

GMP lab

Broad capabilities for cell and gene therapy product development

PPD™ Laboratory services GMP Lab leverages **more than 27 years** of CMC experience to offer a **comprehensive set of services** specifically tailored to the needs of cell and gene therapy development programs.



Experience with **60+**
cell and gene therapies



17+ years experience with
cell and gene therapies



cGMP and **EMA**
compliance

Drug substances experience

- Oligonucleotides including siRNA, RNAi and DNAi
- Encapsulated and naked plasmids and mRNAs
- Viral vectors including adenovirus vectors (AdVs), adeno-associated virus vectors (AAVs), baculoviral vectors (BVs) and lentivirus vectors (LVs)
- Cell-based therapeutics, including modified stem, blood and immune cells, and CRISPR/Cas9

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
- Container/closure integrity testing (CCIT)

Extensive Oligo capabilities and cGMP service offering

- Full compliance with U.S. Food and Drug Administration (FDA) current good manufacturing practices (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

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 cell and gene therapy drug substances

Instrumentation

HPLC/UPLC

- Waters, Agilent HPLC/UPLC with UV, FI, RI, CAD/ELSD, SQD, DAD
- Thermo Scientific™ Dionex UltiMate 3000 Electrochemical Detector with pulsed amperometric detection (PAD) HPLC

Mass Spectrometry

- Thermo QE+ with BioPharm Option
- Sciex 6500+ Q-trap with 2D-UHPLC

Electrophoresis

- Caliper LabChip® GXII
- Beckman Coulter PA-800 CE
- ProteinSimple® iCE™3, Wes™ and Maurice
- Agilent Bioanalyzer 2100

PCR

- BioRad QX200 ddPCR systems
- Applied Biosystems™ 7500/7500 Fast qPCR
- Applied Biosystems™ QuantStudio 7 RT-PCR
- Eppendorf/BioRad PCR thermal cyclers

Cell

- Beckman Coulter Vi-CELL® XR cell counters
- BD Biosciences FACSCanto™ II, Beckman Coulter CytoFLEX flow cytometers
- Tecan EVO 150 automated liquid handler

Other

- Molecular devices SpectraMax® M3, M5, FlexStation and I3 plate readers
- Biotek Cytation 5 and Perkin Elmer Envision plate readers
- Biotek and Perkin Elmer Plate Washers
- MSD® SECTOR® Imager 600
- Beckman Coulter Optima analytical ultracentrifuge equipped with a UV detector, vacuum and chiller
- BiaCore™ T200
- KingFisher Automated Nucleic Acid Extraction System
- SoloVPE and Implen NP80 spectroscopy systems
- Applied Biosystems 3500xL Sanger Sequencing
- Illumina MiSeq Next Generation Sequencing
- BioRad GS-900 and ChemiDoc™ XRS+ Densitometers
- ACL TOP® Coagulation Analyzers
- Beckman Coulter 9703+ liquid particle counter with HRLD probes
- Malvern Panalytical Mastersizer 3000 laser diffraction analyzer

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

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