Assays To Support Your Biopharmaceutical Development & Manufacturing

AVANCE BIOSCIENCES

What We Do

Biopharmaceutical drug development requires extensive biological testing for raw material release, in-process quality control, and final product characterization to secure product safety and satisfy the regulatory requirements of the FDA and other regulatory agencies.

We offer CGMP/GLP-compliant assay development, assay validation, and sample testing services to ensure strict regulatory compliance and a smooth journey to market.

Using ICH guidelines, we offer a broad range of biologics quality control assays, including:

Ensure the Success of Your Biological Drug Development

Avance Biosciences is a world leading CRO providing CGMP/GLP compliant biological testing solutions supporting the biological drug development pipeline from discovery through manufacturing.

- Cell bank characterization
- Plasmid and viral vector ID testing
- Residual DNA and host cell protein testing
- Compendial assays
- Gene therapy drug substance and product release assays
- Custom assay development, validation, and more

CONTACT US

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Our Comprehensive CGMP-Compliant Biologics Testing Solutions

We offer tailored services that provide you with a powerful way to address identity, stability, and safety concerns, satisfying the requirements of regulatory agencies worldwide.

Cell bank and viral seed characterization assays

- Microbial assays for bacterial cell bank release, including identity, purity, stability, viability, and phage contamination
- qPCR and ddPCR for plasmid copy number or inserted gene copy number
- Sanger sequencing for plasmid and inserted gene sequence verification
- Next-generation sequencing (NGS) for plasmid and viral genome confirmation
- Restriction mapping for plasmid evaluation
- Southern blots for integration site and inserted gene structure analysis
- NGS for phage ID

DNA sequencing and residual host cell DNA assays for product release

- Sanger sequencing for plasmid drug products and viral vaccines
- NGS for inverted terminal repeats (ITR), GC-rich, and other challenging constructs
- cDNA sequencing and qPCR for multi-valent RNA vaccines
- qPCR residual host cell DNA testing for protein drug products

CAR-T and other gene or cell therapy product release

- Replication competent lentivirus (RCL) and vector copy number (VCN) testing
- qPCR and ddPCR assays for integrated gene copy analysis
- NGS amplicon sequencing for product characterization
- Potency and infectivity assays
- Transfection assay via single-cell NGS
- Transfection assay via colony picking and Sanger sequencing
- STEMvision for colony-forming unit (CFU) assays

Science - Compliance - Service

CGMP Compliance

The Avance Biosciences team is committed to strict adherence to CGMP regulations and guidelines enacted by the U.S., European, Japanese, and other international regulatory agencies. We support your biological assay needs with a “compliance-first” approach and a clear understanding of the FDA guidance and ICH guidelines.

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.

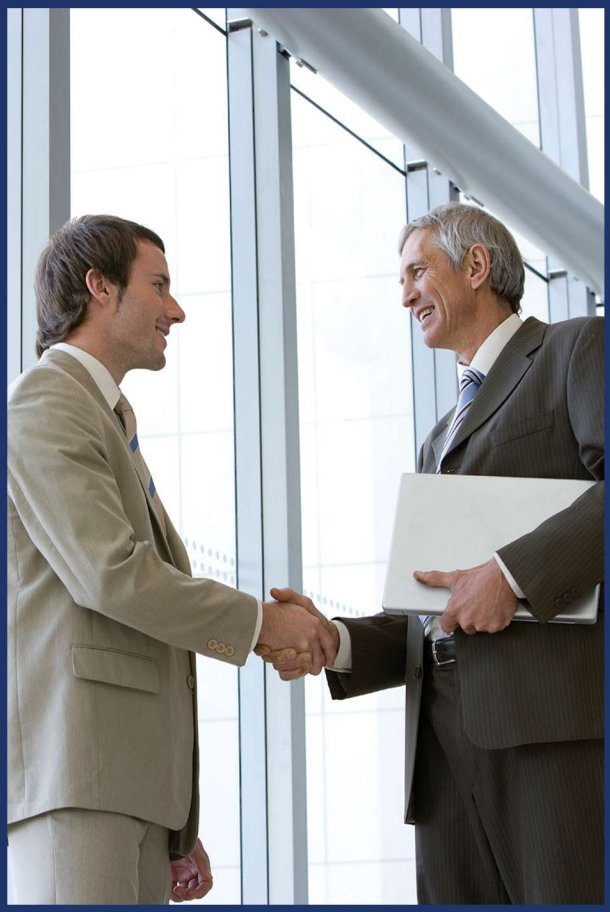
Our team has decades of experience in supporting cell-based drug manufacturing. With our technical expertise, focus on a strong adherence to regulatory guidelines, and dedication to exceeding our client's expectations, we provide creative solutions to assure your drug development success.

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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