Prism Ideas

Case study

Prism provides nominated signatories pending new appointee

Background

Continuous availability of the scientific service is an essential part of Pharma company infrastructure

European law requires pharmaceutical companies to provide a scientific service in charge of information regarding their medicinal products.[1] The law is largely self-regulated by national pharmaceutical industry associations under a common European Code of Practice. The scientific service must include a doctor or, where appropriate, a pharmacist who will approve material prior to release. This is to certify that the final form of any promotional material is, in their belief, in accordance with locally applicable codes, consistent with the Summary of Product Characteristics, and a fair and truthful representation of the product.

The principles of promotion and legal obligations extend beyond the membership of national industry associations to all pharmaceutical companies; national government agencies can apply sanctions where self-regulation is not available for non-members. Continuous availability of the scientific service is therefore an essential component of any Pharma company infrastructure.

Challenge

The product team needed advice from an experienced signatory in relation to the development of new materials

The European regional medical function of a global pharmaceutical company utilised Prism's promotional compliance services for several months on an item-by-item basis. This proved to be an effective solution to manage short term peaks in demand upon their internal team. The resignation of a nominated signatory for a recently launched product left the company in need of additional resource to cover the role, pending the appointment of a permanent replacement. The product team needed advice from an experienced signatory in relation to the development of new materials, and so a simple increase in the volume of items sent to Prism for review did not meet their needs.

Solution

The client expected that they would need to employ a signatory for 4 days per week (0.8 FTE) in order to cover the expected workload, but expressed a concern that there may be breaks in service due to illness or vacation over the predicted six-month contract. There would be little leeway for internal colleagues to address this eventuality, so Prism were asked to provide a solution that also addressed this potentiality.

1 EFPIA Code of Pratcice. Section 20.01.a

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Prism advised that the most effective approach to meet the client's needs would be for two individuals to work in combination with the client's in-house team. This was agreed with the nominated signatory, backed up by an examiner taking on the role, to provide both the necessary expertise and flexibility.

Previous experience in provision interim support of this type aided Prism in limiting the total budget for the service by more than 20%. It is common that the required commitment estimated at the outset of a part-time placement exceeds the actual time needed. Prism agreed to guarantee availability of the service at 0.8 FTE for the full six months, in exchange for a minimum monthly fee equivalent to 0.6 FTE, plus any costs for time spent above the minimum level. This proved to be a close reflection of the work undertaken, realising the savings to the company versus a flat rate contract.

Conclusions

...the approach taken provided a mechanism to guarantee the desired continuity whilst also limiting its budgetary impact

Prism constructed a service solution which met the project needs of an existing client. Importantly the approach taken provided a mechanism to guarantee the desired continuity whilst also limiting its budgetary impact.

Following this appointment, Prism was able to support a smooth handover to the permanent signatory and the budget which had been saved enabled the client to address a subsequent similar but short-term gap in internal resource.