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How far does cloud technology ensure drug safety and operational efficiencies at pharmacovigilance?

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Dr. Anju Agarwal, Director, Global Patient Safety at Advanz Pharma "Cloud-based technology delivers better systems for backup management and data integrity from a good practices (GxP) perspective"



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From popular over-the-counter medications like paracetamol to more complicated drugs and vaccines, pharmacovigilance plays the most crucial role, in ensuring the safety of medical products before they come out in the open for public consumption. If not identified, a single case of adverse effect (AE) may endanger hundreds of thousands of lives.

With numerous trials and results, data has been the tool for success in pharmacovigilance. However, the increasing data volume and data complexity are creating challenges in pharmacovigilance. How are pharmaceutical organisations leveraging the latest technology and solutions to ensure drug safety and operational efficiencies?

Dr. Anju Agarwal, Director, Global Patient Safety at Advanz Pharma, shares how advanced digital transformations in pharmacovigilance within regulatory compliance can improve processes timelines and efficiency in the pharma industry for faster and better safety decisions.

- **What are the common challenges faced by an organization in pharmacovigilance? How did Advanz Pharma tackle such challenges while managing complex products?**

The key challenges faced by Advanz Pharma were related to data control and management. Data pertaining to pharmacovigilance and safety database activities were outsourced to Clinical Research Organisations (CRO). This resulted in an operational bottleneck as data resided within databases of the CROs, leaving Advanz Pharma overly dependent on the CRO each time they wanted to access said data.

Complexities were further exacerbated as the CROs themselves were dependent on their database service providers, leaving Advanz Pharma unable to work or access data according to their requirements. For instance, they were not able to generate line listings or data outputs by themselves. This created complications in areas like effective management of drug-device combinations, as well as compliance with regulations such as E2B(R3) in reporting.

This became an increasing concern for Advanz Pharma when it came to inspections. With Advanz Pharma undergoing an average of 5 -6 inspections from various agencies in a year, these bottlenecks and costs incurred to extract the right data for the inspections become a burden.

As a company thriving on acquisitions and mergers, Advanz Pharma acquires products or merges with companies, cases, and data are imported in bulk, raising challenges involved when working with CROs. Challenges of data management are tackled by an independent safety database, enhancing our ability to analyze information for better identification and remediation of adverse events.

- **How beneficial are the latest technology and cloud-based solutions in overcoming pharmacovigilance challenges?**

Cloud-based technology delivers better systems for backup management and data integrity from a good practices (GxP) perspective. With new GDPR guidelines, this becomes even more important. The latest technologies helped us manage the database with major administrative controls, helping us remain compliant with ever-changing guidelines.

Being not dependent on the product development arm, we are required to migrate large amounts of cases and data to our databases to leverage mergers and acquisitions. Cloud-based technology helps not only with migration from various sources but also with implementation. For example, the use of Oracle Cloud-enabled us to seamlessly migrate and implement data in XML format from 3 different sources in a record time of 7 months.

Of course, the benefits of cloud technology expand beyond our operational and administrative activities, providing better backup data management for disaster recovery and business continuity in the event of unforeseen circumstances. It also helps with better data integrity and facilitates better overall data practices. Cloud technology is also essential in compliance, ensuring databases are delivered with vital updates on a timely basis - especially important in an industry where regulations are ever-changing.

Advanz Pharma's pharmacovigilance practice has been benefiting from next-generation solutions that integrate advanced capabilities like AI (artificial intelligence). A.I. is also utilized in our validation checks to ensure that all crucial parameters are checked. Advanz Pharma is constantly working to bring in more next-gen advantages, exploring ways to improve not only our processes but also our CRO partner's processes.

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