PPD® LABORATORIES

Bioanalytical Lab Capabilities for Biosimilars

The development of biosimilar drugs requires extensive experience, broad technical capabilities and a deep understanding of the regulatory pathway.

BIOLOGICS EXPERTISE

For three decades, PPD® Laboratories has been developing and validating bioanalytical assays for biologics across a wide variety of disciplines, including chromatography, immunochemistry, cell-based and molecular platforms. The PPD Laboratories biologics development team has experience with a range of sample preparation approaches from simple protein denaturation and digestion to complex affinity capture enrichment techniques.

Our bioanalytical lab has experience with nine of the top 10 best-selling biologics of 2014.

BIOSIMILARS ARE DIFFERENT

The development needs for biosimilars are unique:

+ They must demonstrate comparable results (safety, purity, potency, stability and immunogenicity) to the innovator product and across product lots.
+ Assays developed for the innovator product may require adjustments and/or redevelopment and validation due to the physicochemical attributes and functional activity of the biosimilar.
+ Biologics by nature are more variable than small molecules, making the analytical methods subject to variation across instruments, critical reagents, operators and even day-to-day and lab-to-lab differences.
+ Biosimilars development is complex and each project has unique needs.

At PPD Laboratories you will find the scientific expertise and biosimilars experience you need to keep your project on track.

17 biosimilar programs in the last five years

BROAD BIOLOGICS CAPABILITIES

+ Pharmacokinetic (PK) assays
+ Anti-drug antibody (ADA) studies
+ Neutralizing antibody (NAb) assays

EXTENSIVE, RELEVANT EXPERIENCE

PPD Laboratories' bioanalytical lab has developed assays and tested more than 300,000 samples for the following 10 biosimilars:

+ Rituximab
+ Filgrastim and Pegfilgrastim
+ Trastuzumab
+ Bevacizumab
+ Etanercept
+ Epoetin
+ Palivizumab for RSV
+ Low molecular weight heparin
+ Infliximab
+ Adalimumab

In addition, to working on nine of the best-selling biological products of 2014, our expertise spans the therapeutic spectrum and includes oncology, auto-immune diseases, metobolic disorders and vaccines.

Bioanalytical Lab Capabilities for Biosimilars

Demonstrated throughput of > 10,000 PK samples per month with >98% incurred sample reanalysis pass rate.

MULTIPLE ASSAY FORMATS

+ ELISA (chromogenic, chemiluminescent and fluorescent)
+ MSD® electrochemiluminesence
+ GYROS
+ Radioimmunoassay (RIA)
+ Radioimmunoprecipitation (RIP)

HIGH THROUGHPUT CAPABILITIES

+ Validated automated liquid-handling systems for ligand binding assays
+ Electronic notebook systems for data review
+ Sustainable throughput of >10,000 PK samples per month demonstrated across multiple studies

IMPORTANT REGULATORY EXPOSURE

The PPD Laboratories bioanalytical lab was founded in 1985. Since then, we have hosted an average of two to three on-site FDA inspections every year. In the past five years we have supported 17 biosimilar programs for FDA and EMA submissions. This consistent and extensive regulatory interface ensures our procedures reflect current expectations and our data quality remains high.

PPD Laboratories is one of only a few labs that has been audited for its work in support of multiple biosimilar submissions. These audits encompassed PK, ADA and cell-based assays. PPD Laboratories' comprehensive biosimilar development experience and excellent regulatory history mean you can be confident your development program will stay on track.

ABOUT PPD LABORATORIES

PPD Laboratories combines world-class scientific expertise with state-of-the art technologies supported by a commitment to exceptional quality. Our clients benefit from comprehensive lab services spanning bioanalytical, vaccine sciences, GMP, central lab testing and biomarkers. Our laboratory services accelerate pharmaceutical development for small molecules and biologics, allowing clients to make faster decisions about their compounds.