



Potency Assay Development Services

Potency assays are critical in the development of biologics, as they directly measure the biological activity of a drug and its ability to produce a desired effect. These assays are essential for confirming that a biologic is functioning as intended, providing a key indicator of its efficacy. By ensuring consistent potency, these tests support quality control during manufacturing. Regulatory agencies require sponsors to develop phase-appropriate potency assays for their IND and BLA submissions. Finding a capable CRO to advance your potency assay development and validation is an absolute must to ensure the success of your biologics program.

Our Expertise

At Avance Biosciences, we provide comprehensive services to assist our clients in advancing their therapeutic drug development and meeting FDA requirements efficiently and effectively. Our broad array of state-of-the-art technologies, combined with our talented scientific team, enables us to excel in developing and validating custom potency assays. We help our clients create phase-appropriate potency assays with quick turnaround times and highly competitive costs.

State-of-the-Art Platforms



NGS
(MiSeq)



ELISA
(Cytation 5)



ddPCR
(QX 200)



QPCR
(QuantStudio 12K Flex)



Single Cell Sequencing
(Tapestry)



MSD
(MESO QuickPlex SQ 120MM)



Automated Western Blot
(Jess)



Flow Cytometry
(CytoFLEX)

Our Potency Assay Services

- Custom potency assay development
- Conventional assays measuring critical quality attributes
- Cell-based assays measuring indicator cell response
- Relative potency assays for batch release testing
- Client potency assay technology transfer
- Assay qualification or validation under GMP
- Sample testing under GMP

Avance Potency Assay Development Service

Customized Assay Design

We understand that each therapeutic product is unique. Our team works closely with you to design customized potency assays tailored to your specific needs, ensuring an accurate evaluation of your product's efficacy.

Method Optimization

Our scientists have extensive experience in optimizing complex assays. We carefully assess variables, including critical parameters, sample matrices, and analytical techniques, to develop robust and reproducible assays.

Reliable Bioanalytical Techniques

We employ a range of cutting-edge techniques, including flow cytometry, automated western blot, ELISA, MSD, qPCR, ddPCR, and NGS, to measure potency accurately. Our advanced instrumentation and rigorous quality control processes guarantee reliable and precise results.

Regulatory Compliance

We are well-versed in regulatory guidelines, such as those provided by the FDA, EMA, and ICH. Our assays are designed and qualified and/or validated to meet these requirements, ensuring the generation of data suitable for regulatory submissions.

Data Analysis and Reporting

Our team provides comprehensive data analysis and interpretation, delivering clear and concise reports. We ensure that you receive actionable insights and recommendations to support your decision-making process.

Why Choose Avance Biosciences?

Scientific Expertise

Our team consists of highly skilled scientists with vast experience in potency assay development. We provide cutting-edge solutions to our clients to design potency assays based on MOAs and to develop and validate relative potency assays for product release.

State-of-the-Art Facilities

Avance Biosciences is equipped with advanced instrumentation and facilities necessary for developing and executing complex potency assays. We adhere to strict quality control measures to deliver reliable and accurate results.

Timely Delivery

We recognize the importance of timely results in the fast-paced drug development industry. We work efficiently to deliver high-quality data within agreed-upon timelines.

Confidentiality & Data Security

At Avance Biosciences, we prioritize the confidentiality and security of your data. We follow strict protocols to ensure the protection of your intellectual property and sensitive information.

Contact Us

We are always available to discuss your analytical needs for potency assay development. Our experts can help support your rapid journey to market and regulatory approval.