BRIEF INTRODUCTION

mKnal Global Solutions, is a consulting company engaged in providing Pharmaceutical, Information Technology (IT) and Engineering services to Pharmaceutical, Medical Device and Diagnostic, Biotechnology, etc.

mKnal undertakes complete product portfolio/program management of generic pharma companies **from Europe, United States, Australia, Latin America;** where we accomplish complete dossier development in association with our trusted partners.

We design, conduct and manage Clinical studies from **Pharmacokinetic, Pharmacodynamic (Phase-I) to BA /BE** for EMEA, USFDA, TGA, MCC, & Latin America markets.

Our integrated product development services help biopharmaceutical companies **shorten time to market, manage risk and access new global markets** to maximize portfolio value.

With a unique fusion of scientific, regulatory, global network of experts and partners; **mKnal has** been able to **successfully deliver**:

i. Clinical BA/BE studies on more than **42** generic products for **EMEA**, **21 f**or **USFDA**, **14** for **Australia (TGA)**, **02** for **MCC** and **36** products for **Central & Latin America;** Dossier Development for more than **27 therapeutic areas** on dosage forms like **Oral Solids, Liquids, Transdermal Patches.**

ii. More than **07 controlled (Class II) narcotic products** in managing and conducting its clinical studies.

iii. Successful **development of IVIVC models and its application** in product development.

iv. More than **52** products for **medical writing of Module 2** (Clinical (Mod. 2.5) and Non-Clinical overviews (Mod. 2.4)).

v. More than **20** products for **SmPC comparison between different European countries**.

vi. A complete **portfolio management of Medical device from concept development till successful clinical trial and dossier** submission for EMEA & USFDA.

mKnal ADVANTAGE

A unique concept of service offerings on every complete product / program management wherein we assure your SAVINGS on

i. Cost of Manpower
ii. Cost of Individual Area Expertise
iii. Cost of Project Management
iv. Cost on Quality Control & Assurance
v. Cost on appropriate Regulatory strategy
vi. Cost on BA/BE with appropriate study designs and sample size assessment.
vii. Relish on Exclusive Rate Contract with CRO's, vendors, Courier Companies & much more savings

HOW??

A. Our Experience:

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

B. Our Team

Under an experienced Leadership with a team of technical, medical and scientific staff comprising of physician, medical pharmacologist, skilled project managers, bioanalytical and regulatory experts, Pharmacokinetic Scientist & Biostatistician along with global network of industrial experts and business analyst.

C. Our Network & Partners:

A network of CRO's for clinical, formulation development and contract manufacturing with a distinct product expertise and exclusive rate contracts. Exclusive rates with vendors, suppliers, distribution and logistics channels.

Our medical device and engineering partner rendering excellence in diagnostic and medical application devices and industrial design in setting up your manufacturing and production units.

D. Our Quality Assurance:

An independent quality assurance team comprising of trained and rich experienced professionals on every aspect of product development performing audits, compliance assessment and monitoring of clinical studies.

E. Our Project Management:

Skilled, trained, experienced and defined project managers accountable for smooth execution, monitors timelines and budgets and assures the right quality.

F. Our Bioanalytical Expertise:

Highly experienced industrial bioanalytical expertise with hands on experience from macromolecules to nanoparticles assisting in bioassay development and in-depth understanding of product's bioanalytical requirement.

G. Our Regulatory Expertise:

A core team with industrial experts and Ex-EMEA and Ex-USFDA expertise who is involved in every aspect of product development giving insights and navigate a right regulatory approach.

H. Our PK & Statistical Expertise:

Rich experienced team with industrial experts giving guidance on formulation development, study design and sample size assessment for pivotal BA/BE and different statistical approaches for product success.

OUR SERVICES

mKnal Global Solutions was established with the objective of providing solutions to the healthcare and biopharmaceutical industry.

Our unique fusion of scientific, regulatory and business expertise provides **flexible, strategic solutions designed to meet your product requirement**. This includes:

I. GENERIC PRODUCT & CLINICAL DEVELOPMENT

a. API Development and Sourcing
b. Formulation Development
c. Dossier Development (CTD / eCTD)
d. Bioavailability / Bioequivalence studies in Healthy and Patient Population
e. Design, Conduct, Analysis and Interpretation of Clinical Studies
f. Biostatistics
g. Clinical Bioanalysis (Bioanalytical)
h. Quality Assurance (Clinical site Audits, Monitoring, etc.)

II. QUALITY ASSURANCE

a. cGMP Audits & Facility Assessment
b. Facility Qualification Audits in compliance with MHRA and USFDA regulations including 21 CFR.
c. Regulatory Compliance and Quality System Audit
d. Validation and Qualification
e. Training
f. Laboratory Compliance (Compliance and Capacity assessments and Lab Set-up)
g. Quality System Preparation

III. SCIENTIFIC, MEDICAL & REGULATORY

a. Assessment of scientific data and literature search
b. Medical Writing (Protocol, CRF, ICF, Clinical Study reports, etc.)
c. Module 2.4 and 2.5 (Clinical and Non-clinical overviews)
d. SmPC Comparison for EU
e. Product Leaflet and SmPC's
f. Investigational Brochure
g. Writing Regulatory Correspondence
h. Regulatory Query Response
i. Submission via 505 (b) (2)
j. Dossier Compilation in eCTD

IV. MEDICAL DEVICE

a. Concept Design and Development
b. Prototyping
c. Product Development
d. Pilot Manufacturing
e. Product & Process Validation
f. Clinical Study Management
g. IP Management / CE Marking

V. ANALYTICAL SERVICES

a. Permeability Studies
b. Analytical Method Development & Validation
c. Analytical method validation for assay or related substance
d. In-vitro Bioequivalence studies
e. Extractable & Leachable studies
f. Drug excipient compatibility studies
g. Ion Chromatography
h. Dissolution studies
i. Stability testing
j. Impurity synthesis, Isolation and characterization
k. Residual solvent MD, MV & analysis

VI. IT SUPPORT

Software

a. Professional Training Suite
b. Professional E-Batch Document Issuance Suite
c. MaxiQ – Quality Management System
d. EasyTD – eCTD Submission System

VII. ENGINEERING & INDUSTRIAL DESIGN

a. Architectural Design
b. Electrical & Structural Design
c. Lighting & Control System
d. Mechanical & Utility Engineering
e. Project & Construction Management
f. Process Engineering

mKnal Global Solutions is ready to assist you in every step of your generic product development or medical device.

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

GET CONNECTED

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