

OUR CAPABILITIES

- GMP full service repository - receipt, test, store, aliquot, and ship
- On-site pharmacy and pharmaceutical distribution license
- Analytical support—identify confirmation and comprehensive API and drug product testing, including ICH stability testing
- Worldwide distribution and cold chain management
- Storage and Stability
- Drug Product Suite

OUR FACILITIES

- Store and secure drug substances, drug products, and other clinical trial materials
- Foreign-Trade Zone
- Biorepository
- Secure 12,000 sq. ft. repository
- cGMP compliant operations and storage, validated and temperature mapped storage
- VP-LN2, -80°C ultra-cold; -30° to -10°C freezer; 2°-8°C refrigerator; ambient conditions
- Controlled room temperature with validated AmegaView continuous monitoring system
- Separate GMP quarantine and return storage areas
- Separate shipping and receiving bays
- Fire suppression system (DuPont® FE-25™ based, quality-verified non-water-based system)
- 24/7 security monitoring system
- 72-hour auto-backup power system
- High potency containment areas for handling potentially toxic materials
- Automated back-up generator to support the entire facility in the case of a power-outage
- Able to receive, store and ship controlled substances (Schedule III-V)



OUR SOLUTIONS

- Vast experience extends to our secure, limited access, and contiguous space for API and drug product storage
- Facilities maximize workflow efficiency and maintain the integrity of client products
- All work is done in strict accordance to federal regulations—an MRIGlobal expertise
- Repository for over 6,500 compounds for the NCI

QUALITY ASSURANCE

- QA program, an independent unit within MRIGlobal, ensures all work meets stringent client-specific and quality and regulatory agency requirements.
 - FDA GMP and GLP compliant (21 CFR 210/211 and 58)
 - ISO 9001:2015 certified
 - QAU audits
 - Trained QA staff on-site
- Successful FDA Audit (2022)



CUSTOMIZED SOLUTIONS FOR PRODUCT DEVELOPMENT

MRIGlobal helps pharmaceutical clients accelerate their timeline and reduce the risks of getting a product to market by providing customized solutions to their product program. We bring a long history of diverse technical and regulatory expertise as well as a legacy of integrity and collaboration to make certain each client's objectives are achieved - on time and on budget.



OUR FULL SERVICES INCLUDE:

- Analytical Method Development and Phase Appropriate Validation for API DS & DP, Intermediates, and Impurities
- Bioanalytical Method Development and Validation, and Sample Analysis for Analyte Quantitation in Multiple Species and Matrices
- GLP and cGMP Stability and Storage of Drug Substances and Drug Products
- Custom Synthesis, Preclinical Batch Preparation and GLP Characterization, and Metabolite/Impurity Synthesis



ABOUT MRIGLOBAL

Founded in 1943, MRIGlobal is an independent organization performing customized contract scientific and engineering research, as well as management and operations, for government and industry around the globe.

