MRIGlobal

Analytical Capabilities
Integrated Pharmaceutical Sciences

OUR CAPABILITIES

- Experience characterizing chemicals, determining impurities, performing chromatography, mass spectrometry, titrations, and physical/chemical property measurements
- Solve product development challenges such as:
  - Product registration and certification
  - Deficiencies meeting specifications
  - Performance failure analysis
  - Unique or proprietary analysis
  - Process development
- cGMP release testing and stability time points
- GMP formulation

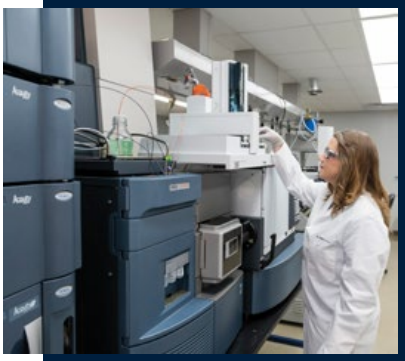
OUR SOLUTIONS

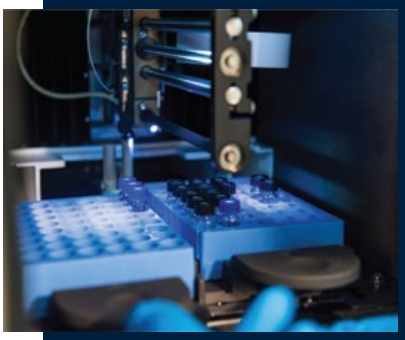
- Experience with all classes of small molecules
- Growing expertise in large molecules
- Fully equipped labs to identify products, intermediates, and impurities
- Method development and phase-appropriate validation
- Pre-formulation and formulation development
- Characterization of materials
- ICH stability studies
- Photostability
- Stability-indicating studies and supporting experiments
- Over 6,500 GLP and GMP projects successfully completed

QUALITY ASSURANCE

All work meets client-specific QA requirements as well as the quality and regulatory requirements of the following:

- ISO 9001:2015
- ISO 17025
- FDA GLP; cGMP
- EPA FIFRA GLP
- EPA-TSCA
- CAP
- CLIA





OUR EQUIPMENT

- Mass spectrometers: QTOF, GC/MS, LC/MS, GC/MS/SIM, LC/MS/MS (ESI and APCI) - GCXGC/MS, GC/HRMS, LC/HRMS
- Fourier Transform IR and NMR
- HPLC/UPLC systems (CAD, UV, diode-array (PDA), ELSD, and fluorescence) with autosamplers and computerized data stations
- GC-FID, FPD, NPD, MECD, TCD
  - Nitrogen chemiluminescence
  - GC-headspace analyzer
- Centrifugal partition chromatography
- Dissolution apparatus and tablet disintegration
  - Karl Fischer titration (volumetric and coulometric)
  - DSC/TGA

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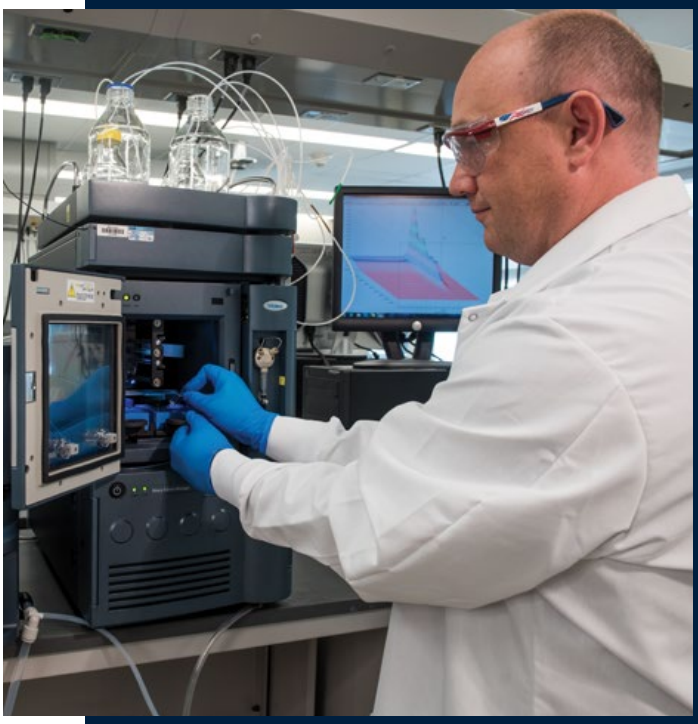
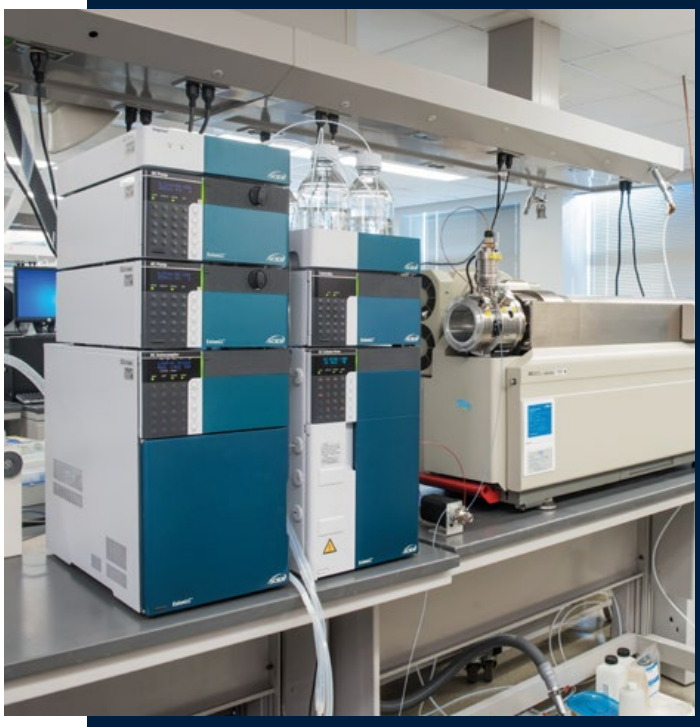
CUSTOMIZED SOLUTIONS FOR PRODUCT DEVELOPMENT

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 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.

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