


 GMP lab

mRNA replacement therapeutics analytical capabilities

Supporting customers with product analytics and comprehensive services for mRNA replacement therapeutics (MRT)

Our **GMP Lab** leverages more than **30+ years** of chemistry, manufacturing and controls (CMC) analytics experience to advance our customers' **mRNA therapeutic programs**.

GMP lab services

- Sample and standard stability storage and management
- Optimization of assay design to comply with U.S. FDA and EU EMA cGMP regulations
- Provide customers with full visibility and ownership of methods, protocols and data
- Consulting services for regulatory agency submission guidance
- Partnership with PPD's bioanalytical, vaccine sciences and central laboratories

Study type experience

- Analytics on encapsulated and naked MRTs
- Platform or custom analytical method development, transfer, and validation
- Drug substance, in-process sample and reference standard characterization
- Release and stability testing
- Comparability and forced degradation studies

Identify

- Concentration
- Size and integrity
- Sequence
- 5' cap and 3' poly-A tail
- Percent encapsulation
- dsRNA

Purity

- Lipid nanoparticle complex purity
- Lipid content
- Particle size
- Residual pDNA, proteins, process enzymes and solvents
- Elemental impurities

Potency

- Transfection
- Translation efficiency
- Expression
- Functional/mechanism of action (MoA) bioassays

Compendial

- Appearance, color and clarity
- pH
- Osmolality
- Subvisible particulates

Safety

- Sterility
- Bioburden
- Endotoxin detection
- Container closure integrity analysis

Our dedicated team works with you to fully understand your MRT program. We can design and validate custom assays, adapt pre-existing methods and provide full transparency to all of your data and documentation.

Key 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 Scientific™ Orbitrap Exploris™ 240
 - Thermo Scientific™ Q Exactive™ Plus
 - 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
 - Eppendorf/BioRad PCR thermal cyclers
- Other
 - Plate readers and washers (Molecular Devices, Perkin Elmer)
 - MSD® SECTOR® Imager 600
 - SoloVPE and Implen NP80 spectroscopy systems
 - Applied Biosystems 3500xL Sanger Sequencing
 - BioRad GS-900 and ChemiDoc™ Densitometers

PPD™ Laboratory services

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/