



Pharmacovigilance and Postmarketing Surveillance Use Case

If You Don't Understand It, You Can't Translate It!

At a glance

Accurate translation of pharmacovigilance and postmarketing surveillance documents—such as adverse event reports, periodic safety update reports (PSURs), and risk management plans—is essential to monitor drug safety, maintain regulatory compliance, and protect patients worldwide after product approval.

Key metrics



>50%

Reduction in Query Resolution Time



99.7%

On Time Delivery



100%

Regulatory Compliance

CHALLENGES



Pharmacovigilance and postmarketing documents involve complex medical data critical for patient safety and regulatory compliance, requiring precise translations without ambiguity. Errors can lead to regulatory action, compromised patient safety, and potential market withdrawal. Meeting strict global reporting deadlines while consistently translating complex safety information across multiple languages further complicates pharmacovigilance processes.

SOLUTIONS



AI-optimized translations combined with experienced pharmacovigilance linguists ensure accuracy, consistency, and global regulatory compliance in postmarketing safety documents.



Clinical Trial Expertise



12 Step Quality Control Process



Scalable To Meet Your Needs

BENEFITS



1

Strengthened Patient Safety

Accurate translations enhance clarity in safety monitoring, significantly reducing risks associated with adverse events and medication errors.

2

Improved Regulatory Compliance

High-quality translations reduce regulatory queries, audit risks, and delays, facilitating smoother pharmacovigilance reporting.

3

Enhanced Global Drug Safety Monitoring

Clear, consistent translations support effective global monitoring of drug safety, ensuring quick and appropriate responses to potential safety concerns.



www.languagescientific.com



info@languagescientific.com



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