

# Arkus Research Private Limited

Your partner in Clinical Drug Development for NDA, ANDA submissions to USFDA, EMA and ROW.

## Company Overview

We are an Ahmedabad based company with extensive experience in monitoring, auditing, regulatory, medical and development strategy support of bioequivalence studies (normal healthy volunteers and patient PK), phase studies, post marketing and real-world evidence generation.

The leadership team is ably led by **Dr. Anupama Ramkumar M.D.(Med.)**, a well-known and regarded GXP and medical expert nationally and internationally, with additional expertise in clinical development strategy.

You would have a well-considered and expert service partner in us driven by a focus on excellence and an in depth experience of hundreds of studies, several successful regulatory audits across varied Quality Management Systems.

Our approach goes beyond templated checklists to truly customized monitoring / audit programs as we understand the Indian regulatory and contract research landscape to help you optimize the potential of your formulations. The team has had regular interactions with regulators, nationally and internationally on several key projects and development programs.

## Services We Offer -

Based on your specific needs we offer customized solutions for:

### 1. Audits

- Due Diligence Assessments
- QMS Gap Analysis
- Vendor Qualification Including CRO Audits
- Site Audits
- Pre-Inspection Audits and Post Inspection Assistance
- Trial Master File and Other Document Review
- GCLP Audits
- CSV Audits

### 2. Monitoring

- Bioequivalence Studies
- PK Studies in Patients
- Early Phase Studies

### 3. Medical Monitoring and Review

### 4. Regulatory strategy support including development of INDs,

**PINDs briefing books, query responses, Pediatric Waiver plans etc.**

### 5. Medical Writing and Review

- Protocol Writing & Review
- CRF Design & Review
- Clinical Study Report & CTDs
- Investigator Brochure
- Product Updates & Brochures

### 6. SOPs Development & Review

### 7. Customized Training Programs

- GCP
- Quality Systems
- PI Training

## ARKUS RESEARCH PRIVATE LIMITED

Reach us at -

**Email:** [anupama@arkusresearch.com](mailto:anupama@arkusresearch.com); [jayesh@arkusresearch.com](mailto:jayesh@arkusresearch.com); [arkus@arkusresearch.com](mailto:arkus@arkusresearch.com)

**Contact No.:** +91 9725886848

**Reg. Office :** #301, Aaradhya Complex, Gala Gymkhana Road, South Bopal, Ahmedabad, Gujarat, India -380 058.

**Web:** [www.arkusresearch.com](http://www.arkusresearch.com)

