Regulatory Affairs and Pharmacovigilance Support for Established Products

Making sure established products stay compliant across multiple countries and regulatory environments can be a time-consuming challenge. As important as it is to business success, it can take the focus – and resources – away from even more important strategic priorities.

With our longstanding commitment to quality and safety, PPD's dedicated focus within the established products market provides an integrated regulatory affairs and pharmacovigilance service model that offers scalability, flexibility and cost efficiency.

Strong experience ensuring compliance in today's global regulatory landscape

Fully understanding the realities of the regulatory climate isn't sufficient. It requires a comprehensive global knowledge and established experience – starting with senior management. PPD's regulatory and safety senior leadership team averages nearly 15 years of experience.

PPD has more than 1,100 staff members well equipped to provide informed safety and regulatory opinions on both global and local levels and safety enterprise. Since 2002, PPD has worked with more than 175 biopharmaceutical clients across the drug development and post-approval spectrum.

Our experience has helped us successfully:

- Develop 140+ final compliance country reports
- Review 12,000+ global product datasheets
- Process 825,000+ individual case safety reports (ICSR)
- Review 40,500+ abstracts related to global literature surveillance activities
- Review 39,500+ full articles pertaining to global literature surveillance activities
- Process 24,000+ adverse events (AE) every month
- Deliver nearly 3,000 labelling and other variations globally

Combining this expertise with our technology infrastructure, a global regulatory intelligence network and database technologies ensures our full understanding of the realities of the global and local regulatory environment.

Why should you partner with PPD?

The world of drug development and maintenance is constantly changing. Partner with PPD's established products business unit to overcome the challenges of:

- Controlling and mitigating compliance risks
- Maintaining profitability late into a product's life cycle
- Minimizing technology, overhead and maintenance expenses
- Operating in global regulatory and safety environments
- Releasing internal expert sources to focus on new developments and potentially accelerating time to market

We're able to help you overcome these challenges by using a "follow-the-sun" model that effectively uses a full 20 hours of each business day. When we place services in specific locales, you benefit through greater business continuity.

A holistic approach to operational excellence

Using a suite of efficient and effective processes that interconnects AE intake, case processing, signal validation, aggregate report generation, management of company core data sheets and label updates helps eliminate duplication of effort. PPD can quickly deploy the

appropriate level of staff to specific tasks and ensure tight transfer of deliverables across functional teams.

An end-to-end regulatory planning and reporting system to ensure compliance and tracking of regulatory licenses and work plans supplements PPD's highly organized team structure. The streamlined document exchanges across functions allow PPD to provide enterprise-level efficiencies and maximize functional effectiveness for its pharmaceutical and biotechnology clients. With this model, PPD can deliver services up to 20 percent faster, and these efficiencies have provided clients total savings of up to 30 percent by leveraging the global market rates of PPD's worldwide operations.

Through its operational excellence, extensive resources and global infrastructure, PPD provides the framework and flexibility needed to support your established products portfolio.

PPD FSP: People who deliver.