Worldwide Clinical Trials

Pharmacy Capabilities

At Worldwide Clinical Trials (Worldwide), we are committed to delivering excellence in clinical research through our state-of-the-art pharmacy services. Our cGMP Phase I on-site pharmacy, coupled with Investigation Drug Services located within our Clinical Pharmacology Unit, is designed to meet the highest industry and regulatory standards, ensuring the utmost security and confidentiality of your study trial and investigational products. With a team of highly experienced clinical pharmacists and certified pharmacy technicians, we provide a comprehensive range of services tailored to support your clinical trials. Our on-site pharmacy is equipped with advanced compounding equipment and sophisticated environmental monitoring systems, guaranteeing precise and reliable dose preparation.

Comprehensive Services

- **Oral Dose Dispensation**
- **Non-Sterile Dose Compounding**
  Per USP Chapter (795).
- **Sterile Dose Compounding**
  Per USP Chapter (797).
- **Radiologicals**
- **Retention Sampling**
- **Handling of Controlled Substances**
  Experience with Schedule I-V substances following FDA, cGMP, GCP and DEA Guidelines.
- **Temperature-Controlled Storage**
  - Room Temperature: 20°C to 25°C
  - Refrigeration: 2°C to 8°C
  - Frozen: -20°C to -80°C

State-of-the-Art Facilities

- **On-site cGMP Phase I Compounding Pharmacy**
  Fully dedicated to clinical trials with established processes and procedures.
- **Dedicated Dose Preparation Areas**
  Over 3,100 sq. ft. with HEPA filtration, segregated IP storage, and secure access.
- **Sterile and Non-Sterile Compounding Suite**
  ISO Class 7 clean room and ISO Class 5 laminar flow unit for sterile compounding.
- **Radiolabel Compounding Suite**
  Complies with USP Chapter (800).

Commitment to Excellence

FDA Compliance
Adherence to cGMP standards for Phase I investigational drugs since 2010.

Secure Access
Security monitoring with cameras, limited access card ID system, and locked drug storage areas.

Comprehensive Training
Includes didactic, observation, mentoring, and QC oversight for all personnel.

Mock Batch Procedures
Ensures detailed and properly sequenced processes before finalizing the Batch Record Template.

Detailed SOPs and Manuals
Provides meticulous protocols for equipment and processes.

In-Depth and Consistent Documentation
Guarantees quality study documentation through well-defined procedures.

Methodological Rigor
Dedicated to upholding the highest standards of quality data and subject safety.

Environmental Monitoring
Continuous monitoring of temperature and humidity.

Why Partner with Worldwide Clinical Trials?

At Worldwide, we have an unwavering commitment to methodological rigor, quality data, subject safety, and personalized attention. With a proven track record spanning more than 17 years, we have successfully conducted a wide range of clinical pharmacology studies. Our integrated services fully support early and late-stage development under one set of SOPs, ensuring seamless and efficient operations. Additionally, we leverage advanced technology, including a fully validated eSource data collection system, to provide efficient and accurate data management, making us a trusted partner for your clinical research needs.

Meet Your Pharmacy Team

Our team boasts extensive cGMP Phase I expertise and is highly experienced in conducting Phase I clinical trials. It includes licensed professionals, such as clinical pharmacists and certified pharmacy technicians, dedicated to ensuring the highest standards of quality control through our specialized Pharmacy Quality Controller Staff.

Lona Sheeran

Senior Vice President, Clinical Operations, Early Phase

- More than 20 years of experience in early phase operations
- Extensive analytical skills mastered from risk and benefit oversight experience

Nishi Soni

Associate Director, Pharmacy Operations, Early Phase

- Brings more than 25 years of extensive experience in the Bio-Pharmaceutical industry
- Specializes in Investigational Drug Service Management and Pharmacy Operations