WHITE PAPER

Current Labeling Compliance Risks, Mitigation/Actions in 2021

When it comes to labeling compliance, historically, BioPharma could argue that they simply did not have the information available to identify potential compliance dissonance across their business units and affiliates: the “needle in a haystack” defense. Companies can leverage data and applying modern analytics to draw insights and navigate the risks across their entire labeling network. In addition, because of COVID disruptions in work and teams in different countries, compliance is given lesser priority by BioPharma. But health authorities will not agree with your constraints or priorities when getting into 2021.

Many companies have not focused on this area, because they have regarded labeling compliance simply as an obligation or even an afterthought. They are missing an opportunity. Using the modern tools available today to ensure strong third-party label risk management can lead to better patient safety and bolster data protection; it can also help craft environmental policies and evaluate risks, which is particularly important as the COVID-19 pandemic has created a rise in remote working.

Start determining whether compliance and labeling personnel have sufficient direct or indirect access to relevant sources of data to allow for timely and effective monitoring and/or testing of data and processes. In turn, this has put a spotlight on how organizations are investing in technology to support these areas.

Sticks & Carrots

Other industries have tech-enabled solutions that can address regulatory requirements and more broadly manage compliance. These efforts demonstrated the power of digital tools to proactively identify, predict, and monitor risks and bad processes. But companies should not see these modern compliance requirements only as a stick. Advanced technology that is predictive and proactive, and that results in better visibility into the risk landscape, offers more than protection from regulatory investigations. For BioPharma that wants to thrive in today’s data-driven environment, such technology provides a technological competitive edge: table stakes that can both mitigate risk and help assess opportunities with more confidence because the risks have been properly evaluated.

In essence, labeling and associate compliance should no longer be seen simply as a backroom cost center. Rather, it is a means of strengthening the business brand, increasing productivity, and driving growth of market share.

Bring tech to the party

Labeling and analytics tools have expanded from an initial document system or due diligence aid to form solutions that combine and consider multiple risk factors or attributes. They include where businesses operate, odd patterns in operations, unusual approvals in countries, or other details that might suggest an increased level of risk or out-of-the-ordinary activity. This analysis, strengthened by the collection of available data, provides insights into both affiliate's activities and operations. And, with each use, these predictive analytics get smarter and more adept at identifying anomalies, effectively building a better mousetrap to prevent noncompliance.

Getting the full value from investment in the technology comes when the insights it produces can be used to develop a more strategic approach to labeling, which could be called a labeling compliance-by-design operating model.

Better command and control

Pharmaceutical companies have long been prone to governance concerns, which has led to many facing fines for poor risk management. This goes beyond simply providing business intelligence because it tells you what's risky, why it's risky, and how to effectively mitigate that risk. That's the special sauce.

Whatever the size of the BioPharma, one of the challenges of using a system that leverages automation or machine learning is building trust among internal stakeholders. False positives and false negatives can occur with machines, just as they can with manual research. People need to know the mousetrap is going to catch the mouse. Pilot programs, running historical data on deals known to have been problematic, can help demonstrate that these modern technologies would have identified the issue in real-time.

Basing regulatory/labeling risk and compliance decisions on machine learning can dramatically impact all areas. It can lead to higher-quality content, operations efficiency, and better patient safety. It can build trust through the whole regulatory chain. The new importance that regulatory authorities are giving to robust compliance data analytics will likely spur investment in these technologies, but the message is that they are not simply a defense. They can be an integral part of strategic decision-making.

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