Kindeva

The bridge to uncompromising fill finish precision

Sterile fill finish is a sequence of tightly connected control points, where performance at each stage directly influences quality, timelines and patient safety. At our Bridgeton, MO facility, we maintain control across the entire fill finish journey. With 155,000 sq. ft. of aseptic operations and 11,000 sq. ft. of advanced fill finish suites, every step is engineered for consistency, from tech transfer through commercial supply.

Technology transfer

Control points

- Critical quality attributes (CQA) and process parameters defined
- Container closure and presentation strategy confirmed
- Analytical readiness for in-process and release testing

Bridgeton benefits

Strategically structured transfer with early scalability assessment and manufacturing alignment, reducing variability and accelerating readiness for clinical and commercial production.

Component preparation and material flow

Control points

- Incoming primary container, stopper and component verification
- Washing and depyrogenation controls
- Sterilized product contact parts

Bridgeton benefits

Defined operating ranges and validated procedures to protect sensitive drug products.

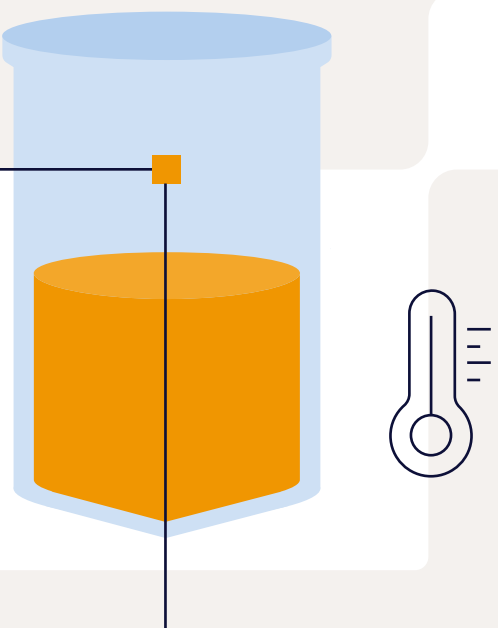
Drug product preparation

Control points

- Controlled mixing speed and temperature
- Bioburden management prior to filtration
- Validated bulk hold times
- Compatible single-use flow paths

Bridgeton benefits

Defined operating ranges and validated procedures to protect sensitive drug products.



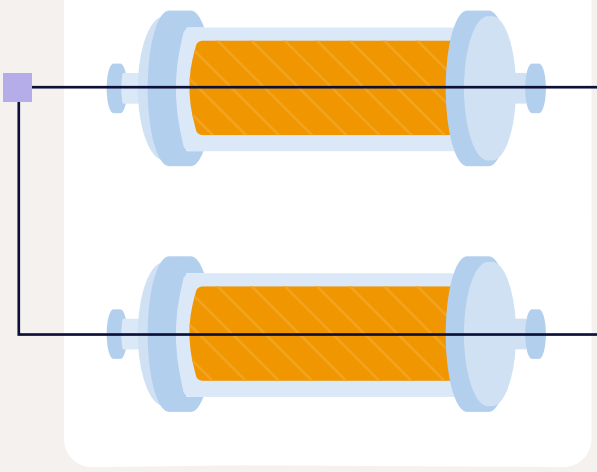
Sterile filtration and aseptic transfer

Control points

- Filter sizing and selection
- Pre- and post-use integrity testing (PUPSIT)
- Differential pressure monitoring

Bridgeton benefits

Validated filtration strategy integrated with closed, controlled transfer practices.



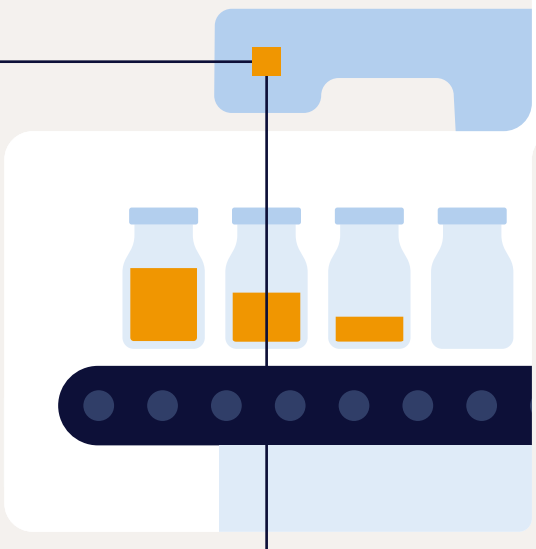
Aseptic filling

Control points

- Defined fill volume limits
- In-process weight checks

Bridgeton benefits

Gloveless/robotic isolators with 100% automatic in-process controls are designed to reduce manual intervention and strengthen sterility assurance.



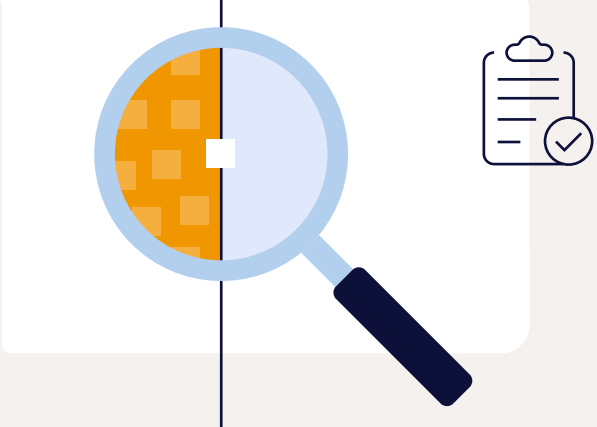
Inspection and quality control

Control points

- Qualified automated visual inspection
- Defined particulate standards
- Container closure integrity strategy
- Sterility and endotoxin testing
- Batch record and data review

Bridgeton benefits

Integrated inspection and digital data oversight aligned with current regulatory expectations.



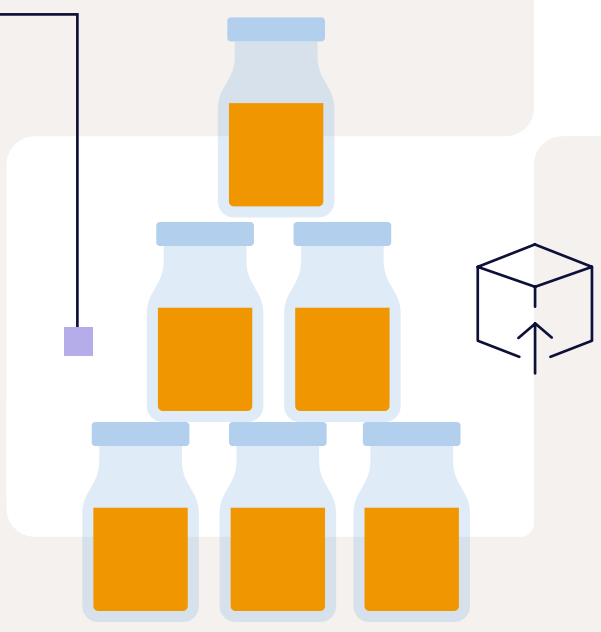
Release and commercial supply

Control points

- Defined release specifications
- Stability program execution
- Packaging and labeling verification
- Capacity and maintenance planning

Bridgeton benefits

Flexible line configurations and scalable infrastructure designed to support clinical through commercial volumes, with an initial capacity of over 150 million units.



Step inside Bridgeton

Discover how we bridge sterile fill finish programs from early development to commercial scale. Explore our interactive guide to experience the facility, technologies and operational precision behind every stage.

Take a tour

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