Assays To Support Your Biological Drug Discovery and Development

AVANCE BIOSCIENCES

Ensure the Success of Your Biological Drug Discovery and Development

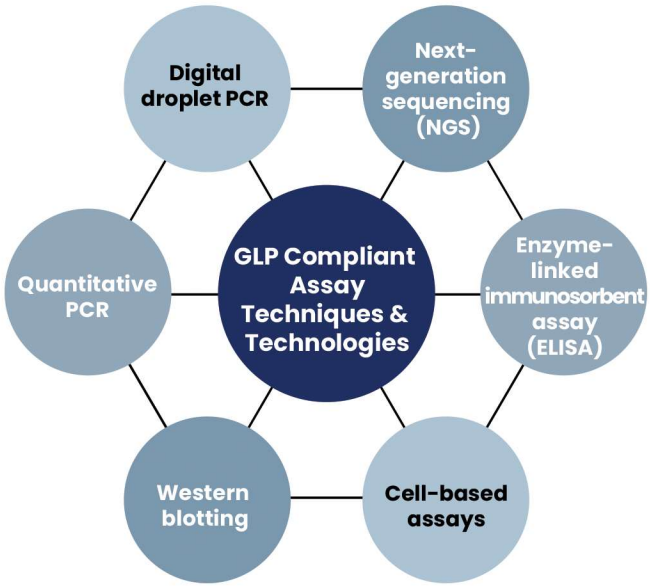
Avance Biosciences is a world-leading CRO providing advanced and customized assay solutions to facilitate your biotherapeutic products' research and development.

What We Do

Biopharmaceutical drug discovery and development requires a solid understanding of the therapeutic target, conformation and characterization of drug candidates, and customized solutions for pre-clinical and clinical testing.

We offer a broad range of assay development services, including assay design, assay validation, sample testing, and technology transfer under GLP compliance to support IND-enabling and clinical studies. With decades of experience helping gene and cell therapy companies, Avance Biosciences has the expertise and track record to assist you with your biological drug discovery and development.

Our assays use the latest biological assay techniques and technologies, including:



CONTACT US

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Applications

We offer tailored GLP-compliant assay solutions in several application areas, driving your discovery and development efforts forward with reliable, trusted results.

- DNA and RNA biodistribution studies
- Gene expression studies
- Protein studies with ELISA and western blot
- CRISPR on-/off-target evaluation
- Gene editing translocation evaluation
- Single-cell amplicon NGS assays
- NGS integration analysis for gene editing and gene therapy
- Vector copy number (VCN) analysis for inserted genes
- Colony forming unit assays (CFU)
- Viral titer determination
- Custom assay design and validation

Our Approach To Your Project

We're here to advance your biological discovery and development. We do it with solid science, strict regulatory compliance, and an experienced team to streamline the process.

Project Management

- Collaboration with you to develop and qualify assays, and perform sample testing
- Dedicated project manager, senior scientist, and study director to lead your project
- Regularly scheduled project check-in meetings to review data and discuss next steps
- Flexible structure to accommodate changing requirements
- Sound scientific approach and methods

Assay Development

- Robust assay design
- Specificity, sensitivity, accuracy, and precision determination
- Development of appropriate control and reference samples
- Advanced development and pre-qualification of all parameters associated with qualification and validation to fully characterize assay performance

Qualification and Validation

- Follow FDA/ICH guidelines for assay qualification and validation
- Parameters include specificity, sensitivity, precision/accuracy, robustness, extraction efficiency, and more
- Mutually agreed on pass/fail criteria determined in advanced development
- QA reviews all data, test plans, and final report
- Ability to validate NGS data analysis pipeline

Science - Compliance - Service

CGMP Compliance

The Avance Biosciences team is committed to strict adherence to regulatory guidelines enacted by the US, European, Japanese, and other international regulatory agencies. With a clear understanding of the FDA GLP and OECD GLP guidelines, the Avance team is ready to support your biological assay needs.

Extensive Experience

We have comprehensive knowledge and experience working with scientists, QA/QC professionals, and project managers from over 100 pharmaceutical and biotechnology companies and organizations worldwide. We are an agile and flexible organization with creative professionals who routinely execute custom assay design and validation projects to fit each client's unique needs.

Open Communication

Transparency and integrity are two of our core values. We pride ourselves on keeping communication channels open and delivering results to your specifications. Our well-trained, friendly, and professional study directors and project managers strive to complete your project on time.

Cutting Edge Science

Avance Biosciences' CGMP/GLP-compliant biological assays use the latest techniques and technologies, including qPCR, ddPCR, NGS, automated Western blotting, and more.

Who We Are

A world leading CRO providing GMP/GLP compliant biological testing solutions supporting the biological drug development pipeline from discovery through manufacturing.

Our team has decades of experience in supporting biological drug development and manufacturing. With our technical expertise, focus on a strong adherence to regulatory guidelines, and dedication to exceeding our client's expectations, we provide creative solutions to assure your drug development success.

Meet With Our Experts Today

We are a team of dedicated scientists, and quality control professionals focused on meeting your needs and completing your challenging drug development and manufacturing projects.

By partnering with us, you'll benefit from collaboration with a scientific team with decades of experience designing, validating, and executing biological assays and tests for regulatory submission.

When you partner with Avance Biosciences, you gain a CRO partner that is creative, collaborative, and dedicated to sound science with a focus on your specific regulatory requirements.

Contact our technical staff to discuss how we can support your next project.

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