Introduction

Pharma Design Limited (PhD LIMITED) is a small, specialised provider of outsourced development services to the pharmaceutical, biotechnology and medical device industries. The company engages in the strategic development and MA approval for medicinal products in EU by means of an integrated approach of multiple functions (R&D strategy, Market Access, Pharmacoepidemiology and Regulatory). Our primary approach is to use a pipeline specialty team, being able to 'design' a broad successful strategy as part of a combined and synchronised work.

PHD LIMITED Global Regulatory Affairs Overview

PHD has a highly experienced EU regulatory group, with a proven track record of success in regulatory submissions (CTA, CTD, MAA) and regulatory agency/authority interactions.

PhD can provide support for all regulatory activities from conception of the strategic regulatory plan, through all operational aspects of product development to submission and deliberation of a licensing application, and for post-licensing activities, of medicinal products, medical devices and combinations.

PhD can provide the following:

CONSULTANCY: strategic consulting advice on global regulatory requirements and regulatory strategy, provision of regulatory intelligence (including competitor information, the regulatory environment, and legal requirements), due diligence, briefing documents, scientific advice and agency meetings (including pre-IND and end-Phase II documentation and meetings), Orphan Drug activities, PIP activities, interaction with regulatory agencies and sponsor representation (including EMA, EU national agencies);

IMPD/CTA and equivalents globally: preparation, submission and maintenance support to clinical trials;

MAA: preparation, submission and maintenance of submission components and scientific documents including clinical, non-clinical and quality summaries and overviews (includes pre-MAA meetings);

MAINTENANCE: all post-licensing activities, supplements, variations, PIL User Testing, Annual reporting, regulatory compliance;

Regulatory support is provided from within the Regulatory Affairs as well as from all other consultants within PHD LIMITED in order to align priorities and raise potential critical steps early in the development or submission process.

PHD LIMITED Global Regulatory Affairs Services

PHD LIMITED can provide the following services

- Strategic Scientific and Regulatory Consulting
- Advice and plans on product development and regulatory strategies;
- Carry out due diligence support
- Prepare briefing documents for scientific advice
- Attend regulatory authority meetings on behalf/with the sponsor company.

As development proceeds, PHD LIMITED can advise sponsors on the likely regulatory impact of any new regulatory guidance and/or non-clinical or clinical data, proposed changes to drug manufacture or formulation.

Expert review and evaluation of the data package

PHD LIMITED can review the existing quality, non-clinical and clinical data package against the local regulatory framework, and provide our expert review and recommendations to sponsors. Review of data will include:

- Regulatory activities and scientific advice to date;
- Quality, non-clinical and clinical data for proposed indication(s);
- Gap analysis to include:
- Review of the current data package and other related documentation for the products against regulatory guidelines (including the basic regulatory framework underpinning medicinal products and specific guidance on therapeutic areas;
- Review of historic information in the public domain on clinical development for other products in the same or similar indication(s);
- Identification of additional data requirements for successful MAA, also allowing strategic positioning of the Briefing Dossier for the regulatory authority meetings and MAA pre-submission meetings

Regulatory Support to Clinical Trial Applications

PHD LIMITED would be pleased to provide Regulatory Support, for the preparation and submission of Clinical Trials Applications specifically:

- Prepare, review and compile the IMPD or equivalent document for each country, by appropriate technical experts.
- Prepare, submit and maintain IND/CTA documents, including managing the appropriate translations as required.
- Organise meetings with health authorities as required.
- Provide ad hoc regulatory and strategic advice to assist sponsors in managing their activities.

Paediatric Investigational Plan

PHD LIMITED can assist sponsors in developing a Paediatric Investigation Plan (PIP) in accordance with EU requirements.

An EU paediatric plan for a given product may include waivers, deferrals and/or planned trials for each age subgroup of the paediatric population. 'Class waivers' are also available for certain diseases and classes of product, but an application must nonetheless be submitted for confirmation. PHD LIMITED can assist in literature reviews, compiling the PIP, and managing the application to the EMA Paediatric Committee (PDCO). Modification of an agreed PIP is often necessary as clinical development progresses, and compliance with an agreed PIP must be confirmed by PDCO prior to submission of the MAA for the adult indication. PHD LIMITED can support these procedures.

Since the July 2008 date for which PIPs became compulsory in the EU, PHD LIMITED has been involved with several PIP submissions, including product specific class waivers, sub-set class waivers, deferral requests, paediatric trial programs, and PDCO meeting.

Regulatory authority Meetings

PHD LIMITED can organise Scientific Advice meetings with relevant regulatory authorities as required, including preparation of briefing documents, attendance at the meeting by one PHD LIMITED consultant and functional experts as required, together with sponsor's personnel, preparation of minutes and management of any follow-up communication with the authority.

Typically PHD LIMITED staff communicate with Health Authority representatives on a regular basis. These interactions include representing or supporting clients at meetings with the National Competent Authorities and other regular and informal communications.

Marketing Authorisation Application

In the past 3 years, PHD LIMITED has supported 5 MAAs (including 2 centralised applications to the EMA). This has included the preparation and submission of responses to agency questions, meetings with assessors during the procedure, and preparation for an oral hearing at EMA. PHD LIMITED also has considerable experience in post-licensing regulatory procedures and can therefore advise on fulfilment of follow-up measures and regulatory strategy for licence maintenance. Moreover, PHD LIMITED can assist sponsors with obtaining local regulatory and business intelligence required for country-entry.

PHD LIMITED Rates

On Rates & Assumptions

To ensure the most cost efficient approach to resourcing, PhD is able to deploy a flexible model that only resources experienced regulatory professionals and functional experts as and when required.

Costs are provided for PhD consultants' services on a Daily or Project basis, depending mainly on the contractual duration. VAT and Pass-through costs are not included.