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# pharma TECH OUTLOOK

ANALYTICAL SERVICES EDITION

## FACILITATING BIOANALYTICAL STUDIES

## PPD

[NASDAQ:PPD]

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# FACILITATING BIOANALYTICAL STUDIES

By Stacey Smith

From generics and biosimilars to cell and gene therapies, every scientific advance brings with it a set of new and sophisticated tools and techniques designed to analyze and evaluate samples with greater speed, precision, and certainty. To reap the utmost benefits from these tools, pharma organizations and biotech companies need a partner with the scientific acumen to quickly incorporate the latest technology into their bioanalytical studies and provide critical guidance on methods that will satisfy regulatory authorities worldwide.

This is precisely where PPD® Laboratories comes in. Over the past 30+ years, the PPD Laboratories Bioanalytical Lab has helped bring thousands of compounds to market by employing some of the most technologically advanced systems to develop assays and apply them to clinical trial samples across every stage of drug development. The company's bioanalytical lab has worked with tens of thousands of molecules across a wide variety of established and evolving technologies. The scientists at PPD are actively involved in the bioanalytical community through participation in industry events, webinars, and peer-reviewed publications.

As a leading global contract research organization, PPD provides comprehensive, integrated drug development, laboratory, and lifecycle management services. The company's customers and partners include pharmaceutical, biotechnology, medical device, academic, and government organizations. With more than 28,000 professionals worldwide, PPD has conducted clinical trials in more than 100 countries and applies innovative technologies, therapeutic expertise and a firm commitment to quality to bend the cost and time curve of drug development.

## Robust Experience in Biologics and Biosimilars

One of the exciting aspects of PPD's bioanalytical lab is its experience with more than 3,000 different

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biologics. At the same time, the company has helped develop eight of the top 10 biologics of 2018. As part of its client engagement, PPD's biologics development team works closely with clients to understand the molecule's intended use, the unique characteristics of the protein biotherapeutic, any potential interferences, and current regulatory requirements. With this knowledge, PPD's teams design and validate custom assays or adapt existing assays and quickly generate meaningful data to help inform project decisions.

> The PPD Laboratories Bioanalytical Lab also offers comprehensive immunochemistry services to support pharmacokinetic (PK) and anti-drug antibody (ADA) safety assessments

The PPD Laboratories Bioanalytical Lab also offers comprehensive immunochemistry services to support pharmacokinetic (PK) and anti-drug antibody (ADA) safety assessments. The company has broad biopharmaceutical experience with various molecules, including monoclonal and multivalent antibodies, antibody fragments, oligonucleotides, PEGylated proteins, and antibody-drug conjugates (ADCs). For the past several years, PPD Laboratories has been applying its more than three decades of experience with chromatography methods to the development and validation of LC-MS/MS analytical methods for biologics.

PPD Laboratories has supported more than 23 biosimilar programs destined for regulatory submission. The development of biosimilar drugs requires a bioanalytical lab with extensive experience, broad technical capabilities, and a deep understanding of the regulatory pathway. PPD understands that the development needs for biosimilars are unique relative to other biopharmaceutical compounds. The company keeps in mind that biosimilars must demonstrate comparable results — safety, purity, potency, stability, and immunogenicity — to the innovator product and across product lots. PPD recognizes that competition in the biosimilar arena involves extremely tight timelines, and they work closely with clients to meet these needs. The company's bioanalytical lab has supported several biosimilar programs connected with U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) submissions.

## Broad Bioanalytical Capabilities

The company has a dedicated team of research scientists experienced in cell culture technologies, cell-based assay development and validation, cell-line engineering, microbiology, virology, and molecular biology. The bioanalytical lab's cell-based assay experience involves the transfer of more than 120 cell-based assays across a wide range of applications, including drug-specific NAb assays (including biosimilars), biomarkers, toxin neutralization assay (TNA), and virus-specific NAb assays.

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PPD's bioanalytical lab is also known for its substantial capacity and expertise in the increasingly sophisticated field of chromatography. The company has applied LC-MS/MS to compounds that range from small molecules to antibody-drug conjugates (ADCs) with measurement in biological fluids and tissues. With over a decade of experience specific to hybrid ligand binding (LBA) LC-MS/MS, PPD has developed and streamlined monoclonal antibody (mAb) and ADC methodologies, significantly reducing method development time and minimizing the need for specialized reagents. The team utilizes advanced automated instrumentation for rapid sample analysis and employs stable isotope internal standards for highly precise quantitation.

In addition, PPD Laboratories has flow cytometry assays integrated into its bioanalytical, biomarker, and central labs. This integration provides flexibility to leverage its operational and organizational structures for a tiered regulatory approach to meet customers' needs. From fit-for-purpose assays to projects that require GCLP-, GLP- or CLIA-compliant assays, the company has it all covered with its technology platforms, clinical expertise, and the collaborative and flexible mindset needed to develop customized solutions for customers. Flow cytometry assays are backed by a dedicated team of scientists at the bioanalytical lab and many cross-trained scientists across the various central lab locations.

PPD also has significant experience in molecular genomics. The company has a custom-built, spacious, leading-edge molecular genomics suite staffed with a dedicated team of experienced scientists. The suite of labs is designed with the appropriate engineering and procedural controls to minimize the risk of reagent and sample contamination.

## Continued Investment and Success

Based upon the success of the lab business, PPD continues to invest and expand its bioanalytical laboratories in Richmond, Virginia, Middleton, Wisconsin, and Suzhou, China, to enhance its ability to provide industry-leading capabilities to meet biopharmaceutical clients' increasingly complex research needs.

"The ongoing enhancements to our bioanalytical lab operations build on the growth of our drug development expertise over the past three decades to the point that we now support pharmaceutical programs from preclinical through post-approval," said Christopher Fikry, M.D., executive vice president of PPD Laboratories. "These additions enable us to more effectively and efficiently respond to the ever-expanding needs of our customers as they seek to deliver life-changing therapies. We're confident our efforts will enable us to continue our record of success with our customers."