aragen.com

Expedite Your Success with Aragen's Comprehensive IND-Enabling Services

Why Our Approach Works

Rapid IND Readiness

From first toxicology study to IND submission in as little as 9 months - driven by optimized timelines, parallelized workflows, and proactive risk management.

Modality-Specific Expertise

Subject matter experts tailor study designs to your asset type - whether small molecules, biologics, or emerging modalities - ensuring fit-for-purpose strategies from the outset.

Leadership with Regulatory Insight

Your program is led by DABT-certified toxicologists and histopathology experts, providing deep mechanistic insight and regulatory foresight.

Integrated Teams Across Continents

An aligned toxicology, ADME, pharmacology, and independent QAU team operating across India and the USA troubleshoots issues rapidly and strengthens your IND package in real time.

Advanced Bioanalytical Precision

Our LC-MS/MS and broad bioanalytical platform delivers reliable quantification in complex matrices, elevating exposure and toxicokinetic data for regulators.

Global Large-Animal Capabilities

Benefit from centrally managed large animal programs with access to premier facilities in the US, Europe, and Asia, all coordinated through a single accountable partner.

Hands-On Scientific Leadership

A dedicated Chief Scientific Officer, experienced program leaders, and proactive project managers guide your asset seamlessly from discovery through IND and beyond.

Robust Global Logistics

Our global supply chain and logistics management keep your studies on schedule with seamless movement of test articles and samples across regions for US and EU submissions.

Aragen's experts support IND-enabling pharmacology, toxicology, metabolism, and manufacturing. We customize programs based on your drug type and objectives, ensuring a streamlined process from candidate selection to regulatory alignment for faster clinical trials and on-time success.

For more information, contact info@aragen.com
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Our Comprehensive IND Services

Drug Metabolism and Pharmacokinetics (DMPK)

Understanding how your drug behaves in the body is crucial. Our DMPK services include:

- Absorption, Distribution, Metabolism, and Excretion (ADME) studies
- Pharmacokinetics (Single/Repeated dose)
- Metabolite profiling and identification
- Bioavailability studies
- Drug-Drug Interaction assessments

Bioanalytical Services

Precision in quantifying drug concentrations is vital for accurate assessment. We offer:

- Method development, validation, and sample analysis (blood, urine, etc.)
- Toxicokinetic/Pharmacokinetic
- Immunogenicity assays
- Biomarker and biodistribution analysis
- Support for bioanalytical method transfer

Safety Pharmacology and Toxicology Assessment

Ensuring safety is paramount. Our assessments include:

- General toxicity studies- Acute/sub-acute/chronic
- Safety pharmacology evaluations- Central nervous system, respiratory, cardiovascular
- Developmental and reproductive toxicology (DART)
- Genotoxicity and carcinogenicity (conventional and transgenic mouse model) testing

Chemistry, Manufacturing, and Controls (CMC)

Streamlining your product's journey from development to manufacturing:

- Drug substance development and manufacturing
- Analytical method development and validation
- Drug product development and manufacturing
- Process optimization and scale-up
- Regulatory compliance and documentation

Why Aragen for IND Services?

With 30+ years of experience, we offer:

- **Regulatory Expertise:** Leverage our global knowledge and expertise to navigate regulations for seamless IND submissions.
- **End-to-End IND Solutions:** Get complete IND services, from preclinical to tailored submission strategies.
- **Advanced Technologies and Quality Standards:** Benefit from top technology, experienced experts, and strict quality controls.
- **Efficient Management:** Streamlined project management, clear budgeting, and personalized client support

Regulatory Experience

USFDA | EMA | EU Commission | EPA | OECD GLP | CDSCO | Indian GLP Authority

Modalities

Small molecules | Generics | Biologics | Vaccines | Biosimilars

Looking to elevate your drug safety assessment?

Reach out to us today to explore how we can empower your IND-enabling study success!

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