



**PPD® LABORATORIES**  
HELPING DELIVER LIFE-CHANGING THERAPIES

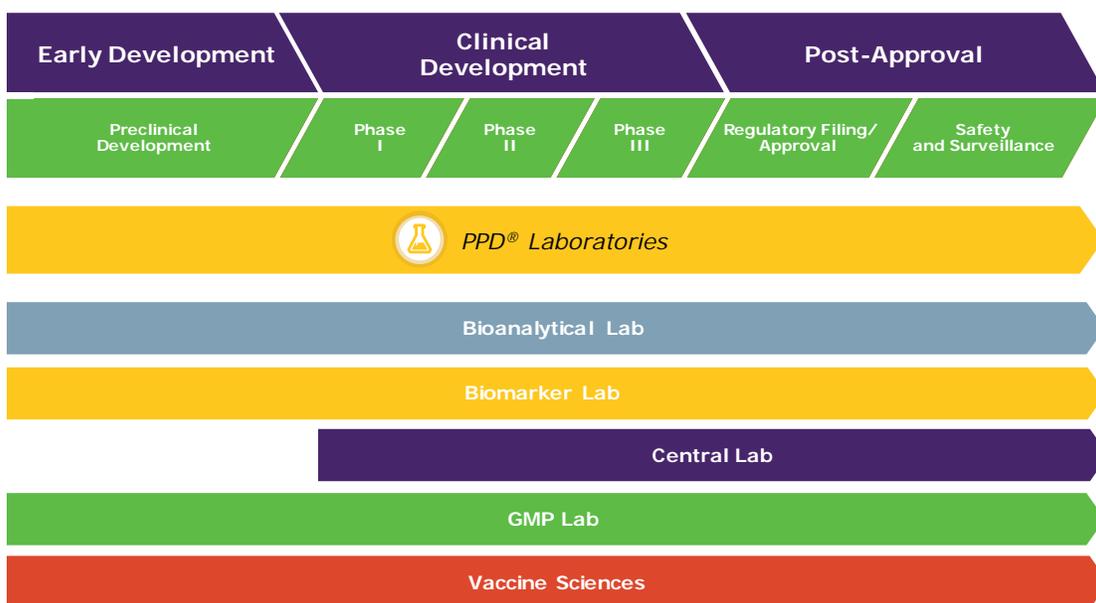


COMPREHENSIVE SERVICES

# PPD<sup>®</sup> LABORATORIES: GLOBAL INNOVATIVE PROVEN

PPD Laboratories combines superior scientific expertise with industry-leading technologies supported by a commitment to exceptional quality. Our clients benefit from comprehensive lab services spanning bioanalytical, biomarkers, central lab, GMP and vaccine sciences. Our laboratory services accelerate pharmaceutical development for small molecules, biologics and vaccines, allowing our clients to make faster decisions about their compounds.

# LABORATORY SERVICES THAT SPAN THE GLOBE AND THE DRUG DEVELOPMENT CONTINUUM





# PPD LABORATORIES OFFERS A COMPREHENSIVE SET OF LABORATORY SERVICES

From preclinical studies through late stage research, PPD Laboratories' clients benefit from comprehensive lab services that are designed to accelerate development for both small molecules and biologics.

## BIOANALYTICAL LAB

PPD Laboratories' bioanalytical lab performs accurate, timely bioanalysis in a good laboratory practice (GLP)-compliant setting to advance small molecule and biologics development from preclinical studies across all phases of pharmaceutical development. Our bioanalytical laboratory capabilities include:

- + Comprehensive immunochemistry services, including ligand-binding and cell-based assay services to provide pharmacokinetic (PK) and immunogenicity (IM) support
- + Substantial capacity and expertise in liquid chromatography/mass spectrometry (LC-MS/MS)
- + An extensive list of validated assays to support bioequivalence, drug-drug interaction and other types of studies
- + Expedited biologics development process from early development through companion diagnostics
- + Integration of vaccine and biomarker development services with the bioanalytical laboratory

## BIOMARKER LAB

As a leading provider of comprehensive biomarker services, our experience spans the clinical and product-development continuum from early development to companion diagnostics. Our integrated biomarker development process focuses on selecting the right approach to validation, developing methods under appropriate regulatory guidelines, providing insight into how to effectively integrate safety and efficacy biomarkers into clinical development, and choosing the best technology platform to meet client needs.

