

## GMP Labs

## Customized assay development and complex testing for two inhaled drugs

### Summary

PPD™ Laboratory services GMP Lab leveraged leading-edge instrumentation and high-quality talent to develop customized assays and conduct complex testing for two different inhaled drug-device combination products.

### Background

When an asthma and chronic obstructive pulmonary disease (COPD) patient receives an inhaler containing a new combination medication, the last thing they want to worry about is the potency of the medication and if the device will deliver the right dose when needed. Data proving the medicine's stability and effective delivery are critical pieces of the NDA submission for a novel drug in a pressurized metered dose inhaler (pMDI).

Our client was in the development phase for two different but related novel drug combination products requiring two NDA registration stability programs off-set by approximately 12 months. Stability studies are an inherent part of any new product development process providing evidence on how the quality of a drug product varies with time under the influence

of various environmental factors (temperature, humidity, light), and establishing a retest period and/or a shelf life. When the drug is delivered to the lungs via an inhaler, the device must also be tested for additional factors including uniformity of dosing, drug particle size, drug potency and purity along with product reliability after being subjected to different device storage conditions.

Our client needed to find a reliable laboratory partner that had the expertise and instrumentation needed for this type of testing, the capacity and depth of experience to develop the methodologies and the ability to ramp up two large complex projects under tight and somewhat overlapping timelines. Partnering with PPD GMP lab services allowed the sponsor to tame this enormous task and generate the necessary data needed by the health authorities to register their new drugs. Our team's extensive depth of knowledge in testing and flexible capacity when managing multiple workstreams simultaneously, kept these large projects on schedule and within budget.

## Objective

Our client needed methodologies developed and testing completed for two different inhaled drug products to generate product characterization and stability registration data for their new drug applications. Both combination products had enormous and complex testing requirements:

- Develop and validate methodologies and finalize testing protocols in conjunction with our client
- Device/apparatus testing to ensure product delivery and device storage robustness
- Execute commercial product testing in both the U.S. and EU for the approved drug(s) once on the market
- Stability testing on over 250,000 units pilot and full-scale registration batches data used to establish shelf-life

## Challenges

The requirements for these studies posed some unique challenges:

- Accelerated ramp up time needed to meet aggressive timelines
- Large amount of lab space, including environmentally controlled laboratories containing specialized equipment for aerosol product characterization testing
- Considerable ICH storage capacity for longer term stability studies including some in the EU
- Specialized expertise for supporting complex pMDI performance testing
- Ability to scale up personnel effectively by leveraging immediate talent pool and hiring and training on complex methodologies. Product A required growing from 8 to 24 full time equivalents (FTEs) over four months. Product B ramped up to 21 FTEs in two months then up to 40 FTEs in another four months.

## Strategy

The client selected us as its partner based on proven expertise managing and conducting the required testing along with the lab's large capacity, immediate talent pool, high-quality standards and the ability to begin work with minimal lead time and oversight.

Once on board, we leveraged our extensive experience providing similar services to a multitude of other companies (performing hundreds of large studies; millions of samples over the past 20 years). Our depth of knowledge allowed us to understand the project's magnitude and the potential pitfalls and proactively modify processes to avoid possible problems while maintaining sample and data integrity. We ramped up personnel by utilizing internal resources and internal subject matter experts. Our nearly 450,000 square feet of GMP lab space in Middleton, Wisconsin, and Athlone, Ireland are equipped with the necessary storage space, environmentally controlled labs, and equipment redundancies which allowed the work to begin with minimal lead time.

## Results

PPD GMP lab services rapidly built up the first project team with joint oversight and developed a plan prior to the start of the testing to anticipate the growth for the second product without delay. We hired new scientists and cross-trained existing scientists to support the testing of our client's products.

The first product ramped up the capacity to 24 dedicated FTEs. Product testing was completed and, stability data evaluated and reported to the sponsor on time for their NDA submission. The NDA has now been approved. Ten FTEs remained on the project for the execution of the commercial testing, while 14 FTEs transferred over to the ongoing second project. This second combination product, which had larger and more complex testing needs, ramped up to 40 FTEs.

Partnering with our PPD GMP lab services provided harmonized data which was sufficient for both U.S. and EU registration. In addition, working with an experienced partner allowed our client to focus on compiling and reporting the volumes of data while continuing to work to identify other new products and therapies to develop. In addition, our client maintained focus on ensuring patients are provided a high-quality, safe product.