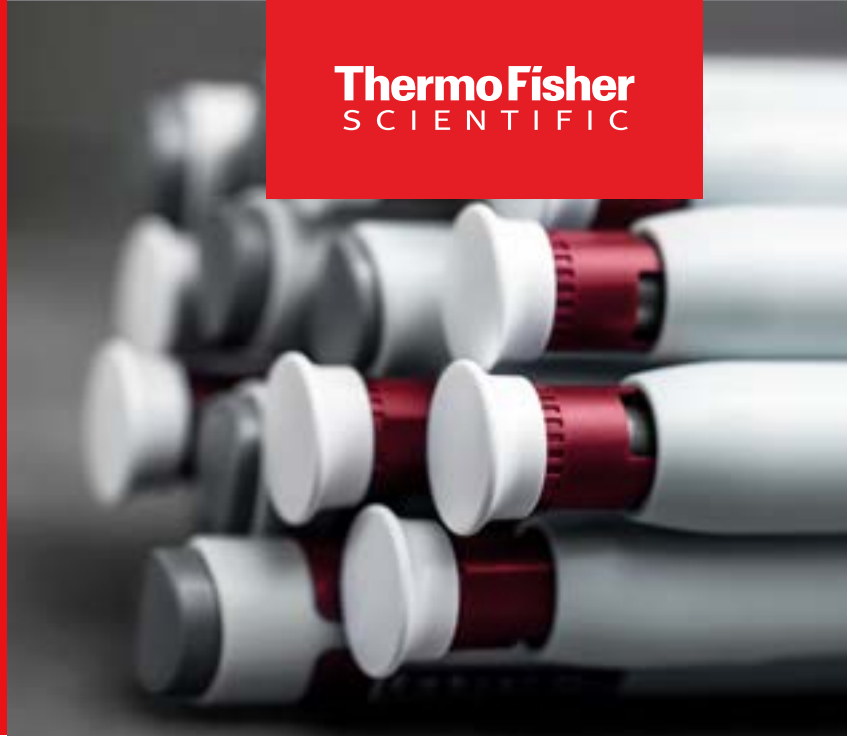
10 reasons sterile drug formulation isn’t getting any easier



Complexity is increasing in sterile injectables, fueled by factors far beyond just formulation and delivery.

Explore 10 reasons sterile drug formulation isn't getting any easier—and how an experienced partner can help.

1 Orphan drugs

Despite their high costs and inherent risks, orphan drugs are projected to grow at a 10% CAGR from 2024-2028.[1] This growth is largely driven by financial incentives and benefits for sponsors developing new biologics for rare diseases.

2 Highly potent molecules

Highly potent cytotoxic molecules are becoming more popular, especially in sterile injectables. Producing these therapies often demands high-containment capabilities. Oncology, followed by immunology, is leading this trend.[2]

3 Larger injection volumes

The ability to deliver higher injection volumes with less pain and discomfort has led to the development of larger-dose autoinjectors. Many IV formulations can now be administered subcutaneously using autoinjector formats.[3]

4 Long-acting formulations

Long-acting injectable formulations have gained popularity for their ability to sustain drug release over extended periods, reducing dosing frequency. Common formats include polymer-based, oil-based, and crystalline drug suspensions.[4]

5 Autoinjectors and on-body wearables

Autoinjectors and on-body wearables are being used to treat common chronic conditions such as obesity, cancer, and immune diseases. By enabling at-home treatment, these advancements are driving growth—the market is expected to expand by double digits annually.[5,6]

6 Regulatory hurdles

More complex formulations create additional work for regulatory bodies, which now must review both the formulation process and its validation. Reviewers look for a strong scientific rationale to support the validation approach—a process further complicated by the global nature of clinical trials and varying regional requirements.

7 Fast-tracking

Every week, the FDA fast-tracks more molecules from Phase II to Phase III and pivotal trials—often in under a year. For certain niche indications, a sponsor's Phase II drug may even meet requirements for registration and first commercial batches.

8 Drug repurposing

The growing appeal of drug repurposing—selecting existing molecules and searching for new indications—can introduce requirements to update formulation and provisioning while still offering cost savings. Bringing a repurposed drug to market costs around US $300 million on average, compared with an estimated $2-3 billion for a new chemical entity.[7]

9 Multiple product strengths

More companies are identifying companion biomarkers to help predict likely drug product pharmacodynamic responses, even in healthy Phase I patients. Therefore, they may choose to test multiple drug product formulation strengths after Phase I.

10 Additional materials for stability testing

New pharma companies may underestimate the product volumes required to support clinical trials, stability studies, and testing. For example, a trial involving 20 patients receiving three doses each may require an extra 1,000 vials for stability studies and 300 vials for testing. Additionally, typical line losses of drug product can reach hundreds of milliliters.

As sterile drug formulation grows more complex, Thermo Fisher Scientific delivers fast, flexible solutions uniquely tailored to your workflow.

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Contact us to get started today.

References

1. EvaluatePharma® Orphan Drug Report 2024 © Evaluate Ltd.
2. IRS Reports HIghly Potent API Manufacturing Market Outlook: 2024-2029
3. Schneider A, Lange J. “The Rise of Large-Volume Subcutaneous Administration of Biopharmaceuticals and Delivery Implications, 168 , 10-15 (2025).
4. Bauer, Andrea et al. “Current State and Opportunities with Long-acting Injectables: Industry Perspectives from the Innovation and Quality Consortium "Long-Acting Injectables" Working Group.” Pharmaceutical research 40,7, 1601-1631 (2023). doi:10.1007/s11095-022-03391-y
5. Autoinjectors Market Size & Share Report, 2025-2034, © Global Market Insights.
6. Autoinjectors Market Size & Share | Industry Report, 2030, © Grand View Research.
7. Nosengo, N. Can you teach old drugs new tricks?. Nature 534, 314–316 (2016).