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Beyond Regulatory Intelligence: How an FSP PV Partner Helps Ensure Global Compliance

Support from these partners can aid drug and medical device developers in keeping up with the evolving regulatory landscape.

The pharmacovigilance (PV) regulatory landscape is continually evolving, driven by the effects of technological advances and political influences on statutory requirements and associated guidance. To ensure conformity to the regulatory requirements that mold and shape PV, every drug and medical device developer requires a robust PV regulatory intelligence (RI) process that enables the identification and analysis of changes as well as the agility to execute changes to their PV systems in a timely manner.

At its core, PV RI is the process of tracking and analyzing new and updated PV-relevant regulations and regulatory guidance. While this may seem like a straightforward notion, implementation of a PV RI process is multifaceted, especially in global markets. Inadequate execution or insufficient maintenance of a PV RI process can have significant consequences, creating obstacles to the compliant development and maintenance of products on a global scale.

Whether you're grappling with new requirements in a mature regulatory market or struggling to make sense of an unclear regulation in a developing region, experience matters. To understand regulatory changes in their full context and to determine the best course of action to take, an effective PV team must go beyond familiarity with core regulations and guidance. This requires an in-depth understanding of wider regulatory publications, review of obscure sources (e.g. Q&A documents, conference presentations, and other publications and meetings) and clarifications sought from individual regulatory authorities. By grasping the full context of regulatory changes, the PV team can evaluate the specific impact and determine the most appropriate actions to be taken.

How functional service provider (FSP) engagements enhance PV RI

FSP models involve the outsourcing of some or all of one or more functions, potentially across an entire product portfolio. By outsourcing individual functions, clients retain control while complementing their existing strengths with an outsourcing partner's deep bench of resources, knowledge, and expertise

For PV RI, an FSP team offers a centralized source of expert regulatory intelligence including a breadth and depth of cross-functional expertise in combination with localized, on-the-ground experts—who, working together, are responsible for detecting PV regulation changes, identifying potential impacts, and driving strategic recommendations.

As biotech and biopharma companies experience the value and flexibility of FSP partnerships, the FSP market continues to grow. A 2023 survey of biopharma and biotech leaders, found that 41% of respondents reported increased use of FSP models.[1] Subsequently, FSP growth is projected to continue at a compound annual rate exceeding 8.6% through 2032.[2]

How does this interest and growth in FSP models relate to PV RI, and what benefits does a FSP partnership offer? The follow sections explore the advantages of an FSP engagement for PV RI monitoring, analysis, and communication.

1. Monitoring

A methodical approach is needed within PV RI to comprehensively monitor a wide range of regulatory intelligence sources, including national and regional laws, regulations and guidance; other information posted to regulatory authority websites; seminars and training sessions led by regulatory authorities; and direct communications from regulatory authorities. The volume of potential sources may be compounded by the number of countries in which a drug or medical device developer is operating.

Monitoring such a wide and diverse breadth of intelligence data requires a PV RI team with broad regulatory and PV domain expertise combined with the right infrastructure and technical platforms to find, store, analyze, and disseminate changes to PV regulations and guidance. For example, PPD FSP Pharmacovigilance solutions operates a proprietary intelligence platform, RegView, that facilitates use and sharing of clear, comprehensive RI including a wide range of PV regulations and procedural guidance across more than 100 countries.

An FSP model not only avails the right PV resources to manage this task day to day, but engaging in an FSP PV partnership with a large CRO also opens up a wealth of access to additional expertise from other functions as needed, including regulatory affairs and clinical operations, creating an integrated intelligence network. This ensures that when highly specialized expertise is needed, the right stakeholders can quickly be accessed, making the RI monitoring process both efficient and effective.

2. Analysis and interpretation

While leveraging a robust monitoring infrastructure is crucial, it is not sufficient alone to ensure compliance with regulatory requirements. A top-tier PV RI team must also move past the data identification step to provide a thorough analysis and interpretation of regulatory changes. This involves detailing what the regulatory changes mean, determining the specific impacts, and providing tailored guidance such as what steps need to be taken and what risks might be involved.

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A well-resourced FSP PV team positioned strategically in locations around the globe—and supported by a larger global network—offers numerous advantages to improve the analysis of regulatory intelligence. This setup facilitates the use of native speakers to perform translations and, if needed, to interact directly with regulatory authorities in local language to minimize the risk of miscommunications. Moreover, an FSP network enhances the PV RI team's ability to develop relationships within the industry over time, opening communication pathways that increase the likelihood of information sharing and potential input to the development of regulatory guidance.

3. Communication and operationalizing change

An integral part of the FSP PV RI process is communication with a broad range of stakeholders, including within the PV function, with other

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functional groups, and with regulatory authorities. It is critical to ensure each step of the PV RI process is operating in a seamless manner—not within silos that can lead to knowledge gaps. Furthermore, in many instances of regulatory intelligence change, timing is essential to maintain compliance and ensure patient safety.

One of the strengths of using a FSP model for PV RI is that by having one central source of regulatory intelligence that covers all the complex aspects of PV, regardless of geographic location, drug and medical device developers can benefit from a streamlined communication process. This model relieves internal stakeholders of the burden of orchestrating these processes and instead positions them as recipients of tailored and essential information that caters to their specific needs.

In contrast, when working with multiple vendors, managing potential differences in PV RI interpretation and ensuring consistency of application can pose additional challenges that may lead to operational delays.

Timely communication of PV RI findings to key stakeholders enables the implementation of changes before new regulations come into effect. This is crucial for maintaining compliance and ensuring that procedural documents and systems are updated to meet the latest requirements.

For example, in recent years, the transition from R2 (Release 2 standards) to R3 (Release 3 standards) for the electronic transmission of Individual Case Safety Reports (ICSR) under the International Conference on Harmonization (ICH) E2B guidelines in various countries, like Taiwan, has necessitated extensive planning and safety database configurations. Similar E2B changes are expected in other countries, including Mexico and Switzerland. A PV RI team can play a vital role in identifying and communicating these changes, as well as ensuring their proper implementation.

PV RI specialists also regularly participate in industry and regulatory conferences and forums, including delivering feedback on draft regulations to ensure the complex nuances of industry impact are considered.

For example, when Turkey changed its PV requirements, PPD FSP Pharmacovigilance solutions professionals directly engaged with regulatory authorities and actively participated in industry discussions to foster a clear understanding of the new requirements. This collaboration helped facilitate the identification of an appropriate transition period for the implementation of the updated requirements.

Conclusion

The wider the geographic reach of a company, the larger the benefit of having one global source of expert regulatory intelligence that stays abreast of changes (and interpretations) across all aspects of PV, no matter how dispersed, to avoid delays in maintaining compliance. Comprehensive monitoring, expert analysis, robust communication channels, and effective operationalization are crucial components of PV RI. With the support of an experienced FSP PV partner, drug and medical device developers can efficiently adapt to regulatory changes and maintain regulatory compliance across their operations.

References

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