# Service & Experience Brochure

## Integrating Drug Development Process

Version 2022

# INTRODUCTION

**mKnal Global Solutions** is a full-service, global consulting pharmaceutical company engaged in providing Biopharmaceutical and Healthcare Solutions.

Our Integrated Product Development services help biopharmaceutical companies shorten time to market, manage risk and access new global markets to maximize portfolio value.

Experts perform an In-depth assessment of product for appropriate decision making with understanding of product's technical, scientific and regulatory requirements.

Our extensive experience in regulatory markets with a strong acumen on individual domain of product development has helped biopharmaceutical companies achieve success with a proven track record.

The company offers an array of services including Formulation Development & Analytical Services, Clinical Development Medical Writing, Quality Assurance and Regulatory, which can be customized to individual needs and complexity of biopharmaceutical product development.

**mKnal Global Solutions** was established in the Year 2016 with focus on providing integrated pharmaceutical product development services.

The company is strategically located in the Industrial hub and financial capital of India.

Our global reach is accomplished by presence in three major continents Asia (India & China), USA (North Carolina) and Europe (Netherlands). The company has been serving clients from this region since its inception.

The company's growth and success is embossed by its expert team and network partners in delivering Quality driven projects with the core values of Transparency, Integrity and Care in its deliverables.

The Clients Trust, Confidence and Reliance over years has been the testimonials to our services.

# OUR MISSION

**mKnal** was established with a mission to support the pharmaceutical and healthcare industry in areas of product development where they face challenges, troubleshoots and/or hurdles in the development pathway.

The company employs its expert team in assuring a successful execution and faster access to the global markets.

mKnal undertakes complete product portfolio/program management or customized tasks with quality driven deliverables using its unique fusion of scientific, regulatory and global network of experts and partners.


# OUR VISION

**mKnal** aims to support the pharmaceutical and healthcare industry and become an integral part of their Drug Development Process.

The company shall achieve its growth with the success of client and meet its mission by fulfilling its clients company objective


# OUR VALUES

**mKnal** is positioned strong in the global markets because of its core values.

The company shall aim and strive hard to be a preferred healthcare solutions provider excelling in customer delivery through its core working principles and enjoy success in every deliverables giving value to:

1. **QUALITY**
2. **TRANSPARENCY**
3. **KNOWLEDGE**
4. **COMMITMENT**
5. **TEAMWORK**

# FORMULATION DEVELOPMENT & ANALYTICAL SERVICES

**Experts in analytical chemistry, Pre-formulation, formulation and nutraceutical development and optimization**, as well as analytical testing and development services.

**Extensive experience working Specialty Complex Products, Potent Products** & variety of dosage forms.

Product Development with **focus only on regulated markets** like US, Europe, Canada, Australia, South Africa, WHO, etc.

**Highly Experienced Formulation Development & Analytical** Support team.

**Six (06) times USFDA Audited** and Accepted Analytical lab delivering world class **services to more than 150 pharmaceutical** companies.

**Largest Resource for Ion Chromatography**; Extractable & Leachable studies & **USFDA Inspected In-vitro Bioequivalence** studies.

# DRUG DISCOVERY / PRE-CLINICAL

- Drug Discovery services including IND & NDA enabling studies, bridging studies for regulatory submissions, qualification of impurities, 505(b)(2) strategies, etc.
- In-depth knowledge and expertise on various aspects of DMPK, genetoxicity, formulation science and bioanalytical (method development and validation).
- We support in various stages of Drug Discovery and Development:

  1. Exploratory Toxicology Studies
  2. DMPK Studies
  3. Mammalian Toxicology
  4. Genetic Toxicology Testing
  5. Safety Pharmacology Studies
  6. Bioanalytical

- The team has wide experience working on different routes of administration *viz.* Oral, Sublingual, Intravenous, Ocular, Dermal, Subcutaneous, Inhalation, Intranasal, etc.
- Species handle: Mice, Rats, Rabbits, Dogs, Minipigs, Guinea Pigs, Cattle, Goat, Sheep, etc.
- Well-equipped In Vitro Cell culture and microbiology laboratory.
- World class Inhalation units for toxicology studies.

# VETERINARY BIOEQUIVALENCE

- The team has experienced working on various Veterinary Bioequivalence studies in different animal species.
- Pharmacokinetic studies includes various ADME model and studies on different routes of administration.
- We are following the CPCSEA (Committee for the Purpose of Control and Supervision of Experiments on Animals), FELASA (Federation of European Laboratory Animal Association) and AAALAC International (Association for Assessment and Accreditation of Laboratory Animal Care) practices for conducting studies.
- Hands on experience with CVM and NADA regulations.

# CLINCAL DEVELOPMENT (BA/BE) & PHASE-I

Complete Project and Clinical Management of biostudy.

Capacity Assessment and Qualification of CROs.

