

GMP lab

Introducing a new dedicated room for controlled temperature and humidity testing of inhaled biologics

A new generation of biological therapies – proteins, oligonucleotides, mAbs etc – are delivered via inhalation. While many of the fundamental post device spray/plume characterization techniques remain the same (Cascade impaction, Droplet size measurements using Laser Diffraction), changes are required both from a technique perspective in terms of sample analysis and detection methods and ensuring adequate containment from a health and safety perspective. Therefore, in Athlone, Ireland, our latest temperature and humidity controlled testing laboratory has been designed with capabilities to handle biological compounds up to Biosafety Level (BSL-2).



Room specifications

- Temperature range 18°C to 25°C ± 0.5°C
- Relative humidity range 30% to 60%
- Containment up to BSL 2
- Dedicated autoclave in an adjoining vestibule room.
- Access-restricted to personnel trained in the handling of BSL-2 material.
- Fresh air supply >260 m³/hour
- >25 room volume air changes per hour

Analysis of biological products' performance ex device

The lab space will perform inhaled characterization tests such as aerodynamic particle size measurement and emitted dose measurement.

Samples will be actuated/nebulized under controlled temperature and relative humidity conditions, recovered from the collection apparatus and prepared for quantitative analysis within the space. Sealed vials/plates etc. will then be transported to the appropriate Instrumentation for analysis.

Examples of techniques offered include:

- UV/Vis Spectroscopy (e.g. A280), Size Exclusion Chromatography, HPLC systems using CAD detection, CE-SDS etc.

One stop analytical services

Our dedicated BioPharm department advises and supports the Inhalation team for a wide variety of other techniques not listed previously, and a variety of speciality and support teams who can enhance the journey of your product from concept to the patent.



Offering deployment and timing

Late 2024: Traditional Controlled Temperature and Humidity laboratory space for Small Molecules

Early 2025: BSL-2 ready room

Have a biological molecule under development for delivery via the inhaled route? Talk to our team to learn how you can become one of the first to use our new lab space's full capabilities.



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

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