GMP lab

Biologic drugs: capabilities and expertise

PPD™ Laboratory services' GMP lab provides **comprehensive services and capabilities** for biologics analysis, including **top-quality characterization services**. For the past 22+ years, we have supported clients' projects with an unwavering commitment to pharmaceutical development. Our well-established portfolio encompasses a diverse variety of molecules.

Service Offerings	Product Characteristic	Assay Capabilities
Product Characterization	Primary Structure	Amino acid composition by U/HPLC-UV, LC-MS (intact mass/peptide mapping/ PTM analysis)
	Secondary Structure	Free thiols, FTIR, CD (far UV)
	Tertiary Structure	CD (near UV), nano-DSC, IF
	Other Attributes	SEC-MALS, AUC, SPR, absorptivity coefficient
Release and Stability	Identity	ELISA, Peptide mapping (UV, MS), intact MS, western blotting (WB)
	Purity	SEC, RP-, IEX-HPLC, HIC/HILIC, CE, iCE, SDS-PAGE
	Potency	ELISA, enzyme kinetics, cell-based assays, SPR, MSD
	Physical/Chemical Properties	Concentration (UV/Vis, slope ratio, micro BCA), turbidity, colorimetry, pH, osmolality, moisture, liquid and aerodynamic particle size
	Safety/Impurities	Residual host cell DNA by q/ddPCR, residual host cell proteins by ELISA, residual process impurities by ELISA, visible and subvisible particulates by HIAC, MFI and microscopy
	Safety - Microbiology	Sterility (filtration), CCIT (vacuum decay, O2 headspace, dye ingress), endotoxins, bioburden, adventitious contamination testing
	Inactive Ingredients	Surfactants by CAD and ELSD, ion chromatography, HPLC-RI
	Drug Product Packaging	Break-loose force, glide force, next-generation impactor/Anderson cascade impactor
Extractables and Leachables	Container/Closure Compatibility	
	Single-Use Manufacturing Process Components Evaluation	

One lab, multiple locations

Athlone, Ireland

More than **84,000** sq. ft. and **390+** staff

Middleton, Wisconsin, USA

More than **550,000** sq. ft. and **2,200+** staff

Functional Service Partnerships

Multiple client locations in **U.S.** and **Europe** with more than **400+ staff**

More than two decades of biologics expertise

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

97% of customer satisfaction survey respondents said our lab met or exceeded their expectations for quality of analytical testing.

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 HRPA 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

PPD™ Laboratory services' 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.

Learn more at **ppd.com/our-solutions/ppd-laboratories/gmp-lab/**