Global Regulatory Affairs (GRA)

Outsourcing Platform

A global biopharmaceutical company entrusted to BlueReg the management of daily regulatory activities for a large portfolio of medicinal products in various therapeutic areas, the objective being to focus their internal resources on strategic projects. The outsourced activities encompassed development and post-authorisation regulatory activities (including publishing services) for Europe in addition to selected activities for intercontinental regions for a large portfolio of medicinal products.

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Challenges

- The implementation of an external operational outsourcing platform was a completely new experience for the client. It was the first time they entrusted such a wide range of regulatory activities on a large portfolio to an external partner.

- The client needed a flexible partner that could adapt rapidly to a changing environment (timelines, scope of work) and had a solid understanding of its product portfolio.

- BlueReg's main challenge was to build a strong partnership with the client in a short timeframe to successfully support this externalisation.

BlueReg support

Due to the variety of activities, BlueReg has rolled out a dedicated team of 10 consultants tailored according to each of the project needs and expertise required, with extensive hands-on experience and project management skills:

A project oversight manager

with expertise in regulatory affairs was assigned to the entire project. Acts as a dedicated contact point for the client's senior management. Interacts professionally at multiple levels within the client's organisation (finance, purchase etc...). Oversees the operational platform which is key to providing the flexibility required by the client, by adapting resources to respond to the different project's needs (additional projects, peaks of activities, new expertise) and to ensure consistency and high quality are maintained across all projects. Shares with the client the BlueReg best practice guide and integration activities to make sure that all team members have access to the same level of information and are correctly trained in the client's processes. Develops specific key performance indicators (KPIs) and processes for continual monitoring to meet the company's needs. Provides regular communication with the client on outsourced activities (specific monthly activity reporting for each project were developed to fit the client's needs, KPIs tracking, management of invoicing and contracts).

BlueReg can provide full management support to lead such projects. In the present case, client's tools were available and integrated within BlueReg structure for project management activities (i.e. templates, project management tracking system, RIM etc).

Regulatory Affairs Project Managers (PM)

A lead contact with confirmed expertise in project management is allocated for each client portfolio product / project. A back-up contact is assigned to ensure continuity. At the start of each project, the key step to ensure milestones are met is for the PM to identify the different phases of the project in collaboration with all stakeholders involved (BlueReg project team, the client's cross-functional team, affiliates and/or client's partners), to define in detail the required activities and associated roles and responsibilities within the team to have a clear and efficacious process in place. The PM will also perform an analysis of critical paths and risks that will be integrated in the project planning and followed closely throughout the project. The PM oversees the entire submission (or project) to ensure deadlines are met by checking there is appropriate communication between all stakeholders, the project milestones are on track and when required making adjustments on project planning in case of unforeseen changes or new information.

A coordinating publisher and dedicated publishers

manage all publishing for the allocated products witha global geographical coverage. The coordinating publisher acts as key contact point for the client, manages publishing resources and ensures team's compliance to client's standards.

BlueReg is managing the following strategic and operational activities across the different projects:

• Acting as the customer's GRA representative (acting as internal GRA key contact point, management of marketing authorisation (MA) portfolio, attendance at cross-functional team meetings, providing regulatory advice and recommendations on behalf of the client on projects)

• Design and implementation of regulatory strategies

• Lead agency consultations including coordination, preparation, review of briefing packages and attendance at meetings.

• CTD dossiers review

• Coordination of post-authorisation activities within the EU (including management of line extensions, variation dossiers (administrative, CMC & clinical/ safety) through national, mutual recognition (MRP), centralised (CP) and worksharing (WSP) procedures, article 61.3 applications, renewals, labelling/artwork updates, PSUSA/PBRER, CCDS writing, eCTD transitioning management)

• Clinical trials activities: coordination and preparation of core documentation for CTAs and related subsequent maintenance, follow-up of submissions with involved CRO(s), acting as key GRA contact point within study teams.

• Publishing services and support: publishing of regulatory dossiers in paper or electronic format (NeeS, eCTD), involvement in the design of publishing strategies and advice to the GRA team, creation of records in the client Regulatory Tracking System and submission packages in the client's eDMS for allocated product portfolio, submission of the dossiers when applicable through agency portals.

Achievements

- Applications were submitted in accordance with client timelines and positive outcomes were received for a wide spectrum of applications (e.g. CTAs, variations, PSURs, labelling). The BlueReg platform dealt with an average of 1100 submissions per year with a peak of activity of more than 2000 submissions during the past twelve months.
- BlueReg has been able to build a long-term partnership by providing the client with an optimised team structure, clear channel of communication (one project oversight manager, one lead contact point per project) and by responding to the needs of the client for an agile framework by providing an adaptable team of experts tailored per project. To achieve this strong partnership, it has been essential to set up clear processes with the client at the beginning of the outsourcing platform project (communication charters, roles and responsibilities matrix, identification of the different stakeholders, IT systems and SOPs needs), to ensure efficient processes, a rapid set-up of outsourced activities and success of the various projects. The dedicated team of consultants is fully integrated as part of the GRA internal department and actively interacts in a collaborative manner with the different internal functions and local regulatory affiliates (regular email communications, teleconferences and on site-meetings).
- Customer satisfaction has been demonstrated by contract extensions for 3 years and beyond.