

Inhalation



A BREATH OF
EXPERTISE



From the concept idea to large scale manufacturing, we're the utmost holistic partner to develop your inhalers. We help our customers succeed in the sprint to market with their formulations targeting the inhalation treatments. We also are an active contributor to the scientific community and we strive to consider in our research evolving trends in inhalation and in patient needs, as well as increasing interest to digital and sustainability related factors.



**We help our customers
succeed in the sprint
to market with their
formulations targeting
inhalation diseases.**

Nemera designs, develops and manufactures inhalers to treat respiratory diseases. We have successful track records with key Dry Powder Inhalers (DPI) and pressurized Metered Dose Inhalers (pMDI) on the market.

Our inhalation products

**TAILOR-MADE
FOR CUSTOMERS**



Inhalers

At Nemera, we are your holistic partner to develop and manufacture patient-centric inhalers.

A unique partner



**Worldwide pMDI & DPI
top pharmaceutical
references**



**Supply reliability &
flexibility**



**Long-standing
expertise in usability
& regulatory
landscape**

Inhalers

From early-stage concept development to manufacturing we are truly a holistic partner in inhalation.

With a long-standing know-how in inhalation delivery, we are today the leader in the Dry Powder Inhalers (DPIs) manufacturing business.



Our expertise covers:

- Capsules DPI
- Blister multidose DPI
- Reservoir multidose DPI

A DPI can be preloaded with the medication(s) or loaded by a patient with capsules as the dose-holding system, prior to use. In DPIs, a patient's breathing capacity is critical in generating the desired therapeutic outcome as the dispersed powder needs to be broken into particles of the right size and be deposited appropriately into the lungs.

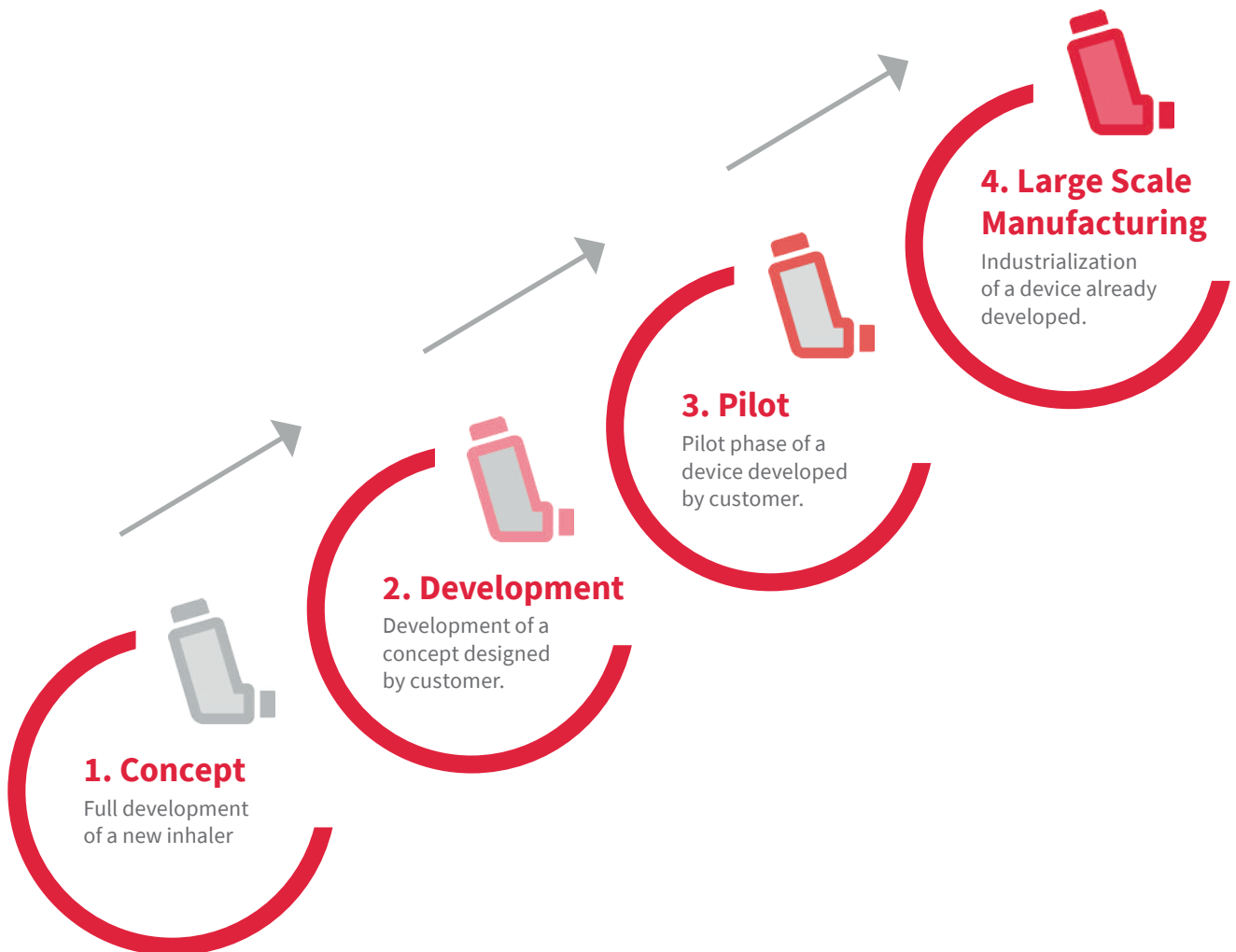
Our expertise in pMDIs covers:

