A bridge to the future: Our world-class site in Bridgeton

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Kindeva

Introduction

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The pharmaceutical sector is witnessing a surge in demand for sophisticated biologics and biosimilar therapies, and other sterile injectables. The global sterile injectable contract manufacturing market is projected to grow from $16.17 billion in 2025 to $28.50 billion by 2030, at a compound annual growth rate (CAGR) of 12% [1].

Cutting-edge biologics are transforming disease treatment, creating an urgent need for scalable manufacturing solutions. GLP-1s are a key example of this, having evolved from diabetes treatments to significant weight loss solutions, driving substantial market demand. Their efficacy in weight reduction has redirected biopharmaceutical investment towards broader therapeutic applications beyond diabetes, marking a transformative shift in the pharmaceutical industry focused on metabolic diseases.

However, producing these sterile injectables is complex, governed by stringent aseptic and evolving regulatory standards requiring significant specialized investment. A common challenge is the fragmented approach of using multiple partners across development, drug substance manufacturing and fill finish. While seemingly flexible, this introduces substantial risks.

The hidden complexity and risks in sterile injectable manufacturing

Increased risk of contamination and errors:

Each transfer between development, drug substance manufacturing and fill finish introduces the potential for deviation.

Tech transfer inconsistencies:

Lack of alignment between formulation teams, process engineers and fill finish operators can lead to delays or reworks.

Potential for delayed timelines:

Coordination between multiple teams and vendors can risk production slowdowns and inefficiencies.

Regulatory complexity:

Multiple quality systems require multiple audits.

Supply chain disruptions:

The advantage of centralized inventory control and logistics planning is lost.

The bottom line is simple:

Fragmentation of processes reduces the ability to be proactive, flexible and hit deadlines. Missed deadlines impede the ability to bring high-quality, life-changing injectable therapies to patients faster and more reliably, as well as impacting the product's commercial viability.

This eBook explores how Kindeva's integrated sterile fill finish facility in Bridgeton addresses these challenges. Providing comprehensive sterile injectable drug manufacturing services all in one site, it offers a streamlined, efficient and reliable pathway to manufacture critical medicines.

In this eBook, you will learn about:

- The integrated capabilities of Bridgeton, MO, which eliminate the risks of fragmentation
- The breadth of projects that Kindeva can support
- Our continuous investment in the facility to ensure it meets today's demands and the needs of tomorrow
- The benefits of partnering with Kindeva

About us

Purpose-built for healthier tomorrows

Kindeva is a purpose-fueled, people-centric drug delivery CDMO dedicated to advancing your project, your ambitions and our industry. With a legacy of innovation and deep expertise in delivering sterile injectables, we serve as a trusted partner to pharmaceutical companies worldwide.

For us, fast-tracking healthier tomorrows starts with industry-leading drug delivery expertise. From clinical manufacturing to full-scale commercial production, we optimize every step to help bring life-changing therapies to patients faster.

Introducing Bridgeton

Our Kindeva Bridgeton facility is a key part of the support we can provide you in manufacturing more tomorrows for patients.

Boasting over 155,000 square feet of dedicated aseptic operations space, Bridgeton features state-of-the-art laboratories for rigorous quality control and formulation suites meticulously designed for precision and sterility.

The site includes almost 11,000 square feet of dedicated fill suites, which serve as the heart of our sterile manufacturing processes. It also encompasses 14,000 square feet of laboratory space, approximately 29,000 square feet of warehouse capacity and 14,000 square feet of expansion space to support future growth.

This infrastructure underscores our capacity to handle a diverse range of projects with uncompromising quality, meeting the demands of today and the possibilities of tomorrow.

155,000 sq.ft
of current Good Manufacturing Practice (cGMP) compliant aseptic operations space

11,000 sq.ft
of dedicated fill suites

14,000 sq.ft
of laboratory space

29,000 sq.ft
of warehouse capacity

14,000 sq.ft
of expansion space

Exceptional by design

The Bridgeton facility is engineered to provide a seamless and efficient pathway for your sterile injectable products, with key features to help you navigate obstacles, embrace opportunities and turn long-term possibilities into achievable milestones.

Scalability and versatility:

- Clinical trial batches to large-scale commercial manufacturing

Our facility can handle projects ranging from clinical trial batches and niche commercial productions to large-scale commercial manufacturing. This flexibility allows us to partner with you at any stage of your development and commercialization journey.

