

# GMP/GLP Analytical and Bioanalytical Services

MRIGlobal

MRIGlobal is dedicated to helping our clients meet today's demands for regulatory compliance. We offer analytical method development and validation, and regulatory services and support to the chemical, pharmaceutical and bio-pharmaceutical industries operating under GMP and GLP guidelines.

## Pharmaceutical Analytical Testing

- ▲ APIs and Formulations
- ▲ Stability-Indicating Method Development and Validation
- ▲ Bioanalytical Sample Analysis
- ▲ Structural Identity and Confirmation
- ▲ Identification and Quantification of Impurities
- ▲ Residual Solvents
- ▲ Certificates of Analysis

## Bioanalytical Testing

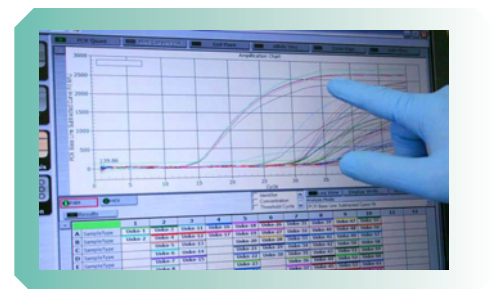
- ▲ Small Molecule, Peptide and Protein APIs and Formulations
- ▲ Composition and Identity Testing
- ▲ Method Development and Validation according to FDA guidelines (ICH and/or CDER)
- ▲ Quantitative Analysis of Drugs and Metabolites in Biological Matrices
- ▲ Experience with a variety of matrices including
  - Whole blood
  - Plasma/Serum
  - Lung
  - Urine
  - Saliva
  - Amniotic fluid
  - Feces
  - Tissues

## Pharmaceutical Stability Testing

- ▲ Preformulation Studies
- ▲ Dissolution and Characteristics Profiles
- ▲ Stability-Indicating Methods Development
- ▲ Stability Studies (Accelerated, Long-term, Photostability) according to ICH Guidelines

## Product Release Testing

- ▲ Physical Testing of Vaccine Formulations
  - Identity tests using PCR and genetic sequencing
  - Osmolality, pH, and moisture
- ▲ Sterility Testing
- ▲ Mycoplasma Testing
- ▲ PERT Assays
- ▲ Endotoxin Testing
- ▲ Viral and Prion Clearance Studies
- ▲ Vaccine Safety and Efficacy Studies
  - Multiple Animal Models
  - Aerosol Challenge Capabilities



Validated methods for quantitative real time PCR using an ABI 7900 Thermocycler.



## About MRIGlobal

MRIGlobal is a not-for-profit organization that performs contract research for industry and the government in the areas of national security and defense, energy and environment, life sciences, agriculture and food safety, and engineering. For more information, please visit our website:

[www.mriglobal.org](http://www.mriglobal.org)

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## Facilities and Equipment

- ▲ Chromatography Laboratories
  - GC
  - HPLC
  - UPLC
- ▲ Mass Spectrometry Laboratories with Validated Systems\*
  - Micromass Quattro II LC/MS/MS\*
  - ABI 4000 LC/MS/MS\*
  - ABI 4000 QTRAP (LC/MS/MS)\*
  - ABI-DE STR MALDI-TOF MS\*
  - GC/MS
  - GC2/MS
  - GC-TOF
- ▲ Dedicated molecular facilities with validated systems\*
  - ABI 7900 Thermocycler\*
  - ABI 3130 Genetic Analyzer \*
- ▲ (A)BSL2 and (A)BSL3 Laboratories
  - CDC & USDA Select Agent Registered
- ▲ AAALAC Certification
- ▲ Stability Facility with Environmental Conditions Compliant with ICH Guidelines
- ▲ Spectroscopy Facility with FT-NMR (400 MHz) and FT-IR
- ▲ Thermal Analysis (TGA/DSC)
- ▲ Validated Data Management Systems
- ▲ Validated Kaye-Labwatch Monitoring System

## Experts in Regulatory Compliance

MRIGlobal's instrumentation is fully validated to include IQ/OQ/PQ. Our in-house Instrument Services staff perform regularly scheduled preventative maintenance and performance qualifications on all project instruments. Instrument software is installed and validated to conform to 21 CFR Part 11 regulations.

All studies are audited by MRIGlobal's independent Quality Assurance Unit. We offer full compliance with regulations and guidelines of EPA-FIFRA, EPA-TSCA, FDA GLP, FDA cGMP, OECD, and the Japanese Ministry of Health, Labor, and Welfare. MRIGlobal's Kansas City facility is ISO 9001:2000 certified.



Analyst (Brendan Scott) examines the contents of a walk-in stability chamber.