



Scientific Focus:

## GMP SUPPORT FOR BIOTHERAPEUTICS

**BioAgilytix leverages the more than 100 years of combined experience within our GMP technical leadership team to develop, qualify, and validate GMP assays in a variety of forms and formats.**

Our experience with cell lines is unrivalled, including challenging HUVECs and SAOSDs among others. We can develop de novo, based on the primary literature, from transferred methods or using commercially available kits.

### Diverse GMP Expertise Across Drug Modalities & Assay Types

While deeply versed in assessing potency, BioAgilytix has also developed and validated numerous ELISA assays for the quantitation of trace level impurities including host cell proteins, residual insulin, residual antibiotics, and others. These assays require technical acumen to further the safety and efficacy of your product.

We've also worked extensively with all common forms of biotherapeutics and understand that each has their own unique challenges. We apply this knowledge to make your product successful.

### Robust Assays in Line with Global Standards

To support GMP cell-based methods, BioAgilytix will establish and hold GMP cell banks—Master and Working. This includes growing and aliquoting the cells and characterizing the banks with respect to the intended assay and general performance.

It is this attention to detail that ensures following development and validation, our assays are robust and ready to support batch release and routine testing. We provide the level of control your biologic and process need to meet manufacturing standards and the expectations of global regulatory agencies.

### Potency Assays through Cells or Immune-Based Detection for:

- ✓ Peptides
- ✓ Proteins
- ✓ Monoclonals
- ✓ Gene Therapies
- ✓ Cell Therapies
- ✓ Vaccines

Performed to the **global regulatory requirements of the FDA, EMA, MHRA, ICH** and others where appropriate.

# Setting the Global Standard for **Scientific Excellence in Large Molecule Bioanalysis**

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

## Global Support for All Large Molecule Bioanalytical Needs

With advanced laboratory facilities in North Carolina and Boston, as well as in Hamburg, Germany, BioAgilytix is able to support all phases of large molecule global studies, from discovery through Phase IV trials and post-market surveillance.

## A Global Leader in Large Molecule Drug Development

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

## Globally 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 Project with Our Scientists Today.

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



### Services

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



### Platforms

- ✓ ELISA
- ✓ MSD-ECL
- ✓ qPCR
- ✓ ddPCR
- ✓ Gyrolab
- ✓ Luminex
- ✓ Biacore
- ✓ ImmunoCAP
- ✓ Western Blot (LI-COR)
- ✓ Flow Cytometry
- ✓ ELISPOT
- ✓ ProteinSimple Ella



### Quality

- ✓ GLP
- ✓ GMP
- ✓ GCP
- ✓ CLIA



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