WHITE PAPER

PPD
Part of Thermo Fisher Scientific

PPD FSP Pharmacovigilance Solutions

Ensuring Effective Pharmacovigilance Regulatory Intelligence with FSP Partnerships

Pharmacovigilance (PV) is a critical component of drug and medical device development and commercialization and effective PV regulatory intelligence (RI) is important in ensuring that PV is executed accurately and cost-effectively. Considering the important role that PV RI plays, every party in the industry has a stake in it.

Many pharma, biotech and medical device companies rely on functional service provider (FSP) partnerships to ensure comprehensive and cost-effective PV RI. FSP partnerships involve the outsourcing of some or all of one or more functions, potentially across the entire product portfolio. In this white paper, we outline some of the key PV RI capabilities that differentiate top-tier FSP PV partners from other service providers, including:

- Monitoring regulation changes
- Analyzing and interpreting regulations and guidance
- Communicating regulatory requirements and operationalizing change
- Guiding the development of new and updated regulations and guidance

What is PV Regulatory Intelligence and Why is it so Important?

At its core, PV RI is the process of tracking the publication of new and updated PV-relevant regulations and regulatory guidance. While this may be a very straightforward concept, in the real world it can be incredibly complex, and insufficient management can have significant consequences. Some of the complexity arises from identifying when a change in PV regulation has occurred. For example, the location of publication may be obscure, there may be delays in the publication being posted/shared publicly and the publication may be in local language. Additionally, the global scope of most pharma, biotech and medical device manufacturers contributes to the complexity of PV RI processes, making it a necessity to have a PV RI team that spans multiple countries and languages.

Deficiencies in keeping up with regulatory change can have significant impacts for the sponsor/marketing authorization holder, health care professionals and consumers. In this high-stakes environment, engaging with the right FSP PV partner for PV RI is critically important.

Monitoring is the First Step to Staying on Top of Constantly Changing Regulatory Requirements

A strong PV RI team delivers value in many ways. Every drug or medical device developer needs a PV RI team that is actively involved in the regulatory process, effectively and expertly monitors and translates intelligence, analyzes how that intelligence applies to a product, and makes timely and accurate recommendations or changes. For multinational companies, those PV RI experts need considerable depth and breadth of expertise to accomplish these critical tasks.

Your FSP PV partner will need to have a structured and methodical approach in place for the proactive collection, interpretation and presentation of a wide range of intelligence. This requires regulatory and PV domain expertise, combined with the right infrastructure and technical platforms to store, analyze and disseminate PV regulations and guidance.

Leveraging RegView for Regulatory and Pharmacovigilance Intelligence

PPD™ FSP PV solutions, part of the PPD clinical research business of Thermo Fisher Scientific, operates a proprietary intelligence platform, RegView, that facilitates use and sharing of clear, comprehensive RI across more than 100 countries. The RegView platform includes PV intelligence across various stages of the drug and medical device development cycle and enables us to capture a wide range of country-specific PV regulations and procedural guidance effectively, including:

- Legislation/regulations, processes and timelines
- Industry practices
- National/regional differences
- Regulatory analysis
- Regulatory precedence
- Guidelines/directives
- Opinions/advice

The RegView Platform Receives More than 500,000 Views Per Year as Our Global Teams Use it to Develop Reports and Disseminate Critical Information to Our Clients

RegView is also directly connected to our client-facing centralized regulatory authority and ethics committee tracking (CREST) system, which automates and centralizes the safety report submission process for clinical trials. By integrating data from our clinical trial management system (CTMS) and the RI database, CREST delivers real-time safety report submission data and intelligence to help in oversight and compliance.

Analysis and Interpretation are Key to Effectively Adapting to Regulatory Change

Expert analysis and the ability to discern how regulations and associated guidance need to be applied in real world operations are key components of a top-tier PV RI team.

The most effective teams will take that data and develop their own analysis on precisely what the impact is on any given client project, rather than simply redistributing data obtained from commercial sources.

For PV RI experts to deliver real value, these specialists should be knowledgeable in some of the more obscure regulatory publications and other information well beyond core regulations and guidance so that they can appropriately analyze and interpret regulatory requirements within the required context. This includes staying on top of clarifications sought from individual regulatory authorities, Q&A documents, conference presentations, and other publications and meetings by regulators and international bodies that contribute to a deep understanding of "gray areas" and industry norms.

For effective PV RI analysis and interpretation, a global presence and regional expertise are key, as PV RI can be hard to effectively access outside of the country. Having one central FSP PV partner overseeing all PV RI globally mitigates the likelihood of communication errors and other hurdles that may be present where multiple vendors/partners are used. Effective gathering and monitoring of PV RI entails many nuances and is best accomplished by an experienced team that collaborates and facilitates information sharing with regulatory affairs and clinical operations teams, as well as other experts across the PV lifecycle. Likewise, the PV RI team should include native speakers who can navigate regulatory complexities for their geographic location.

