Introduction

Pharma Design Limited (PhD) 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 Audit Services

PhD has a highly experienced group, with a proven track record of successful operations in internal, affiliate and service provider audits.

PhD can provide support for all PV activities from conception of the strategic safety monitoring plan for clinical studies, through all operational aspects of submission of safety data for the purpose of a licensing application, and for post-licensing activities of medicinal products, medical devices and combinations.

CONSULTANCY: strategic consulting advice on Quality Management Systems requirements and standards, EU and global pharmacovigilance requirements (GPV and ICH), signal detection, ongoing safety monitoring, risk-management plans, due diligence, additional risk minimisation plans and agency meetings with regards to safety aspects. Consultancy also includes PV inspection preparation, assistance in building internal audit plans and specific training on PV documentation and legislation.

Internal Audit: PhD prepares an audit plan based on the information provided on the scope of the audit and systems and processes in use by the client. The audit can span through all customer's quality management systems, SOPs, contracts, PSMF, risk-management, training, communication and specific compliance, depending on the need. A full audit report is released soon after completion of the audit.

Service provider/Vendor audit: Audit of external providers and vendors is generally performed on site and by means of a pre-drafted questionnaire. Subjects for audit include MAH oversight, communication, training of personnel, performance, SOPs, reconciliation.

Affiliate/Licensee audit: Audit of external providers and vendors is generally performed on site and by means of a pre-drafted questionnaire. Subjects for audit include MAH oversight, communication, training of personnel, performance, SOPs, reconciliation.

PV inspection preparation: PhD has assisted companies facing imminent Competent Authority inspections. In most cases, we have helped clients reduce the burden and impact of inspection findings. Our support has also provided a good occasion for reviewing Companies' standards and methods in addressing compliance.

Audit of Documents: PhD performs audit of Regulatory Documents like PSMF, CTD, CSR, PSUR, DSUR, RMP and Product Information.

PhD Consultancy Services

PhD can provide the following consultancy services:

- Strategic and Risk-based approach, algorithms for small and medium-sized companies.
- SOP and CAPA management as part of a global QMS.
- PSMF maintenance, our practical experience, so far.
- Inspection preparation training, Responses to Authorities.
- Changes in Legislation and Questions raised during public seminars.

Auditing Experience

In the past 5 years, PhD has performed 12 audits and assisted 6 companies before Competent Authority Inspections.

PHD 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.