MEDPACE

CLINICAL PACKAGING AND SUPPLIES

As part of a full-service CRO model, Medpace offers a dedicated Clinical Packaging and Supplies (CP&S) department to assist Sponsors with the complexities of providing timely and compliant product throughout the clinical trial process. With CP&S as an internal function, Medpace provides a consolidated unified approach to study start-up, recruitment, treatment, and follow-up.

CP&S develops, plans, implements, and manages Investigation Product (IP) supply chain activities to insure timely and compliant product availability including label development, approval, and compilation for regulatory submissions. This advantage allows for improved communication, collaboration, roles and responsibilities, thereby eliminating potential inefficient gaps and/or duplications.

STRATEGIC SERVICES

- Vendor recommendations
- Timeline development
- Depot set-up and management
- Internal and external IRT collaboration
- Supply chain management

OPERATIONAL SERVICES

- Vendor, supply, and inventory management
- Manage timelines
- Initial and resupply strategies
- IRT specifications and User Acceptance Testing
- Label development and packaging

MAKING THE COMPLEX

SEAMLESS™

EXPERTS

- Accomplished CP&S team managed by long-time industry experienced experts in the clinical packaging and supplies space for research and development
- Access to a global network of colleagues and pre-qualified vendors which ensures all operational activities are coordinated to meet first patient dose date
- Wholly supported by Medpace's full-service CRO

EXPERIENCE

- Knowledgeable in small and large, global studies with CP&S requirements
- Skilled in strategic and operational CP&S requirements
- Adept in global complex studies with multifaceted needs for every stage of clinical development

EXECUTION

- Provide strategic vision and operational excellence for development and accountability
- Communicate and collaborate with Sponsors by taking the lead, or serving in a supporting role
- Develop, manage, and coordinate timelines to meet global, regional, and/or local requirements
- Provide timely and compliant IP
- Involved as needed from inception through study close-out
- Provide initial and ongoing proactive risk identification, risk mitigation, and risk management
- At study close-out all IP are reconciled and destroyed based on Sponsor needs

SUPPLY CHAIN MANAGEMENT

Working in collaboration with Medpace's study start-up team, CP&S develops, plans, implements, and manages Investigation Product supply chain activities to ensure timely and compliant product availability including label development, approval, and compilation for Regulatory submissions.

To ensure maximum compliance, labels are developed, for on site or for take home use, based on ease of directions. Labels are where the IP timelines are made or broken. To provide a fully useable global inventory with the fewest restrictions, Medpace works to include all countries in a global booklet label. This process avoids subsequent booklet label manufacturing as well as unnecessary regional or single panel labels.

Label development, review, approval, and printing must be concurrent with supply chain activities, to insure simultaneous availability of labels and bulk product.

DEPOT SET-UP AND MANAGEMENT

Based on study timelines, country approval dates, site initiation schedules, and enrollment forecasts, Medpace will develop and implement a depot set-up strategy. An accurate depot set-up strategy ensures depots have a confirmed Importer of Record strategy and adequate quantities of IP. Medpace CP&S will manage and maintain depot inventory to ensure product availability throughout the study. To avoid excessive or limited shipments, along with excess depot inventory or shortages, Medpace will track and optimize shipments and inventory levels at the depot and sites.

ClinTrak IRT® UTILIZATION

Medpace utilizes ClinTrak® for Internal and external Interactive Response Technology (IRT) collaboration to develop IRT specifications and User Acceptance testing. ClinTrak is customized to provide the exact level of functionality required for studies including real-time subject status/visit tracking, drug supply/shipment management, and randomization. For CP&S purposes, ClinTrak is invaluable for seamlessly tracking and organizing critical data.

CP&S Management with ClinTrak

- Inventory management at the depot and site level
- Initial and resupply shipments
- Use-by date management
- Product disposition
- Temperature excursions
- Subject dosing
- Reconciliation, returns, and destruction

As many clinical studies are performed concurrent with stability programs, use-by dates are printed on global labels. ClinTrak allows Medpace's CP&S team to access data and stability pull dates to maximize use-by dates, while minimizing date extension labeling activities.

FULL-SERVICE CLINICAL DEVELOPMENT

Medpace is a scientifically-driven, global, full-service clinical contract research organization (CRO) providing Phase I-IV clinical development services to the biotechnology, pharmaceutical and medical device industries. Medpace's mission is to accelerate the global development of safe and effective medical therapeutics through its high-science and disciplined operating approach that leverages local regulatory and deep therapeutic expertise across all major areas including oncology, cardiology, metabolic disease, endocrinology, central nervous system and anti-viral and anti-infective.

WE CAN'T SIMPLIFY CLINICAL DEVELOPMENT – BUT WE CAN EXECUTE IT SEAMLESSLY.