Syngene

Putting Science to Work

Clinical Development

Innovate | Integrate | Customize | Accelerate

Clinical Development

Capabilities

BA/BE Studies to Support Development of Generic Drugs

- Over 150+ validated methods available as per USFDA guidelines
- Total Mass Specs: 10 [API 4000s and API 6500s]
- State-of-the-art instrumentation [with qualification]
- Analysis of drug(S) and/or metabolite(s) in biological specimen [e.g. blood, plasma, serum etc.] to support TK< PK, early phase clinical development, BA/BE and TDM studies
- Team of 40 qualified and experienced researchers with experience in method development, validation and regulated Bioanalysis for a wide range of chemically diverse drug molecules

Clinical Trial Management (Phase I-III Trials) of Novel Drugs and Biosimilars

- One of the most experienced Indian CROs in conducting patient-based trials
- Over 100 clinical trials conducted for registering products in US, Europe, India and ROW countries
- Deep experience in Oncology, Diabetes and Auto-immune disorders
- Full service solutions, incl. Clinical Supplies Management, Central Lab and CDM & Biometrics

Central Laboratory Services Encompassing Clinical/ Safety Lab and Bioanalytical Services for Small Molecules & Biologics

- CAP accredited Central lab offering clinical testing services exclusively for Phase 1-IV clinical trials and BA/BE studies
- GLP-certified, FDA-inspected bioanalytical lab offering PK, ADA and Nab assays
- 21CFR-11 compliant laboratory information management system with customizable project management and reporting capabilities
- Supported over 100 NDAs/BLAs submitted to US FDA, EMA and PMDA
- r HbA1c

Regulated Bioanalytical Lab for Large Molecules

- 3 blockbuster MAbs approved by USFDA and EMA, based on the bioanalytical data submitted from this lab
- Experience with 7 Biosimilars, 22+ Monoclonal Antibodies and few vaccines
- 600,000+ samples imported (from various parts of the globe) and analysed till date, with a track record of Zero compromise on sample shipment
- Existing customers include 5 of the top 10 global Big Pharma/Biotech companies and 1 of the top Animal Health companies
- 15+ years of rich and diverse experience
- Adept at Method Transfer, Development and Validation based on FDA/EMA/WHO guidance
- Influenced favourable change in Indian Govt's policy on import of biological samples for testing – no wait period for license, ~4-6 days sample travel time from US/EU, no wait period for clearance from customs, expedited reporting can be handled, especially for Dose Escalation studies requiring 1 week TAT

Clinical Data Management and Biometrics

- Stand alone or integrated data management for Phase I-IV studies
- Statistics and SAS programming for Clinical and non-clinical development programs

Data Acquisition:

- Web based through in-house eCRF – Oracle clinical / Inform
- Paper CRF based data capture - Oracle

Regulatory Track Record

- Audited by major life sciences Co's & Regulatory agencies from North America and Europe
- Certifications/ Accreditations: ISO 9001:2008, 14001, OHsAs 18001, AAALAC, GLP
- HPU & Bioanalytical labs are inspected by:
    - US-FDA – 9 audits
    - EMA – 3 audits
    - Thai FDA for GLP – 2 audits
    - ANVISA – Brazil – 2 audits
    - UK-MHRA – 1 audit

For more information, contact bdc@syngeneintl.com

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