Bioanalytical lab

Biosimilar capabilities and expertise overview

Our bioanalytical lab provides **comprehensive services and capabilities** for the **development of biosimilar drugs**. Our biologics team has **extensive experience, broad technical capabilities** and a deep understanding of the regulatory pathway needed to keep clients' projects on track.

Extensive and relevant Biosimilar experience

Our bioanalytical lab has developed assays and tested more than 300,000 samples for the following Biosimilar:

- Adalimumab
- Aflibercept
- Bevacizumab
- Denosumab
- Eculizumab
- Epoetin
- Etanercept
- Filgrastim
- Infliximab
- Low molecular weight heparin
- Palivizumab for RSV
- Pegfilgrastim
- Ranibizumab
- Rituximab
- Trastuzumab
- Ustekinumab

Mulitple assay formats

- ELISA (chromogenic, chemiluminescent and fluorescent)
- MSD electrochemiluminesence
- GYROS
- Radioimmunoassay (RIA)
- Radioimmunoprecipitation (RIP)
- SiMoa Quanterix

Unique development needs for Biosimilar

- 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
- Biosimilar development is complex and each project has specific needs

Broad biologics capabilities and experience

Our biologics development team has experience with a range of sample preparation approaches from simple protein denaturation and digestion to complex affinity capture enrichment techniques.

Capabilities include:

- Pharmacokinetic (PK) assays
- Anti-drug antibodies (ADA) assays
- Neutralizing anitbody (NAb) assays
- BioMarkers (PD) assays

PPD™ bioanalytical lab has experience working with **nine of the top 10 Biosimilar**

Important regulatory exposure

PPD Laboratory services bioanalytical lab was founded in 1985 and since then, has hosted an average of two to three on-site Food and Drug Administration (FDA) inspections every year. In the past five years we have supported more than 20 biosimilar programs for FDA and European Medicines Agency (EMA) submissions. This consistent and extensive regulatory interface ensures our procedures reflect current expectations and our data quality remains high.

We are one of the few labs that has been audited for its work in suport of multiple biosimilar submissions. These audits encompassed PK, ADA, plate based NAbs, and cell-based assays. Our comprehensive biosimilar development experience and excellent regulatory history mean you can be confident your development program will stay on track.

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 mutliple studies

20+ biosimilar programs destined for regulatory submission

In addition to consistently working with many of the best-selling Biosimilar, **our experience spans the therapeutic spectrum** and includes **oncology, auto-immune diseases, metobolic disorders and vaccines**.

Learn more at **ppd.com/our-solutions/ppd-laboratories/bioanalytical-lab/**