Built for better tomorrows:
How Bridgeton delivers for patients and manufacturers

As the injectable drug landscape grows more complex, aseptic fill finish has become a critical differentiator. Kindeva's Bridgeton facility offers a purpose-built solution that combines high-speed isolator lines, modern automation and integrated quality systems to help pharmaceutical partners accelerate therapies to patients, reduce risk and simplify scale-up. In this Q&A, we explore how the Bridgeton facility sets a new standard in sterile injectable manufacturing, delivering efficiency, consistency and long-term scalability.

1

What challenges in sterile injectables was Bridgeton built to solve?

As therapies such as glucagon-like peptide-1 receptor agonists (GLP-1s) reshape the treatment landscape for metabolic diseases and biologics become more specialized and potent, the expectations for injectable manufacturing have never been higher. Speed, sterility and scale are essential but are often held back by siloed approaches that separate formulation, drug substance manufacturing and fill finish across different partners and sites. That separation can introduce delays, inconsistencies and regulatory friction at critical stages of development and commercialization.

The Bridgeton facility was built to solve that problem from the ground up. Core functions are co-located across the site and operate within integrated systems, governed by a unified quality and operations team. By removing the need for external tech transfers and reducing handoffs between sites, the Bridgeton model helps minimize risk, shorten timelines and improve overall process control.

This design is an operationally efficient, patient-focused solution. With fewer barriers between drug development and delivery, therapies can move from concept to clinic with greater speed and consistency. That's what Bridgeton was built to do: provide our partners with the manufacturing clarity and continuity needed to deliver injectable medicines safely and at pace.

2

What makes Bridgeton different from other fill finish CDMO facilities?

Bridgeton is more than a manufacturing site. It was designed to meet the practical demands of today's sterile injectable programs, from early-phase clinical production through to commercial-scale supply. The facility supports a wide range of container types, product classes and batch sizes, giving pharmaceutical partners the flexibility they need as their programs evolve.

The site includes over 155,000 square feet of current Good Manufacturing Practice (cGMP)-compliant aseptic operations space and is equipped with isolator-based filling lines for vials, syringes and cartridges. Each line is built to deliver sterile, high-precision output at scale. In addition to fill finish, Bridgeton houses dedicated formulation suites, quality control (QC) laboratories and final packaging capabilities, all designed to support streamlined product flow and oversight across the full production lifecycle.

Unlike legacy facilities that have been retrofitted to accommodate newer standards, Bridgeton was purpose-built to support advanced aseptic processing from day one. It reflects the latest expectations for compliance, flexibility and operational efficiency in sterile manufacturing.

The facility is also approved to handle DEA Schedule III and IV controlled substances and is fully compliant with both CFR and Annex 1 standards. Its scale, flexibility and quality infrastructure make it a strong fit for complex injectable programs that require rapid scale-up and regulatory confidence. Facilities with this combination of integrated capability and built-in compliance remain rare in the contract development and manufacturing organization (CDMO) space. This site was engineered to bridge that gap.

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How does Bridgeton maintain speed and sterility throughout the manufacturing process?

Bridgeton was designed for efficiency and sustained performance across every production run. Its ability to deliver injectable therapies at pace starts with isolator-based manufacturing, which supports stringent contamination control while reducing human intervention. This approach aligns with the latest Annex 1 guidance and plays a critical role in preserving product integrity from batch start to batch release.

The facility features four high-speed filling lines from Groninger, Optima and Syntegon, each supporting a different container format: vials, cartridges or syringes. These lines incorporate advanced process controls, including 100 percent in-process control (IPC), real-time statistical process control (SPC) and camera-based monitoring of critical process points. For syringe production, automated pre-use post-sterilization integrity testing (PUPSIT) is used to verify filter performance before each run.

Fast hydrogen peroxide decontamination cycles enable quick product changeovers, and automated glove integrity testing further supports cleanroom control. Bridgeton also integrates digital tools throughout the operation, including electronic batch records, automated data capture and virtual reality systems for training and facility navigation.

Together, these technologies enable faster decision-making, early deviation detection and consistent execution, helping ensure that every dose is manufactured to specification, with both speed and sterility built in from the ground up.

