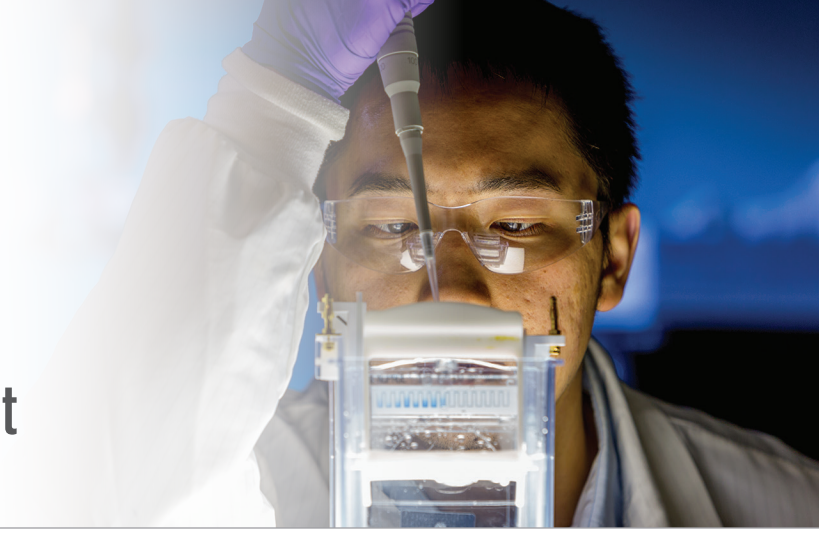
PPD® LABORATORIES
GMP LAB



Broad Capabilities for Cell and Gene Therapy Product Development

PPD Laboratories GMP lab leverages **more than 25 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

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 (AAV), baculoviral vectors (BVs) and lentivirus vectors (LVs)

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)

15+ yrs
experience with
cell and gene therapies

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

cGMP and **EMA** compliance

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