CASE STUDY

FUNCTIONAL SERVICE PARTNERSHIP: POST-APPROVAL REGULATORY SERVICES

BACKGROUND

With PPD's extensive experience in post-approval services, this large pharma client sought our support with a multi-year regulatory post-approval program. The client's limited internal resources needed to accommodate the ever-increasing burden of post-approval work and simultaneously support the R&D pipeline development. This was proving to be a challenge, with the global maintenance resulting in more than 180 countries maintaining approximately 5,000 licenses.

OBJECTIVE

The client wanted a comprehensive outsourcing solution that would allow for the maintenance, support and growth of its global portfolio of mature products.

CHALLENGES

There were several hurdles for this innovative project, the most significant being the size and scale of the project. At the time, this was one of the most extensive outsourcing of worldwide regulatory maintenance activities to an external provider that had ever been attempted. Apart from the purely organizational and operational challenges, a significant paradigm shift was required to bring together all of the client stakeholders.

STRATEGY

PPD was able to bring together our change and project management acumen, lean practitioner skills, regulatory expertise and partnership approach to:

+ Set up a partnership with a dedicated governance, including both client and PPD program managers to manage the forecasting, resourcing, budget and deliverables, as well as supporting internal client communications
+ Re-evaluate the existing process and use "lean" techniques and establish revised, fit- for-purpose processes
+ Establish six regulatory submission leads and more than 30 specialists within three months of project award
+ Lend functional expertise, including chemistry, manufacturing and control (CMC), labeling and electronic publishing and submission management
+ Support end-to-end maintenance of the client's regulatory information management
+ Provide long-term, in-depth product knowledge and management through dedicated manager-level resources

RESULTS

The partnership reaped many benefits for the client, starting with reducing the workload for the client's staff. This facilitated strategic thinking and allowed for a much more proactive role collaborating with their R&D colleagues. While this improved work productivity for the client, it also enhanced the employees' overall job satisfaction.

In addition, the partnership helped simplify a complex process. Due to the significant changes, all relevant processes were reviewed, made fit for purpose and then were reviewed by a PPD Lean Six Sigma practitioner. The results of the partnership and the process review have been greater efficiencies and more effectiveness. Some examples of the regulatory process improvement include

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the introduction of standard planning timelines and country-specific checklists.

The introduction of key performance indicators (KPI) and key quality indicators (KQI) allowed for quantitative measurement and benchmarking in order to improve team performance and the overall partnership.

Through expertise and resources, PPD successfully achieved the submission requirements, delivering more than 18,000 regulatory outputs in over 155 countries as of December 2015. PPD also was able to significantly reduce full-time equivalents (FTEs) on the project by nearly 40 percent. PPD further controlled costs by focusing 75 percent of the project team in low-cost countries and just 25 percent in high-cost countries.

PPD FSP: People who deliver.

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