

# CLINICAL TRIAL PACKAGING SOLUTIONS

**BALANCING COST,  
TIME AND QUALITY**

patheon

- API
- BIOLOGICS
- VIRAL VECTOR SERVICES
- EARLY & LATE PHASE DEVELOPMENT
- **CLINICAL TRIAL SOLUTIONS**
- LOGISTICS SERVICES
- COMMERCIAL MANUFACTURING



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# Introduction

In today's highly competitive market for new drug development, sponsors are challenged with balancing cost, time and quality to deliver the best possible outcome for their trial, and more importantly for their patients.

Cost overruns can be critical—especially for emerging companies who are tasked with raising funds to cover development costs. For large pharma, where an outsourcing strategy allows them to focus on core strengths, managing their budget is equally important.

Timing is everything. Accelerating the product approval process translates to a faster income stream that offsets the sponsor's development investment. As trials evolve and progress through phases, change is inevitable. Clinical trial packaging is often impacted by changes to the protocol such as dosage changes, increases or decreases in volumes, changes to expiry dates, inclusion/exclusion of countries that weren't part of the original plan. Accurately identifying and predicting issues that might impact schedules, while remaining nimble to adjust to changes is imperative.

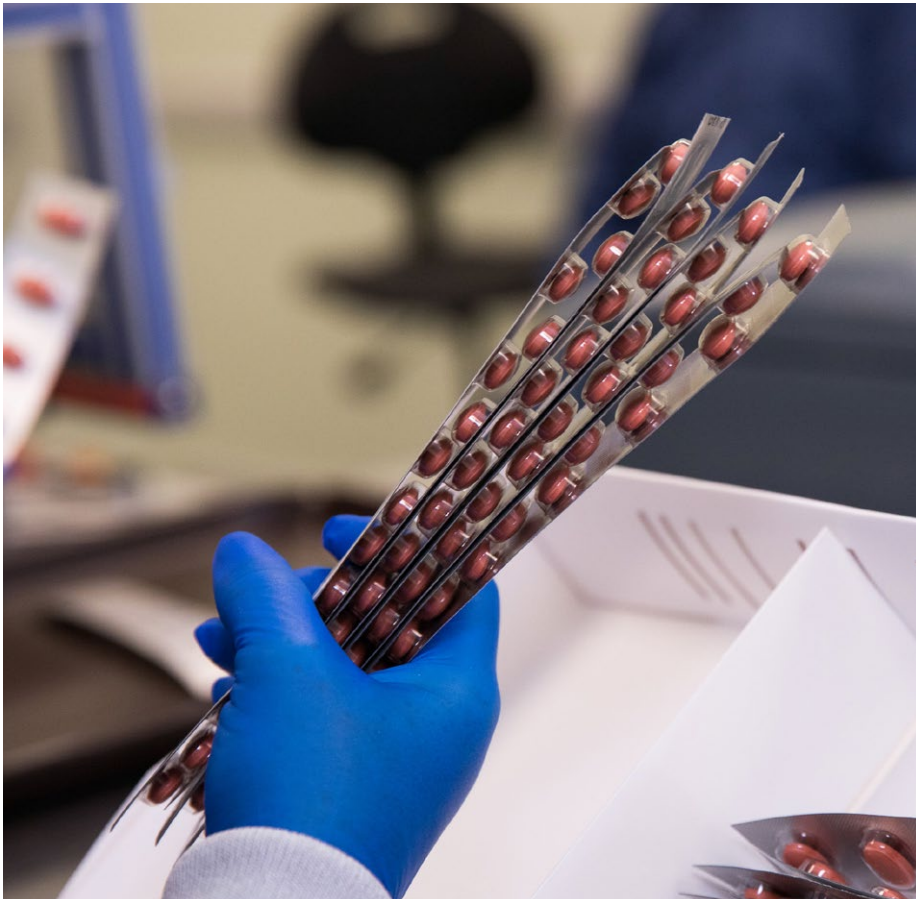
Most importantly, quality can never be sacrificed. It's important to recognize that quality has a cost and time impact on the study. Through diligent upfront planning we integrate quality assurance into every facet of the packaging design plan, proactively anticipating risks and identifying an action plan that mitigates that risk.

The Fisher Clinical Services team leverages 30+ years of clinical trial packaging design experience when working with study sponsors. We understand the importance of taking the time required to establish a detailed understanding of your needs. Throughout the thoughtful collaboration process, we serve as a trusted advisor to help you strike the best balance of cost, time and quality.



# Managing cost

No one likes surprises. Establishing a project plan and supporting budget that stays on track throughout the study is vital. Yes, it may seem overwhelming for the first-time trial sponsor, but it is a fully transparent process intended to alleviate the unexpected.



To establish a firm plan that you can rely on requires establishing requirements at a great level of detail. For example:

- What components will be required in support of packaging the drug product? (e.g. film, foil, closures, plastic trays)
- Who will source those materials—the sponsor or the vendor? At what cost, and with what kind of lead time?
- Is there special tooling required and if so, at what cost and lead time?
- What kind of overage is required to ensure processes can be executed at the required quality standard?
- What assumptions have been made with respect to storage volume, freight volume and distribution patterns by destination?
- How will the project be managed? Is there an hourly fee that might become unmanageable if the scope of project is constantly changing? Or is it a fixed, predictable cost?

