# INHALATION AND NASAL DEVELOPMENT AND MANUFACTURING SERVICES


*Recipharm offers inhalation and nasal product development services in compliance with regulatory guidelines from the ICH, EMA and FDA.*

At Recipharm we support New Drug Applications (NDA), 505(b)(2) and generic pathways (ANDA). Our dedicated team for development of inhalation formulations supports the following dosage forms for new chemical entities (NCEs) and active pharmaceutical ingredients (APIs):

- Pressurised metered dose inhalers (pMDI)
- Dry powder inhalers (DPI)
- Soft mist inhalers
- Nebuliser solutions
- Unit dose and multi dose nasal sprays
- Nasal aerosols and powders

## Particle engineering technologies

Our scientific team uses spray drying technologies to generate particles suitable for inhalation. We offer a variety of methods to analyse particle size, including:

- Laser diffraction
- Light obscuration
- Microscopy

## Preformulation

We provide the following services for drug candidate selection and characterisation:

- Salt selection
- Polymorphism evaluation
- Amorphous content determination
- Physical and chemical stability evaluation and degradation pathway identification
- Solubility profile in aqueous/organic systems and HFA propellants
- Excipient compatibility

## Formulation development

Our product development group has extensive experience in formulating suspensions, solutions and dry powder blends. For inhalation and nasal dosage forms we offer:

- Dosage form selection
- Formulation selection and optimisation
- Aerosol characterisation
- Reverse engineering (e.g. Q1 and Q2 matching of generics)
- *In vitro* bioequivalence studies

## Device selection and evaluation

As part of product development, we offer selection and evaluation of suitable devices and components, including:

- Valves, cans, actuators, and spacers for pMDIs
- Capsule, blister and reservoir based DPIs
- Jet and vibrating mesh nebulisers
- Pumps and containers for nasal sprays
- Our joint venture Resyca offers a unique soft mist delivery platform for inhalation and nasal applications

## Product characterisation

We provide analytical method development, validation and testing services to support all phases of product development, from feasibility to regulatory submission and life-cycle management. This includes supporting for early phase product feasibility development, process scale-up, clinical batch manufacturing, release, stability, CMC stability and product characterisation studies.

- Emitted dose and dose content uniformity
- Delivered dose by breathing simulation
- Aerodynamic particle size distribution by cascade impactor
- Spray pattern and plume geometry

## Stability testing

We provide product release and stability testing services for inhaled dosage forms. Our cGMP stability storage facilities with back-up power supply include:

- 21 CFR part 11 compliant walk-in and reach-in chambers
- Real time, accelerated and stress conditions per ICH guidelines

## Process development, scale-up and tech-transfer

Our engineers can develop and optimise manufacturing processes to meet a variety of project requirements. We offer:

- One and two-step pressure filling techniques for pMDIs
- Blending and device filling services for DPIs
- Formulation manufacturing of inhaled aqueous dosage forms
- Tech-transfers of manufacturing processes

## Batches for GLP and cGMP studies

We offer full-scale batch production of inhaled drug products for:

- GLP manufacture for pre-clinical and toxicology studies
- cGMP manufacture of pivotal batches, clinical trial materials and commercial products

## Our facilities include:

- Commercial manufacturing capabilities for pMDI and nasal spray
- DPI manufacturing suite, ready for customer's bespoke equipment
- Pilot plant, including small scale pMDI manufacture (directly scaleable to commercial manufacturing)
- Seven clinical and development suites with dedicated team of scientists and engineers
- State-of-the-art quality control laboratories
- Extensive suite of ICH stability cabinets
- In house microbiology laboratory

Recipharm

## Case study

A pMDI development programme was initiated for a customer in response to the reformulation requirements imposed by the Montreal Protocol. Our R&D product development contributions included the HFA formulation development, selection of device components as well as scale-up and tech-transfer of the manufacturing process. A New Drug Application (NDA) was submitted for the product in less than five years. The product, Xopenex® HFA, received regulatory approval within a year.

*Note: Xopenex® is a registered trademark of Sunovion.*

# Recipharm Inhalation Solutions™

Recipharm is a leading CDMO in the inhalation space, with a long history in inhalation drug product and device development and manufacturing. Recipharm offers an end-to-end service for inhalation drug products and devices from early stage development through to commercial manufacturing for MDIs, DPIs and nasal sprays.

Delivering market leading design, development, and the manufacturing of drug delivery devices to the global pharmaceutical market, in conjunction with Bespak by Recipharm, the integrated CDMO can comprehensively cater for, inhaler, nasal and auto-injector projects, as well as providing access to a team of experts with decades of expertise that allows them to manage complexity and accelerate routes to market. These expertise form part of Recipharm's Inhalation Solutions™, an end-to-end solution spanning early phase development to commercial manufacture.

As a global CDMO, Recipharm is at the forefront of global compliance requirements for inhalation products.
For more information, please visit: recipharm.com

**About Recipharm:** Recipharm is a leading contract development and manufacturing organisation (CDMO) headquartered in Stockholm, Sweden. We operate development and manufacturing facilities in France, Germany, India, Israel, Italy, Portugal, Spain, Sweden, the UK and the US and are continuing to grow and expand our offering for our customers.

Employing around 9,000 people, we are focused on supporting pharmaceutical companies with our full service offering, taking products from early development through to commercial production. For over 25 years we have been there for our clients throughout the entire product lifecycle, providing pharmaceutical expertise and managing complexity, time and time again. Despite our growing global footprint, we conduct our business as we always have and continue to deliver value for money with each customer's needs firmly at the heart of all that we do. That's the Recipharm way.

For further information please contact:
Shabbir Mostafa, Key Account Director for Inhalation
+44 7753 469 835 shabbir.mostafa@recipharm.com

recipharm.com