

PHARMABIDE

PHARMACEUTICAL SERVICES

Company's Profile

- o PHARMABIDE 's **mission** is to provide to all our customers tailored approach to projects with commitment to high quality Services in the Pharmaceutical Industry
- o Our **aim** is our qualitative consulting to be focused always in the regulatory requirements frames initiated by each local authority
- o We assist our clients to expand their operations in regulated markets like the European Union and our full scheme of operations safeguards **regulatory compliance**
- o PHARMABIDE's **philosophy** is to work as a team with the business partners and help them overcome the challenges within the rapidly evolving pharmaceutical market

Key Therapeutic Areas

Allergy / Immunology
Biotechnology
Cardiovascular Diseases
Dermatology
Endocrinology

Gastroenterology
Genitourinary Diseases
Haematology
Oncology
Neurology & Psychiatry

Ophthalmology
Orthopedics
Pediatrics
Pulmonary / Respiratory Diseases
Virology

Services

Business Development

Product Development

In-licensing of EU
certified products

Clinical Trials

Regulatory Affairs

Pharmacovigilance

Finished Dosage
Formulation

API Sourcing

Regulatory Affairs

Our Regulatory Affairs team has extensive experience in providing liaison support for organizations seeking regulatory approval in the European region.

Pharmacovigilance

- o Provision of QPPV and 24/7 Safety Contact Person Services
- o Registration of Sponsor, MAH, AMP and Trial IMPs in Eudravigilance
- o Development of CT-specific Supportive Documentation Related to Safety Reporting
- o Performing literature search and obtaining literature articles and reviews, to guarantee up to date information.
- o Pharmacovigilance SOP writing (if it will be needed) and maintenance.
- o Establishing and maintaining pharmacovigilance system ensuring any emerging safety concern or ADR is detected and reported to the PhV department, in order to be evaluated and accessed.
- o Preparation of periodic safety update reports (PSURs).
- o PhV Inspections by the local Pharmacovigilance Center including development and maintenance of documents, follow-up of corrective and preventative actions.

Clinical Development Planning And Execution

- ✓ Study Design & Planning
- ✓ Protocol CRF, & ICF Development
- ✓ Investigational Site Selection & Feasibility
- ✓ Regulatory Strategy & Consulting
- ✓ Investigators Meetings Organization & Training
- ✓ Patients Recruitment & Retention
- ✓ Project & Site Management
- ✓ Site Monitoring & Auditing
- ✓ On - Site Study Coordination
- ✓ Drug Safety & Pharmacovigilance Support

Project Portfolio

- ✓ Phase II-IV Clinical Trials
- ✓ Medical Device Studies
- ✓ Non-Interventional Studies
- ✓ Post - Authorization Safety Studies
- ✓ IIS (Investigator Initiated Studies)
- ✓ Epidemiological Studies
- ✓ Therapeutic Equivalence Studies

Clinical Trials Performed

PHASE	No TRIALS	No SITES	No PATIENTS
I	2	7	10
II	2	10	11
III	26	21	276
IV	22	37	519


20+ years of experience in the Pharmaceutical Industry

50+ clinical trials conducted

100+ clients already benefited from our services

1000+ NDAs, DMFs, CTDs cases prepared or reviewed

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**"IN A RAPIDLY EVOLVING
PHARMACEUTICAL INDUSTRY,
WE HELP OUR BUSINESS PARTNERS
OVERCOME THE
CHALLENGES AHEAD"**

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