4

What types of therapies is Bridgeton ideally suited for?

Bridgeton was built to support the evolving needs of today's sterile injectable market, including therapies that require specialized formats, complex handling or tight process control. That includes biologics, suspensions, controlled substances and low-volume, high-potency formulations, all of which demand flexible infrastructure and consistent execution.

Each line is capable of handling varied fill volumes, supports ready-to-use (RTU) components and operates within an inert, isolator-based environment to help preserve sensitive molecules. The facility also supports suspension-based therapies and combination products that require precise component control and assembly. This makes Bridgeton a strong fit for programs involving oxygen-sensitive biologics, GLP-1 receptor agonists and other advanced therapies with narrow margins for variability.

The facility's ability to manage Schedule III and IV controlled substances also expands the scope of projects we can support, particularly in areas such as pain management, metabolic disease and emergency preparedness. With the infrastructure to scale from clinical trials to commercial supply, and dedicated expansion space already built into the facility, Bridgeton gives developers a long-term manufacturing home for complex injectable programs.

Whether supporting clinical innovation, manufacturing national emergency stockpiles or anything in between, Bridgeton is suited for any program where sterility, scalability and speed are paramount.

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How does the Bridgeton model help reduce tech transfer risk?

Tech transfer presents both operational and regulatory challenges. Each transition between facilities or partners introduces the potential for documentation gaps, misaligned quality systems or changes in process controls that can impact validation, compliance and ultimately product approval. For sterile injectables in particular, where every step must be tightly controlled and well-documented, these inconsistencies can delay timelines and complicate regulatory filings.

Bridgeton addresses this by unifying all core manufacturing and testing capabilities within a single quality framework. Formulation, aseptic fill finish, in-process control, final packaging and analytical testing are all managed by one team, using harmonized documentation and systems. This approach maintains traceability and alignment from early development through to commercial launch, which reduces the need for revalidation and helps ensure consistent, audit-ready records.

By eliminating the need to transfer knowledge, equipment or products between locations repeatedly, Bridgeton minimizes variability and preserves compliance continuity. This makes regulatory interactions more straightforward and gives our partners confidence that their programs can scale without introducing new risk.

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How does Bridgeton support public health and emergency preparedness?

Bridgeton plays a central role in Kindeva's emergency response and global health security capabilities. The facility supports the development and production of medical countermeasures for governments, military organizations and public health agencies that need a secure, compliant and responsive manufacturing partner.

Through our legacy in medical readiness, we have built deep partnerships with agencies in more than 30 countries. That expertise now extends through Bridgeton, which is equipped to handle a range of time-sensitive programs involving controlled substances, biologics and other sterile injectable treatments critical to emergency preparedness.

The site's high-speed lines, isolator-based environment and controlled substance handling approvals enable it to meet the stringent requirements of national stockpile initiatives and battlefield medical programs. Our teams are trained to manage surge scenarios, ensure compliance and respond quickly to evolving public health needs.

Whether supporting pandemic readiness or rapid deployment of life-saving treatments, Bridgeton provides a secure foundation for emergency programs that cannot afford delay or uncertainty.

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What does "patient-centric" manufacturing really mean at Kindeva?

For Kindeva, being patient-centric means making decisions that prioritize access, reliability and therapeutic impact. It is not just about what we manufacture, but how we approach it with processes and systems designed to deliver quality and consistency at every stage.

At Bridgeton, this philosophy is reflected in how the site was built and how it operates. The facility's design supports faster, safer delivery of sterile injectable therapies by reducing manual error, simplifying production flows and maintaining full control over quality and compliance. From flexible filling capabilities to digital oversight tools, every element is selected to protect product integrity and support timely, reliable delivery to patients.

Patient-centric manufacturing also means thinking ahead. Bridgeton was developed with future growth and evolving therapeutic needs in mind, from new biologics to medical countermeasures. The goal is to ensure that life-changing therapies can reach patients faster.

This mindset shapes how we invest, how we work with our partners and how we view our role in the health ecosystem. It is ultimately about building systems that serve people.