



**TRUSTED PARTNER IN INTEGRATING THE PHARMACEUTICAL DRUG
DEVELOPMENT PROCESS**

INTRODUCTION

- **mKnal Global Solutions**, is a consulting company engaged in providing Pharmaceutical, Information Technology (IT) and Engineering services.
- Our integrated product development services help biopharmaceutical companies shorten time to market, manage risk and access new global markets to maximize portfolio value.
- **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.
- Our Experts perform an In-depth assessment of product for appropriate decision making with understanding of product's technical, scientific and regulatory requirements.
- Our team design, conduct and manage Clinical studies from **Pharmacokinetic, Pharmacodynamic (Phase-I) to Bioavailability/Bioequivalence** for EMEA, USFDA, TGA, MCC, & Latin America markets.



OUR EXPERIENCE

mKnal's unique fusion of scientific, regulatory, global network of experts and partner has been able to successfully deliver:

- Dossier Development for more than **27** therapeutic areas on dosage forms like Chewing Gums, Oral Solids, Liquids, Transdermal Patches and ER/IR combinational release products.
- Clinical BA/BE studies on more than **42** generic products for EMEA, **26** for USFDA, **14** for Australia (TGA), **02** for MCC and **36** products for Central & Latin America.
- More than **07 controlled (Class II) Narcotic** products in managing and conducting its clinical studies.
- Successful development of **IVIVC models** and its application in product development.
- More than **52 products** for medical writing of Module 2 (Clinical (Mod. 2.5) and Non-Clinical overviews (Mod. 2.4)).
- More than **20 products** for SmPC Translation & Comparison for European Pharma countries.
- Complete portfolio management of Medical device from concept development till successful clinical trial and dossier submission for EMEA & USFDA of a Vaginal Applicator, Rectal Cream & Gel Applicator, Ophthalmic Container (Mould) & Inhalation system.

OUR SERVICES – GENERIC PRODUCT DEVELOPMENT

GENERIC PRODUCT & CLINICAL DEVELOPMENT

- ✦ API Development & Sourcing
- ✦ Formulation Development
- ✦ Dossier Development (CTD / eCTD)
- ✦ Bioavailability / Bioequivalence studies in Healthy and Patient Population
- ✦ Design, Conduct, Analysis & Interpretation of Clinical Studies
- ✦ Biostatistics
- ✦ Clinical Bioanalysis (Bioanalytical)
- ✦ Quality Assurance (Clinical site Audits, Monitoring, etc.)

INSTRUMENTAL & ANALYTICAL

- ✦ Permeability Studies
- ✦ Analytical Method Development & Validation for assay or related substance
- ✦ Drug excipient compatibility studies
- ✦ Ion Chromatography
- ✦ Extractable & Leachable Studies
- ✦ In-Vitro Bioequivalence Studies
- ✦ Dissolution Studies
- ✦ Stability testing
- ✦ Impurity synthesis, Isolation and characterization
- ✦ Residual solvent MD, MV & analysis

SCIENTIFIC, MEDICAL & REGULATORY

- ✦ Assessment of scientific data and literature search
- ✦ Medical Writing (Protocol, CRF, ICF, Clinical Study reports, etc.)
- ✦ Module 2.4 and 2.5 (Clinical and Non-clinical overviews)
- ✦ IVIVC Corelation & Report
- ✦ Scientific Writing for Medical Discussion with Regulatory Authorities
- ✦ SmPC Comparison for EU
- ✦ Product Leaflet and SmPC's

QUALITY ASSURANCE

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

OUR SERVICES – FORMULATION DEVELOPMENT & ANALYTICAL

- Experts in analytical chemistry, Pre-formulation, formulation and nutraceutical development and optimization, as well as analytical testing and development services.
- Extensive experience working on Specialty Complex Products, Potent Products & variety of dosage forms.
- Highly Experienced Formulation Development & Analytical Support team.
- Five (05) times USFDA Audited and Accepted Analytical lab delivering world class services to more than 200 pharmaceutical companies.
- Largest Resource for Ion Chromatography; Extractable & Leachable studies & USFDA Inspected In-vitro Bioequivalence studies.



OUR SERVICES – MEDICAL DEVICE & DIAGNOSTIC

- Core competency in medical device design & development *viz.* Need Identification, Concept Development & Customized Instrument Design & Development.
- ISO 13485 – 2003 certified by BSI
- Experience of working with global companies from America, Europe and APAC.
- ✓ Clean room manufacturing area
 - Bangalore
 - ✓ Class 100k – 10,000sq.ft
 - ✓ Class 10k - 2000 sq. ft
 - Pune
 - ✓ Class 100k – 18000 sq.ft
 - ✓ Class 10k – 2000 sq.ft
 - ✓ Class 1k – 300 sq.ft



Vaginal Applicator



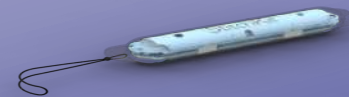
Tissue Morcelator



Suture Clip



Automatic Hair Transplant System



Robotic Surgery Kit



Protein Analyser



OUR SERVICES – INFORMATION TECHNOLOGY & ENGINEERING

INFORMATION TECHNOLOGY

- Professional Training Suite
- Professional E-Batch Document Issuance Suite
- MaxiQ – Quality Management System
- EasyTD – eCTD Submission System



ENGINEERING & INDUSTRIAL DESIGN

- Architectural Design
- Electrical & Structural Design
- Lighting & Control System
- Mechanical & Utility Engineering
- Project & Construction Management
- Process Engineering



OUR STRENGTH & ADVANTAGE



- Extensive Network of Expertise & Verified Vendors.
- Experienced Project Management & Program Management for Various Product Development activities.



- In-Depth Assessment of Product for various Regulatory and Product Specific Requirements with Complete Support.



- Strong Bioanalytical Expertise for extensive data analysis & Review.
- An experienced Scientific & Medical Team to take care of Product Development at every stage.



- Our senior-level auditors conduct unbiased assessments of all aspects of a product, site, manufacturing facility including auditing clinical sites.



- PK Guidance on formulation development, study design and sample size assessment for pivotal BA/BE and different statistical approaches including IVIVC for product success.

CONTACT US

mKnal Global Solutions is ready to assist 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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