




Validating Innovation
bioserve

www.bioserve.co.in





Mission

At Bioserve, our mission is to provide world-class clinical research services to sponsors across the globe by

- ▮ Providing services that exceed the sponsor requirements of quality, compliance, time and cost .
- ▮ Committed compliance to regulatory and ethical Standards .
- ▮ Ensuring the safety, dignity and well-being of all study participants.

Company Overview

At Bioserve, we are committed to facilitating the development of new and innovative products/technologies by our customers, in a responsive, reliable and compliant manner. Bioserve is promoted by professionals having over 30 years of experience in the Healthcare and Pharmaceutical industry. Our Team is committed to science and meeting the challenges of research by providing seamless outsourcing solutions with professionalism, flexibility and reliability. Our strict compliance to regulatory requirements and our dedication to high quality, accurate results and a commitment to meet sponsor timelines is uncompromising.

Bioserve is also an ISO 9001: 2000 certified facility approved by the Drugs Controller General of India and US-FDA Inspected

Services

- ▮ Bioavailability and Bioequivalence
- ▮ Phase I and Pharmacokinetic Studies (Dose Response, Steady State, Food Effect, DDI, Pharmacoscintigraphic Imaging).
- ▮ Bioanalytical Services
- ▮ PK/PD Analysis and Statistical Analysis
- ▮ Regulatory Affairs (Dossier Preparation, Query

Project Management

Bioserve has a dedicated Project Management team to serve as a single, knowledgeable point of contact with the sponsor. The team handles study requests, quotes, contracts, billing, final reports and all other sponsor communications while ensuring confidentiality, accountability and accessibility. Close collaboration with the scientific and QA teams ensures the timelines and other outcomes exceed sponsor requirements.

Clinical Services



Bioserve currently offers a 92 bed clinical unit with two independent clinics. The clinic has a full time medical staff, an extensive data base of healthy volunteers and the ability to recruit patient population through partnerships with hospitals and clinics. Our facility has the capabilities to support a variety of studies including:

- ▮ Bioavailability and Bioequivalence.
- ▮ Phase-I and PK including Dose Response, Food Effect, Efficacy Studies, DDI and Multi-dose Steady-state.

At Bioserve, our well qualified and experienced team of full time doctors and clinical staff are committed to offering the most reliable and timely services while ensuring compliance to the evolving regulatory and ethical requirements of the pharmaceutical industry.

- ▮ Access controlled clinical units
- ▮ Experienced and trained clinical staff
- ▮ Central monitoring with CCTV in all clinical areas
- ▮ Large database of registered and eligible volunteers
- ▮ Well equipped emergency room and attachment to super speciality hospitals
- ▮ Inhouse dining and recreation for study participants
- ▮ Dedicated sample collection/seperation areas
- ▮ Sample storage with $-40/-80^{\circ}$ C deep freezers
- ▮ Facility to handle light sensitive and other products requiring special handling
- ▮ Inhouse canteen with dietician to plan and provide standardised study specific diet to the subjects
- ▮ Comprehensive biosafety program to ensure the safety of the study participants and clinical staff



BioAnalytical Services



Bioserve offers a well equipped bioanalytical facility providing comprehensive bioanalytical services across the spectrum of drug development. Our strict compliance to regulatory requirements and dedication to delivering high quality, precise and accurate results on time is uncompromising.

At Bioserve, our experienced and well qualified bioanalytical team is capable of addressing complex analytical problems and can support the development and validation of methods in accordance with the highest standards imposed by regulatory agencies. We take pride in our commitment to ensuring that our sponsors receive reliable and quality bioanalytical services, with rapid turnaround times, resulting in faster approvals for sponsor submissions

Bioserve offers a comprehensive array of services:

- ▢ Analysis of Drugs and Metabolites in Biological Matrix.
- ▢ Method Development and Validation.
- ▢ Custom Assay Development
- ▢ Bioanalysis for preclinical ADME/Discovery DMPK

