Kindeva
DRUG DELIVERY
Manufacturing More Tomorrows™

Pulmonary & Nasal Delivery

Innovative products, unrivaled expertise

Getting your pulmonary & nasal drug-device products successfully to your patients takes deep collaboration, renowned experts, and ever-expanding technical know-how. Since creating the first metered-dose inhaler (MDI), Kindeva has led the ongoing evolution of pulmonary & nasal drug delivery, supporting the development and manufacturing of a full range of solutions for respiratory and systemic diseases from ideation through commercialization, optimizing first-in-human timelines and maximizing drug-device product success.

Your optimal device

Determining the right device for storing and delivering your drug is a matter of science. Leading with our customized approach, Kindeva determines the best option for your therapy by following a detailed process, offering both device-agnostic and turnkey solutions.

CUSTOMER INPUTS
Molecule | Existing Data | Existing Product | Objectives | Questions

FORMULATION & DELIVERY TECHNOLOGY EXPERTISE
Proven Development Processes

SYSTEMATIC ASSESSMENT FRAMEWORK

TECHNICAL STARTING POINTS

- **DOSAGE (PAYLOAD)**
  How much mass per dose for therapeutic impact?
- **PHYSICAL AND CHEMICAL PROPERTIES**
  E.g., drug solubility in water (logP), ethanol, and/or propellant

REFINEMENT
Guide Delivery Technology Selection | Specific Device & Design

- **PRE-FORMULATIONS**
  - Solubility
  - pKa
  - Chemical Stability
  - Physical Properties/Stability
  - Viable Excipients/Additives
- **USE REQUIREMENTS**
  - Environment of Use
  - Human Factors
  - Frequency of Dose
  - Urgency of Therapeutic Need
  - Clinical Requirements
- **PATIENT**
  - Indication
  - Demographic
  - Physical Capabilities
  - Physical Constraints
  - Dosing Regimen
- **BUSINESS CASE**
  - Cost/Pricing
  - Speed to First-in-Human Data
  - Speed to Market
  - Legal/Freedom to Operate
  - Regulatory Guidance/ Requirements
  - API/Drug Substance Availability

SELECTION OF DELIVERY TECHNOLOGY

pMDI | DPI | SMI | Nebulizer | Nasal sprays

Our pulmonary & nasal platform technologies

Pressurized metered-dose inhaler (pMDI)

- Deliver your drug directly to the affected area
- Dose typically up to 2mg
- Local delivery, therefore lower side effects
- Noninvasive
- Avoid first-pass metabolism in the liver
- Potential for improved bioavailability
- Multidose platform (up to 200 actuations)

Pulmonary & nasal dry powder inhaler (DPI)

- Improved stability for biologics/ macromolecules versus solution formulations
- Efficient dose delivery with stable, dispersible, and flowable powders
- High payload
- Room temperature stability
- Single or multiuse devices offering doses of 50mg or more per actuation

Soft-mist inhaler (SMI)

- Easier to breathe in regardless of patient's grip strength or lung capacity
- Multidose (up to 60) containers that require no cleaning
- Aqueous formulation of small and large molecules

Nebulizer

- Aqueous formulations, delivered using off-the-shelf nebulizers
- Low cost
- Silent and discreet
- Easy-to-use unit dose, reusable device
- Quick to the clinic
- High payload and increased lung deposition

Nasal Spray

- No inhalation effort, assisting with treatment of incapacitated patients
- Direct delivery to CNS
- Delivery route minimizes first-pass metabolism
- Aqueous and non-aqueous formulations
- Full capability from vial filling through actuator assembly, labeling, blister packaging, and cartoning
- Preformulation through commercial launch including analytical method development and validation, raw material and finished product release testing, and full microbiological capabilities

Going green

As the industry shifts toward green propellants, Kindeva can keep you ahead of the curve with pilot scale lines and two new cGMP manufacturing lines capable of filling inhalers with HFA-152a and/or HFO-1234ze, which have 90% and 99.9% lower Global Warming Potential (GWP) than current options. Clinical product supply is already available and with a full opening planned for 2025, we will offer some of the first commercial lines using these propellants in the world.

