



GMP SERVICES

Supporting Biological Drug
Development and Manufacturing

Successful development of a biopharmaceutical requires extensive biological testing for raw material release, in-process quality control, and final product characterization to ensure the safety of the product to satisfy US FDA and other regulatory agencies' requirements.

Avance Biosciences provides custom CGMP compliant assay development and testing solutions to evaluate the identity, purity, and genetic stability of biologics in support of drug research and development, clinical trials and CGMP manufacturing.



CELL BANK AND VIRUS SEED CHARACTERIZATION ASSAYS

- Microbial assays for bacterial cell bank release (identity, purity, stability, viability)
- qPCR and ddPCR gene copy number analysis
- Sanger sequencing for plasmid and inserted gene sequence verification
- Nextgen sequencing for plasmid and viral genome confirmation



GENETIC STABILITY ASSAYS FOR MCB, WCB, AND EOPC

- Sanger sequencing for plasmid and mRNA
- qPCR for plasmid copy number or inserted gene copy number
- Restriction map analyses for plasmid evaluation
- Southern blot integration site and inserted gene structure analysis



CUSTOM ASSAY DESIGN AND VALIDATION

- Microbial assay development and validation
- qPCR and ddPCR assay development and validation
- Nextgen sequencing assay development and validation



CAR-T AND OTHER GENE OR CELL THERAPY PRODUCT RELEASE

- qPCR for replication competent lentivirus (RCL) testing
- qPCR for integrated gene copy analysis
- ddPCR for integrated gene copy analysis
- Nextgen amplicon sequencing for product characterization



DNA SEQUENCING AND RESIDUAL HOST CELL DNA ASSAYS FOR PRODUCT RELEASE

- Sanger sequencing for plasmid drug products and viral vaccines
- cDNA sequencing and qPCR for multi-valent RNA vaccines
- qPCR residual host cell DNA testing for protein drug products



CLEANING VALIDATION AND ADVENTITIOUS AGENTS TESTING

- qPCR residual DNA testing for plasmid carry-over in CMO facility
- Custom nextgen sequencing viral detection of dsDNA, ssDNA, ssRNA, and dsRNA viruses
- Custom qPCR based viral detection assays



9770 West Little York Road
Houston, TX 77040



Main: (713) 849-3380
Toll Free: (877) 909-5210



info@avancebio.com
www.avancebio.com