As we work with a trial sponsor to understand scope, we apply our experience to identify any opportunity to gain efficiency. We understand that managing costs includes adding value, and introducing cost-efficiencies. Instead of you worrying about all the details, our Project Managers and their support teams are continually asking questions:

- Is there a way we might benefit from automation?
- Can we remove non-essentials?
- Could we create a scalable solution to support multiple trial phases and/or countries while minimizing waste?

As a full-service clinical packaging provider, we have the added value of leveraging the skills of Clinical Supply Chain Managers specifically focused on optimizing the end-to-end supply chain. For example, where should packaging activities take place to most effectively support a global trial? With their expertise we can identify if there might be advantages to an alternate approach that, over the long run, might prove more efficient.

# Controlling timelines

We have all heard the saying “measure twice, cut once.” It should come as no surprise that establishing the design and overall plan for a packaging project consumes a significant amount of time. By investing in a detailed planning process, we can identify areas where our experience will reveal opportunities to streamline.

It is equally important that we identify any process that may be outside of our control, and that we plan accordingly. Once again, clinical trial sponsors don't need surprises. Critical steps that must be accounted for include:

- **Qualified Person (QP) declaration and/or label design that requires approval**—These must be included as part of the Clinical Trial Application (CTA).
- **Release testing**—Any time we include a manufacturing process in the packaging program (e.g. Pre-filled syringe assembly, overencapsulation, pen assembly) there may be a quality requirement that requires samples go through release testing. It is critical this be identified up front as part of establishing the overall timeline.

The Fisher Clinical Services Project Manager with their multidiscipline support team will lead you through the project requirements phase. For the emerging biopharma company, that experience can prove invaluable to establishing the assurance that the program will be executed on time and at specification.

## For example:



### SPECIALIZED EQUIPMENT AND TOOLING

We have the expertise and capability to produce most of this in-house. This enables us to provide you, the sponsor, the highest degree of flexibility while giving us control of both cost and timing.



### PACKAGING COMPONENTS

We have experience across a broad range of projects. We understand which combinations work best, and can make recommendations that will improve overall quality and/or deliver predictable timelines.



### MOCKUPS

They say a picture is worth a thousand words. Imagine what a 3-dimensional mockup might mean to ensuring processes will work, and that procedures are thorough. Mockups can also help with identifying where problems may arise, saving time in the long-run. Our in-house engineering team is often engaged to support through 3-D design projects.



### LABELING

Our fully-integrated label production service eliminates the need for an external vendor, where supply chain handoffs and the potential for missed deadlines can impact a project. As an added bonus translation management is part of that service, eliminating yet another potential external relationship.



### VALIDATION

Because of the large volume of projects we have successfully completed, detailed validation processes can often be eliminated or streamlined. We've solved the problem before.

# Ensuring quality

We understand that what we do matters. Through the work we perform on behalf of trial sponsors we are helping to bring hope to patients around the globe. To that end, quality can never be compromised and the patient always comes first.

Ensuring the highest possible standard of quality is our corporate culture—it is designed into everything we do.

- **Being responsive to your needs is our top priority.** Our experienced quality leaders ensure we always provide transparent and open communication. We provide end-to-end quality oversight of every facet of our programs and dedicate 10% of our staff to that function. The end result is a zero recall operation that has stood the test of time.
- **We manage our daily operations using comprehensive quality management systems.** Standard Operating Procedures are tightly defined and implemented globally. To make sure we stay on task we establish Key Performance Indicators across the organization. In our production areas these are constantly reviewed with team members so we remain vigilant, proactively addressing things before they become an issue.
- **Our Quality Management team supports an extraordinary number of client and regulatory audits with very low levels of critical observations.** In fact, we even offer a ‘virtual’ audit so that sponsors requiring support from remote regions can conduct a detailed review via on-line, real-time connections with our facilities and their staff.
- **Continuous improvement is part of our daily routine.** Whether investing in our people, systems or processes, our primary focus is to ensure operational excellence that exceeds client expectations. We share our client’s passion for making an impact and improving lives. When we approach each project with a ‘quality first’ mindset, we will design the best possible solution to help ensure positive patient outcomes.

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# Delivering experience

No matter how large or small the project at hand, it takes a team working as an extension of our client’s organization to execute a successful program. To serve as a trusted advisor requires open collaboration that involves every discipline that will be part of delivering a solution. Quality, Engineering, Operations, Information Technology, Client Services—each is an essential player as part of the Project Manager’s team, offering their unique expertise to ensure the solution will best serve the client’s needs.

Over the years we have defined best practices that help us deliver consistent, predictable results. Processes have been standardized, project management tools have been built and systems have been deployed so that our clients can be confident they will get what they need in the timeframe that has been communicated. Our Project Managers coordinate internal communication across all disciplines, keep track of milestones and timelines driving the project to completion, engaging the client as needed. And for the client that wants to remain connected throughout the process, our Global Gateway web portal provides real-time visibility to status and inventory information.

While we understand it’s essential to deliver a project as it was defined, experience informs us that it is equally important is to maintain a long view. We constantly seek ways to refine and improve. Whether investing in new facilities, next generation equipment or designing new capabilities through improved systems and processes—we are deeply committed to ensure we stay one step ahead of our client’s needs both today, and in the years to come.

