propharma

CASE STUDY

Streamlining Adverse Event Reporting in JAPAC

challenge

A ProPharma Medical Information (MI) Lead working alongside a pharmaceutical company faced the challenge of harmonizing the adverse event (AE) reporting process across the Japan and Asia-Pacific (JAPAC) region.

The need for this was heightened by the dissatisfaction of a local safety vendor in China. The stringent requirements for AE reporting in China meant that any misalignment with local regulations could lead to significant delays in reporting to local authorities.

This was the case with the existing process, which was not tailored to the specific needs of the Chinese market, resulting in a **100% rejection rate** of reports by the local vendor.

solution

Action: The MI lead took a proactive approach by initiating a collaboration between the local Chinese Affiliate and the global MI team. Through a series of discussions and workshops, they identified the gaps in the current process and developed a new strategy that met local needs while still adhering to global standards.

Solution: The team proposed a series of process changes, including:

- Implementing a **localized reporting template** that met the specific criteria of the Chinese regulatory environment.
- Establishing a t**raining program** for the MI team to ensure understanding and compliance with local requirements.
- Introducing a **quality check** mechanism before report submission to minimize errors and re-work.

results

Outcome: The implementation of these process changes led to a dramatic improvement in the efficiency and effectiveness of the AE reporting process:

- There was a significant reduction in report rejection rate by the local vendor, with only one report requiring further clarification since implementation.
- The MI team saw a **considerable increase in work efficiency**, with a 50% reduction in time spent on AE reporting.
- The timeline for adverse event reporting to local authorities improved, achieving a 100% on-time submission rate to local Safety.

conclusion

The intervention of the MI lead enhanced the operational efficiency of the team and ensured that patient safety was not compromised due to administrative delays. This case study underscores the importance of regional expertise and the ability to adapt global processes to meet local market needs in the JAPAC region and exemplifies the pivotal role of an MI Lead in navigating the JAPAC medical landscape, ensuring both local relevance and global consistency in critical processes such as AE reporting.