



Passion and Enthusiasm | Perseverance and commitment | Aiming High | Integrity | Team work

Redressal of Roadblocks in post marketing Pharmacovigilance: Strategic solutions by AWINSA

WWW.AWINSALS.COM



A mid-sized US based pharma company

Business Challenge: Absence of repository for the safety information, Challenges in assessing the information for periodic reports, Signal management and Risk Benefit assessment of the products.

Services Provided: Transition of safety data from safety reporting portal (SRP) to own safety database. Further streamlining of the inhouse safety database and provision of repository for periodic reporting, signal management and risk benefit management.

KEY BUSINESS NEED

Before the alliance with AWINSA, one of our US based clients was using Safety reporting Portal for fulfilling the PV obligations to FDA. The unstructured data from sources like literature, spontaneous reporting was requiring additional efforts for the duplicate check, follow up management and processing of safety information. The Quality and compliance efforts also became quite intensive over a period of time. The acquisition of a new company with multiple products made the PV management activities even further complex.



Seasoned Team Of Professionals



Improved Monitoring and Compliance



Enhanced Safety Analysis

BUSINESS SOLUTION

When it comes to the regulations, both quality and compliance are the essential parts. Since every task is time-based activity, a proactive approach is required where the work can be completed timely with minimal manual efforts. Emerging global regulations, compliance to ICH guidelines and increased emphasis of risk assessment requires a robust PV system which can fulfil all the expectations.

- AWINSA implemented a validated Argus safety database for the client. A highly seasoned PV team demonstrated how the highly validated database will not only work as a repository to all safety information reported till date, but also fulfill the reporting requirements.
- Later, the stored information could be reproduced for the aggregate reporting, signal management and Risk Management activities. Since every single piece of information was going to be stored, so there were minimal chances of missing out any important part. The client was also demonstrated the real time dashboards to keep a tab on compliance.
- After a complete data migration and reconciliation of the old information, real time entry of the cases from different sources was started into the safety database and submission process was shifted from manual data entry into SRP to database-to-database electronic transmissions. Eventually, PADERs were also prepared using the listing from the information already stored in the database, which could be extracted in a single click. Since the accessibility for the safety information was enhanced, it helped in the deeper analysis of signals and risk benefit assessment.
- The successful transition not only improved the storage, reporting and analysis of the safety data but also helped the client in scaling up the process and effortless addition of more products.



WHO WE ARE

Planning for a paradigm shift in the delivery of Pharmacovigilance services, AWINSA Life Sciences aims to provide end to end PV services including in its ambit both clinical trial and post marketing services. Manned by people with discernment and an eye for quality, we at AWINSA Life Sciences ensure astute analysis of safety reports so that clinical scenarios emerge in perspicuity.

Intricate and deep-rooted knowledge of the subject and the international regulations will ensure that you are delivered services of the highest order within the stringent timelines.

NORTH AMERICA

59 E,
Shrewsbury
Place, Princeton,
NJ 08540
United States

ASIA

513 B, Sector
22, Pocket B,
Gurgaon
122015,
India

LATIN AMERICA

Cerrada Ahuizotla 53,
Col. Santiago
Ahuizotla
Del. Azcapotzalco
CP. 02750,
Ciudad de Mexico,
Mexico

EUROPE

Wilhelmina
Druckerlaan 10,
6532 SR,
Nijmegen,
The Netherlands

Business inquiries: info@awinsals.com

www.awinsals.com | [linkedin.com/company/awinsa-life-sciences](https://www.linkedin.com/company/awinsa-life-sciences)

Passion and Enthusiasm | Perseverance and commitment | Aiming High | Integrity | Team work