
Pgf
PHARMA INTERNATIONAL

WELCOME TO

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Our core service is regulatory, and as experts in the field, we're constantly called on to explain how international drug registration functions and why it has to be so complicated.

Assist

Assist pharmaceutical companies in out-licensing their pharmaceutical and health related products to partners in international markets.

Help

Help pharmaceutical companies in finding products for in-licensing and distribution in their countries.

Understand

Gain an understanding of your needs and objectives.

Explain

Explain alternative strategies and their associated timelines.

Estimate

Estimate the total cost of the chosen route.

Implement

Implement the agreed-upon plan and secure registration.

SERVICES

REGULATORY STRATEGY & IMPLEMENTATION

Regulatory has been the core of our business from the start, and over the years we've developed an experienced team who pride themselves in helping clients not only with strategy, but also with implementation, a key component to successful commercialization.

Regulatory Strategy & Management of Drug Development

- Provide regulatory advice in the early phases of development projects
- Define the product's concept
- Interpret regulations and guidelines
- Develop strategies for technical aspects of drug development (quality, pre-clinical and clinical)
- Design and manage drug development programs
- Determine market access requirements and develop strategies in the early phases
- Identify and manage external resources/experts

- Regulatory evaluation of feasibility of products/projects (medicinal products and non-pharma products as medical devices, food supplements, FSMPs, cosmetics).
- Regulatory Affairs for medicinal and non-pharma products.
- Monitoring of regulations, regulatory intelligence.
- Preparation and submission of new marketing authorization applications and maintenance applications (variations, renewals, PSUR submissions…).
- Management of regulatory procedures, interaction with regulatory authorities (NCAs).
- Compilation of eCTD.
- Compilation and procurement of relevant regulatory documents for new submissions and maintenance activities.
- Text management for product information texts, e.g. SmPC, PIL, primary and secondary packaging materials, proof-reading, artwork.

Our pharmacovigilance team helps you manage and monitor all safety aspects of your product so that it meets the required regulations.

Our services include:

- An EU-qualified pharmacovigilance specialist
- Local Pharmacovigilance qualified person
- Pharmacovigilance quality system preparation and management
- Good pharmacovigilance practice auditing
- Post-marketing case processing management, including EudraVigilance reporting
- Signal detection
- Local and global literature reviews
- Safety database management
- Periodic safety update report preparation
- Risk management plan preparation
- Clinical trial pharmacovigilance services, including preparation of development safety update reports and case processing
- Pre- and post-marketing pharmacovigilance project management

PHARMACOVIGILANCE

Strategic Advice

Understanding our clients' challenges is the basis of what we do. We focus on listening and brainstorming before creating strategic solutions, offering advice and preparing quality plans that meet your objectives. Strategic advice is critical in regulatory, as it's often used to decide which filing option is most appropriate for a particular development or product. It also frequently involves having clients obtain scientific advice for regulatory and HTA requirements as early as possible in the development cycle.
However, a strategy is only as successful as its implementation, which is why we always develop solid plans of action to meet project deliverables.

Pharmaceutical Development

Our pharmaceutical development team has many years of experience and can support you in the following areas:

General

Set-up of development plans ■ Management of pharmaceutical development ■ Vendor selection and follow up of vendors ■ Support in GMP requirements for development programs, including those for investigational medicinal products and drug substances used during their manufacture ■ Interaction with competent regulatory authorities as required during pharmaceutical development ■ Special experience for the design of combined development programs in different regions (the EU, South East Europe and ASEAN)

Project Management

Our team offer project management for entire projects or individual steps, including planning, organization, partner selection, coordination, monitoring, and controlling of development processes.

More specifically, we can:

Define product development concepts ■ Design and implement development programs for quality, pre-clinical and clinical processes ■ Control the various steps of the development process ■ Ensure all quality aspects are covered ■ Select, qualify, and manage vendors ■ Prepare, control and monitor budgets

Auditing

Our auditing team, supported by internal and external experts, assists in all aspects of auditing and provides the following services:

Third party audits

GMP audits for drug substances and products, including investigational medicinal products and supply chains (with special experience in Asia) ■ GMP certification application submission and liaison with EU authority ■ GDP audits for warehouses, distributors, and supply chains ■ Wholesale Distribution License Applications ■ GMP and GDP training ■ GLP audits for safety, pharmacology, toxicology, and human and animal bioanalytical studies, as well as other studies conducted under GLP ■ GCP audits for CROs, study sites and other vendors, including central labs and drug repositories ■ Pharmacovigilance audits Vendor Qualification Audits ■ Preparation of Inspections (Mock Audits)

Market Access

By gaining an understanding of clients' commercial needs, key decision makers, and route to market, we recommend market access solutions that bring your products efficiently to market.

Product development strategies to ensure the market access, payer, and regulatory requirements are incorporated into clinical programs, e.g., the right comparators are being included and the relevant end point and outcomes are being considered ■ Liaison with Healthcare Technology Assessment (HTA) agencies to confirm all development programs include the necessary requirements for approval ■ Development of dossiers to satisfy HTA agencies and payer requirements, e.g., value-based pricing ■ Negotiations with HTAs and insurers ■ Patient access and adherence programs ■ Local support for market access ■ Development of route to market solutions for all types of products, including Rx, OTC, medical and biotech devices, and food supplements and cosmetics ■ Planning of route to market strategies, including assessing market potential by introducing third parties, investment partners, and distributors ■ Marketing plans, including regulatory guidance on branding

Portfolio Analysis & Life Cycle Management

Portfolio and business strategies ■ Portfolio analysis and management, including process implementation ■ Product portfolio completion via licensing in/out and partnering/gap filling ■ Product launch facilitation ■ Post-launch life cycle management ■ Supply chain management

Due Diligence

Our cross-functional team offers a wide variety of due diligence services in mergers and acquisitions and is carefully selected to investigate and deal with requirements in your countries of interest.

All regulatory matters, including dossiers and their potential ■ Regulatory resources (staff, equipment, and expertise) ■ Product supply, including GMP aspects and audits ■ Product portfolio and pipelines (gaps, competitors, development plans, etc.) ■ Product portfolio continuation and valuation ■ Risk/opportunity assessment for product portfolios ■ Market access to other territories ■ Growth strategies

QM Systems And Licenses

Achieving an optimal quality system, which fulfills EU country specific requirements and fits to your company internal strategy and processes, is mandatory for successfully achieving the required licenses and enhancing a high internal compliance. Our team, involving local expertise where necessary, supports you with any service that will benefit your existing or intended system, be it for gaining a wholesaler or import license, establishing a system or fulfilling GMP requirements.

Background information on the system and license requirements in the EU member states ■ Strategic advice on the optimal solution for your company ■ Complete system set up or adaptation of your existing system for a principal with several subsidiaries in several EU member states ■ System set up or adaptation of your existing system for a single company in one EU member state ■ Support during implementation of your system ■ Training ■ Compilation and submission of applications for the required licenses including follow up with the authorities ■ Mock inspections and support during inspection preparation Support during inspection ■ Support during follow up of authority inspections

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