

GMP lab

Cell and Gene Therapy (CGT) analytical capabilities

Supporting customers' analytical testing needs for novel CGT products

PPD™ Laboratory Services, GMP Lab leverages more than **30 years** of chemistry, manufacturing and controls (CMC) experience, **leading-edge** instrumentation and **extensive** analytical capabilities to support our customers' CGT product development programs.



Experience with 150+
cell and gene therapies



20+ years experience with
cell and gene therapies



cGMP and EMA
compliant

Drug substances experience

- Oligonucleotides including siRNA, RNAi and DNAi
- Encapsulated and naked plasmids and mRNAs
- Viral vectors including:
 - Adenovirus vectors (AdVs)
 - Adeno-associated virus (AAV)
 - Lentivirus (LV)
 - Modified hematopoietic stem cells (HSCs)
- Genome editing
 - CRISPR Cas Nucleases
 - TALENs
 - gRNA, sgRNA

Study type experience

- Analytical method development and validation
- Drug substance and reference standard characterization across a range of formulations and delivery routes
- In-process sample analysis
- Quality control and release testing
- Stability testing and storage
- Comparability studies
- Forced-degradation studies
- Process and formulation development support

One lab, multiple locations



**Athlone,
Ireland**

More than **82,000** sq. ft and
450+ staff



**Middleton,
Wisconsin, USA**

More than **580,000** sq. ft. and
2,400+ staff



**Functional
Service
Partnerships**

Multiple client locations in **U.S.** and
Europe with more than **600+** staff

Our GMP Lab has been working with CGT products since 1997.

Extensive oligonucleotide capabilities and GMP service offering

- Full compliance with U.S. FDA cGMP regulations and rules governing medicinal products in the European Union
- Customized method development, transfer and validation under cGMP
- Full range of physicochemical and molecular characterization and potency assays
- Bioburden and endotoxin testing
- Safety testing inclusive of rcAAV, mycoplasma, and adventitious viral agents

Expertise

- Specialized sample handling to minimize nucleases and moisture uptake for hygroscopic substances
- Developing denaturing HPLC methods
- Extensive work with complex formulation types
- Separation methodologies and complete impurity analysis using multiple techniques
- Transfer of unique, analytical techniques for a wide range of CGT drug substances
- Unique expertise in next-gen sequencing, methodology, capsid titer, viral genome titer, and cell bioassay development

About us

PPD Laboratory services provides high-quality scientific expertise with industry-leading technologies supported by a commitment to exceptional quality. Our customers benefit from comprehensive lab services spanning bioanalytical, GMP, central lab testing, vaccine sciences and biomarkers. Our laboratory services accelerate pharmaceutical development for small molecules, biologics, vaccines, and cell and gene therapies allowing customers to make faster decisions about their compounds.



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

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