PPD Functional Service Partnership (FSP) Regulatory Affairs solutions

Proven regulatory expertise to increase your probability of approval success

The regulatory landscape is dynamic and continually evolving, driven by local regulatory requirements; medical, scientific, and technological advances; and industry and political influences. In the face of rapid regulatory change, with further significant change anticipated, it is critical to find a partner you can trust to employ a scalable regulatory affairs approach that brings the right resources at the right time.

Through unmatched regulatory expertise and insights — available in a flexible functional service partnership (FSP) model — **PPD™ FSP Regulatory Affairs solutions** helps biopharmaceutical, biotech, and medical device organizations navigate dynamic global regulatory environments to increase the probability of approval success. With a proven track record built from decades of experience, we deliver the right talent and expertise to deliver your projects on time — while providing much-needed resource flexibility, reliability, and continuity.

30+ years of regulatory services experience

Successful preparation and management of regulatory submissions in **160 countries**

Senior staff members' average experience:
24 years in pharma
18 years in regulatory affairs

End-to-end regulatory solutions with the ease of a single partner

Drawing upon recognized experience built over 30 years, we provide strategic and technical services — across the entire product lifecycle — with the ease and convenience of a single global partner. Whether supporting a critical business task or a clinical trial, supervising an entire portfolio, or providing post-approval lifecycle management, we employ a scalable approach that brings the right resources at the right time with an uncompromising commitment to quality.

Proven Results

In the last 5 years we've supported...

- 50+ New drug applications/ marketing applications
- 140+ agency meetings
- Nearly 900 new market expansion licenses
- 5,950+ Clinical trial applications/ investigational new drugs
- 34,900+ lifecycle submissions
- 54,200+ clinical trial applications/ investigational new drug updates

And we delivered…

- 99% first cycle approval
- Zero licenses lost or compromised
- Zero dossiers failing validation
- 99% submission milestones achieved

Expert support across all phases and product groups

No matter where you are in your product lifecycle and no matter which products are represented in your pipeline, we can serve as your worldwide partner. We offer you access to unmatched expertise and the flexibility to choose end-to-end regulatory support or discrete solutions according to your specific needs.

Support for all clinical and peri- and post-marketing needs...

- Regulatory strategy & expertise
- Investigational new drug (IND) services
- Regulatory intelligence
- Regulatory publishing solutions (RPS)
- Regulatory science and innovation
- Labeling services
- Market access strategies
- Project management and oversight
- Technical expertise: CMC, non-clinical, clinical
- Medical devices and diagnostics

Our proactive approach

to navigating regulatory requirements

We apply our extensive clinical and regulatory experience and expertise — and long-standing and trusted relationships with national and regional regulatory authorities — to monitor potential risks and challenges and anticipate and address queries raised.

… across all product groups

- Small molecules
- Vaccines
- Medical devices and diagnostics
- Biologicals
- Generics
- Consumer
- Biosimilars
- Advanced therapies
- Over-the-counter products

Cross-functional experts increase your probability of success

Creating and executing a regulatory plan with a high likelihood of product approval requires specialized, cross-functional expertise every step of the way. Our cross-functional teams employ a mix of highly qualified senior staff members with long-running regulatory experience in the pharmaceutical and medical device industries.

Every regulatory team includes a customized mix of roles aligned to skills and task requirements, guided by experienced decision-makers empowered to provide scalable solutions that meet your unique needs over time. By bridging regulatory affairs knowledge with extensive commercial experience, our team provides convenient access to the right expertise at the right time to develop regulatory strategies that enable the most efficient registration pathways, and maximize the probability of approval success and fair market access.

Extensive team expertise

- Regulatory oversight directors
- Regulatory affairs leads
- Regulatory country managers
- Regulatory specialists
- Regulatory assistants
- Publishing specialists
- Chemistry, manufacturing & controls (CMC) specialists

Worldwide reach and thought leadership accelerate outcomes

With regulatory staff located across the globe — including one of the largest and most experienced regulatory teams in China — we deliver the specialized expertise needed to navigate local regulatory requirements, facilitate efficient reviews of applications, and accelerate outcomes. We also effectively scale to manage your changing needs by leveraging our regulatory FLEX Solutions Team, an adaptable resource pool in strategic locations.

Regulatory resources strategically located

Staff locations

- North America
- Europe
- Asia Pacific
- Middle East
- Africa
- Latin America

FLEX solutions team locations

- Latin America (Mexico)
- Asia (India and the Philippines)
- Eastern Europe (Bulgaria)

Charting the course for a regulatory future

We proactively address current challenges and influence future strategies across multiple geographies, product classes, and regulatory agencies by applying:

Our local, regional, and central regulatory intelligence

Active engagement and influence with industry and global health authorities

Regulatory thought leadership across a range of health authorities and stakeholders

Proven systems provide the foundation for successful submissions

Up-to-date regulatory intelligence is fundamental to a successful regulatory strategy. To stay current on the latest regulatory environments, we continuously share intelligence gathered from our successful regulatory submissions at relevant meetings and our forums worldwide. We also incorporate our intelligence and learnings into our systems to offer clients easy access to their data and submission archive and allow multiple parties to securely move in harmony from one step to the next.

Support from our systems and technologies

RegView proprietary intelligence platform

- Provides actionable regulatory intelligence from around the world for colleagues and customers
- 13,000+ summaries in 150+ countries through early development through post-approval
- 1,300+ cross-country reports updated daily
- Based on published official data and contemporary experience

Publishing solution

- Expedites delivery and validation of submissions via a follow-the-sun resourcing model
- Ensures quality published outputs satisfy technical requirements for health authority gateways and portals

Veeva vault regulatory information management system (RIMS)

- Supports timely and compliant management of end-to-end regulatory processes
- Handles planning and tracking documents, submissions, registrations, commitments, etc.

The benefits for you

Easy access to current, actionable, and reliable data and intelligence

Better-informed decision making

More consistent, accurate, and efficient submissions with a greater chance of success

Learn more at **ppd.com/fsp-regulatory-affairs**

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