

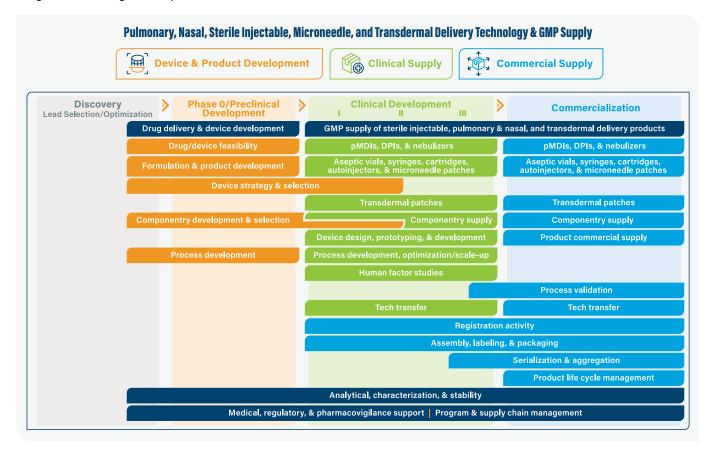
## **Your Full-Service Powerhouse CDMO** Bring high-quality products to your patients around the world

Bring high-quality products to patients around the world with comprehensive CDMO services that accelerate your timeline while minimizing risk. A global force in development and manufacturing, Kindeva meets all your challenges with innovative solutions backed by more than a century of know-how, large-scale capacity, and cutting-edge technology platforms.



## Services for every stage

At any stage of your process, collaborating with Kindeva means accessing a robust skill base informed by the entire organization. Whether you're starting off in discovery or already in commercialization, you gain reductions in time, cost, and risk from our integrated knowledge and capabilities.





**75** inventions in use

years of

product firsts

commercial devices

shipped annually

~ 111

## **Device & product development**

In your program's early stages, collaboration with our unrivaled experts yields tailored solutions for developing a stable, viable drug formulation, and our extensive technical capabilities ensure you have an effective delivery device with optimal shelf life. From feasibility to process development, Kindeva works with you, customizing every service to your unique product to build your program from a solid foundation that complies with the appropriate standards and regulations

# **Clinical supply**

Keep pace with evolving needs and your program goals for pulmonary, nasal, sterile injectable, microneedle, and transdermal therapies with our expansive hands-on experience. Our customized strategies encompass device design, prototyping, human factor studies, scale-up, and more.

# **Commercial supply**

Bring high-quality products to your patients around the world with Kindeva's comprehensive, scalable development and commercialization capabilities, guided by our deep knowledge of device and drug quality system requirements. From commercial supply and process validation to assembly, labeling, packaging, serialization, and aggregation, we provide full product life cycle management. Each solution is backed by proven regulatory know-how and supported by manufacturing and R&D facilities with industry-leading capacity.

# Why partner with Kindeva?

- Creators of the MDI, autoinjector, and drug-in adhesive patch
- 100+ years of experience
- 60+ years of pMDI experience
- 60+ years of autoinjector experience
- 50+ years of transdermal experience
- Small & large molecule development

- 10 manufacturing and R&D facilities
- ~1M ft<sup>2</sup> cGMP footprint
- ~100M commercial devices shipped annually
- · Aseptic injectable fill-finish capacity available now
- Low-GWP propellant capabilities



#### **Expert regulatory support**

With decades of experience in global regulations and standards, Kindeva's regulatory services provide confidence throughout the life cycle of your product with skilled compliance, strategy, and global operations support. <u>See how we streamline your regulatory pathway</u>.



# Sterile fill-finish

We have aseptic injectable fill-finish capacity available now at large commercial, niche commercial, and small clinical scales in a fully Annex 1 compliant facility. By servicing sterile fill, device manufacture, and final assembly in one geographic location, we maximize efficiency and minimize your carbon footprint.

### Our new injectables fill-finish facility



Our engineer-designed facility in Bridgeton, Missouri, greatly expands our capabilities:

- 155,000 ft<sup>2</sup>
- Syringe, cartridge, and vial filling
- 3 fully isolated high-speed fillers (Phase I)
- Each suite operates independently
- Utilities to support up to 8 filling suites (Phase II+)
- 13,000 square feet of uncommitted space in the existing footprint for dedicated/custom aseptic operations (Phase II+)
- Leading technology: isolators, ionized hydrogen peroxide, disposable formulation tank bagging system, automated/integrated PUPSIT filter testing
- Cold storage
- DEA Class II-V, controlled substance
- Annex 1 compliance with every line
- Designed for max efficiency, compliance, and patient safety



# **Pulmonary delivery**

No matter your molecule, we develop formulation, device, and manufacturing solutions that effectively meet your challenges. We bring the right product to the right patients, with expertise across delivery platforms.



## Nasal delivery

We offer horizontally and vertically integrated capabilities for nasal delivery platforms, backed by a proven legacy of U.S. and European product approvals.





### Join the green revolution

Kindeva is leading the charge toward greener inhalers with plans to open one of the first commercial green propellant lines using low-GWP options and reducing the associated environmental impact of pMDIs by 90% or more.



### **Microneedle innovation**

Designed for accurate dosing and reliable delivery of liquid or solid vaccines, peptides, proteins, biologics, and small and large molecules, our microneedle platforms have the potential to offer:

- Enhanced immunogenicity
- Elimination of cold-chain storage
- Room temperature stability
- Greater efficacy
- PK improvement

- Faster onset of action
- Better compliance & adherence
- At-home administration
- Elimination of needle phobia



## **Transdermal delivery**

From patches and pharmaceutical- and medical-grade cGMP coating capabilities to tech transfers, we help you deliver effective transdermal therapies to your patients across the globe. We partner with you to create tailored drug-in adhesive patches, gel patches, and other therapies in cGMP facilities.

### Deliver your product to the patients who need it

As a full-service CDMO, Kindeva helps optimize your progress at any stage of development, manufacturing, and commercialization. We offer comprehensive solutions for a broad range of large and small molecule and an ever-expanding selection of delivery methods, all backed by an unparalleled history and unrivaled innovation that accelerate your product program.

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

**COMBINE FORCES WITH KINDEVA** 

Kindeva Drug Delivery is a leading global powerhouse CDMO for sterile injectable, pulmonary, nasal, transdermal, and intradermal finished dose. We are committed to manufacturing more tomorrows for our customers, colleagues, and patients around the world. We deliver unrivaled expertise across development, manufacturing, and comprehensive analytical services for a broad range of drug-delivery formats. Through strategic investments in cutting-edge technology, we proactively tackle critical industry challenges, including expanding aseptic injectable fill-finish capabilities and leading the way in green propellant initiatives. Combining forces with a diverse global client base, Kindeva operates state-of-the-art manufacturing, research, and development facilities across the U.S. and U.K.

