Bioanalytical lab

Biosimilar capabilities and expertise overview

We recognize that the needs for biosimilar development and delivery are unique. As a leader in automation and innovation, we provide comprehensive services and regulatory expertise for the development of biosimilar drugs.

Extensive and relevant biosimilar experience

Our bioanalytical lab has developed assays and tested more than 750,000 samples for the following biosimilars:

- Abatacept
- Adalimumab
- Aflibercept
- Bevacizumab
- Denosumab
- Eculizumab
- Etanercept
- Infliximab
- Ocrelizumab
- Pegylated Filgrastim
- Pegylated interferon beta (IFB)
- Pembrolizumab
- Pertuzumab
- Ranibizumab
- Rituximab
- Secukinumab
- Trastuzumab
- Ustekinumab

Mulitple assay formats

- ELISA (chromogenic, chemiluminescent and fluorescent)
- MSD electrochemiluminesence
- GYROS

Unique development needs for biosimilar programs

- They must demonstrate comparable results (safety, purity, potency, stability and immunogenicity) to the innovator product and across product lots
- Assays for the innovator product need to be developed and validated to account for the physicochemical attributes and functional activity of the biosimilar. This is necessary to bring the methods up to current regulatory expectations and to utilize more sensitive and drug-tolerant platforms
- Regulatory requirements for reassays, Anvisa in scope, and patient batching are critical
- Accelerated timelines requiring logistical expertise, rapid database cleaning, and fast analysis turnaround times
- Biosimilar development is complex and each project has specific needs

Innovative process for biosimilar program delivery

- Multiple experienced R&D teams for parallel development of PK, ADA, Nab and PD methods if required
- Large sample analysis teams with high throughput biosimilar experience to run methods concurrently to meet timelines
- Dedicated Automation team with industry leading expertise and experience
- Regulatory inspection history with all major agencies

PPD™ bioanalytical lab has experience working with **all of the top 10 biosimilars in 2024**

Regulatory experience

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 35 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 support 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.

Automation and high throughput capabilities

- Automated workflows reduce assay cycle time from 5 to 2 days, speeding up batch execution and program timelines
- Increases operational efficiency by 3 times, requiring fewer analyst hours while maintaining high throughput, benefiting lean, time-sensitive programs
- Increase assay acceptance rates by 10-15% over manual processes, reducing costs and accelerating timelines
- Achieves over 95% assay reproducibility, exceeding regulatory SOP thresholds and minimizing documentation gaps

35+ biosimilar programs destined for regulatory submission

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

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