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A bridge between design and delivery: Exploring sterile fill finish integration for combination product success

The global sterile injectable contract manufacturing market is currently projected at $16.17 billion and is expected to grow to $28.50 billion by 2030, at a compound annual growth rate (CAGR) of 12% [1].

This growth is driven by increasing demand for advanced biologics, GLP-1 therapies and complex combination products that pair drugs with delivery devices to support patient-centric care. Biopharmaceutical companies are increasingly focused on scaling therapies for metabolic diseases and other chronic conditions, many of which require delivery through combination products that integrate drug formulation with device functionality. This creates pressure to deliver high-quality, sterile injectable therapies and their associated devices in a coordinated, compliant and scalable manner.

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However, sterile injectable manufacturing presents unique challenges. These products often require highly specialized environments and processes, including cold-chain storage, low-volume fills and compatibility with complex delivery systems. Many programs also involve controlled substances or highly potent active pharmaceutical ingredients (HPAPIs), which demand additional safeguards, licensing and containment protocols. At the same time, evolving regulatory expectations and global quality standards add layers of scrutiny, especially for combination products involving multiple components. Programs developed for emergency preparedness or public health response face some of the highest expectations, where reliability, speed and regulatory alignment are non-negotiable.

Many manufacturers attempt to meet these challenges by working with separate partners for drug substance production, formulation development, fill finish and packaging. While this approach can appear flexible, it often introduces unnecessary risks. Contamination, delays, misalignment during tech transfer and regulatory complications are common consequences of a fragmented manufacturing approach. To address these challenges, integrated CDMO (Contract Development and Manufacturing Organization) models are becoming essential.

The risks of a fragmented model for sterile injectables

Managing sterile injectable programs through multiple disconnected vendors can lead to a lack of alignment, making it harder to maintain control, ensure consistency and meet project timelines. These misalignments introduce a range of downstream risks that can derail even the most promising programs:

- Increased risk of contamination or deviation during each transfer
- Production delays due to miscommunication between partners
- Loss of centralized inventory control and logistics coordination
- Duplication of quality systems and regulatory burdens
- Tech transfer mismatches that can cause rework or batch failures

These risks can compromise a program's success and delay patient access to life-saving medicines.

To mitigate these challenges, many companies are turning to fully integrated CDMO partners that are equipped to handle development, device integration and sterile fill finish manufacturing within a single quality system and facility.

A solution that bridges these gaps

Our world-class Bridgeton facility in Missouri offers a unified, end-to-end sterile fill finish platform. With over 155,000 square feet of cGMP-compliant aseptic manufacturing space and 11,000 square feet of dedicated fill suites, Bridgeton is designed to eliminate the risks associated with fragmented manufacturing.

1. Key capabilities at Bridgeton

- **Annex 1–aligned design:** Our facility is engineered to comply with the latest Annex 1 requirements, prioritizing contamination control through isolator technology, unidirectional flow and rigorous environmental monitoring.
- **Scalable manufacturing:** From clinical trial material to commercial-scale production, we support growth across the product lifecycle.
- **Integrated services:** Fill finish, device assembly and packaging all occur under one roof, reducing handoffs and timelines.
- **Controlled substance expertise:** Approved for DEA Schedules III and IV, with handling capabilities extending to Schedule II.
- **High output capacity:** Initial capability of over 150 million units annually,
- **Flexibility in formats:** Supports syringes, cartridges and vials with volumes from 0.1mL up to 100mL.with cleanroom expansion space available.

2. Advanced infrastructure and innovation

Bridgeton is engineered for excellence in sterile manufacturing with capabilities that extend well beyond traditional fill finish operations. We support a range of technologies and infrastructure built to meet evolving regulatory expectations and support the full lifecycle of modern injectable therapies.

Facility infrastructure highlights

- High-speed Groninger, Optima and Syntegon filling lines with isolator technology
- Real-time statistical process control (SPC) and 100% in-process control (IPC)
- Integrated depyrogenation, washing and siliconization
- Online integrity testing (PUPSIT) for sterilizing filters
- AI-powered process design and digital tracking for full traceability

This robust infrastructure is paired with rapid decontamination cycles, automated glove integrity testing and advanced HVAC systems to maintain sterility and regulatory compliance.

3. Integrated support for combination products

As combination products become the standard in chronic disease management, we offer end-to-end support for programs that require both complex formulation and integrated delivery systems. From primary container filling to final device assembly and packaging, we ensure full alignment between drug and device components.

Our combination product capabilities include:

- Assembly of autoinjectors and other supported device formats
- Secondary packaging and labeling in compliance with global regulatory standards
- Support for design verification, usability testing and device performance assessments
- Integration of combination product GMPs in line with FDA's 21 CFR Part 4 and EU MDR

This level of coordination helps ensure that combination products are not only compliant and scalable, but also safe, reliable and ready for patient use. For biologics and therapies requiring precision delivery, we deliver the consistency and control required to meet the evolving expectations of regulators and developers for combination product manufacturing.

Protecting tomorrows through global health security products

Through our legacy as part of Meridian Medical Technologies, our Bridgeton facility plays a critical role in emergency preparedness. We support government and military clients in over 30 countries with essential medical countermeasures. These products must consistently meet the highest standards for safety, reliability and speed. When lives are at stake, the ability to deliver combination products that perform flawlessly under pressure is vital. This heightens the importance of a trusted, integrated manufacturing partner capable of meeting both routine and emergency needs with confidence.

4. Transforming tomorrow together: The value of an integrated CDMO partnership

Combination products demand seamless integration of formulation, device expertise and regulatory foresight from day one. Bridgeton was purpose-built to meet the evolving demands of sterile injectable and combination product development, bringing together quality, scalability and speed under one roof. We do this through:

- Accelerated timelines through minimized tech transfer
- Enhanced sterility assurance via isolator-based systems
- Seamless scalability from clinic to commercial
- End-to-end transparency, traceability and regulatory alignment
- Proven alignment of drug and device manufacturing under a single quality system

Bridgeton is more than a facility. It is a strategic bridge between product development and patient-ready delivery. By reducing fragmentation and maintaining quality at every step, we help innovators manufacture more tomorrows by bringing therapies to patients faster.

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.

References

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

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