



Potency Assay Development Services

Supporting Cell and Gene Therapy

Potency testing is an essential part of developing cellular and gene therapy (CGT) products. The US Food and Drug Administration (FDA) requires sponsors for Investigational New Drug (IND) and Biologics License Applications (BLA) to provide in vitro or in vivo data to demonstrate the potency of the drug product. As such, potency testing plays a critical role in the development and approval of CGT products.

At Avance Biosciences, we provide comprehensive services to assist our clients in advancing their therapeutic drug development and meeting FDA requirements efficiently and effectively. We use a case-by-case approach to develop, qualify, or validate custom potency assays in accordance with current Good Manufacturing Practice (cGMP) regulations, ensuring that they comply with the necessary standards for GMP product release.



**Custom potency
assay development**



**Client potency assay
technology transfer**



**Assay qualification or
validation under GMP**



**Sample testing
under GMP**

CONTACT US



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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, qPCR, ELISA, 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 assay development and the biologics field. We stay up-to-date with the latest advancements to provide cutting-edge solutions for our clients.

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.

Customized Approach

We understand that each project is unique, and we tailor our services to meet your specific requirements. Our collaborative approach ensures that your goals and expectations are met.

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.

About Avance Biosciences

Avance Biosciences is a leading contract research organization (CRO) specializing in molecular biology, genomics, and cell-based assays. We provide a comprehensive range of services to support drug development, from assay development and validation to clinical sample analysis. With our scientific expertise and cutting-edge technologies, we are committed to delivering accurate, reliable, and timely results to our clients.



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