OUR MISSION: Precise Research, Proven Results

We are focused on the specific expectations of our customers and a smooth communication thus to establish long term relationships.
We are targeting to offer complete high quality services and price for value in line with the relevant regulations.

- We achieve our goals through innovation and highly professional approach
- We obtain our results within reasonable time lines and manageable risk

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sopharma® PHARMACEUTICALS

LABORATORY

PHARMACOKINETICS AND CLINICAL TRIALS

Precise Research, Proven Results

MRA medical and regulatory affairs

Sopharma PLC`s Pharmacokinetics laboratory was established in 1969 to provide bioanalytical services in the area of pharmacokinetic and bioavailability/bioequivalence studies.

All PK laboratory activities are carried out in accordance with Good Laboratory Practice (GLP) and Good Clinical Practice (GCP) principles and in compliance with the regulatory requirements of the Bulgarian Drug Agency (BDA), European Medicines Agency (EMA), Food and Drug Administration (FDA), International Conference on Harmonisation (ICH), and the World Health Organization (WHO).
We are recognized on the market with complete bioanalytical services, flexibility, highly qualified staff, easy communication and competitive price, along with high quality.

SERVICES

- Time-critical development and validation of new methods in accordance with customer's requirements
  - Drugs and Metabolites
  - Combined drugs
- Assay of analytes in biological matrices

- High volume sample analysis
- Study report writing

As a part of the Medical and Regulatory Affairs Department at Sopharma PLC, we can offer also complete BA/BE project management, including regulatory submission and consultancy in compliance with the international standards.

SERVICES THROUGH SUB-CONTRACTORS

Our long-term partnership with leading Contract Research Organisations (CROs), scientific and research organisations and academic facilities enables us to provide a complete service for pharmacokinetic and bioavailability/ bioequivalence studies (Study design and documents preparation, Submission to Ethics Committee and Regulatory authority, Clinical phase, Statistical analysis, Final study report).

QUALITY ASSURANCE

- Implemented GLP principles
- Independent GLP quality assurance unit
- Regular audits, according to quality assurance programmes, to ensure GLP compliance (internal audits, including both internal and external expertise)
- Readiness to comply with requirements in customer audits or regulatory inspections

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