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PPD® LABORATORIES

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**PPD**

**GMP LAB**

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# PPD<sup>®</sup> LABORATORIES GMP LAB: PARTNERSHIP AND INNOVATION TO SUPPORT YOUR PRODUCT'S SUCCESS

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

# THE RIGHT SERVICES. THE RIGHT EXPERTISE. ALL RIGHT WHERE YOU NEED THEM.



Middleton, Wisconsin

Athlone, Ireland

## FULFILLING REGULATORY REQUIREMENTS

Our regulatory experience spans the global community with a GMP laboratory in Athlone, Ireland to help clients fulfill regulatory requirements for release testing and qualified person (QP) services for clinical and marketed pharmaceuticals in the European Union, including small and large molecules and inhaled products.

This facility has:

- + Ancillary space for quick expansion
- + The ability to offer fully integrated solutions for product and analytical development

## THE FLAGSHIP FACILITY

In 1991, PPD Laboratories established our premier pharmaceutical analysis facility in Middleton, Wisconsin.

Our extensive capabilities include:

- + Analytical method development and validation
- + Release and stability testing and storage
- + Physical, biological and chemical characterization
- + Extractables and leachables testing
- + The industry's most advanced instrumentation and technology to support testing of inhaled products

## CREATIVE SOLUTIONS FOR YOUR STAFFING CHALLENGES

In addition to strategically located laboratories, we can provide full-time employees to work in your facility. As the first company to offer on-site staffing solutions, we have more than 150 employees placed in our clients' facilities.

- + Our on-site staffing solutions provide efficient use of existing space, instrumentation and systems while reducing direct staffing costs and maintaining workflow
- + We hire, manage and train on-site staff to work with your processes and our standard operating procedures to ensure data integrity and quality
- + We place staff trained in chemistry, quality assurance, quality control, laboratory support, program management and information technology and will work closely with you to create a custom solution to meet your unique needs



# EXPERT PERSONNEL STATE-OF-THE-ART INSTRUMENTATION

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As a leading provider of chemistry, manufacturing and controls (CMC) pharmaceutical development services, PPD Laboratories remains focused on providing exceptional partnership and service. We work in close alignment with you, responding quickly and effectively to all requests through our dedicated team approach.

Our specialized, cross-functional teams have the expertise needed to test complex products, as well as provide analytical solutions.

Examples of our technical expertise include inhaled biopharmaceutical testing and impurity identification studies.

## THE HALLMARKS OF PPD LABORATORIES

- + Experienced staff
- + State-of-the-art technologies
- + Breadth of quality services
- + High degree of flexibility

## KEY PRODUCT TYPES

- + Small molecules
- + Inhalation products
- + Biopharmaceuticals
- + Device characterization

## KEY TECHNOLOGIES

- + Chromatography
- + Spectroscopy
- + Molecular characterization
- + Immunochemical assays
- + Cell-based assays
- + Emitted dose performance

Consistently  
rated highest for  
overall quality and  
customer service  
in client surveys

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# CUSTOMIZED SOLUTIONS TO MEET GROWING AND CHANGING DEMANDS

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PPD Laboratories offers comprehensive CMC laboratory services to support all phases of drug development for active pharmaceutical ingredient, drug product, aerosols and medical devices. Our breadth of services includes high-quality analytical testing capabilities for all dosage forms for small molecules, peptides, proteins, oligonucleotides and other biomolecules.

## INNOVATIVE SOLUTIONS CUSTOMIZED TO MEET YOUR UNIQUE NEEDS AND MARKET DEMANDS

This flexibility means we deliver exactly what you expect and increase efficiencies by:

- + Using client and/or our standard operating procedures (SOPs), methods, protocols and report templates
- + Seamlessly supporting and transitioning programs between sites
- + Dedicating lab personnel and instrumentation
- + Providing full-time staffing at your facility

## CMC LABORATORY SERVICES

- + Pre-formulation and materials characterization
- + Method development and validation
- + Quality control and release testing
- + Stability and photostability testing, storage and management
- + Activity and other cell-based methods for biopharmaceutical products
- + Aerosol performance testing
- + Extractables/leachables testing
- + Microbiology testing
- + Unknown identification and reference standard/impurity marker synthesis
- + Raw materials and other compendial analyses
- + CMC regulatory and product development advisory services

Fully integrated  
product analytical  
development services  
for all phases

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For more information about our comprehensive CMC laboratory services, 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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