IQVIA

Balancing Compliance Among the Shifting Sands of Pharmaceutical Data Privacy Regulations

Maximize compliance, increase revenue potential and improve patient safety by leveraging proven technology

Today's regulatory environment for global pharmaceutical companies is a complex one filled with a myriad of local compliance rules that change frequently to better address patient safety, economic concerns, data privacy and other regional concerns. As more data is digitalized and as healthcare companies share information for clinical research, testing and more, it is critical that the data remains protected at all times.

What are regulatory bodies doing to improve data privacy?

Regulatory bodies at the regional and local levels are stepping up to strengthen existing data privacy requirements and regulatory compliance requirements across the pharma industry. Here are just a few that are delving deeper in an effort to ensure patient safety:

Northern Ireland stands out in the UK region with different protocols, as it will continue to broadly follow the EU regulatory standards. As a result, UK-approved medicines are not able to enter Northern Ireland without EU approval, although the UK's Medicines and Healthcare products Regulatory Agency (MHRA) is working on guidance to adjust this, following Brexit.

Canadian legislators are working on the Canadian Consumer Privacy Act (CPPA) which provides individuals with greater control of their personal data. CPPA is similar to the EU's GDPR.

The European Federation of Pharmaceutical Industries and Associations (EFPIA) released a code of conduct in early 2022 on how data may be shared for clinical trials and pharmacovigilance.

Recently, the Spanish Data Protection Authority (AEPD) approved the first code of conduct on personal data. The result is that companies operating in Spain must adhere to stricter data privacy regulations and codifying of data to ensure information is protected at all times.

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Pharma companies must keep pace with regulatory change

At the heart of these – and other regulations yet to be levied – is the patient and the protection of their information. And for pharma companies, staying on top of these changes requires a different approach that combines expert resources, streamlined processes and leading technologies. As such, organizations must take regulatory strategies into consideration throughout a product's lifecycle – from the initial research and identification of a molecule for pharmaceutical purposes, to the rebranding and relaunching of that molecule or drug for a different treatment at the end of its lifecycle.

CHOOSING THE RIGHT TECHNOLOGY FOR COMPANY SIZE

While this type of forward-thinking planning is commonplace in larger organizations, they may find that the increase in regulatory changes between regions adds a new layer of complexity to their planning processes. Further, smaller organizations may not have established a long-term strategy, and must leverage the technology resources available to maximize compliance and, therefore, revenue potential and patient safety. Regulatory advice, along with the proper regulatory workflow enabled by advanced technologies, such as AI and ML, can lower administrative burdens for companies. IQVIA's Global Regulatory Affairs team partners with pharmaceutical companies of all sizes offering comprehensive technology-enabled regulatory services.

LOWER YOUR ADMINISTRATIVE BURDEN ACROSS THE COMPLETE PRODUCT LIFECYCLE

Our Global Regulatory Affairs team helps sponsors handle regulatory workflows more flexibly, productively and efficiently. From strategic regulatory advice to regulatory maintenance and lifecycle support, our expert resources, streamlined processes and leading technologies provide:

- Optimized time to key decision points

- Regulatory and operational risk mitigation

- Streamlined regulatory pathway

- Flexible approaches to generating more informative evidence earlier

- Improved transparency and proactive problem-solving

Comprehensive Global Regulatory Affairs Services

Regulatory Strategy

Regulatory Affairs

Regulatory Operations

Gap Analysis

Technical Scientific Due Diligence

Indication Prioritization & Selection

Marketing Applications

US Agent / HA Liaison

Lifecycle Maintenance

RIM Data Maintenance

Submission-Ready Document Preparation

eCTD, Paper Lifecycle Publishing

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