CHeT - CMSU

Clinical Materials Services Unit

EXECUTIVE DIRECTOR

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Registered with the New York State Board of Pharmacy as a wholesaler re-packager of drugs and devices, the Clinical Materials Services Unit (CMSU) provides contract pharmaceutical services to the Clinical Trials industry.

The staff of CMSU have over 150 years of collective pharmaceutical experience and have serviced 15-20 multi-center studies concurrently, with an average study size of 200 participants, 25 sites and up to 5 years in duration. CMSU has provided regulatory support for 14 investigator initiated INDs, services to 90 drug and device multi-center clinical trials, and drug/device supplies to over 25,000 participants at more than 2,100 sites.

About Us

CMSU was founded in 2008 when clinical investigators from the University of Rochester determined the need for a dedicated, on-site facility to manage entire supply chains in support of clinical trials conducted at or through the University, a major player in NIH and industry sponsored clinical research globally.

Clinical Trial Services Leading to 3 FDA Approvals

Clinical Trial Packaging and Labeling Services

Clinical packaging services include kit design, label creation, and production, all compliant with cGMP regulations. CMSU uses its validated, 21 CFR Part 11 compliant labeling system (ClinPro LBL™) to produce labels per the Clinical Protocol and Federal Regulations. Packaging and labeling follow customized SOPs, and clinical materials are QA inspected upon receipt, during processing, and at order completion. Material movement is overseen by the Quality Assurance Unit.

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Storage: Controlled Room Temperature [+2° to 8° C, and -20° C]

Monitored HVAC systems, refrigerators and freezers are backed up by emergency natural gas-powered generators. A dedicated monitoring system alerts CMSU staff in the case of deviation or temperature excursion.

Cold Chain Shipping

CMSU utilizes qualified, cold chain shippers, with Sensitech Temp Tales® programmed to the allowable temperature range, which monitor the in-transit temperature of the clinical materials through to its ultimate destination. The data-logger reports are retrieved from sites, QA reviewed and filed in the regulatory files. Any excursions during transit are vetted to determine if product continues to be fit for use.

Supply Chain Management

We utilize our in-house expertise to assure that the entire supply chain of primary and secondary components, clinical labels, investigational drug distribution and device supply, and concomitant medications are delivered on-time and within budget.

Drug Supply Sourcing

CMSU works with other supply-side vendors and wholesale distributors to ensure the highest quality lowest cost materials are sourced, managed/handled in compliance with Federal and State regulations and all project requirements.

Returns Handling

Return and Disposition of used and unused materials must be carefully coordinated with Sites and Sponsors to assure adequate accountability of supply status. CMSU possesses many years of experience in handling of returns in a regulatory compliant manner from the perspective of both FDA and EPA.

Destruction of Used and Unused Supplies

Once full accountability of the investigational articles is established CMSU will petition the Sponsor to approve its final disposition and ultimate destruction in a regulatory compliant manner.

Regulatory and Support Services

CMSU can provide regulatory support services for IND's, CTA's and IMPD's as necessary to complete your applications. CMSU has provided input and "technical writing support for nearly 100 INDs and numerous CTA's and IMPD's.

Quality System

CMSU's Quality System is designed to comply with International Standards for the production of Investigational Product (IP); 21 CFR parts 210 and 211 (current Good Manufacturing Practice (cGMP) regulations for the production of Pharmaceuticals, 21 CFR Part 812 (Investigational Device Exemptions) and Volume 4, Good Manufacturing Practices, Annex 13, Manufacture of Investigational Medicinal Products.

CMSU also provides project management support:

- Kit design to align with dispensing visits
- Creation of drug accountability logs and operations/pharmacy manuals
- Presentation of drug/device supplies at Investigator Meetings
- Management of expiration/retest dates

Your Comprehensive Resource for Clinical Trial Materials