Communicating Regulatory Requirements and Operationalizing Change

Effective communication of PV RI is important both internally and externally, and the ability to break down information silos is a key factor in the internal component. For example, when the regulatory affairs function is first aware of a PV-relevant regulation change, there must be mechanisms in place to ensure that data quickly makes its way to the PV function. Identifying changes in regulatory requirements quickly and efficiently drives the FSP PV partner's ability to provide PV RI to its clients and subsequently allows for quick action to be taken to operationalize the change. Setting up a regular cadence for communication, whether real-time notifications or regular meetings, helps reduce delays in taking action on major changes that could impact compliance — such as changes that may require safety database configurations or procedural document updates.

"Whether a change in regulation is identified by a regulatory affairs function or a local affiliate, a communication pathway with clearly documented expectations is important to ensure that PV RI changes are quickly recognized, analyzed and shared."

Timely analysis and communication can enable pharma, biotech and medical device companies to quickly operationalize change to be fully compliant by the time the new regulations are mandated to take effect. The wider the geographic reach of a company, the bigger the benefit to having one source of regulatory intelligence that stays abreast of changes (and interpretations) across all aspects of PV, no matter how dispersed. In contrast, where multiple vendors are involved, the company has an additional burden of managing potential differences in PV RI interpretation and ensuring that operational changes are applied across vendors.

Expert PV RI Teams Ensure Drug and Device Developers' Viewpoint Shapes Regulatory Requirements

The best PV RI teams have a breadth and depth of cross-functional expertise that isn't just recognized by pharma companies, it is also recognized by other industry peers and regulators. RI specialists may participate in industry and regulatory conferences and other forums, including delivering feedback on draft regulations and guidance, to help contribute to the development of regulations and to ensure the complexities of industry impact are considered. This is only possible with years of real-world experience that enables deep understanding of the evolving principles behind PV-regulation (CIOMS, ICH, etc.) and exposure to regulatory frameworks across many different jurisdictions.

For example, when Turkey recently overhauled its PV requirements — including what safety reporting content would be reportable and which formats would be accepted — our PPD team was there to support. Our PPD FSP PV solutions experts directly engaged with the regulator and participated in industry discussions to help ensure there was a clear understanding of the new requirements. Our PPD FSP PV team worked to identify a ramp-up period for when the new requirements would be implemented and, where needed, negotiated bespoke timelines with the regulator on behalf of clients. Due to this engagement with the regulator and other similar relationships with regulators developed over time, we can support the regulatory changes and ensure that safety reporting compliance is not impacted.

An FSP PV RI Solution Creates a Strong Foundation for Success

Across the complex global landscape of pharma, biotech and medical device product development, solid regulatory expertise and effective safety reporting are key to ensuring patient safety and regulatory compliance. In the face of a global regulatory environment that is constantly evolving, companies must be proactive, well-informed and flexible — and a committed and experienced FSP PV partner is the best way to meet these needs. A dedicated PV RI team should include multilingual experts responsible for the detection and analysis of changes in PV regulation and highly adept at identifying how those changes impact pharmacovigilance. In PV RI, maintaining data on requirements across various product types is just the beginning. By staying abreast of constantly changing regulatory considerations and delivering thoughtful, timely guidance as to how those regulations affect real-world drug and device development, PV RI experts create a strong foundation for success.

Experience Matters

Whether you're managing the more obscure aspects of mature regulatory markets or struggling to make sense of a newer regulator that is less clear in the publishing of their requirements — experience matters.

With more than 25 years of experience, our PPD FSP PV solutions experts have worked with hundreds of clients across a wide variety of product types in all stages of development. Our PV RI team has a level of expertise that comes from extensive real-world interactions with regulators. Through our reliable network of professional colleagues across the globe, we seek to ensure that no "gray area" escapes our notice or understanding.

Our PPD FSP PV solutions specialists maintain PV RI for almost 100 countries in medicinal products and medical devices and provide PV RI support for over 250 clients.

Each of our clients can rest easy knowing our services are made more successful by our commitment to PV RI. This includes companies that count on us to deliver effective functional service provider partnerships. The value-added capabilities available to FSP clients include a gap analysis to help identify any possible discrepancies in RI interpretation and guidance on addressing any compliance risks.

Ready to ensure your PV regulatory intelligence process is robust and effective?

Partner with a team whose breadth of expertise can ensure compliance with regulatory requirements, and subsequently contribute to the on-budget success of your next product.

LEARN MORE AT PPD.COM/FSP-PHARMACOVIGILANCE

For more information visit our website at
ppd.com/fsp-pharmacovigilance


twitter.com/PPDCRO


facebook.com/PPDCRO


youtube.com/PPDCRO


linkedin.com/company/ppd

PPD®
Part of Thermo Fisher Scientific