Bioassay and Potency Testing of Biologics and ATMPs

Bioassays are essential for the development of new drugs. In particular, per regulatory requirement, they are performed to determine the biological activity (potency) of the product, a critical quality attribute according to ICH Q6B, using mode of action assays.

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

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 Germany work closely together to design and execute customized binding assays and cell based bioassays.

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

Regulatory Compliance

Our validation strategies are based on 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.
Our facilities are fully GMP certified.

Potency Assay Experience

Our scientists have a wealth of experience performing a variety of binding and cell based potency assays to support development, transfer/validation and commercial release and stability testing of various biopharmaceutical products. In addition, we have gained a deep understanding of potency evaluation using different software.

We have established and validated various sponsor- specific assays and compendial methods.

Product types

- Monoclonal Therapeutic Antibodies
- Bispecific Monoclonal Antibodies
- Antibody Drug Conjugates (ADC)
- Complex Antibody like constructs
- Proteins/Peptides
- Vaccines
- mRNAs
- Gene and Cell Therapeutics (ATMPs)

Assay types

- Cell Based Potency Assays e.g. ADCC, ADCP, CDC
- Various Readouts including Flow Cytometry, qPCR and ddPCR
- Binding Assays e.g. ELISA, HTRF, AlphaLISA, Electrochemiluminiscence, SPR Biacore, Octet
- Bioprocess Residual Assays as HCP and residual DNA
- Assay (semi) automation possible
- Critical reagent qualification

Why Choose Eurofins BioPharma Product Testing Germany?

- Longstanding experience in development, validation and performance of bioassays (1984 - present) with global client base
- Release and stability testing for US, EU, Japan and many ROW countries
- Deep understanding of regulatory requirements for potency bioassays
- Dedicated analyst /scientist training and coaching teams
- Realization of special requests possible using Full Time Equivalent (FTE) team approach (e.g. shortening TAT to 10 business days for cell-based assays)
- Dedicated project management and sample management teams
- One Stop Shop: Bioassay & Protein analytics & Microbiology
- Network of harmonized bioassay labs in EU, US and Japan

Phone: +49 89 899 650 0
Email: PharmaTesting@eurofins.com
Visit our website: https://www.eurofins.de/

0922