The PPD Laboratories approach to biomarker development includes:

- + Integration of biomarker services into both the bioanalytical lab and the central lab to provide flexibility, leverage the collective experience of PPD Laboratories and enable a tiered approach to biomarker development
- + Development support for diagnostic, prognostic, staging, predictive, pharmacodynamics, companion diagnostics and surrogate endpoint markers
- + Fit-for-purpose to highly regulated assays utilizing flow cytometry/cell-based assays, immunoassays, chromatography and genomics/molecular platforms

## CENTRAL LAB

The PPD Laboratories central lab services provide real-time access to clean data for the entire project team through:

- + The Preclarus® central lab database, PPD Laboratories' proprietary laboratory information system, which creates a single, web-based global database that eliminates the need for integration of regional lab data sets
- + Innovative processes and technologies that deliver an accurate study setup in approximately five weeks
- + Standardized global testing platforms and a comprehensive quality assurance program, GLASS (Global Laboratory Assay Standardization Survey), that eliminate the need for standardization/normalization of data from different sources and provide consistent, high-quality results
- + Spotfire™ dashboard tools that summarize integrated data and facilitate project oversight from start to finish
- + The Preclarus investigator site portal, that provides central lab investigator sites with secure, real-time access to studywide data
- + Integration of biomarker development services with the central lab
- + Strategic locations in Asia (Singapore and Shanghai, China), Europe (Brussels, Belgium) and North America (Highland Heights, Kentucky) to ensure clients have access to central laboratory services regardless of where study sites are located
- + Broad scientific expertise and extensive experience gained through completion of more than 1,200 studies in 25 different therapeutic areas in the past five years

# THE EXTENSIVE SCIENTIFIC AND TECHNICAL EXPERTISE OF PPD LABORATORIES ENSURES QUALITY RESULTS



PPD Laboratories is committed to delivering innovative technologies, systems and business models that create efficiencies for our clients.

## GMP LAB

PPD Laboratories' GMP lab is a leading CRO providing laboratory testing services in the chemistry, manufacturing and controls (CMC) pharmaceutical development space. Our clients depend on us to consistently deliver accurate data to ensure product quality, potency and stability.

We perform CMC testing on APIs and all manner of pharmaceutical products independent of the chemical nature or dose formulation. Method development and validation; stability, release and QC testing; extractables/leachables analysis, microbiological evaluation and physicochemical characterization are core competencies.

The GMP lab provides fully integrated analytical services across all phases of pharmaceutical development and commercialization.

- + We have more than 20 years of analytical experience working with both small molecules and biologics.
- + Our excellent regulatory record and customer loyalty mean that our clients trust us to deliver consistently high-quality data at agreed upon timelines.
- + We have both depth and breadth of specialized expertise in the analyses of inhaled pharmaceuticals and nasal products.
- + With more than 200,000 square feet of state-of-the-art lab space operating under current Good Manufacturing Practices (cGMP) regulations in Middleton, Wisconsin, and Athlone, Ireland, the GMP lab has a higher capacity than most other labs in this space and can manage large and/or complex global studies.
- + The GMP lab also offers customized staffing solutions (i.e., full-time employees to work in the client's facility) to help clients increase productivity and shorten development timelines. We take a collaborative approach to tailor a solution that meets the client's needs. We hire full-time PPD Laboratories employees, not temporary staff to ensure quality results and provide consistency through the course of a program.

# PPD LABORATORIES' 2,000+ EMPLOYEES ARE BENDING THE COST AND TIME CURVE OF DRUG DEVELOPMENT

For more than 25 years, PPD Laboratories' vaccine sciences lab has provided well-defined assays to support our clients' vaccine programs at every stage of development

## VACCINE SCIENCES

PPD Laboratories' vaccine sciences lab offers a full range of vaccine testing services that focus on incorporating cost and operational efficiencies that move life-changing vaccines to market faster. Our vaccine capabilities include:

- + More than 25 years of experience in providing a full range of vaccine testing services
- + A useful collection of commercial vaccine assays, including molecular, immunology and cellular/functional assays
- + Scientific expertise in biologics with therapeutic experience in neuroscience, infectious diseases and oncology
- + A wide variety of validated platforms and technologies including ELISA, the Luminex® platform, MSD®, PCR, ELISPOT, virus microneutralization and opsonophagocytic assays (OPA/OPK/MOPA)
- + PPD Laboratories has supported 15 FDA-approved development programs

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PPD Laboratories was named Best Contract Research Organization at the 9th Annual Vaccine Industry Excellence (ViE) Awards in March 2016

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For more information, please contact us  
at [labs@ppdi.com](mailto:labs@ppdi.com) or +1 877 643 8773.

[www.ppdi.com/labs](http://www.ppdi.com/labs)

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