Complete product assessment to understand complexity, clinical and regulatory challenges for successful execution.

Protocol review and recommendations on study design, statistical approaches and sample size determination

Provide Technical and Scientific rationale for overcoming Regulatory hurdles.

Successful Execution and Management of Para IV (First To File)

Biowaiver Approaches.

Monitoring and Quality Assurance of Clinical Data.

Bioanalytical Audits and Data Verification of MD/MV & Bioanalysis.

Review and Compliance of Clinical Reports.

# OUR EXPERIENCE

➢ Experience on complete project and clinical management of more than 350 BA/BE studies including 18 patients based PK/PD studies for regulated markets (USFDA, EMA, TGA, ANVISA, etc).

➢ Extensive experience of managing clinical studies on a range dosage forms including Oral Solids, Liquids, Transdermal patches, Inhalation Products (MDIs and Powder Inhalers), Injectable Emulsions, Suppositories, Chewing Gum, Sublingual and Oral Films and Implants

➢ Managing Clinical studies on Healthy Male/Female, Geriatric, Post Menopausal Women, Genotype (Slow & Fast Acetylators), etc.

➢ Vast Experience on managing clinical biostudies for Narcotics / Psychotropics and/or Controlled Substance (CII) products

➢ Good experience of working on IR/ER combination products and products with BE estimation on Partial AUCs, Steady State (Multiple Dose)

➢ Experience working Ex-MHRA and Bfarm, USFDA Regulatory Experts for consultation on study design and approach for successful submission of Clinical BE studies to respective regulatory and/or in Europe.

# CLINICAL MONITORING & AUDITING

- Experience of Monitoring > 350 Bioequivalence studies for National (DCGI) & International regulatory submissions *viz.* USFDA, EMA, TGA, Health Canada, MCC, WHO, ANVISA, Health-Malaysia, Chile and China (CFDA).
- Extensive experience on Monitoring of PK/PD based Clinical studies *viz.* COPD, Nicotine Chewing Gums, General Anaesthesia, Psychotropic and Controlled Substances (C II).
- Hands On experience with Monitoring of Bioequivalence (Healthy subjects) and Patient based (Phase I, II and III trials).
- Monitoring of Different Population based (Healthy Male & Female), Post Menopausal Women, Geriatric and Differential Genotype subjects.
- Vast Experience on Different Dosage Forms *viz.* Inhalation Products, Injectables, Chewing Gums, Transdermal Patches, Suppositories, Oral Films, Sublingual, Oral Solids, Liquids, etc.
- Good experience of clinical monitoring of Psychotropic products.
- Strong acumen of Clinical, Bioanalytical and Statistical aspects of a Clinical Study.
- Customized Monitoring of Bioanalytical area and aspects of a study.
- Good Experience of Risk Based Approach (Remote Monitoring).


- Vast experience of conducting System / Qualification Audits of CROs in India.
- Capacity Assessment Audits for Specific Product related biostudy requirement (*viz*. Inhalation, Chewing Gum, etc.).
- Conducted numerous complete Bioequivalence Retrospective Audits and Review.
- In-Process Audits for Bioanalytical sample analysis and related activities.
- Vendor Audits / External Service Facility Audits (*viz*. Clinical Pathology Laboratory, Catering, Hospitals, etc.)

# QUALITY ASSURANCE SERVICES


- GMP/GLP, ICH and ISO Standard Compliance Audits
- Quality System Design and Implementation
- Preparation for regulatory agency inspections to FDA, EMA, MHRA and PIC/S standards
- Risk Assessment, Strategy Development and Management of Corrective Actions
- Regulatory Agency Compliance including FDA 483s, EDQM Observations, Warning Letters, etc.
- Clinical (GCP) Compliance Audits & Capacity (CRO) Assessment Audits
- Retrospective Evaluation and Compliance Management


- Designing and implementing a customized Quality Management System
- Perform independent audits of internal Quality Management Systems and controls
- Remote and Virtual Audits (Desktop Audits)


# OUR EXPERIENCE

- More than 400 audits including API, FDF, CMO and Medical Devices company
- More than 21 Clinical CRO audits.
- On site Validation batches supervision and compliance
- Preparation of Regulatory Agency Audits for API, FDF and CMO
- GAP Analysis, Correction Actions and Management
- Suggestions on CAPA and Responses to FDA 483, EDQM Observations, etc.
- Preparation and Implementation of Quality standards and Quality Management System.
- Risk Assessment on Data Integrity, Consent Decree Remediation and Verification Activity
- Extensive experience on pharmaceutical grade API, finished product and excipients.

