

# Cell and Gene Therapy (CGT) Development Expertise

Supporting customers through an efficient end-to-end journey for their CGT programs.

PPD® LABORATORIES

The PPD® Laboratories bioanalytical lab has been working with **cell and gene therapies** for more than **two decades** and has the experience needed to **understand and execute** programs for our customers.

**Our team works with you to understand your program.**

**We can design and validate custom assays or adapt existing assays to quickly generate meaningful data to help inform your project decisions.**



Extensive regulatory experience



PK, ADA/nAb and biomarker assays



20+ years working knowledge



300+ cell/gene therapy assays

## Comprehensive capabilities for cell and gene therapy programs

- Extensive immunochemistry, chromatographic, flow cytometry and molecular services to support preclinical studies and clinical trials Phases I - IV
- High-throughput liquid handling and sample analysis
- Gene expression product analysis
- Anti-drug antibody and cell or plate-based neutralizing antibody assays for analyte, protein product, and delivery vector
- Bioanalysis by ion-pair liquid chromatography coupled with tandem mass spectrometry
- CAR-T cell enumeration for cellular kinetics and immunophenotyping via flow cytometry

## Extensive expertise

- Method development, transfer and validation, and sample analysis following U.S. FDA good laboratory practices (GLP) customized for CGTs
- Analytical expertise across a wide range of common and rare matrices, including more than 20 years of experience with tissue processing and analysis
- Technology selection guidance based upon sensitivity, selectivity, complexity, dynamic range, throughput and specific program needs

PPD Laboratories' bioanalytical lab has been working with cell and gene therapies since 1997 and has a wealth of experience in pharmacokinetic/pharmacodynamic (PK/PD), immunogenicity and molecular genomics.

### Analytes and delivery mechanisms

- Oligonucleotides
- Messenger RNA (mRNA)
- CAR-T therapy
- CRISPR/Caspase9
- Enzyme replacement therapy
- Lipid nanoparticles
- Polymers
- Adeno-associated virus (AAV)
- Targeted delivery mechanisms

### Key instrumentation

Including but not limited to:

- Flow cytometry
- BioRad QX200™ Droplet Digital™ PCR System
- RT-PCR
- Sanger and Next-Generation Sequencing (NGS)
- ELIspot
- Millipore SMCxPro™
- ProteinSimple Jess and Ella
- GE Healthcare AKTA FPLC
- Quanterix® Simoa®
- Various instruments for liquid chromatography, fluorescence detection and mass spectrometry including SCIEX, Waters and Thermo Fisher Scientific platforms

## PPD Laboratories

PPD Laboratories 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.

