Bioanalysis Services

We primarily perform immunological ligand-binding assays (LBA) and enzymatic assays to measure large molecule drugs, ADA, and biomarkers in biological fluids and formulation buffers. Our method validations and sample analyses are compliant with current GLP regulations and FDA guidance on bioanalytical method validation (BMV). While our large molecule bioanalysis services predominantly support GLP preclinical and regulated clinical studies, we also support non-regulated studies, such as exploratory PK and biomarker assessments.

Bioanalysis for Large Molecules

Pharmacokinetic Method Validation and Sample Analysis

- Most PK sample analyses we conduct use LBA or enzymatic assays that had been validated pursuant to GLP regulations, FDA BMV guidance documents, and current industry standards.
- We commonly use MSD electrochemiluminescence for LBA because of high sensitivity. ELISA methods are also customary for LBA, while our enzyme methods mostly use fluorescence.
- We also conduct fit-for-purpose (FFP) "validations," commonly referred to as a bioanalytical qualification (as distinguished from biomarker qualification for diagnostics).
- The FFP approach represents a spectrum of assay characterization protocols specifically designed to address the client's needs, while conserving on expense and time.
- Either full or FFP validations can be applicable to PK, ADA, and biomarker assays, depending on the needs of the client and the expected level of regulatory review.

Immunogenicity Testing for Anti-Drug Antibody (ADA) and Neutralizing Antibody (NAb), and Characterization of ADA Isotype

- We can transfer in your ADA assay or make the assay from scratch in our lab. Clients are expected to provide drug reference standard and typically a positive control (PC) antibody. We can subcontract PC antibody production, if necessary, in addition to tending to all other matters required to make an ADA assay for your drug.
- We evaluate the ADA responses to large and small molecule drugs using a multi-tiered approach as outlined by the 2019 FDA Guidance for Industry: Immunogenicity Testing of Therapeutic Protein Products —Developing and Validating Assays for Anti-Drug Antibody Detection. The multi-tiered approach involves detection of ADA (screening assay), confirmation of ADA specificity by competitive inhibition, and titration of ADA reactivity.
- Neutralizing ADA (NAb): We have >12 years of experience with NAb, particularly with enzyme therapeutics. Our services can include design and development of a NAb assay in our lab, or transfer-in your method for partial or full validation.
- Isotypes of ADA: Characterization can include determinations of the predominant ADA isotype(s), such as IgG, IgM, IgA, and IgE; and, if needed, subclasses of IgG.

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Biomarker Assays

- The most common approach for biomarker analysis is use of commercially available kits. However, we are also experienced with making biomarker assays from "scratch" and with method transfers from clients. We conduct FFP level validations for most biomarker studies and fully GLP compliant validations and sample analyses, when requested by clients for later stage clinical trials. There are two basic formats for biomarker analyses, single analyte (singleplex) and multiplex assays, as described below.

Singleplex Biomarker Assays

- Single analyte commercial kits are very useful but can vary greatly regarding sensitivity, specificity, consistency, and availability. We have experience with a broad array of biomarkers from many kit and reagent vendors and can identify the best option(s) for your biomarker project.

Multiplex Biomarker Assays

- Our primary technology for multiplex biomarkers analysis uses MSD electrochemiluminescence to achieve high sensitivity, but we are also capable of doing multiplex fluorescence. We have substantial experience with custom multiplex designs and can expertly help you design a custom biomarker assay to suit your needs.

LC/MS/MS Biomarker Assays

- Development and validation of bioanalytical methods for the simultaneous quantitation of multiple biomarker peptides or epitope peptides of monoclonal antibodies in serum or plasma matrices.

Pharmacokinetic Analysis & Reports

- Model-dependent or model-independent PK/TK analysis of bioanalytical data from discovery, preclinical, GLP toxicology, and clinical studies.

Enzymatic Activity Assays

- Assess the potency of recombinant enzymes/enzyme inhibitors, monitor PD biomarkers, and measure the ADA neutralization activity against recombinant enzymes.
- Enzyme method validations, like that of LBA PK assay methods, can be fully compliant with current guidance or can be FFP. We model enzyme method validations and sample analyses after current FDA guidance on BMV.

Contact us for more info or to request a quote.

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