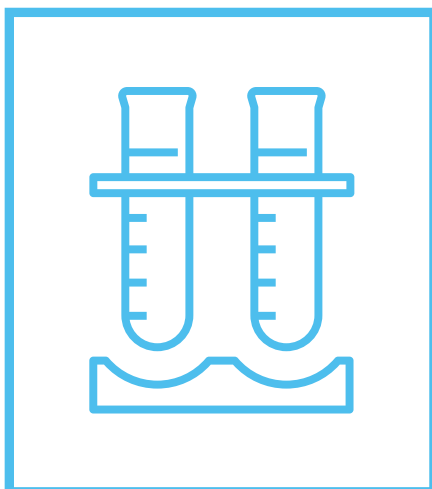


WE'VE GOT DRUG DEVELOPMENT DOWN TO AN EXACT SCIENCE

GET RAPID SOLUTIONS WITH OUR COMPLETE SUITE OF CAPABILITIES

AMRI provides scientific expertise and state-of-the-art technology to solve your most complex challenges and deliver integrated pharmaceutical drug development programs from preclinical to commercial. We provide development services at four locations within the United States and Europe. Our process development services are strategically located to deliver timely execution through convenient local points of contact.



Drug Development

Drawing from diverse branches of chemistry, biology, physics, engineering and pharmaceutical sciences, AMRI's development services include preformulation and material science, formulation development, analytical and solid state services, separations sciences and bioanalytical services.

DELIVERING COMPLEX SCIENCE AND EXPERT SOLUTIONS

Chemical Process R&D

Equipped with technologically advanced process and analytical instrumentation, AMRI's team of 150 scientists supports all your chemical development needs, offering integrated, continuous service through the drug development life cycle. We conduct rapid process development, optimize reaction conditions and scale up materials for preclinical trials or large-scale manufacturing.

- Continuous flow processing up to kilo scale for faster, safer material production
- Custom synthesis, including synthesis of reference standards, impurity markers and scaffolds, with rapid turnaround and competitive pricing
- Process safety assessment to proactively identify potential hazardous reactions
- Scale-up capabilities of cGMP raw materials or process intermediates, scaling from hundreds of grams to tens of kilograms
- High-potency and controlled substances capabilities (Schedule I-V)
- Specialized team in biotransformations and fermentation



Complex Science. Expert Solutions.

North America • Europe • Asia | 1.518.512.2000 | www.amriglobal.com

Preformulation and Material Science

AMRI characterizes and modifies a drug substance's physical, chemical and mechanical properties so you can select the best solid form for progression into animal and human dosing trials. Our customized services include:

- Comprehensive solid state characterization
- Systematic solubility enhancement
- Systematic salt screen for selection
- Co-crystal screen for selection
- Polymorph screening
- Crystallization process troubleshooting and optimization with PAT capabilities
- Particle size reduction and characterization
- Physical form stability and quantitation
- Structural elucidation
- Foreign particulate identification
- Spray drying process development
- Amorphous stabilization
- Early formulation composition design and development, including compatibility, stability and degradation mechanism elucidation

Formulation Development

With deep experience in the development of pharmaceutical formulations for oral, topical and injectable dosage forms, we will identify the parameters that impact the clinical performance and safety of formulations, manufacturability of dosage forms and stability in primary packaging.

- Drug substance, blends or dry granulation in capsules/bottles
- Sterile liquid, freeze-dried, colloidal or viscous formulation
- Sterile suspension feasibility
- Formulation composition design and development
- Topical ointment, cream or lotion development
- Solid dosage form development for tablets and capsules

Analytical and Solid State Services

Our capabilities help you achieve the desired properties and performance of your compound from the world's leading experts. Our comprehensive suite of analytical services includes chromatography, micromeritics, microscopy, spectroscopy and wet chemistry. In addition, we offer:

- Particle engineering
- Release testing
- Method development and validation
- Material science
- Container qualification and integrity testing
- Medical device and drug delivery testing
- Extractables/leachables and impurities detection
- Chiral and achiral separations via GC, HPLC and SFC
- Chemical purification
- Impurity isolation

Bioanalytical Services

We develop sensitive, robust bioanalytical methods for extraction and quantitation of drug and metabolites in biological fluids and tissues.

For inquiries, email us: ClientServicesDDS@amriglobal.com

Albany, NY | Grafton, WI | Hyderabad, India | Frankfurt, Germany