

# PILOT PLANT



## Inhalation development and manufacturing for early and late-stage clinical supply

*Recipharm Inhalation Solutions™ offers comprehensive contract development and manufacturing solutions for early and late-phase clinical supply from our stand-alone pilot plant as part of our end-to-end inhalation offering.*

*Our pilot plant comprises seven independent suites totalling approximately 900m<sup>2</sup> of manufacturing space to enable GMP supply of investigational medicinal products (IMPs), with a focus on nasal sprays and inhalers.*

### Beyond our pilot plant

We can support product development and transition to commercial supply with processing equipment directly scaleable to the commercial processes within our manufacturing facilities. Our dedicated team of experienced engineers, technical experts and project managers collaborate closely with our inhalation product development teams to provide flexible, dynamic solutions for our customers to deliver new drug products from early stage to clinical supply through to full scale GMP manufacture.

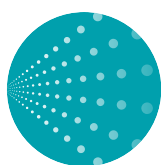
### Our track record

At Recipharm we have successfully developed robust and reproducible manufacturing processes for customers within tight timescales. In one case our proposal for pressurised metered dose inhalers (pMDI) process development reduced one customer's critical path to market by more than five months.



## At Recipharm we offer:

- ▶ IMP licence (issued by our national regulatory agency, the MHRA) allowing us to manufacture and supply products for clinical studies
- ▶ GMP pilot plant facility with seven manufacturing suites, each suite having its own change room, airlock and wash bay
- ▶ Aerosol pMDI processing equipment directly scaleable to commercial process
- ▶ Ability to accommodate customer specific bespoke manufacturing equipment, for example for dry powder inhalers (DPIs), with installation and qualification completed by a dedicated team of experienced scientists and engineers
- ▶ Process development and optimisation for clinical supply and commercial manufacture
- ▶ Analytical method development and validation
- ▶ Quality control (QC) release and ICH stability testing, storage and shelf-life setting
- ▶ Microbiological testing including preservative efficacy testing
- ▶ Cleaning method development and verification
- ▶ Extractables and leachables method development



## 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 Bepak 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](http://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:

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