At Recipharm we support New Drug Application (NDA), generic and 505(b)(2) regulatory pathways. 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)
- Nebuliser solutions and suspensions
- Nasal solutions and suspensions
- Nasal aerosols and powders

### Particle engineering technologies

Our scientific team uses jet milling and spray drying 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

### Formulation development

Our inhalation product development group has extensive experience in formulating suspensions, solutions and dry powder blends. 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

Recipharm offers inhalation and nasal product development services in compliance with regulatory guidelines from the ICH, EMA and FDA.
Recipharm can develop and deliver a variety of inhalation dosage forms including:

- MDIs
- MDI cannisters and valves
- Nasal sprays
- DPIs
- Nebuliser and face mask
- Capsule based DPIs
- Nebuliser
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

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.
- Emitted dose and dose content uniformity
- Delivered dose by breathing simulation
- Aerodynamic particle size distribution by cascade impactor
- Spray pattern and plume geometry
- Impact of flow rate or orientation
- Device cleaning studies and simulated patient testing
- Excipient assays and drug related impurities

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:
- Cold filling, and one and two-step pressure filling techniques for pMDIs
- Blending and device filling services for DPIs
- Formulation manufacturing of inhaled aqueous dosage forms
- Technical transfers of manufacturing processes

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.

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 5,000 people, we are focused on supporting pharmaceutical companies with our full service offering, taking products from early development through to commercial production. For over 20 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.

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