

The Comprehensive Resource For Clinical Trial Materials.

Clinical Materials Services Unit (CMSU) 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 support you need to keep your trials on time, on budget and in compliance with FDA and ICH standards.

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.

Our Services

CMSU offers a complete range of supply services for clinical trials. We can manage your supply needs from start to finish, or help you with any of the more specific needs you have.

- Clinical Supply Chain Strategy
- Clinical Supply Chain Project Management
- Label Design, Printing and Application
- Study Specific Randomization
- Primary Packaging Solutions
- Secondary Packaging Solutions
- Storage Options
- Secure Environment
- International Trial Distribution
- Returns Management
- 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.

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.
- Handle 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.

LABEL DESIGN, PRINTING, AND APPLICATION

- Optimize material utilization, supply and re-supply strategies, expiry/retest dates and costs.
- Provide our cGMP compliant labeling system:
 - Documented label production
 - Audit log
 - Print run batch records
 - Labels with unique codes
 - Strict label control and issuance

PRIMARY AND SECONDARY PACKAGING SOLUTIONS

- 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, double and unblinding cards
 - Manual labeling
 - Dedicated patient kit assembly
 - Inclusion of dosing instructions
- Just-in-time packaging.
- Temperature-sensitive material preparation.

STUDY SPECIFIC RANDOMIZATION

- Sample size/power calculation.
- 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.
- Creation of drug disclosure envelopes.

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.

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MEDICINE of THE HIGHEST ORDER