

## GMP lab

## Biosafety capabilities and expertise

Advanced mycoplasma and viral testing services to support development of biologics and cell & gene therapies

Our **GMP** lab has expanded testing capabilities offering **compendial and novel validated biosafety methods**. With **extensive expertise in GLP and GMP regulations and PCR technologies**, our biosafety lab offers **fast, simple, and reliable options** for characterization of cell banks, unprocessed bulk and final products.



A culture of quality and service for **30+ years**



**Extensive regulatory experience** in the U.S., U.K., Ireland and the EU



**Flexible, customized solutions** to meet customer needs

### USP/EP/JP/PTC compliant mycoplasma assays

- Culture method
- Indicator cell culture method
- MycoplasmaStasis assay
- MycoSEQ™ Plus real-time PCR assay
- Enrichment MycoSEQ Plus real-time PCR assay

### Product type experience

- Analytical/master/working cell banks
- Cell and gene therapy
- Monoclonal antibodies
- Media

### Viral safety testing

- In vitro adventitious viruses assays
- ViralSEQ real-time PCR assay for minute virus of mice
- Replication-competent assay for adeno-associated virus
- Replication-competent assay for lentiviruses
- Product-Enhanced Reverse Transcriptase (PERT)

### Study type experience

- Quality control and release testing
- Cell bank qualification and storage
- Comparability and validation studies
- Method transfer

**PPD Laboratory Services GMP lab met or exceeded expectations for quality of analytical testing for 98% of our customers**

Based on customer survey data

### Well-designed environmental control systems

- Dedicated 2000 sq ft of HEPA filtered, restricted access lab space
- Dedicated lab areas for:
  - Mycoplasma testing
  - Viral testing
  - Pre- / Post-amplification PCR
- REES Scientific automated temperature monitoring system

### Key instrumentation

- Nikon® microscope models Upright Eclipse Ci and Inverted Ts2-FL
- Eppendorf/BioRad PCR thermal cyclers
- Kingfisher Automated Nucleic Acid Extraction System
- Applied Biosystems™ 7500 Real-Time qPCR
- Implen NanoPhotometer® NP80 Spectrometer
- NucleoCounter® NC-202

### One lab, multiple locations



**Athlone,  
Ireland**

More than **84,000** sq. ft.  
and **360+** staff



**Middleton,  
Wisconsin, USA**

More than **605,000** sq. ft. and  
**2,200+** staff



**Functional  
Service  
Partnerships**

Multiple client locations in  
**U.S. and Europe** with  
more than **400+ staff**

### 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/](https://ppd.com/our-solutions/ppd-laboratories/gmp-lab/)

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