- Dose indicators
- Dose counters
- Actuators for a pMDIs

A pMDI is a device used to deliver medication into the lungs. It is composed of a pressurized canister of medication that fits into a mouthpiece. In most instances, a dose of medication is released into the lungs by pushing the canister into the mouthpiece. Breath-activated pMDIs release medication automatically when the patient inhales.

From idea to reality, we take care of your inhaler.

Over 20 million patients rely everyday on inhalers manufactured by Nemera.



Our integrated combination product services

ANALYTICAL SERVICES & DESIGN VERIFICATION

Our team of experts is dedicated to ensuring the safety, efficacy, and compliance of your combination product including:

- Comprehensive analytical services and design verification
- Advanced testing methods tailored to your formulation and active ingredients
- Testing method development, administration, and reporting
- Performance and integrity verification of your device and drug product
- Adherence to global standards throughout the process



HUMAN FACTORS & USER EXPERIENCE MANAGEMENT

We provide exceptional support for combination products across diverse regulatory pathways, device types, and patient populations for global markets including:

- Human Factors program strategy and risk management
- Formative/summative testing (design validation) administration
- Human Factors Engineering documentation for regulatory submissions
- Enhances safety, usability, and overall satisfaction of your combination product.
- Aligns with FDA Human Factors Engineering guidelines and ISO 62366 standards
- Extends beyond the device to include instructions for use, packaging, and training programs to optimize user adherence and engagement



REGULATORY STRATEGY & SUBMISSION AUTHORIZING

We provide tailored strategies and support for all stages of the regulatory process, including:

- Development of a comprehensive regulatory strategy including pre-market to post-market support
- Guidance on FDA regulations and international standards (ISO 14971, ISO 10993)
- Expert support in regional regulatory guidelines
- Assistance in authoring and compiling regulatory submissions, including: Premarket Approval (PMA), 510(k) submissions, CE marking documentation, and Notified body opinion support
- Accelerated submission processes, drawing from, our experience in over 54 markets



Our Inhalation featured services

INTEGRATED SERVICES FROM DEVICE SELECTION TO GMP MANUFACTURING

We provide comprehensive end-to-end services for your device and combination products. Our expertise spans front-end innovation, device development, and clinical and commercial manufacturing. We customize your patient-centric solutions to meet specific needs during development.



DEVICE VERIFICATION TESTING FOR DPI AND PMDI

Defining test methods and specialized fixtures to assess performance, functionality, and safety, ensuring compliance with regulatory standards. For example Drug dispersion testing, Dose uniformity testing, Mouthpiece Functionality, among others.

AERODYNAMIC PARTICLE SIZE DISTRIBUTION TESTING

Measuring particle size distribution based on specific customer's formulation to ensure optimal drug delivery to the respiratory tract, including Inhalation flow rate, flow resistance as well as spray pattern, spray plume and front velocity.



