

Scientific Focus: GMP Support for Biotherapeutics



BioAgilytix has expertise in a wide array of analytical readouts and experience with many therapeutic modalities through all phases of drug development. Our experience with cell lines includes challenging human primary cell lines among others. Our focus, no matter the assay format, is on addressing the Mechanism of Action in the development of GMP Compliant assays.

Trace-level Impurity Measures

While deeply versed in assessing the potency of therapeutics, BioAgilytix has also developed and validated numerous ELISA assays for the quantitation of trace level impurities including host cell proteins, residual insulin, and others. These assays require technical acumen to understand complex matrices and to assure the safety and efficacy of your product. We apply our experience to the specific needs of your product to accelerate your GMP assay development.

Robust Cell Based Assays

To support GMP cell-based methods, BioAgilytix will establish and hold GMP cell banks—Master and Working. These banks are characterized with respect to the intended assay and general performance (viability, growth properties and similar). We also are vigilant in our assessment of critical reagents and their qualification for use in assays. It is this attention to detail that ensures our GMP-validated assays are robust and ready to support batch release and the lifecycle management of your product. We provide assays that meet the standards and expectations of global regulatory agencies.

Performed To The Global Regulatory Requirements Of The:

- ✓ FDA
- ✓ EMA
- ✓ MHRA
- ✓ ICA
- ✓ And many others

Platforms Used For GMP:

- ✓ ELISA
- ✓ MSD
- ✓ Flow Cytometry
- ✓ qPCR/ddPCR
- ✓ LI-COR

Potency Assays To Support Lot Release Of:

- ✓ Small Molecules
- ✓ Peptides
- ✓ Proteins
- ✓ Monoclonal Antibodies
- ✓ Gene Therapies
- ✓ Cell Therapies
- ✓ Vaccines

Setting the Global Standard for Scientific Excellence in Bioanalysis

Quality science, quality data, and a quality partnership — it's how we ensure your small and large molecule bioanalytical needs are met with accuracy, high performance, and timely results.

Overall Support for All International Bioanalytical Services

With advanced laboratories in Durham, Boston, San Diego, Hamburg, Germany, and Melbourne and Brisbane, Australia, BioAgilytix can support all global studies through every phase of development, from discovery through Phase IV trials and post-market surveillance.

A Leader and Partner in Drug Development

BioAgilytix is comprised of true experts in bioanalysis, with a veteran team averaging over 10 years of bench experience and comprised of approximately 50% Ph.D. and Master's-level scientists.

Totally Committed to On-Time Delivery of Quality Results

We deliver our bioanalytical services by pairing our unique scientific capabilities, extensive QA expertise, and collaborative project management processes to ensure reliable, timely, high-quality results.

Discuss Your Program with Our Scientists Today

Let's talk scientist-to-scientist about the bioanalytical needs of your small and large molecule projects.

Services

- ✓ Pharmacokinetics (PK) / Pharmacodynamics (PD)
- ✓ Immunogenicity / Anti-Drug Antibodies (ADA) / Neutralizing Antibody Assays (NAb)
- ✓ Biomarkers
- ✓ Cell-Based Assays (CBA) / Potency Assays

Platforms

- ✓ ELISA
- ✓ MSD-ECL
- ✓ LC/MS
- ✓ qPCR/ddPCR
- ✓ HPLC
- ✓ Gyrolab
- ✓ Luminex
- ✓ Biacore
- ✓ ImmunoCAP
- ✓ LI-COR
- ✓ Flow Cytometry
- ✓ ELISpot
- ✓ ProteinSimple
- ✓ Ella

Quality

- ✓ GLP
- ✓ GMP
- ✓ GCP
- ✓ CLIA



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