*symbiosis
Pharmaceutical Services

Protecting the Manufacturing Slot:

Avoiding fill-finish delays in clinical development

Safeguarding clinical timelines
in aseptic manufacturing



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Introduction

Securing a manufacturing slot is a critical milestone in clinical development on the path to delivering your injectable therapy to clinic.

Once secured, maintaining project momentum is vital to meeting the manufacturing schedule. Any deviation directly impacts upon on-time Investigational Medicinal Product (IMP) batch release. Good Manufacturing Practice (GMP) aseptic fill-finish involves complex technical considerations which act as key drivers of project momentum.

In this guide, we explore how to proactively mitigate delays in clinical development that threaten your secured manufacturing slot and clinical trial start dates.

The impact of delay

Extended upstream product development phases compress the remaining timeline, reducing contingency buffers before reaching the aseptic fill-finish phase.

Navigating complex modalities introduces additional technical and regulatory considerations, compounding logistical and compliance demands.

> "Before fill-finish, clients have often had upfront activities – whether that's from product development or drug substance manufacture – take longer than they expected. By the time they then reach the fill-finish stage with us, they're typically looking to get everything through as quickly as possible so that they can meet their drug product supply timelines."
>
> **Shona Smyth**
>
> Head of Project Management, Symbiosis

$500,000 - $800,000

per day of delay [1,2]

A single day of clinical trial delay is estimated to cost $500,000 - $800,000 in unrealised prescription drug sales, alongside $40,000 in direct daily costs.

Key drivers of fill-finish delays

During the GMP aseptic fill-finish process, different variables can potentially impact your drug development timeline:

Documentation

The volume of documentation required to initiate manufacturing is high and often underestimated. This shortfall can push teams to work beyond capacity, under tight timelines, leading to missed deadlines that cascade into a missed manufacturing slot.

Tech Transfer

Achieving a seamless transition into fill-finish requires deep modality expertise across both liquid and lyophilised formulations. During tech transfer, complex biologics face strict Investigational New Drug (IND) or Clinical Trial Application (CTA) regulatory frameworks. A common bottleneck is a delayed Certificate of Analysis (COA) for the incoming drug substance. Without this verified analytical data, project initiation is stalled and the planned manufacturing window is compromised.

Material Change

A change in material specifications during development is a frequent driver of delay. For example, a standard membrane cartridge filter may unexpectedly bind to your protein. Resolving this requires pivoting to a specialised membrane cartridge filter, which can have long procurement lead times. In a tight supply chain environment, waiting weeks for GMP-compliant replacement components can result in reallocation of a fill-finish slot to another project.



Protecting clinical development timelines

Safeguarding a clinical project schedule requires shifting from a transactional CDMO relationship to a collaborative CDMO partnership built on the dual pillars of operational flexibility and technical rigour. To prevent the effect of cumulative upstream delays, a collaborative partner proactively intercepts bottlenecks before they threaten batch release timelines:



Early Documentation Alignment

To avoid timeline reworks, upfront communication and CDMO documentation guidance is important. At Symbiosis, project initiation begins immediately with materials handling and cross contamination assessments, TSE/BSE certifications, supplier approvals, technical and quality agreements. Fragmented communication networks introduce operational delay. Utilising a dedicated, single point of contact from project sign-off ensures complete ownership across development. This single project manager builds deep product-specific knowledge, allowing the cross-functional team to pivot quickly and execute corrective actions if unexpected events or delays occur.



End-to-End Project Ownership

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Integrated Quality and Regulatory Rigour

An agile timeline relies on access to comprehensive regulatory oversight. With both MHRA issued IMP and MIA licences, Symbiosis bridges the gaps between development, clinical supply and commercial scale manufacture. By managing complex process controls, validations and the Quality Management System (QMS) under a single architecture, in-house Quality Assurance (QA), Quality Control (QC) and Qualified Person (QP) teams help to accelerate batch release timelines. This integrated framework ensures that complex drug products transition seamlessly from aseptic manufacture through to QP-certified release, minimising regulatory bottlenecks.



Facilities to Suit Your Programme

Technical alignment requires manufacturing suites designed for the required scale and handling of your drug product. Operating within FDA inspected and MHRA-licensed GMP facilities, Symbiosis offers tailored scaling pathways. The Scion House facility is engineered for small-batch requirements, enabling the aseptic manufacture of lyophilisates, small volume liquids and suspensions. For greater demand, the Bruce Building facility can accommodate production runs of up to 15,000 vials.

Securing the Pathway to Clinical Initiation

When the fill-finish timeline is proactively managed by an agile CDMO partner, clinical-stage drug development timelines are de-risked, maintaining commercial momentum and the path to clinical trial execution. Operational and regulatory excellence serve as the safeguard against scheduling disruption. Symbiosis has a proven track record, including:

Credible Regulatory Excellence Inspection History

Since 2011, Symbiosis has consistently delivered GMP compliance to the highest standards as currently recognised by both the FDA and MHRA. Our latest FDA Inspection (January 2025) returned zero Form 483 observations, demonstrating our team's commitment to regulatory readiness.

Regulatory Guidance

Our Quality and Technical teams help clients navigate and integrate the complex regulatory environment surrounding aseptic manufacturing, including the most recent updates to Annex 1.

Proven Global Experience

Symbiosis has become a global leader in the GMP manufacture of injectable drugs into vials. In 2025 we manufactured our 1000th batch and in the same year, the business was awarded the King's Award for Enterprise in International Trade in the UK.



> “Symbiosis has many clients that started off in early-phase. Working with them, guiding them and building on that partnership and trust, many clients remain with us through the various clinical phases. We also have clients that have progressed through the clinical phases and are now moving into commercial stages where we are continuing to support them.”
>
> **Cheryl Ballentyne**
>
> Operations Director, Symbiosis

Avoiding fill-finish delays is not simply about keeping to agreed timelines, with the right CDMO partner, it is about proactively, safely and compliantly accelerating the production of life-changing medicines to get them to patients who need them most.



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Contact us to find out how Symbiosis can protect your aseptic fill finish programme and help get your drug product to patients faster.

Contact us →

References:

1 Ken Getz MBA. How Much Does a Day of Delay in a Clinical Trial Really Cost? 2024;33. Accessed March 25, 2025. https://www.appliedclinicaltrialsonline.com/view/how-much-does-a-day-of-delay-in-a-clinical-trial-really-cost-

2 Z. Smith, J. DiMasi & K. Getz. Quantifying the Value of a Day of Delay in Drug Development. 2025. Accessed September 21, 2026. https://csdd.tufts.edu/sites/default/files/2025-02/Aug2024%20Day%20of%20Delay%20White%20Paper%20Final.pdf

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symbiosis-pharma.com contact@symbiosis-pharma.com