Article

Boost Compliance by Monitoring Social Media Channels

Companies that fail to monitor social media channels for potentially reportable complaints and product quality issues might be missing a key piece of their quality and regulatory compliance puzzle.

Michael King, who is a senior director of products and strategy for the technologies division of IQVIA, pointed to regulatory mandates that require companies to capture and report adverse events in a timely manner. While the specifics of those mandates vary from country to country, the principle of monitoring post market product performance to safeguard patient safety exists in a significant number of global country regulations. In the case of Europe these requirements have been strengthened further by recent changes to regulatory policy on postmarket surveillance under the medical device regulation and in vitro diagnostic regulation.

"If your product could have harmed someone or has, that is something you need to jump on immediately, both for the benefit of the patient and also to make sure that the regulator has confidence that the company's processes are in place and suitable to protect patient safety," King explained.

In addition to the compliance benefits, analyzing social media can also provide a "wealth" of information around product performance and product quality. King recalled having worked for a company once that accidentally shipped some boxes with no product inside. Angry customers swiftly took to social media to report the issue.

"It was moderately amusing, but incredibly aggravating because it then took a lot of work to remediate," King said. "The clinicians were not happy, that dealers were not happy, the business unit wasn't happy. But due to the speed of social media that was caught very quickly and identified as a product quality issue. We were able to get into the production files, see what the issue was, put our arms around the specific batch in question, conduct a health hazard evaluation, and then ultimately make a decision around whether certain actions were needed."

The critical step: Define your scope

Typically, companies must report any adverse events that they are aware of — which includes events documented on company-owned websites and company-managed pages on major social media sites. Additionally, firms may need to monitor online forums devoted to third parties such as equipment dealers who operate in the company's name.

Gathering and sorting through that information is not always easy. Given the volume of information that's available in structured and unstructured forms, cutting

through hugh data volume in an effective way, is often a challenge. That is where tools like AI can support with the gathering of data across a variety of sources.

A critical first step for a company in developing a social media monitoring program is to define the scope of the information they wish to gather. Identifying what data sources a company has, what type of information these sources can provide, and whether that data is company-owned or controlled by a third party is critical. In addition to company assets, target data sources might include patient group information, public registries and data from other available forums.

Data gathered from those sources can then be fed into software to identify patterns that might lead to new product performance claims, unseen safety issues, or other concerns that need addressing. Such software needs to be programmed to take multiple factors into account, such as where products are used, potential failure modes and the intended purpose of the device, to optimize the insights given to the quality and regulatory professionals that would use such software.

Human review still critical

Once those patterns are identified, human review is still needed to follow up on the captured information and to potentially provide clinical context to the AI generated insights. The human can use other methods, such as reaching out to the customer, to validate which cases seem to be legitimate product quality issues which may require further review as a potential adverse event. Product quality information may also provide insights that can be brought back into design and development activities to support the innovation pipeline.

"Where there's information that's lacking, particularly whether it's a potential safety issue, that [human] follow-up is often critical for a company to gather the right information to make the right assessment around that product," King said, adding that information gathered by humans can also be used to further train the AI algorithms.

In utilizing AI enabled technology to monitor social media channels there are two main challenges to be addressed. First, the software needs to be checked against a company's existing complaints and adverse events data to ensure it's watching for issues that are specific to the product types, failure modes and clinical context to the company's product portfolio. And second, it's important that the technology is just one piece of a functional end-to -end, validated complaint handling process. Such technology needs to meet global regulatory requirements and connectivity to a broader quality management system ensures that identified issues pull through into targeted actions that improve product quality and protect patient safety.

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As senior director of product and strategy within the technology solutions business of IQVIA, Michael King is responsible for ensuring that life sciences solutions support increasingly complex and diverse global regulations. He is particularly focused on optimizing business workflows through intelligence-driven simplification and automation within and across safety, regulatory, and quality functions.

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