- ▢ Well equipped lab offering multiple Agilent HPLC and API 3200 and API 4000 LC/MS/MS platforms
- ▢ Qualified and experienced team with over 40 man years of experience
- ▢ Access controlled secure sample storage/archival area with -40/-80 °C deep freezers with data logger for temperature monitoring
- ▢ Dedicated sample processing area with all accessories including Positive Pressure Solid Phase Extraction (SPE)
- ▢ Two level power back up system with UPS systems and auto start Diesel Genset to ensure uninterrupted power
- ▢ Bioanalytical QA team ensures online compliance with SOPs, Protocol, Regulatory and Sponsor Requirements
- ▢ Comprehensive Biosafety program in accordance with applicable regulatory and environmental guidelines.



Pharmacokinetics and Statistics



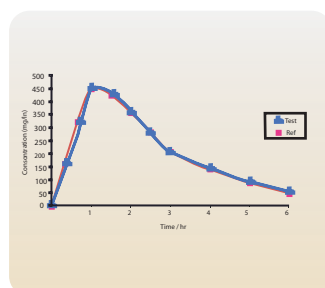
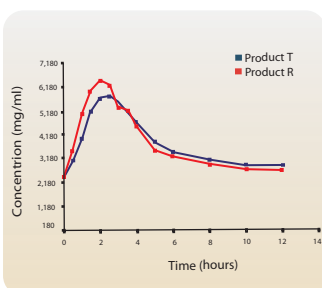
Bioserve has a dedicated and experienced Pharmacokinetics and Statistics team with expertise in the application and presentation of Pharmacokinetics (PK) and Statistical principles critical for successful approval of product submissions. The group has proven expertise in the design and data analysis of Bioequivalence and individual PK studies and sub studies to expedite the drug development and approval process. Our group is also committed to development of new and innovative modeling approaches to enhance more efficient and informative drug development. Our services include:

- ▮ Bioequivalence Analysis
- ▮ PK and PK/PD Analysis.
- ▮ In Vitro In Vivo Correlation (IVIVC)
- ▮ PK and Statistical Reports for Regulatory Submissions (using WinNonlin & SAS)
- ▮ Population PK analysis

At Bioserve, we provide comprehensive support for a variety of PK and Statistical applications including:

- ▮ Study Design & Protocol Preparation
- ▮ Sample Size and Statistical Power Estimation
- ▮ Randomization Services
- ▮ PK/PD Modelling and Analysis
- ▮ Sparse Sampling Analysis
- ▮ Bioequivalence & PK Analysis of Study data identification
- ▮ Analysis & Report preparation for regulatory submission

The PK group also independently manages an access and temperature controlled pharmacy for the receipt, storage, handling & archival of study drug products in accordance with the regulatory requirements.



Quality Assurance and Regulatory Affairs



Quality Assurance

At Bioserve, our independent Quality Assurance unit provides the expertise and established systems and processes to ensure that all projects are conducted in accordance with the protocol and regulatory requirements. QA independently conducts project specific audits covering all phases to ensure studies are conducted according to:

- ▢ Standard Operating Procedures (SOPs) and Sponsor Approved Study Protocols
- ▢ Good Clinical Practices (GCP) and Good Laboratory Practices (GLP)
- ▢ Regulatory requirements of relevant agencies

QA is also responsible for the development, improvement and control of all operating procedures. QA also ensures the archival of all study data and reports in an access controlled fire proof archival facility in accordance with protocol and regulatory requirements.

Regulatory Affairs

Our Regulatory Affairs (RA) team comprises a wealth of experience in all areas of drug development, approvals and manufacturing and can extend support for a diverse range of services including:

- ▢ Regulatory Dossier preparation (NDA/ANDA) and submission
- ▢ GxP compliance audits of CROs, Manufacturing and Clinical Research Sites
- ▢ Regulatory Affairs support for post submission query resolution and responses to facilitate successful approvals.

Our QA and RA team is committed to ensuring strict compliance to regulatory standards and our dedication to high quality, accurate results ensures the prompt and successful approval of our customers innovative products.

