iPHARMED

Corporate Profile

Bringing your research ideas to life….

iPharMed is a niche consulting firm specialized in Regulatory, Pharmacovigilance and Toxicology as our portfolios, with our customized product specific strategies, we have earned many small to mid companies confidence and long-term association.

Quick Glance

- Privately owned company with headquarters in UK
- Business hubs are in Sweden, USA and India
- Niche consulting firm for Regulatory, Pharmacovigilance, Toxicology and Medical Writing
- Supporting Pharma, Medical Device, Consumer and Cosmetic companies
- Quality & Processes: GxP, FDA, TQM

Why iPharMed?

> Single Point of Contact project management
> Therapeutically Inclined Teams
> Training on process and solutions

> Focused on end to end processes and systems Strong multi-regional experience on regulatory, Safety and Toxicology
> Effective operations team and strategy

> Cost effective services
> Optimisation of cost with volume and long term association
> 10- 15% greater cost reduction by improving communication and process

> True Partnership Approach

> SLA driven matrices

> Performance and Quality measurement

Business Models

- Project Based
- Functional Service Provider (FSP)
- Full Service
- In sourcing / FTE

Consulting Services

Pre and Post marketing – Pharma Regulatory Affairs

Medical Devices and Invitro Diagnostics

Toxicology Management

Pharmacovigilance

Medical and Scientific Writing

Consumer and Cosmetics

Value Added Services

Technology Consulting

Regulatory Services

Pharmaceuticals:

- Regulatory writing for DMF, Dossier and Gap Assessment with customization
- End to End support for eCTD, Post Approval Life Cycle Management
- MA Holding, UK/EU representation, Translations and Advisory Consulting
- Global Regulatory and Market Intelligence

Medical Devices & IVD:

- IDE / 510 k / PMA applications / CE marking/ QMS 9001, 13485
- Preparation and review of CEP, CER and BER's.
- Medical Device and In-Virto Diagnostics Labelling and Review

Pharmacovigilance and Medical Writing

- End to End ICSR Management
- QPPV (UK & EU)
- Aggregate Report writing and Submission
- Global and Local Literature Search
- Medical Writing
  - Investigator's Brochure (IB)
  - Investigational Medicinal Product Dossier (IMPD)
  - Company Core Data Sheet (CCDS)

Toxicology

- Preclinical and Clinical Summaries
  - Module 2.4 and 2.6- Preclinical Summaries
  - Module 2.5 and 2.7- Clinical Summaries
- PDE and OEL Preparation & Calculations
- Ingredient Safety Assessment and Profiles
- Medical Device and Invitro Diagnostics
  - Biological Safety Assessments
  - Biocompatibility and Risk Assessments
  - Gap Assessments

Consumer and Cosmetics

- Product Safety Assessments
- Claims and literature Search
- FSSAI, ASCI , ISO/FSSC 22000
- EU/US FDA 21 CFR 101 Labelling Services
- Product Information's, Technical file preparations
- Raw Material Review
- Region-specific Requirements Compliance/Consulting

Value adds

- **Lean & Mean Operating Model –** Gives iPharMed an edge to offer highly cost-effective solutions
- Functional SME's significant experience of over 35+ years across multiple companies
- SOPs are globally standardized and implemented
- Strong group divisions to leverage for scale-up and right talent identification
- Flexibility with local/global resource optimization for speed and better ROI
- Excellent globally integrated infrastructure

Benefits

- Experienced RA and Safety teams
- Local and Global teams
- Flexible business models
- Centralized project management

PHARMACEUTICAL and MEDICAL DEVICE

REGULATORY SERVICES and LIFE CYCLE MANAGEMENT

iPharMed is a European based consultancy company which offers regulatory services. We provide ONE-STOP-SHOP comprehensive regulatory services on Pharmaceutical and Medical Device companies.

