



The Comprehensive Resource for Clinical Trial Materials

The Clinical Materials Services Unit (CMSU) of the University of Rochester Medical Center is one of the leaders in providing high quality clinical trial supplies for all phases and indications of clinical research. We specialize in clinical trial packaging, labeling and logistics, giving you the customized support you need to keep your trials on time, on budget and in compliance with FDA and ICH standards. The CMSU is licensed by the New York State Board of Pharmacy #028772.

Working with us is refreshingly different. Since we are part of an academic medical center, we have a culture of working closely with researchers. As a result, we thoroughly understand your needs. We offer not only a completely integrated solution from strategy through labeling, but a more thoughtful, collaborative approach that makes the whole process seamless and trouble-free, while meeting aggressive timelines.

Our Services

CMSU offers a complete range of supply services for clinical trials. We can manage your supply needs from start to finish and provide solutions for any specific needs you have.

- Primary & Secondary Packaging of Clinical Trial Materials
- Label Design, Printing and Application
- Clinical Supply Chain Strategy
- Clinical Supply Chain Project Management
- Study Specific Randomization
- Package Development, Integrity & Performance Testing
- Cold Chain and Transportation Strategies
- Storage Options
- Secure Environment
- Returns Management/Destruction
- Trial Archiving

How We Can Help

CMSU has carefully considered each step of the clinical trial supply process. In our work with researchers both here and across the country, we have tested and developed the very best methods for meeting your supply needs. Here is how we can help you at every stage of the supply process:

PRIMARY AND SECONDARY PACKAGING OF CLINICAL TRIAL MATERIALS

- Design creative and effective packaging
- Meet product requirements and patient security standards
- Meet patient and investigator compliance standards
- Offer labeling & assembly options including:
 - Single and multi-language labeling
 - Booklet design and procurement
 - Open-label, randomized treatment disclosures
 - Manual labeling
 - Dedicated patient kit assembly
 - Inclusion of investigational drug/device handling instructions for site personnel
- Just-in-time packaging
- Temperature-sensitive material preparation



LABEL DESIGN, PRINTING, AND APPLICATION

- Provide our 21 CFR part 11, cGMP compliant labeling system: documented label production, audit log, print run batch records, labels with unique codes - Strict label control and issuance
- Optimize material utilization, supply and re-supply strategies, expiry/retest dates and costs

CLINICAL SUPPLY CHAIN STRATEGY

- Develop optimal packaging and supply strategies
- Help you avoid delays and control costs
- Utilize extensive experience and knowledge in the regulated environment
- Manage issues associated with couriers and delivery challenges

CLINICAL SUPPLY CHAIN PROJECT MANAGEMENT

- Apply expertise in large, long-term and complex protocols
- Assess packaging, labeling and dosing instructions with patients, nurses and physicians
- Monitor packaging, labeling, distribution, expiration/retest monitoring and returns/destruction

STUDY SPECIFIC RANDOMIZATION

- Randomization plan, including initial and re-supply shipment sizes to sites
- Collaboration with the Department of Biostatistics and Computational Biology at the University of Rochester to provide randomization services and sample size/power calculation
- Creation of drug disclosure labels and/or envelopes

PACKAGE DEVELOPMENT, INTEGRITY AND PERFORMANCE TESTING

- Protocol development (package integrity, thermal insulation qualification, transport package testing)
- Selection of (ISTA, ASTM, ISO) certified package testing lab
- Project management of package testing through final report
- Test data review and package impact assessments

COLD CHAIN AND TRANSPORTION STRATEGIES

- Identification of transportation packaging solutions
- Experience with domestic and international distribution
- Use of prequalified, pre-validated cold chain shipping cartons

STORAGE OPTIONS

- Room temperature and humidity controlled warehouse
- Automated environmental monitoring system
- Refrigerated storage from 2°C to 8°C
- Temperature monitoring upon request

SECURE ENVIRONMENT

- External building security via swipe card only
- Visitor entrance allowed only with an escort
- 24/7 motion-sensitive security camera monitoring of external building and storage warehouse
- All room access via swipe card with 21 CFR part 11 compliant logging of all activity 24/7

RETURNS MANAGEMENT/DESTRUCTION

- Develop site return procedures, receive used/unused investigational product, perform accountability and destroy product in compliance with cGMPs and OSHA regulations

TRIAL ARCHIVING

- Archive all trial files in compliance with GCPs and store on off-site long term storage facility