MRIGlobal

Bioanalytical Capabilities

Integrated Pharmaceutical Solutions

OUR CAPABILITIES

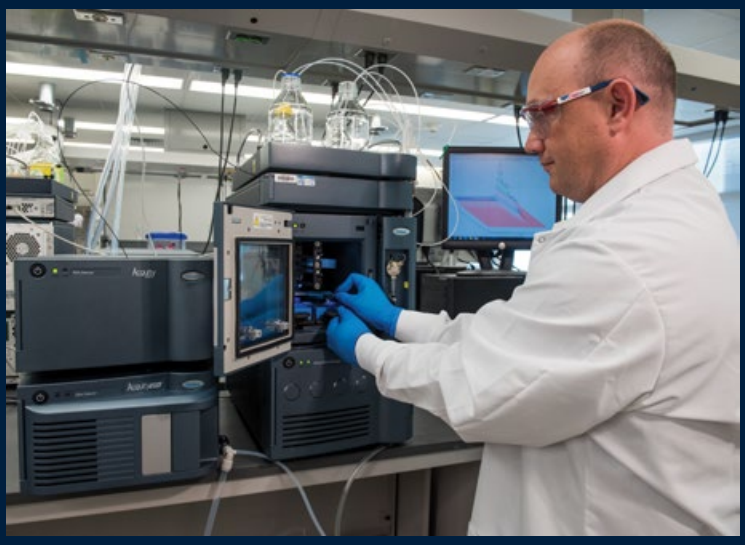
- Method development/validation and analysis of biological samples generated by toxicology, pharmacokinetic and drug metabolism (PKDM), toxicokinetic (TK), safety, and preclinical studies
- Chemical procurement/handling
- Metabolite identification and custom synthesis
- Characterization (chemical and formulation)
- Dose formulation and analysis
- Preliminary/definitive TK and toxicology studies
- Analytical method development/validation
- Sample analysis with statistical assessment

OUR SOLUTIONS

- Extensive corporate experience in method development, validation, and bioanalysis of a variety of analytes
  - Drugs of abuse, environmental contaminants, investigational drugs, and pharmaceutical APIs
  - Small molecule, peptide, and protein APIs as well as formulations
- GLP method development/transfer/validation and long-term stability studies conducted in full compliance with FDA guidelines
- Evaluation of fundamental performance and validation parameters
- Quantitation of analytes and metabolites in biological matrices following GLP protocols
  - Extensive QC and QA review
- Experience with a variety of matrices
  - Amniotic fluid/Mother's milk/plasma/serum/ saliva/semen/urine/whole blood
  - Adipose tissue/Bone marrow/ Brain/Feces/Liver/Lung

QUALITY ASSURANCE

- Independent Quality Assurance Unit (QAU)
- FDA GLP compliant (21 CFR 58)
- ISO 9001:2015 certified
- QAU audits, informing PI/management of regulatory status of projects
- Internal SOPs offering full federal agencies compliance
- EPA GLP/FIFRA/TSCA
- OECD



OUR FACILITIES

- Dedicated and comprehensive bioanalytical laboratories
  - Sample preparation
  - Sample analysis
  - Physical chemistry evaluations
- Sample preparation techniques
  - Liquid-liquid extraction (LLE), salt-assisted LLE (SALLE), supported-liquid extraction (SLE), protein precipitation (PPT), solid-phase extraction (SPE), and phospholipid removal
  - SPE pressure manifold 96 well plate
- Chromatographic analysis
  - Gas chromatography (GC): FID, MS, MS/SIM, FPD, µECD, NCD
  - Liquid chromatography (HPLC/UPLC): MSn, UV, PDA, fluorescence, ELSD, RI, radiochemical
  - LC-MS/MS ionization sources: APCI, ESI,
- APPI, nanospray, 96 well plate auto samples (chemical handling room for large scale dose formulation, blending, operations - stainless steel floors and outer wall)
  - QTOF, GC/HRMS, LC/HRMS
  - Column chemistries: C18, C8, phenyl, HILIC, chiral, PFP, and phenyl-hexyl
  - Software: Validated, 21 CFR 11 compliant

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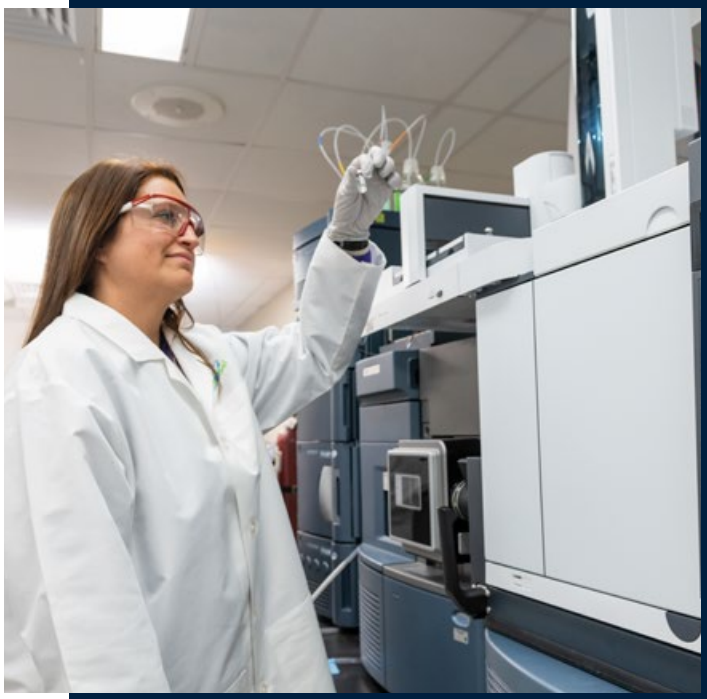
CUSTOMIZED SOLUTIONS FOR PRODUCT DEVELOPMENT

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 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.

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