We assure to save you time and resources by bridging the gap between the regulations and regulators to companies , ultimately providing fast service and safer products to the patients.

www.ipharmed.com

PHARMA REGULATORY SERVICES

Regulatory requirements vary at the global level, within every region, Health Authorities (HA) and product category. iPharMed supports all type of regulatory activities, from investigational pharmaceutical products to full generic or bibliographical applications to achieve product approvals for new and established drug substances and the corresponding drug products. These includes pharmaceutical products containing chemical and biotechnological products. Among post-marketing activities our expertise lies with annual reports, dossier updates, variations, renewals, and line extensions in ROW countries. We ensure you smooth and fast drug approvals with 100% regulatory compliance.

WE HELP OUR CLIENTS WITH:

- Preparation of Dossiers for NDA, ANDA, MAA's and Global (ROW) Markets
- eCTD Publishing, Content and Formatting, NeeS and Paper Submissions
- Drug Master Files (DMF) and EDQM Certificate of Suitability applications
- Comprehensive Labelling Support
- Product Life Cycle Management, Variations and Annual reports
- Gap Assessment of DMF and Dossiers
- RIMS Management and Manufacturing Site registrations

PHARMACOVIGILANCE AND MEDICAL WRITING:

- Complete End to End Pharmacovigilance support to US, Europe and ROW Markets
- Act as EU and UK QPPV and 24-hour designated point of contact
- Dedicated Phone line and email address
- Act as Local Safety Officer
- Preparation of Risk Management Plan (RMP) and US PEDAR's
- Investigator's Brochure (IB) and Investigational Medicinal Product Dossier (IMPD)
- Local and global literature surveillance Signal management
- Company Core Data Sheets (CCDS) for existing products
- Clinical summary and overview

MA HOLDING

We act as MA Holder and help you in Batch release, QP Support and GMP Audits

TRANSLATIONS

We gladly translate your specialized texts (English- European Languages-English)

EXPERT REPORTS

We provide expert reports on quality, efficacy and safety of your product or expert opinions for you.

PRE-SUBMISSION AND SCIENTIFIC ADVICE MEETING

We provide support as required to prepare pre-submission or scientific advice meetings with authorities, filing brief packages and accompany you. We also support all kinds of documentation (CMC, clinical and non-clinical).

DUE DILIGENCE

Within the scope of licensed negotiations, in case of planned purchases or sales of MAs and in financing rounds with venture capital providers, we promise to perform due diligence of regulatory documents and dossiers.

MEDICAL DEVICES AND IVD

Medical devices, IVD's and drug-devices combination products differ in their regulatory requirements compared with medicinal products. We help manufacturers to obtain certification to these products as a prerequisite to get market access. Clinical evaluation, assessment of biological safety and the collation of technical documentation along with device registrations are our core capabilities.

As expert partners, we oversee the certification of substance-based medical devices, IVD's and drug-device combination products and all type of due diligence pertaining to technical files/ dossiers and documents in this context.

We support in the development and market access of medical devices, IVD's and combination products.

RISK ANALYSIS

With our experience in the field of biological and clinical safety, we support you in compiling or updating the risk analysis in this domain.

CERTIFICATION

We support in contacting Notified Bodies, preparing scientific advice meetings, supervising the certification process, reviewing your documentation, and in the complete development of your product.

DEVICES COMPOSED OF SUBSTANCES

Devices composed of substances must fulfil rules and requirements for medicinal products.

We help our clients to identify specific requirements for the products and compile the corresponding documentation.

CLASSIFICATION

We experts support on demarcation and classification of devices to authorities or Notified Bodies.

CLINICAL EVALUATION

Clinical performance and safety of medical devices are evaluated based on clinical data. We prepare the clinical evaluation based on both, literature, and clinical trial reports.

BIOLOGICAL SAFETY

The key prerequisite for certification of medical devices is the assessment of biological safety. We establish this assessment to provide a corresponding report on your behalf.

TECHNICAL DOCUMENTATION

To provide evidence that the medical device meets the basic requirements of rules and regulations, we compile, review and maintain your technical documentation.

- Preparation of Device Master and Technical File
- Device Labelling and Review
- Regulatory and Market Intelligence
- Representation and Distributorship Services in Europe and India
- Implementation of Unique Device Identification (UDI) and EUDAMED related services
- IVD registration and preparation of technical files