Syngene

Putting Science to Work

Clinical Development

Innovate | Integrate | Customize | Accelerate

Clinical Development

Capabilities

BA/BE Studies to Support Development of Generic Drugs

- Conducted over 600 BA/BE or PK/PD or Phase-1 trials [incl. FIH studies]
- Clinic with 190 ward care beds and 12 ICU beds
- Over 200+ validated methods available as per USFDA guidelines
- Total Mass Specs: 11 [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, human aqueous humor etc.] to support TK< PK, early phase clinical development, BA/BE and TDM studies
- Team of 45 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
- Conducted multiple COVID-19 related trials in India
- 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

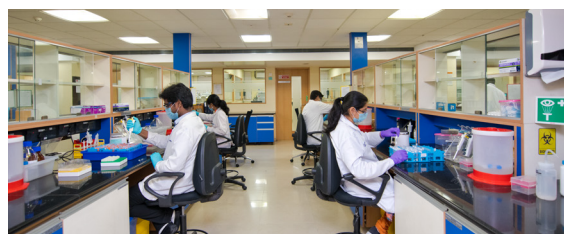
- 3 blockbuster MAbs approved by USFDA and EMA, based on the bioanalytical data submitted from this lab
- Experience with 7 Biosimilars, 22+ Monoclonal Antibodies and few vaccines
- 600,000+ samples imported (from various parts of the globe) and analysed till date, with a track record of Zero compromise 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
- Paper CRF based data capture



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 – 3 audits
    - UK-MHRA – 1 audit
- Regulatory track record for Regulated Bioanalytical Lab for Large Molecules :
    - US-FDA – 1 audit
    - PMDA – 1 audit

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About Syngene

Syngene Syngene International Ltd. (BSE: 539268, NSE: SYNGENE, ISIN: INE398R01022) is an integrated research, development, and manufacturing services company serving the global pharmaceutical, biotechnology, nutrition, animal health, consumer goods, and specialty chemical sectors. Syngene's more than 6000 scientists offer both skills and the capacity to deliver great science, robust data security, and quality manufacturing, at speed, to improve time-to-market and lower the cost of innovation. With a combination of dedicated research facilities for Amgen, Baxter, and Bristol-Myers Squibb as well as 2.2 Mn sq. ft of specialist discovery, development and manufacturing facilities, Syngene works with biotech companies pursuing leading-edge science as well as multinationals, including GSK, Zoetis and Merck KGaA.

For more details, visit www.syngeneintl.com or write to us at bdc@syngeneintl.com

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