

Scaling Aseptic Production: From Small Batch to





Commercial Success



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Introduction

Scaling aseptic manufacturing from pilot to full commercial production is a complex

endeavor that requires careful planning, regulatory compliance, and sterility assurance. Many companies struggle to maintain sterility consistency when transitioning from smallbatch clinical manufacturing to larger-scale commercial operations.

Challenges in Scaling Aseptic Manufacturing

1. Maintaining Sterility across Batch Sizes

As production volume increases, ensuring sterility across thousands of doses becomes more difficult.



Facility and Equipment Limitations

Manufacturing facilities often lack the environmental controls, ventilation, and unique features needed to safeguard sensitive drug products from small to commercial production.



3. Regulatory Compliance at Scale

Every batch must meets GMP and global regulatory standards.

During preclinical and Phase 1 development, the unknowns far outnumber the knowns. Will lyophilization be used to stabilize the drug product? What will the delivery mechanism be? Management capabilities with agility as a feature will keep the drug development process moving forward as smooth as possible.



What It Takes to Scale Successfully

Versatile Fill/Finish Suites:

Able to fill a variety of delivery devices: vials, prefilled syringes, autoinjectors, and produce varying batch sizes with adequate speed and under highly sterile conditions.

Robotic Aseptic Filling:

To reduce human intervention to enhance sterility and consistency.

Process Optimization:

Fine-tuned parameters for efficient scale-up without compromising quality.



Regulatory Confidence:

Ensuring every batch meets GMP and global regulatory standards.

Highly-skilled Personnel:

Skilled in aseptic processing and developing lyophilization cycles, as aseptic formulations often require stabilization through freeze-drying.

Aseptic production and fill/finish operations are complex and unexpected challenges should be anticipated but not disrupt the outcome of delivering needed pharmaceutical products to patients.

Successfully scaling aseptic manufacturing for complex and niche drug products requires a strategic approach that accounts for sterility assurance, regulatory compliance, and process adaptability. These products often demand specialized handling, containment strategies, and flexible manufacturing solutions to accommodate small-batch production, high-potency APIs, or lyophilization requirements.

Companies must evaluate not only capacity and technology needs but also supply chain reliability, CDMO expertise in specialized aseptic processing, and long-term scalability to ensure consistent quality and compliance as market demands evolve.



The Role of Analytical R&D in Scale-Up

Without a robust, data-driven strategy, inconsistencies in process control, sterility risks, and regulatory hurdles can stall commercialization, this is especially true for HPAPIs, biologics, and cytotoxic compounds—where even the smallest deviations can compromise quality. Comprehensive analytical R&D, embedded into every phase of aseptic manufacturing, ensures regulatory success and commercial viability with:



1. Early-Stage Method Development & Validation

Every formulation behaves differently, requiring tailored analytical approaches to optimize bioavailability, solubility, and sterility.

- Custom method validation ensures test accuracy and consistency.
- Forced degradation studies identify potential stability risks before production begins.
- In-process testing monitors formulation integrity to detect issues early.

2. In-Process Controls for Real-Time Quality Assurance

Real-time monitoring and in-process testing ensure that every step aligns with cGMP requirements and supports regulatory compliance.

- Sterility testing confirms aseptic conditions are maintained throughout processing.
- Environmental monitoring ensures cleanroom integrity and contamination control.
- Endotoxin and bioburden testing verify product safety and compliance.

3. Release & Stability Testing for Commercial Readiness

Even after aseptic fill-finish, rigorous release and stability testing ensures long-term product quality and regulatory adherence.

- Container closure integrity testing (CCIT) verifies sterility throughout shelf life.
- Accelerated and long-term stability studies assess performance in real-world conditions.
- Oissolution and potency testing confirm batch-to-batch consistency.





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