Integrated solutions:

- Integrated fill finish, product assembly and final packaging

We offer fully integrated capabilities across fill finish, product assembly and final product packaging, all within one geographic location. This streamlined approach minimizes complexity, reduces lead times, and enhances control over the entire manufacturing process.

Significant initial capacity with expansion potential:

- Fills 150 million+ units annually

The facility possesses an initial capacity to fill over 150 million units annually across a variety of container types, including vials, cartridges and syringes. Our infrastructure is strategically designed to support future growth, with 12,600 square feet of additional cleanroom space readily available for expansion. This capacity translates to the potential to positively impact the lives of millions of patients worldwide.

State-of-the-art cGMP compliance:

- cGMP compliant manufacturing

Our cGMP footprint incorporates the latest advancements in facility design principles. This ensures a robust and compliant manufacturing environment, adhering to the highest industry standards.

Controlled substance handling expertise:

- DEA Class III-IV approval

The Bridgeton facility can handle DEA Schedule II–IV controlled substances and is currently approved for Schedules III and IV, providing a trusted and reliable solution for your complex projects involving these critical medications.

Patient safety and Annex 1 focus:

- Annex 1 compliant

Our facility design principles are intrinsically linked to ensuring patient safety and facilitating compliance with stringent regulatory guidelines, including Annex 1. Every aspect of the facility is engineered to minimize risk and maximize product integrity.

Advanced filling technology:

- 4 high-speed filling lines

Featuring four high-speed filling lines for handling syringes, cartridges and vials. These are equipped with cutting-edge isolator technology, the facility also has utilities in place to support future line expansion. Incorporating automation, unidirectional flow, and other advanced features, our filling suites ensure accuracy, efficiency and the highest levels of sterility.

Support for specialist emergency preparation projects

For more than 60 years, Kindeva's global health security business unit (previously Meridian Medical Technologies) has been a trusted partner in global health security (GHS), providing essential medical countermeasures to protect those on the front lines.

From Bridgeton, we can provide essential medical countermeasures to protect those on the front lines. Governments, military organizations and emergency response teams in over 30 nations rely on Kindeva's strategic GHS expertise and life-saving solutions to prepare for and respond to public health emergencies and battlefield threats.

With Bridgeton's emergency preparedness support, we meet the demands of today to protect tomorrow.

Designed to advance your product and your ambitions

At the core of the Bridgeton facility is a fundamental design philosophy: To deliver speed, flexibility and unwavering compliance without any compromise. We understand the critical importance of timelines in drug development and commercialization. Our facility is engineered for efficiency, enabling us to accelerate your product's journey to market.

Our capabilities

Bridging fill finish needs across our expertise

Kindeva harnesses the latest filling technology at the Bridgeton facility across diverse presentations to provide a bridge to the future for you, whatever the nature of your sterile injectable project.

Vial filling

Line features

- **20-40 million** units per annum
- Fills **400 units per minute**
- Vial sizes **2-100mL**
- Fill volumes as **low as 1mL**

To meet the demands of today's complex vial filling projects, the site features a high-performance Groninger aseptic filling line.

The line supports both clinical and commercial-scale manufacturing with exceptional speed and precision. It accommodates a wide range of vial sizes and fill volumes, and can support low-dose formulations. The system was designed for flexibility and sterility, and uses a bulk glass process alongside ready-to-use (RTU) closing components, with future-ready support for nested vial formats.

An inert environment protects sensitive molecules, while advanced robotics and an eight-head filling system, as well as dedicated engineering controls, ensure accuracy with minimal human intervention. The line includes on-line crimping inspection and re-stoppering capabilities, with all critical process data captured in real-time via statistical process control (SPC).

High-speed vial filling

Full line inspection

Real-time SPC data capture

Syringe filling

Line features

- **80-100 million** units per annum
- Fills RTU syringe sizes **1-50mL at commercial scale**
- Fill volumes **down to 0.1mL**
- Fill rate up to **300 units per minute**

100% IPC of fill weight and plunger height

Real-time SPC data capture

PUPSIT sterile integrity testing

The demand for prefilled syringes has outpaced industry capacity, especially for products requiring low-volume fills or specialized components. Kindeva's investment in two Optima syringe filling lines at Bridgeton reinforces our position as a full-service, end-to-end CDMO partner.

