due to their complex nature, bioassays are one of the most challenging assays to perform. Therefore, consistent assay performance requires a controlled environment, skilled analysts with a thorough understanding of cell physiology and a well-developed and characterized method.

Eurofins BioPharma Product Testing offers extensive experience in all aspects of bioassay development, validation, method transfer and long-term assay maintenance. We provide a dedicated turnkey service for all your bioassay needs. The bioassay teams of Eurofins BioPharma Product Testing Munich, Germany, Dungarvan, Ireland, Columbia, MO, San Diego, CA, and Lancaster, PA, work closely together to design and execute customized binding assays, cellular in vitro bioassays.

Our unmatched expertise and proven track record for cGMP potency assay testing ensures successful and timely completion of your testing program.

Why Choose Eurofins BioPharma Product Testing?

We have a success rate of greater than 95% on potency assay transfers.

We have more experienced Ph.D.s than any other contract laboratory, including Ph.D. scientists dedicated to troubleshooting problematic assays and developing new assay platforms and methodologies.

We perform approximately 90 potency development and transfer projects per year.

Regulatory Compliance

Our validation strategies are based on a sponsor's requirements, as well as international regulatory guidelines and recommendations, such as ICH, US FDA, ISO, EMA and USP/EP. Our development, optimization (using Design of Experiments), validation and performance of bioassays and potency assays are US FDA approved and are conducted according to GMP regulations. We also offer regulatory consulting services to support your project.

Potency Assay Experience

Our scientists have a wealth of experience performing a variety of binding and cell-based potency assays to support development, licensing and commercial release of various biopharmaceutical products.

We have established and validated various sponsor-specific assays, pharmacopeia methods, as well as generic biosimilar methods.

Product types

- Therapeutic antibodies (monoclonal Ab, Bi-specific Ab, Fab, antibody drug conjugate/immunoconjugate)
- Recombinant proteins (growth factors, cytokines, soluble receptors, Fc or other fusion proteins)
- Peptides
- Gene therapy products (viral and plasmid based)
- Cell therapy products

Substance Class	Type of Assay	Assay Readout
Therapeutic Antibodies	Binding Assay, Cell Proliferation Assay, Cytotoxicity Assay, Apoptosis Assay, Reporter Gene Assay, Cellular Binding Assay, Cell Migration Assay, ADCC, CDC, ADCP, Signal Molecule Assay (cAMP, AP, Protein Phosphorylation), Viral CPE Assay	Plate Reader Based (Absorbance, Luminescence, Fluorescence, FRET, HTRF, AlphaScreen, AlphaLISA), SPR, Octet, MSD, Flow Cytometry, qPCR/ddPCR
Recombinant Proteins		
Synthetic Peptides		
Gene Therapy Products (Viral and Plasmid Based, VLP) and Cell Therapy Products (Autologous and Allogeneic)	Transfection/Transduction Assay, Target Gene/Cytokine Expression and Functional Assay, Cell Proliferation and Cytotoxicity Assay, Cell Surface Marker Analysis	

Contact Us

North America: BioPharmaProductTesting@BPT.EurofinsUS.com
Europe: Information@BPT.EurofinsEU.com
APAC: easl.cserv@BPJP.EurofinsAsia.com
www.Eurofins.com/BPT