



Passion and Enthusiasm | Perseverance and commitment | Aiming High | Integrity | Teamwork

# Advancing patient safety in neurology drug development

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### BACKGROUND

Developing and marketing neurology drugs presents unique and complex challenges. These challenges include managing long-term effects and ensuring the safe use of these medications in vulnerable patient populations. Such complexities necessitate stringent pharmacovigilance (PV) measures and a robust PV system to ensure patient safety and regulatory compliance. A US-based biotechnology firm specializing in neurology faced significant struggles in managing PV for their neurology product due to a high volume of cases. This case study explores how AWINSA helped this firm navigate these challenges and achieve regulatory compliance.

## BUSINESS CHALLENGE

The biotechnology company focused on a key molecule designed to treat chronic neurological disorders. However, they encountered significant obstacles in maintaining regulatory compliance and quality standards. Rapid expansion into new territories and obtaining approvals for additional indications resulted in a substantial backlog of cases and pending regulatory submissions. The company's internal resources were overwhelmed by the surge in case volume. Additionally, difficulties in reconciling cases from various business partners exacerbated the situation. They urgently needed a pharmacovigilance partner capable of ensuring regulatory compliance, managing case processing demands, conducting comprehensive gap assessments, and optimizing their PV processes.

## BUSINESS SOLUTION

AWINSA Life Sciences was selected to address these multifaceted challenges with a comprehensive, phased approach. The strategic plan included a detailed ramp-up of transitioning all pharmacovigilance activities to AWINSA, designed to handle increasing volumes and unexpected surges.

1. **Strategic Evaluation and Blueprint Development:** AWINSA conducted an initial assessment to understand the company's current PV processes, case volumes, and specific challenges. A tailored transition plan was developed, including clear milestones and timelines.
2. **Resource Integration and Skill Building:** Over two and half months, AWINSA's dedicated, skilled resources were systematically onboarded. The initial focus was on training the team and clearing the backlog of non-serious cases. This phase included intensive training sessions to ensure the team was well-versed in the company's processes and regulatory requirements.
3. **Case Management:** A prioritization strategy was employed to address the most critical cases first, ensuring timely and accurate processing.
4. **Regulatory Submissions:** All pending submissions were completed within the first month of the transition. Regular Quality & Medical review meetings were instituted to maintain high standards. The data entry manual was updated, and comprehensive reconciliation plans with pharmacies and business partners were developed to ensure data accuracy.
5. **Compliance and Transparency:** Throughout the transition, AWINSA maintained full transparency with the client, ensuring compliance with Service Level Agreements (SLAs). Technical challenges were effectively managed through coordinated communication with the client, ensuring smooth operations.
6. **Process Improvement:** AWINSA's experts revised existing Standard Operating Procedures (SOPs), updated the data entry database, and developed detailed work instructions to enhance audit readiness. Continuous process improvement initiatives were implemented to streamline operations further.



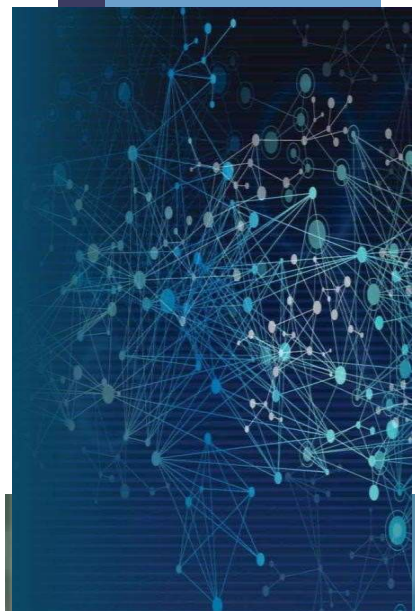
# RESULTS

AWINSA's comprehensive approach enabled the biotechnology company to achieve compliance and audit readiness, allowing it to refocus on its core commercial activities. Key outcomes included:

1. **Elimination of Backlogs:** The backlog of cases was systematically cleared, and all pending regulatory submissions were resolved promptly.
2. **Enhanced Regulatory Compliance:** AWINSA ensured that all processes adhere to the latest regulatory standards, providing the company with confidence in its compliance status.
3. **Streamlined Processes:** Streamlined processes and automation significantly reduced case processing times. The implementation of efficient workflows and advanced PV technology ensured that cases were processed quickly and accurately.
4. **Quality Assurance:** Regular review meetings ensured high-quality case management and reporting. AWINSA's commitment to quality assurance was evident in every aspect of their work, from case processing to regulatory submissions.
5. **Capacity Expansion:** The team was expanded to meet the growing pharmacovigilance demands. AWINSA's scalable resources allowed the company to handle increased case volumes without compromising on quality or compliance.
6. **Comprehensive Management:** AWINSA assumed responsibility for clinical trials and business partner cases across various regions. This included managing Safety Data Exchange Agreements (SDEAs) to improve reconciliation and compliance.

AWINSA has become the preferred partner for managing all types of PV cases, including post-marketing surveillance, clinical trials, and business partner activities (aggregate reporting, literature monitoring, etc.). This successful partnership enabled the client to explore new opportunities, such as conducting additional clinical trials for other cancer indications, securing new Marketing Authorization Holder (MAH) approvals for more territories, and enhancing the long-term benefit-risk profile of their product.

This collaboration highlights AWINSA's capability to scale operations, ensure compliance, and support the client's strategic objectives in the neurology sector. The biotechnology firm can now confidently navigate the complexities of the pharmaceutical industry, knowing they have a reliable partner in AWINSA to manage their pharmacovigilance needs.





## 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 international regulations will ensure that you are delivered services of the highest order within stringent timelines.



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