

MEDPACE INDIA

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Resources and Experience

- Office established in 2006
- 15,000 sq ft office area
- General Manager – approximately 10 years experience in managing clinical trials
- Laboratory Director – 10 years experience as clinical pathologist with vast experience in managing the operational and laboratory aspects of clinical trials in the Indian scenario
- Clinical Trial Managers – Cumulative of 12 years industry experience at pharma companies and various CROs, GCP trained and with audit experience
- Clinical Research Associates – noteworthy experience and expertise in numerous therapeutic areas
- Regulatory Submissions Coordinator – 5 years industry experience
- Laboratory Technicians – Experienced and certified support staff with a proven track record in central lab services

Therapeutic Expertise

Medpace India employees have collective experience in the following therapeutic areas and types of trials:

- Phase II-IV
- Bioequivalence and bioavailability
- Drug interaction
- Epidemiology
- Animal
- CLAMP
- Biomarkers/gene arrays
- Cardiovascular – stroke, acute MI, CHF, hypertension, arrhythmias, MI, PVD
- Anti-infectives – tuberculosis, pneumonias, COPD, malaria
- Endocrinology/metabolic disorders – dyslipidemias, type I and II diabetes, hypertriglyceridemia
- Oncology – breast, ovary, cervix, non-small cell lung cancer, gastric, head and neck, chronic myeloid leukemia, endometrial carcinoma, prostate, lymphomas
- Neurosciences – diabetic neuropathy, partial epileptic seizures, Parkinson's disease, major depressive disorder, attention deficit hyperactivity syndrome
- Nephrology – chronic renal failure
- Respiratory tract infections
- Rheumatoid arthritis, osteoporosis
- Infectious diseases – septicemia hepatitis B, malaria, urinary tract infection, antifungal
- Dermatology – skin and skin structure infections
- Special patient groups – Cushing's syndrome, insulinomas

Services

Site Monitoring

- Perform site evaluation, initiation, routine monitoring, and closeout visits
- Ensure drug accountability
- Collect and maintain essential documents
- Perform data and safety monitoring, including EDC and CRFs

Regulatory

- Submit regulatory submissions and ongoing reports to authorities
- Correspond with ethics committee and central and local IRBs, as appropriate
- List and maintain trial details on Clinical Trial Registry of India
- Export permit application and renewals for international material transfer
- Prepare, distribute, and track essential trial documents and master file

Project Management

- Ensure feasibility and protocol compliance
- Perform site identification and evaluation
- Coordinate local investigator meeting, if applicable
- Negotiate and manage investigator agreements and payments
- Oversee clinical trial supply importation and distribution
- Manage audits
- Manage archival of trial materials
- Manage auxiliary services such as translations and courier services

Quality Assurance

- Ensure GCP and ongoing protocol-related training of site staff
- Prepare sponsor audits

Central Laboratory

- 4,000 sq ft laboratory, with additional space of 1,500 sq ft available for logistic support
- Industry-appropriate quality assurance and accreditation, lipid standardization, NGSP (level I) certification, and CAP accreditation
- Secure on-site archival storage of specimens
- Process samples related to hematology, biochemistry, lipid profile, urinalysis, immunoassays, and thyroid function

Why India?

- Low cost – 60% cost reduction compared to the US
- High quality data
- Faster patient recruitment – access to a large number of patients, less competing protocols
- Faster study start-up – predictable regulatory processes