



PPD® LABORATORIES  
GMP LAB

## Biologic Drugs: Capabilities and Expertise



PPD Laboratories GMP lab provides **comprehensive services and capabilities** for biologics analysis, including **top-quality characterization services**. For the past 20 years, we have supported clients' projects with an **unwavering commitment** to pharmaceutical development. Our **well-established** portfolio of expertise encompasses a diverse variety of molecules.

### Comprehensive characterization service offerings

- Aggregation: SEC, SEC-MALS, AUC and native page
- Protein folding/thermal stability: CD and nano-DSC
- Binding/kinetic characterization: specific activity, surface plasmon resonance and enzyme kinetics
- Charge heterogeneity: IEX and icIEF
- Physical and chemical characterization:
  - DLS, FTIR and LC/MS
  - Viscosity
  - Particulates and compendia assays
  - GC/MS impurities identification
- Extractables and leachables:
  - Container/closure compatibility
  - Single-use manufacturing process components evaluation

### Diverse testing methodologies

- Feasibility
- Method development, qualification and validation
- Product characterization
- Forced degradation studies and analysis
- Stability testing and storage of active pharmaceutical ingredient (API) and finished products
- Quality control (QC) testing of API (in process samples) and finished products
- Release testing
- Pre-formulation support and formulation evaluation
- Coagulation analysis:
  - Prothrombin time (PT)
  - Activated partial thromboplastin time (aPTT)
  - Anti-Xa and anti-IIa
- Cell-based assays
- Cell and gene therapy assays

### One lab, multiple locations

#### ATHLONE, IRELAND

More than

**47,000 sq. ft.**

and **200 staff**

#### MIDDLETON, WISCONSIN, USA

More than

**390,000 sq. ft.**

and **1,400 staff**

#### FUNCTIONAL SERVICE PARTNERSHIPS

Multiple client locations in the

**U.S. and Europe**

with more than

**300 staff**

## Two decades of biologics expertise

- Proteins: recombinant, PEGylated and glycosylated
- Monoclonal and polyclonal antibodies
- Antibody-drug conjugates (ADCs)
- Hormones
- Peptides and polypeptides
- Nucleotides and oligonucleotides: siRNA, DNA, mRNA, DNAi and RNAi, synthetic and PEGylated
- Cell and gene therapy products including oligonucleotides, messenger RNAs, plasmids and viral-vectored products
- Carbohydrates and polysaccharides
- Liposomes
- Inhaled biologics
- Process impurity assays: host cell protein and DNA, isopropyl  $\beta$ -D-1-thiogalactopyranoside (IPTG), surfactants and antibiotics

**97%** of 2018 customer satisfaction survey respondents said PPD Laboratories GMP lab **met or exceeded their expectations for quality** of analytical testing.

<sup>1</sup> Data on file from 2018 customer surveys

## PPD Laboratories GMP Lab

We provide high-quality analytical services for small molecules, biologics, vaccines, and cell and gene therapies. We work with active pharmaceutical ingredients (APIs), drug products and medical devices, including inhaled drug/device combinations across all phases of development. As a leader in CMC lab services, we focus on responding to our clients' needs with experienced staff, the latest technology, quality data and a high degree of flexibility.

## The quality difference

Our focus on continuous improvement and client satisfaction ensures superior results in a highly customizable environment.



Culture of quality and service for more than 20 years



Excellent U.S. FDA, U.K. MRHA, Ireland HRP and EU EMA regulatory history



Innovative, responsive and stable operational team



Flexible, customized client solutions



Depth and breadth of expertise across a wide range of APIs, drug products and advanced therapies



Industry-leading instrumentation and laboratory facilities in the U.S. and Europe