RECRO®

Focused, Flexible, and Responsive Clinical Trial Services

Today's clinical studies are increasingly complex and ever-changing. Whether you are an emerging biotech, midsize pharma, or clinical research organization, we will deliver the clinical trial services (CTS) and solutions you need when you need them, packaged and labeled to your exact specifications. Below is a snapshot of Recro®'s offering:

CLINICAL MANUFACTURING

- Global procurement and deblistering/debottling of comparator products
- Over-encapsulation of tablets, capsules, pellets, granules, etc.
- Pouch and sachet filling
- Multiproduct over-encapsulation

PRIMARY AND SECONDARY PACKAGING AND LABELING SERVICES

- Specialized labeling for drug supply flexibility
- Customized kits for compliance, quality, and storage ease
- Blistering and bottling
- Single and multi-panel, booklet labels
- Card/wallet sealing
- Labeling of vials/kits/prepackaged materials

WAREHOUSING AND DISTRIBUTION

- cGMP monitored and validated warehousing
- Controlled room temperature monitoring
- Reconciliation services for clinical site returns of investigational product
- Limited-access and security-enabled storage areas
- Post-reconciliation cGMP storage

CLINICAL PACKAGING

- Multi-container kit design
- Facilitation of label design and translation services
- Supply chain strategy and management
- Global procurement of comparator medication

SPECIALTY PRODUCT DEVELOPMENT AND MANUFACTURING

- Potent compounds
- Moisture-sensitive products
- Controlled drug substances
- Modified release formulations
- Regulatory expertise

REGULATORY EXPERTISE

- Expertise in streamlining the product's path from IND to NDA, and regulatory approval
- Successful inspection history with FDA, DEA, and foreign health ministries
- Assistance with end-to-end filing strategies
- Regular quality audits, including virtual visits
- Regulatory and compliance documentation support

Why Recro for Your Clinical Trial Services?

Ours is an agile, low-bureaucracy organization where you'll have direct access not only to our global supply chain experts but also to unparalleled regulatory expertise. With access to a cross-functional team and expertise, Recro gives you the confidence you need to take your product from start to finish.

CONSOLIDATING CTS/CMC SERVICES SAVES TIME AND REDUCES ERROR

- Silo-free, comprehensive end-to-end clinical trial coverage misses nothing.
- Management of master services agreement is made easier with streamlined contracting and invoicing.
- Quality audits merge into a single quality agreement and quality system.
- Project management oversees development, manufacturing, packaging/labeling, and distribution activities and timelines.
- There is no need to ship clinical trial materials to another vendor for primary/secondary packaging, labeling, or distribution, minimizing the risk of shipping delays or material taking excursions outside its controlled-temperature environment.
- Delays are minimized, avoiding missed milestones.
  - Activities from each area can be initiated in parallel, avoiding delays that generally occur with separate vendors because projects at each respective CDMO are started at different times.
  - If a manufacturing delay occurs, the packaging line/group is aware and can reorganize resources to ensure availability when the materials are ready.
- There is no need for tech transfer of analytical methods.
- Assure supply through forecasting/demand planning to decrease the risk of stockout.
- Reduce errors with consistent documentation templates.

OUR END-TO-END SERVICES AND DEEP REGULATORY EXPERTISE KEEP YOUR PROJECT MOVING AHEAD

- Start with Recro and stay with Recro for development, manufacturing, scale-up, packaging/labeling, and distribution for early phase, late phase, and commercial
- Integrated regulatory support from start to finish
- Stability and storage

The Exact Clinical Trial Services You Need — **When You Need Them**

RECRO®