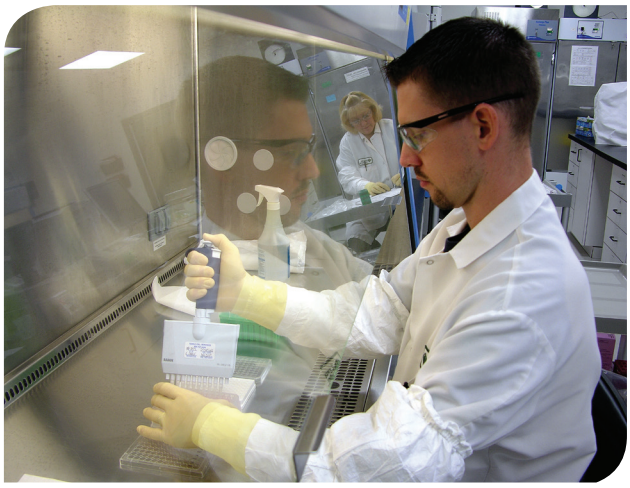
eurofins | BioPharma Product Testing



Bioassay and cGMP Potency Testing



Bioassays are essential for the development of new drugs. 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 and Eurofins Lancaster Laboratories, US, work closely together to design and execute customized binding assays, cellular *in vitro* bioassays, as well as non-cell-based *in vivo* 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 80 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 and *in vivo* bioassays 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, including Erythropoietin, Filgrastim, Interferon, Etanercept, Adalimumab, Golimumab, Bevacizumab, Rituximab and Trastuzumab.

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)

eurofins

BioPharma Product Testing



Assay types

- Binding assays (ELISA, HTRF, AlphaLISA, SPR)
- Cell based assays (cell proliferation assay, cytotoxicity assay (including ADCC and CDC), apoptosis assay, reporter gene assay, cellular binding assay, cell signaling assay (cAMP, phosphorylated protein), cell migration assay, virological assay (CPE, transduction with ELISA/qPCR end point)
- *In vivo* assay

Assay/Instrumentation Readouts

- Absorbance
- Fluorescence/HTRF/TRF
- Luminescence
- ^{3}H Thymidine incorporation
- FACS
- SPR

Services

Chemistry/Biochemistry
Cell Banking Services
Facility & Process Validation
GMP Manufacturing
Method Development & Validation
Microbiology
Molecular & Cell Biology
Raw Materials Testing
Release Testing
Stability Testing & Storage
Viral Clearance & Viral Safety
Professional Scientific Services®

Facilities

Australia
Belgium
Denmark
France
Germany
Ireland
Italy
Netherlands
Spain
Sweden
UK
US

The largest network of harmonized bio/pharmaceutical GMP product testing labs worldwide.

www.eurofins.com