# A Focus on Inhalation: Integrated Product Development Services

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Vectura integrates formulation, device, and development capabilities to offer a broad range of services to help customers bring inhaled medicines to market. With more than 20 years of experience focused on inhaled product development, the company's track record offers customers confidence in Vectura as a trusted development partner; since 2012, Vectura's formulation and device technology have contributed to the success of 11 inhaled medicines, launched by partners and licensees, generating \$10 billion in sales and used by 9 million patients worldwide.<sup>1</sup>

## From Pre-clinical Development to Commercial Scale-up

Vectura offers comprehensive services from the pre-clinical stage of development, when customers are looking to overcome complex inhaled formulation challenges, select a delivery device, and move quickly to the clinic. With expertise in powder and liquid formulations, as well as a portfolio of proprietary device and formulation technologies, Vectura can help customers developing a wide range of small molecules, biologics, and complex combinations.

As products progress through the clinical development phases, customers require greater dosing flexibility, and confidence in process scalability, as well as robust, commercial-ready delivery devices. Vectura's integrated approach ensures these key considerations are designed into a customer's program, allowing seamless scale-up from laboratory to pilot scale and through to commercial scale, enabling effective transfer to commercial manufacturing.

Being able to provide customers with a single partner for formulation and device expertise from early development to late-phase clinical trials and beyond offers real benefits in terms of continuity, shortened timelines, and reduced costs.

#### The Right Delivery Device?

No two development programs are the same, and many factors influence the selection of the most appropriate device, including the development stage, technical considerations, and patient/disease-state characteristics. In early development, a unit-dose capsule or blister device, or a nebulizer, may offer benefits in terms of speed and cost, while a multi-dose dry powder inhaler (DPI), pressurized metered dose inhaler (pMDI) or nebulizer may be required as a commercial-ready platform to support a later-phase program.

Vectura has development expertise across a range of technology platforms, including unit-dose and multi-unit dose DPIs, pMDIs, and smart nebulizers. This allows a "device agnostic" approach to best meet the needs of the customer, their development program, and ultimately, the patient.

Vectura's proprietary DPIs are derived from a commercially-validated platform, with a range of user interfaces and payload volumes, giving customers confidence of performance and a proven regulatory track record.

The company's breath-actuated nebulizers with guided inhalation have been developed to improve lung delivery, with the aim of achieving better clinical outcomes and/or shortened treatment times.

pMDIs remain an important option for many patients, and all the device components have important roles in determining characteristics of the aerosol and drug delivery to the lung. Vectura's extensive expertise in pMDI development can help customers developing a new product or optimizing the formulation and device performance of an existing product.

### Supporting Development Success

With extensive analytical testing facilities and equipment, Vectura's large, experienced group of analytical scientists can undertake the comprehensive array of test methodologies and physical properties characterization required for inhaled products, as well as stability studies and device verification testing.

Crucial to any inhaled program's success is navigating the complex regulatory requirements. Vectura's medical, regulatory, device vigilance, and pharmacovigilance teams can support programs and help ensure the smoothest path to product approval. Vectura offers particular expertise in global regulatory strategies and submissions for both new chemical entities and generics, as well as providing regulatory support for medical devices and combination products.

### The Next Generation of Inhaled Medicines

Inhalation continues to be an important route of administration for both respiratory and non-respiratory product development. Optimizing drug formulation and delivery device development can unlock the potential for innovative inhaled medicines that can revolutionize patients' lives. Vectura is at the forefront of integrated drug and device development, and helping customers to deliver the inhaled therapies of the future.

If you would like to find out how your inhaled development program could progress with Vectura's capabilities, contact enquiries@vectura.com.

#### Reference

1. Evaluate Pharma; internal estimates, 2018.



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