Volt Pharma Associates - Case Studies

Product Development – Clinical and Regulatory (PDCR) Services

CASE STUDY 1

SITUATION

A virtual UK-based biotech company with limited knowledge of GCP requirements needed to source a service provider qualified to deliver their Phase I study with a potential biologic analgesic. They were unaware of the regulatory risks associated with lack of compliance, delivery, quality and cost when insufficient due diligence was ensured through a non-rigorous selection and capability assessment process.

SERVICE

VPA worked with the client to define the critical success criteria for the selection of a fit for purpose phase I unit. They acted as the outsourcing department of the client developing a request for proposal versus the study requirements and critical criteria. In addition, the PDCR team also worked with four full-service, MHRA-accredited phase I service providers and guided the client through a robust selection process including capabilities assessment and risk assessment to enable the identification of the most appropriate candidate.

RESULT

A Master Services Agreement was developed with the selected phase I unit. Contracts including key success criteria were developed for study start up and for full-service delivery.

CASE STUDY 2

SITUATION

A mid-sized pharmaceutical company was in the middle of a de-centralised regulatory procedure when it suddenly needed additional expertise to complete the on-going procedure. There was a need to respond to questions, finalise the labelling and manage an unexpected complication due to a member state having raised national health concerns at the end of the procedure.

SERVICE

VPA partnered with the various departments of the client to prepare, review and submit the responses.

RESULT

The client was provided with satisfactory responses which were handled in time through personal contacts with the health authorities. The company obtained the approval of the medicinal product in the EU according to their original regulatory plan.