With the ability to fill a range of sizes and fill volumes at commercial scale, these lines support even the most precise and sensitive injectable formulations. Designed for RTU components, they handle pre-sterilized glass syringes and rubber stoppers in nested formats, with a 10-head filling system capable of high-speed operation.

The lines feature an inert environment to protect sensitive products, along with 100% in-process control (IPC) at the start and end of each batch, with spot checks throughout to ensure dose accuracy.

Real-time SPC-enabled data capture and online camera monitoring of critical process points provide end-to-end visibility and compliance confidence. Site acceptance testing (SAT) is scheduled for the first line in the first half of 2025, and for the second line in the second half of 2025. These lines will further expand Bridgeton's capabilities for scalable, high-quality syringe manufacturing.

A distinctive feature of these lines is the integration of on-line automated PUPSIT, enabling integrity testing of sterilizing filters and assemblies before use. This reduces the risk of post-use filter or assembly failure.

Cartridge filling

Line features

- **20-40 million** units per annum
- Fill cartridge **sizes 1-10mL**
- Fill volumes as **low as 0.2mL**
- Operates at **300 units per minute**

Kindeva's Syntegon filler reflects a strategic investment in integrated, end-to-end cartridge processing.

With a high capacity and flexible fill volumes, the line supports a wide range of sterile products, including biologics and suspensions requiring micro-dosing. Featuring an 18-head filling system, the line offers both speed and accuracy at a commercial scale.

Featuring integrated depyrogenation, washing and siliconization, the line streamlines key pre-fill processes and minimizes the risk of contamination. It handles bulk cartridges along with RTU closing components such as rubber stoppers and seals.

The inert filling environment protects oxygen-sensitive products, while 100% IPC for volumetric fill checks ensures dose consistency at the start and end of each batch. Real-time SPC-enabled data capture and process cameras add a layer of digital quality oversight.

Looking ahead, the line is being equipped for bead insertion, enabling support for suspension-based therapies, expanding Bridgeton's capabilities even further.

