



Athlone, Ireland overview

Comprehensive chemistry, manufacturing and controls (CMC) analytical services for pharmaceuticals and biopharmaceuticals

Our **GMP Lab** is focused on meeting our customers' needs in **Europe, the Middle East, and Africa (EMEA)** with **high-quality** analytical testing based in our **leading-edge** Athlone, Ireland facility.



A culture of quality and service for **32+ years**



Extensive regulatory experience in the U.S., U.K., Ireland and the EU



Flexible, customized solutions to meet customer needs

Analytical testing services

- Method development, transfer and validation for inactive ingredients, drug substances, drug products and medical devices
- Stability testing and storage
- Release and quality control testing
- Physicochemical characterization
- Extractables and leachables analysis

Industry-leading inhalation testing

- Commercial release and stability in the EU
- Device performance and aerosol and particle characterization
- Dry powder inhalers (DPI)
- Pressurised metered dose inhalers (pMDI)
- Nasal and nebulizer testing

Biologics testing

- Commercial release and stability in the EU
- Solutions, lyophilised powders, pre-filled syringes (PFS) and vials
- Antibodies, proteins, peptides, antibody drug conjugates (ADCs) and gene therapy products (AAVs)
- Mass, identity, purity, activity, binding protein content and impurities
- Bioassay and molecular biology labs
- Oligonucleotide testing

Small molecule and specialty testing

- Commercial release and stability in the EU
- Tablets, capsules, lyophilised powders, pre-filled syringes (PFS), vials, solutions, stents, catheters and other medical devices
- Oligonucleotide analysis
- Assay, purity, content uniformity, dissolution, related substances and residual solvent determinations
- Identification and quantification of low level-impurities (genotoxic, nitrosamine and elemental)

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

Dedicated quality assurance (QA) team

The independent QA staff in Athlone, Ireland conducts in-process system/facility audits and out-of-specification/atypical data investigations. It also provides quality metrics, corrective and preventive action (CAPA) plans, document control, data archives, and training for both new and current employees.

QP services for investigational medical products

- Associated batch documentation review
- EU clinical trial products approval
- Partial testing review and release
- Active pharmaceutical ingredients (API) audits
- Vendor audits

Comprehensive services for pharmaceutical and biopharmaceutical products

Discipline/Methodology	Testing Services	Key Instrumentation/Platform
Inhalation testing	<p>Our service offering includes:</p> <ul style="list-style-type: none"> • Drug content assay • Dose content uniformity • Net content or fill weight • Microscopic evaluation • Foreign particulate matter • Aerodynamic particle size distribution • Impurities and degradation products • Moisture content • E&L testing • Plume geometry • Spray pattern measurements 	<ul style="list-style-type: none"> • Anderson and Next generation impactors • Copley (CITDAS) software, TPK critical-flow controller • PPD™-patented dose collection tubes for foreign particulate matter analysis • Humidity and temperature controlled testing rooms • Malvern Spraytec® droplet-size analyser • MDI FD-10 automated wasting station • Malvern Mastersizer 3000 solid particle size and distribution analysis • NGI chiller unit • Proveris Scientific® SprayVIEW® • Proveris Vereco® Actuator SFMDx® and NSx® • Copley Scientific BRS 2100 breathing simulator • Temp/RH test hood
Biologics testing	<p>Our service offering includes:</p> <ul style="list-style-type: none"> • Drug substances • Drug products • Identity • Purity and impurity • Potency • Product/process related impurities • Safety <p>Our cell-based assays:</p> <ul style="list-style-type: none"> • Cell proliferation and cytotoxicity assays • ADCC assays • Reporter gene assays 	<ul style="list-style-type: none"> • HPLC (Waters and Agilent) and UPLC • Wide range of detectors: ELSD, CAD, UV, FLR, RI • Beckman Coulter PA-800 Plus (PDA, UV, LIF) • ProteinSimple iCE™ 3 and Wes • Coagulation analysers • SoloVPE • Molecular devices SpectraMax® and SpectraMax M5 • Bio-Rad GS-900™ and ChemiDoc XRS+ • Hach® turbidimeter and moisture analyser • Applied Biosystems® 7500 and 7500Fast RT-qPCR
Small molecule and specialty testing	<p>Our service offering includes:</p> <ul style="list-style-type: none"> • Drug substances and drug products • Release, stability and validation • Identity and purity • Content uniformity • Microscopic evaluation • Foreign particulate matter • Particle size distribution • Moisture content • Impurities and degradation products • Genotoxic impurity analysis • Trace metal and elemental impurity analysis • Residual solvents • E&L (vials, syringes, mouthpieces, foils, stoppers) • Oligonucleotide analysis, LC-MS impurity • Container closure integrity testing (CCIT): Oxygen headspace and dye ingress • Osmolality 	<ul style="list-style-type: none"> • HPLC (Waters and Agilent), UPLC, HClass • Wide range of detectors ELSD/CAD/UV/FLR/RI/PDA/UV • FTIR • Dissolution Ap I/II and Ap IV • HIAC • Volumetric and coulometric Karl Fischer • Malvern Zetasizer • Microscope • Water testing • GC-FID/headspace • GC-MS, LC-MS and ICP-MS <p>Mass spectrometry specific equipment detail:</p> <ul style="list-style-type: none"> • GC-MS Agilent (1 x 7890A, 5975C), (1 x7890B 5977A) • LC-MS Agilent (2 x G6130) • LC-MS/MS SCIEX QTRAP® 6500+ • ICP-MS Agilent 7700

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