



PPD® LABORATORIES

HELPING DELIVER LIFE-CHANGING THERAPIES



GMP LAB

PPD[®] LABORATORIES GMP LAB: PARTNERSHIP AND INNOVATION TO SUPPORT YOUR PRODUCT'S SUCCESS

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, vaccine sciences, GMP, central lab testing and biomarkers. Our laboratory services accelerate pharmaceutical 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 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
- + 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. We have been offering on-site staffing for more than 20 years and have placed more than 300 employees 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 INDUSTRY-LEADING INSTRUMENTATION

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
- + Industry-leading technologies
- + Breadth of quality services
- + High degree of flexibility

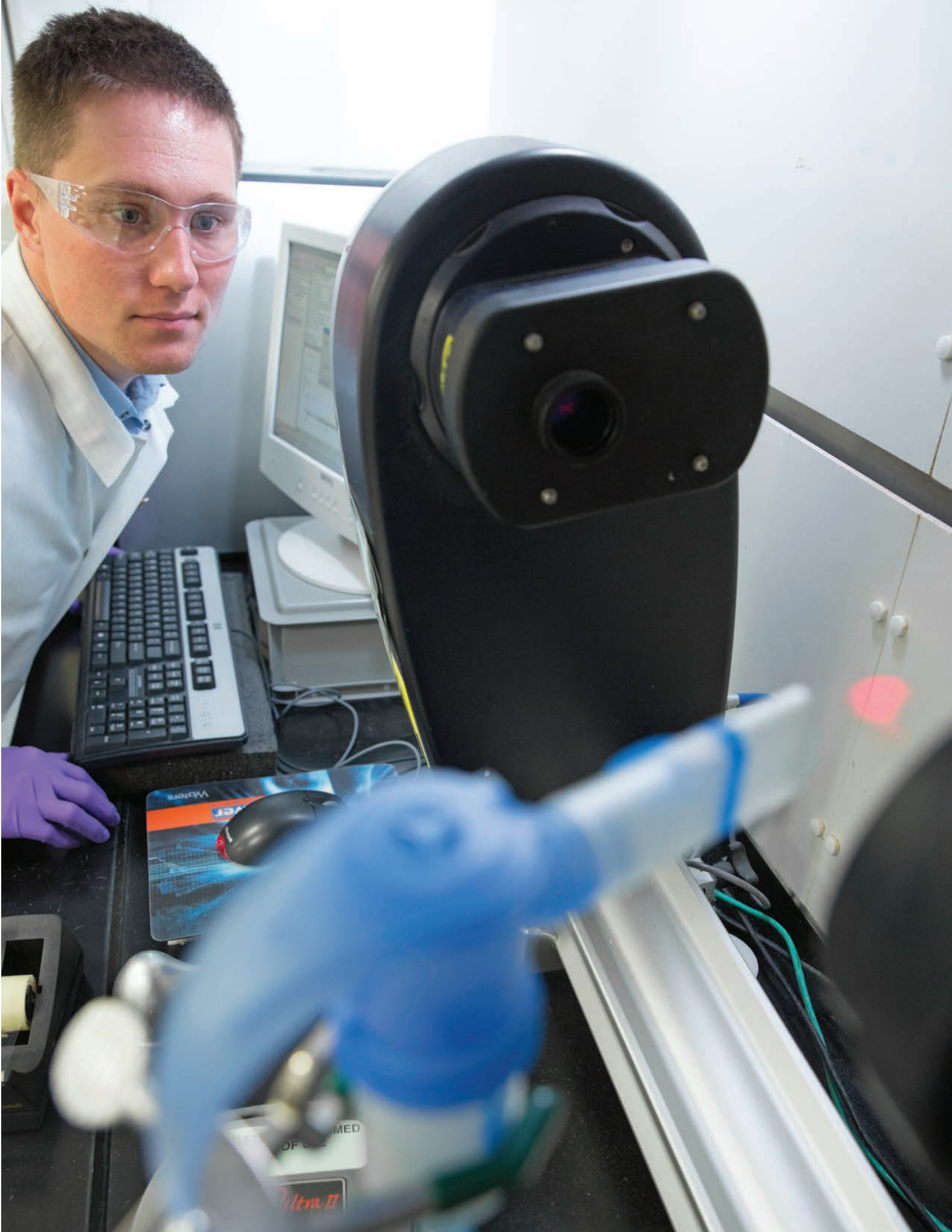
KEY PRODUCT TYPES

- + Small molecules
- + Inhalation products
- + Biopharmaceuticals
- + Device characterization
- + Cell and gene therapies

KEY TECHNOLOGIES

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

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



CUSTOMIZED SOLUTIONS TO MEET GROWING AND CHANGING DEMANDS

PPD Laboratories offers comprehensive CMC laboratory services to support all phases of drug development for active pharmaceutical ingredients, drug products, 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



For more information about our comprehensive CMC laboratory services, please contact us at labs@ppdi.com or +1 877 643 8773.

www.ppdi.com/labs

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