Integrated depyrogenation, washing and siliconization

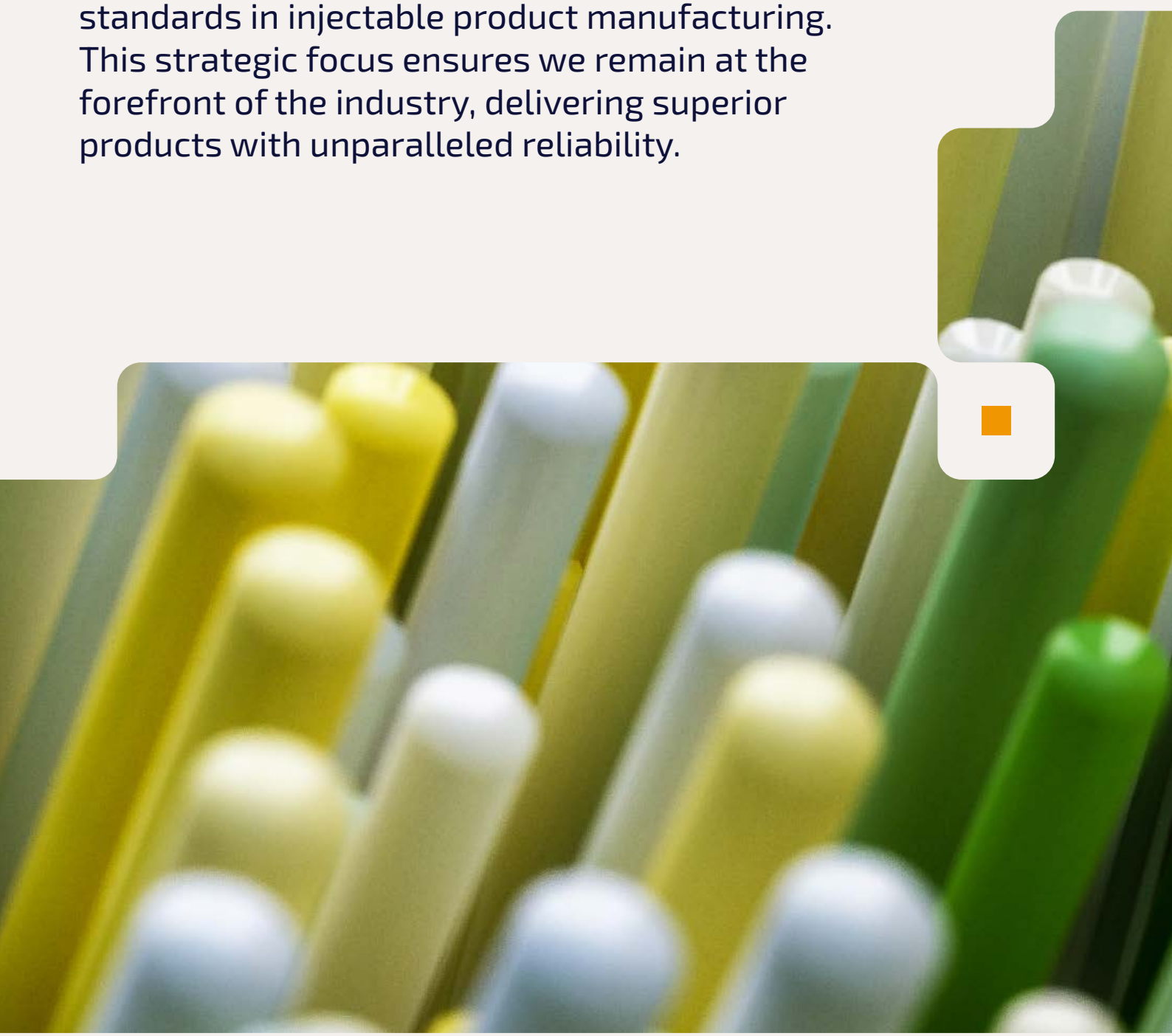
100% IPC at batch start

Real-time SPC data capture

Recent investments

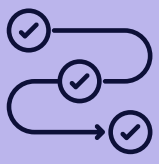
Bridgeton and beyond: **Built for tomorrow**

At Kindeva, we proactively invest in cutting-edge technologies for Bridgeton, to not only meet but consistently exceed the highest quality standards in injectable product manufacturing. This strategic focus ensures we remain at the forefront of the industry, delivering superior products with unparalleled reliability.



Advanced isolator systems

Our compounding, sterilization and fill operations are conducted within an advanced isolator system, providing a closed, controlled environment that expands and elevates our end-to-end capabilities. These state-of-the-art aseptic processing lines in our Bridgeton facility are engineered for maximum sterility and complete compliance with both CFR and Annex 1 regulations, ensuring the highest levels of product integrity.



Streamlined product changeovers

Each isolator features rapid decontamination cycles (≤1 hour) utilizing hydrogen peroxide, enabling faster turnaround between batches and maximizing operational efficiency. Integrated automated glove integrity testing and a multistep HVAC filtration system further enhance environmental control. These design elements collectively support a robust contamination control strategy that meets the most stringent global regulatory standards.

Digitally driven, from design to delivery

From virtual reality tools used in facility design, training and client tours to automated process controls, every step at our Bridgeton facility is digitally enabled and optimized to enhance operational precision and efficiency. This integrated approach streamlines onboarding, reduces manual error and enhances collaboration between teams and clients.

Manufacturing more tomorrows

Where progress meets purpose

As the injectable landscape grows more complex, aseptic fill finish has become more than a manufacturing step; it's a critical success factor. Bridgeton delivers a unified platform that reduces risk, streamlines tech transfer and accelerates time to market to provide a purpose-built solution.

Today's sterile injectable programs are more complex than ever – with stricter regulatory expectations, fragmented supply chains and pressure to scale efficiently from clinical to commercial. Technology transfer challenges can derail timelines, increase costs and put patient access at risk. Bridgeton was designed with the sole purpose of addressing these pain points head-on, combining isolator-based sterility assurance, format flexibility and end-to-end integration to optimize even the most complex programs.

Ready to find out what a true CDMO partnership feels like? Let us show you how our world-class facilities, technologies and analytical capabilities can provide your project with strategic value that bridges beyond manufacturing.

Let's transform tomorrow together

Find out more about Bridgeton

References

[1] Sterile Injectable Contract Manufacturing Market Size & Share Analysis - Growth, Trends, and Forecasts (2025 - 2030), Mordor Intelligence

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