# MEDICAL & SCIENTIFIC WRITING SERVICES

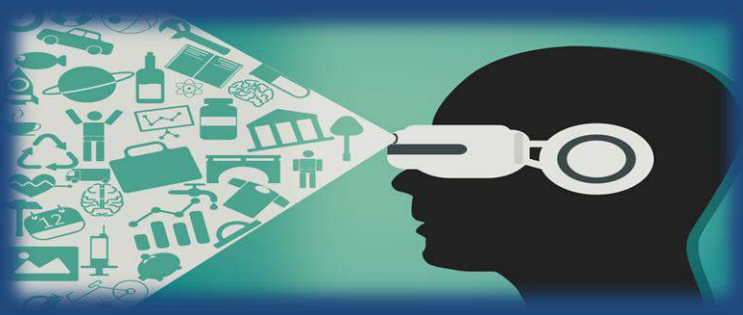
- Module 2 Writing including Non-Clinical & Clinical Overviews and Summaries (Mod. 2.4, 2.5, 2.6 and 2.7)
- Risk Management Plan (RMP)
- Patient Information Leaflet (PIL)
- Product Monograh / Label (PM/PL)
- Summary of Product Characteristics (SmpC)
- Periodic Safety Update Reports (PSUR)
- Investigational Brochure (IB)
- Clinical Pharmacology & Toxicology Reports
- Bio waiver Monographs

- Rationale on Clinical / Statistical / Product Development Approaches
- Conference materials (abstracts, poster presentations and slide sets)
- Manuscripts
- Article Writing in peer scientific Journals
- Literature Reviews (Meta-Analysis)
- Statistical Analysis Plan (SAP)

# OUR EXPERIENCE

- Module 2 writing for more than 110 products
- Risk Management Plan for 18 products
- SmpC Comparison and Preparation for 27 products
- Biowaiver Write-Ups for 02 product
- Clinical Pharmacology & Toxicology reports for 11 cases
- Abstracts, Posters, Manuscripts, Commercial Brochures and Journal Submissions for 63 cases
- Statistical Analysis Plan for 13 Clinical Trials

# REGULATORY SERVICES



- Regulatory Agency Query Response
- Controlled Correspondence
- Scientific Discussion material with Regulatory Advisory Board
- Rationale on Product specific Regulatory approaches
- Dossier Preparation & Compilation (CTD / eCTD)
- Drug Master File (DMF) Preparation
- GAP Analysis in Submission Content

# OUR EXPERIENCE

- Regulatory Agency Query Responses to more than 36 different products (EMA, USFDA, TGA, WHO, MCC, etc.)
- Working with different Ex-regulatory (MHRA / USFDA) experts on subject matter concerns.
- Controlled Correspondence to USFDA on many occasions including:

- OGD Recommendations when BE recommendations not published (Tranylcypromine, Methanamine Hippurate, Chlorzoxazone);
- Inclusion of additional strength in a single ANDA application;
- when RLD is not present and consideration of RS product, Study Design and Statistical approach different from the recommendation, etc.


- Successful development of IVIVC models and its application in product development.
- Experience working with Reputed Biostat and Pharmacokinetic Scientist for statistical approaches and increasing the probability of success on products with High Variability, Atypical pharmacokinetic profiles, etc.
- Dossier Compilation for 12 products
- DMF Preparation for 07 products
- Speaker and Presentation on International platforms

# MEDICAL DEVICES

- Rich professional experience in Product Innovation, Engineering and Realization.
- The team brings both design, manufacturing and regulatory knowledge on the table right from early stages of design.
- Quality Proof of Concepts for an Idea or Converting Concepts into Products with a quick turn-around time.
- Complete IP management of the device from the concept stage.
- State-of-the-art testing services for medical devices under GLP and ISO 10725 standards.
- Biocompatibility studies for all classes of medical devices (ISO 10993, ISO 7405, ISO 11979) and preclinical services for performance & safety evaluation of medical devices and therapeutics (ISO 25539-2:2012 and 21 CFR 58).
- Routine projects accepted by USFDA (for 510K & PMA), EU (for CE Marking).
- Experience on orthopedic, dental, ophthalmic, cardiovascular, respiratory, PPEs, and other preclinical medical device testing programs.
- In-depth knowledge of the regulatory requirements and practical handling of complex projects.
- Assist in Scientific Writing and Clinical Evaluation Reports in compliance to International regulatory standards.
- IP management team handles complete concerns on Patents, Trade Secrets (if any) and also support on any litigations.
- Our routine work includes Cytotoxicity, Skin sensitization and Irritation, Systemic Toxicity, Hemocompatability, Pyrogencity, Implantation studies, etc.
- Complete support on 510(k), a Premarket Approval, IDE, QSR audit, US Agent, product or facility registration or the filing of petitions, exemptions and responding to warning letters or FDA form 483s,

# CONTACT US

**mKnal Global Solutions** is ready to support you in every step of your Pharmaceutical Product Development.

Reach us and learn how we can assist you in your objective. **Write us at info@mknal.com**

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