

# Considerations When Selecting a Partner for Clinical Trial Supply Services



Clinical trial supplies are crucial to the development of new drugs, impacting everything from data integrity to the speed, efficiency, and cost-effectiveness of the entire process. Proper oversight and management of supply services is vital for ensuring timely, secure, and compliant access to the investigational drug and other materials needed for a successful clinical trial. These services encompass a wide range of activities, including manufacturing, packaging, labeling, kitting, storage, distribution, returns, and destruction services. Successfully handling these tasks requires specialized expertise, resources, and facilities, along with the ability to navigate complex supply chain and regulatory requirements to maintain compliance. Having sufficient agility to adapt to changes is also critical, as protocols, sites, and timelines can all shift during the course of a clinical development program.

To address these requirements, many clinical trial sponsors opt to partner with specialized clinical trial supply service providers. These companies offer the necessary capabilities, expertise, infrastructure, and global networks to effectively manage these complexities.

This white paper outlines key criteria to consider when selecting a partner for clinical trial supply services and details the primary steps involved in the services workflow, from planning and sourcing to the return of unused drug products from trial sites.

## Attributes of a World-Class Services Provider

By thoroughly evaluating the factors listed below and performing comprehensive due diligence, you can identify a partner that aligns with your overall objectives and the specific needs of your clinical study.

- **Proven Track Record:** Look for a partner with extensive experience in clinical trial supply project management on a global scale. A history of successful projects and satisfied clients is a strong indicator of their reliability and competence. Take the time to gather references and assess the provider's reputation within the industry. Seek feedback from other sponsors or research organizations who have worked with the provider previously to gauge their satisfaction.
- **Comprehensive Service Offerings:** Your partner should offer a full spectrum of services including procurement, packaging, labeling, and distribution. The partner should also excel in contingency planning as some aspects of the clinical trial process can be unpredictable such as the pace of patient enrollment. Temperature-controlled and secure storage capabilities to ensure reliable shipping are essential. Additionally, the partner should manage returns, reconciliation, and destruction of supplies efficiently.

To streamline the entire process of clinical trial supply services and have one point of contact for the overall program, choose a partner with a resource network that offers additional support, such as label design, translation, and comparator sourcing. If hiring a supply chain manager isn't practical for your company, some clinical trial supply services partners may have access to professionals within their network who can assist.

- **Regulatory Expertise and Compliance:** The partner must have a strong understanding of regulatory requirements for clinical trials, including Good Manufacturing Practices (GMP), the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), and relevant guidelines from regulatory agencies such as the United States Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

If the clinical trial includes home administration of the drug product, your supply services partner should be well-versed in requirements related to child-resistant packaging as defined by the Poison Prevention Act.

Regulatory compliance also encompasses the packaging and labeling of controlled substances and highly potent drugs, which must meet rigorous standards set by authorities like the United States Drug Enforcement Administration (DEA) and other regulatory bodies worldwide. These types of products may involve securing additional licenses, permits, and registrations, along with adhering to strict labeling, storage, and reporting requirements.

- **Scalability and Flexibility:** The ability to handle trials of varying sizes and complexities is important. Assess the service provider’s capacity and scalability to accommodate the size and scope of your study – now and in the future. Ensure they have the infrastructure, resources, and capabilities to grow with you, handling both small-scale and large-scale trials, including global distribution capabilities if needed.

Remember that change is constant. An experienced partner will be able to quickly adapt to alterations in trial protocols, sites, and timelines, with flexible production planning and forecasting to accommodate evolving needs.

- **Quality Control and Assurance:** Ensure the partner has a robust quality management system (QMS) in place to maintain high standards throughout the trial and ensure the integrity, safety, and quality of clinical trial supplies. They should be able to ensure the necessary quality, documentation, and compliance throughout the supply chain.
- **Geographic Reach:** Global distribution and logistics capabilities are key for supporting international trials. The partner should have strategically located facilities and a network of partners that can be leveraged for efficient global distribution. They should also have a strong understanding of local regulations, customs requirements, and cultural nuances.
- **QP Services:** European and United Kingdom regulations require that all Investigational Medicinal Products (IMPs) be certified by a Qualified Person (QP) before being released for use in a clinical trial. Your clinical trial supply services partner should collaborate closely with your QP on all aspects of these requirements, including audits, QP declaration, and batch release.

## The Clinical Trials Supply Workflow

The clinical trial supply services workflow is a multi-step, meticulously coordinated process that ensures the timely and efficient delivery of investigational products to clinical sites (Figure 1). A thorough understanding of each aspect of this workflow is critical for selecting the best partner.



Figure 1. The clinical trial services supply process.

The process begins with **planning and sourcing**, which establishes the production schedule and highlights any challenges that may arise due to the number of clinical trial sites and the unpredictability of patient enrollment. Effective production planning establishes the framework for adapting to changes in site recruitment, managing overages, and executing rapid responses to maintain drug supply, including decisions related to safety stocks. This phase also focuses on implementing efficient inventory control and proactive risk assessment of supply scenarios and contingency planning.

When planning the clinical trial supplies workflow, sponsors should be prepared to provide several key pieces of information and materials to their services partner.

- The study protocol outlines the objectives, design, procedures, timelines, and endpoints of the clinical trial and provides information about the investigational product, including dosage regimens, treatment arms, and administration routes.
- Detailed specifications for the investigational product, including its formulation, strength, dosage form, stability profile, and packaging requirements.
- Forecasted enrollment and dosing estimates.
- Detailed information on the formulation, strength, packaging, and labeling requirements of any comparator products.
- Relevant regulatory documentation including Investigational Medicinal Product Dossier (IMPD), Investigational New Drug (IND) application, or equivalent regulatory submissions.
- Labeling and packaging requirements for the investigational product, including instructions for use, dosing instructions, cautionary statements, and associated regulatory information.
- Supply chain logistics, including shipping requirements, storage conditions, temperature monitoring, and distribution logistics.