Exceptional products start here

- Pressure and cold pMDI filling
- Lab-scale and commercial experience formulating stable products
- Formulations ranging from small molecules to macromolecules
- Particle engineering & raw material screening
- Phase appropriate method development & cGMP validation
- Globally minded regulatory approach and leadership
- Expert data analysis and interpretation
- Expert analytical method development
- Automated filling and packaging lines
- Micronization and powder handling technologies
- Small-to-large order packaging flexibility
- Proven track record

Pulmonary & Nasal Delivery

Bringing complex generics to market

Kindeva has a rich heritage in the generic medicine space, characterizing and developing equivalent products that extend access to more patients. One example is our launch of the first FDA-approved generic version of Symbicort®, Breyna™. We also developed a generic alternative to Seretide®, Sirdupla™, for launch in the U.K.

Why choose Kindeva

Unrivaled experts

As the creators of the first MDI, breath-actuated inhaler, CFC-free MDI, and CFC-free nasal MDI, we live and breathe your project, applying scientific excellence built on a history of innovation, industry publications, ongoing academic research, and more.

Expansive capabilities

Our world-class range of products, scope of therapeutic compound experience, and extensive array of delivery and development capabilities ensure unsurpassed solutions.

Focused facilities

Among our ten facilities, dedicated pulmonary & nasal services include:

Union City, CA

- Inhalation drug delivery (IDD) development; particle engineering; dry power formulations; liquid formulations; offers fast track to first clinic

Northridge, CA

- pMDI pressure and cold filling; packaging and on-site QC laboratory

Woodbury, MN

- Development laboratory with full range of capabilities including plume geometry, spray pattern analysis, extractables, and leachables; lab scale filling with any propellant (134a, 227ea, 152a, & 1234ze)

Clitheroe, U.K.

- pMDI valve, can, and sleeved can manufacture; supply of coated cans and componentry
- Low-GWP propellant friendly component development

Loughborough, U.K.

- pMDI pressure and cold filling; packaging and on-site QC laboratory; clinical supply; nasal; pilot scale filling with any propellant (134a, 227ea, 152a, & 1234ze); development laboratory with the full range of capabilities from feasibility to commercial scale

Lexington, KY

- Nasal spray drug product formulation, filling, assembly, labeling, and packaging; preclinical, clinical, and commercial needs; unit-dose, bi-dose, and multidose options; DEA registration for the handling of Class II-IV controlled substances

Proven track record

With over a century of expertise under our belt, we know what it takes to achieve success in the drug-device combination product marketplace, and our informed, holistic approach helps us properly pivot in the face of emerging issues.

1956 Invented first metered-dose inhaler

1989 Invented first breath-actuated inhaler

1995 Invented first CFC-free MDI

2012 Launched first CFC-free nasal MDI

2023 Launched first FDA-approved generic version of Symbicort®, Breyna™

2025 Commercial green propellant line (1234ze & 152a)

Our integrated approach

Kindeva protects timelines and minimizes risk by moving tasks between our ten state-of-the-art cGMP facilities and interconnected departments, ensuring a smooth transfer of information and a clear, informed path from ideation to commercialization.

Regulatory expertise

We stay up to date on regulatory guidelines across the globe, ensuring your submissions are always in alignment.

Analytical specialty services

With capabilities including phase appropriate methodology, complex methodology validation, extractables, leachables, and more, we *offer a wide range of analytical support*.

Industry presence

We maintain a robust presence through industry organizations such as IPAC, IPAC-RS, EPAG, PBOA, Medical Alley, DDL, and DCAT.

Ongoing growth

Your product benefits from an ever-expanding knowledge base at Kindeva. Along with collaborative efforts undertaken with a variety of partners, we continue to bring new capabilities in-house, adding differentiated expertise that bolsters our solutions and expands the possibilities of what we offer, including work on liquid and dry-powder format small and biological molecules for local and systemic treatments, lung surfactant for neonatal delivered via nCPAP, and gene therapies with live virus and organism and RNAi/mRNA for lungs and cardiovascular.

Your partner for combination product success

With Kindeva, collaboration is key. We work with you at every step, tailoring solutions to your specific challenges, so no matter your starting point or the size of your project, our proactive, informed partnership delivers high-quality pulmonary & nasal products on time, in full, every time.

Your therapy is a force for good.
Our expertise brings it into the world.

COMBINE FORCES WITH KINDEVA

Kindeva Drug Delivery is a global contract development and manufacturing organization focused on drug-device combination products. We develop and manufacture products across a broad range of drug-delivery formats, including pulmonary & nasal, injectable, and transdermal. Our service offerings span early-stage feasibility through commercial scale drug product fill-finish, container closure system manufacturing, and drug-device product assembly. Kindeva serves a global client base from our state-of-the-art manufacturing, research, and development facilities located across the U.S. and U.K.