

## **Our New Injectable Aseptic Fill-Finish Facility** Bringing aseptic manufacturing excellence to Bridgeton, MO

Our new aseptic injectable fill-finish site raises the standard for vials, cartridges, and syringes filling with an initial annual capacity of 100M+ units. We designed every aspect of this facility around automation and Annex I compliance, backed by a \$150M investment and our extensive expertise in combination product development and manufacturing.

Kindeva is one of only a few CDMOs in the world capable of servicing sterile fill, device manufacture, and final assembly in one geographic location. The integrated capabilities of our Bridgeton, MO, facility showcase our commitment to fulfill your product requirements.





### **Built for the future**

# Our Bridgeton facility is built from the ground up to address today's most pressing challenges:

- DEA Class II-V, controlled substance approval
- Facility design principles enable patient safety and Annex I compliance (3 fully isolated high-speed filling lines with utilities for up to 7, automation, unidirectional flow, etc.)
- 1 microBatch isolated filling line which accommodates
  < 2,500 batch sizes</li>

# **Unrivaled filling capacity**

#### Bridgeton can currently fulfill the following for your product:

- 1mL & 3mL nested syringes
  20-40 million units/year
- 11mm & 13mm Cartrix custom syringes, cartridges
  - 13-20 million units/year
- 300/min line speed for cartridges and syringes

2R & 10R vials (Groninger line)

- 20-40 million units/year

- In the future, you will also benefit from capabilities for:
- 3-50mL nested syringes
- 2R-50R nested vials

- 8.6-18.2mm diameter bulk cartridges
- 1.5-10mL nested cartridges

400/min line speed for vials



# Why choose Kindeva for injectable fill-finish?

- 50+ years of aseptic fill-finish experience
- Veteran leadership with decades of injectable experience
- Ability to fill any currently available ready-to-use formats
- Device-agnostic approach to identify the best format for your therapy, whether vial, cartridge, or syringe
- Unparalleled degree
  of automation
- In-house, integrated capabilities
- Industry-leading efficiency through AI and automation



## Our key design principles

Kindeva is building the CDMO of tomorrow and our world-class aseptic injectable fill-finish facility is one example of this commitment to innovation. Through our focus on quality, scale, automation, and efficiency, we have created a site that is truly unique in the combination product manufacturing space. Through this new facility, we offer innovators small scale clinical and niche commercial to large commercial scale, assuring a proactive relationship and reliable delivery on your product's timeline.



### Quality

- Annex 1 compliance from day one, across every line; facilities just beginning the process can expect wait times of 16-18 months
- Protecting your product's quality and security with serialization and supply chain management



#### Scale

- Capabilities to support your product's entire life cycle
- Installed facility infrastructure scaled to support doubling of filling lines, offering rapid access to commercial cGMP manufacturing capacity



### Automation

- Built with enhanced engineering controls
  to minimize operator intervention
- Isolators and automated PUPSIT testing
- Substantial investment of time and resources to maximize your value



#### Efficiency

- Maximizing efficiency to save you time, money, and hassle
- Automation processes, modular filling suites, and rapid line changeover
- Minimizing knowledge transfers and reducing delays through integrated capabilities

## **Ready to achieve a new level of excellence?**

Unlock better quality and efficiency across your product's life cycle with a powerhouse CDMO partner. Our new facility in Bridgeton takes our injectable fill-finish capabilities to the next level; our facility design principles achieve best-in-class patient safety and Annex 1 compliance.

### **Discover Our Aseptic Injectable Fill-Finish Capabilities**

**COMBINE FORCES WITH KINDEVA** 

Kindeva Drug Delivery is a global contract development and manufacturing organization focused on drugdevice 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.