[CLICK HERE](#) to download our detailed checklist to help you prepare to meet with your CTS partner

If the clinical trial supply services partner offers a full complement of services, the next step is **manufacturing** which includes chemistry, manufacturing, and controls (CMC) process development and formulation. **Quality and analytical support services** include method development and validation, product release and ICH-compliant stability testing. Partnering with a clinical trial supply service provider that offers manufacturing and analytical services at the same location under the same quality system can offer both operational and financial benefits.

During **packaging and labeling**, customized solutions are developed to meet specific study requirements. Clinical trial packaging involves specialized techniques and materials to meet regulatory requirements and ensure that the products, which may include controlled substances or highly potent drugs, remain safe, stable, and effective throughout the trial period. Moreover, well-designed packaging safeguards against contamination, tampering, and damage, thereby protecting patient health and the sponsor's investment.

Compliance with stringent regulations set by agencies like the FDA and EMA is also critical, as it ensures the validity of trial results and the safety of participants. In trials requiring blinding and randomization, specialized packaging techniques are employed to maintain these protocols, minimizing bias and supporting valid outcomes.

Efficient packaging also ensures timely and secure delivery of products to trial sites. By reducing the risks of product wastage, re-packaging, and regulatory non-compliance, clinical trial packaging also contributes to cost efficiency, allowing organizations to allocate resources more effectively. In addition, your partner should offer a wide range of primary and secondary packaging to meet your needs for current and future trials. including:

In many clinical trials, blinding and randomization are essential to minimize bias and ensure the validity of the results. Specialized packaging techniques, such as over-encapsulation to conceal tablet and capsule products, should be available from your partner, if needed, to maintain blinding and randomization protocols throughout the trial.

A range of labeling options and translation services are also needed to address the needs of clinical trial locations in different countries.

A successful clinical trial supply process also includes **temperature-controlled storage**, ensuring that temperature-sensitive products are stored under precise conditions, from controlled room temperatures to ultra-low frozen conditions. Redundancy should be built into the system in case of power outages. Proper temperature control must also be maintained throughout the supply chain, from receipt and manufacturing to storage and **distribution**, to ensure the integrity of these materials. In addition to maintaining product integrity through prequalified cold chain logistics, timely and reliable distribution to clinical trial sites or directly to patients is also essential.

The return, reconciliation, and destruction of drug products are critical final steps that ensure compliance with regulatory requirements and maintain the integrity of the trial. **Returns** involve the systematic retrieval of unused or partially used investigational products from trial sites, which is needed for accurate inventory tracking and to prevent unauthorized use. **Reconciliation** is the process of accounting for all drug products distributed during the trial, ensuring that every unit is accounted for and that there are no discrepancies. This step is crucial for validating the accuracy of the trial's supply chain and for preparing regulatory documentation. Finally, the **destruction** of returned drug products must be carried out in compliance with environmental and safety regulations, ensuring that all materials are disposed of in a controlled and secure manner.

## Overcoming Common Challenges

To effectively address common challenges faced by clinical trial sponsors when engaging a supply services partner, strategic approaches related to budgeting, lead times, and planning are essential.

Budgeting can be closely managed through itemized pricing and flexible pricing models that offer transparency and control over expenses as the number of trial sites and shipments per site evolve. Implementing efficient processes and comprehensive risk mitigation strategies can streamline development timelines and minimize unexpected delays in drug supply, further ensuring that costs are kept in check.

Challenges related to planning and logistics can be minimized by an experienced project management team and proactive communication. This team's adaptability and flexibility are key to adjusting and responding to evolving trial requirements, while their expertise should provide valuable peace of mind for the trial sponsor.

## Conclusion

Selecting the right partner for clinical trial supply is paramount for the success of any clinical trial. Outsourcing clinical trial supplies and services provides many benefits, including access to specialized knowledge, global capabilities, the agility to respond to dynamic and evolving supply needs, and flexibility that enhances cost efficiency and streamlines development timelines. While sponsors focus on their own core competencies, their clinical trial supply services partner will handle the complexities of trial supply and logistics, ultimately contributing to the successful and timely advancement of new therapies.

## Experience the Experic Difference

As a capable and experienced partner, we not only ensure the efficient management of supply chains and regulatory compliance but also offer valuable expertise in addressing logistical and operational challenges, all while putting your clinical trial needs at the center of the solution.



*"Being part of the solution for the development of new therapeutics and impactful pharmaceutical innovations fills me with immense pride. Our team's dedication goes beyond managing logistics and manufacturing programs; it's about crafting the most effective, custom solutions with clinical success in mind. From selecting the optimal packaging to ensuring seamless distribution, we put patients at the heart of everything we do, knowing that our expertise directly impacts a product journey towards commercialization and providing hope."*

— Brian Fagan, Vice President of Operations

With decades of expertise, locations in both the US and EU, and high-touch customer care, we will bring peace of mind to your next clinical trial.

[CLICK HERE](#) to learn more about our clinical trial supply services



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Experic, a contract development and manufacturing organization (CDMO) and clinical trial supply services company, supports every phase of a product's life cycle from conception to clinical and commercial scale, across a range of dosing and packaging formats. While being a specialized inhalation CDMO, we provide drug product development and manufacturing expertise across a variety of modalities from early phase development to clinical and commercial packaging and labeling. Leveraging our state-of-the-art cGMP facility, we manage global delivery of the highest quality products and services, even for expedited projects, while providing unparalleled knowledge, expertise, and customer service.