

# LifeSphere Vet Safety™

## KEY BENEFITS

- Helps report veterinary safety data to meet regulations of global and regional regulatory authorities including US FDA, EMA, CV MP, European countries, South Africa and Australia
- Supports submission of electronic reports in XML format required by FDA and EMA EudraVigilance for veterinary products
- Automates adverse event reporting with the help of pre-built report templates and knowledgebase of common questions and processes by building robust repository of FAQs, documents & literature
- Automates case processing and report distribution with exible work ows
- Aids faster action by tracking all regulatory submissions and correspondences in a single integrated view

Today all pharmaceutical organizations regardless of producing human or veterinary medicines are compelled to have a comprehensive system in place to facilitate compliance with increasing number of legislations. And Veterinary pharmaceutical companies in specific are still relying on an outdated, manual or disconnected IT systems lacking appropriate automation.

LifeSphere Vet Safety™ is a Comprehensive solution for veterinary Pharmacovigilance and compliance. LifeSphere Vet Safety is specifically designed for veterinary pharmaceutical companies to reduce their manual burden by streamlining the process of capturing, tracking and reporting of all safety events related to veterinary medicines.

## End-to-end solution for Veterinary Pharmacovigilance and Compliance

LifeSphere Vet Safety, a web based system which provides a complete VAER(Veterinary Adverse Event Reporting) case processing for animals or for humans(by virtue of indirect exposure to animal medicines).LifeSphere Vet Safety facilitates capture, assessment, routing and distribution of VAER by veterinary pharmaceutical companies to ensure regulatory compliance with regional and global reporting requirements. The system also provides an extensive feature set that facilitates the capabilities of sending a correspondence, comparison between multiple versions ofVAERs, Data privacy, customizable workflow and submission tracking and charts. LifeSphere Vet Safety can be deployed out-of-the-box with standard features or can be easily tailored to support specific company processes and SOPs.

## Automatic data capture and superior user-interface

The system uses state of the art technology for centralized intake and triage of adverse event information. LifeSphere Vet Safety allows automatic import of E2B XML cases which are received from authorities or partners via gateway. The system automatically checks for duplicates before creating VAERs from the imported E2B XMLs. The system also supports automatic creation of VAER via e-mails from which the key information is automatically copied to the corresponding fields in the VAER data entry forms. The email itself is retained as the "source document" for that VAER. With the availability of various libraries and standard dictionaries, the easy-to-use user interface aids in faster and accurate data entry, coding and report generation.

#### ABOUT ARISGLOBAL®

ArisGlobal is a visionary technology company that's transforming the way today's most successful life sciences companies develop breakthroughs and bring new products to market. The ArisGlobal LifeSphere™ cognitive technology platform integrates machine-learning capabilities to automate the core functions of the product lifecycle. Designed with deep expertise and a long-term perspective that spans more than 30 years, our cognitive platform delivers actionable insights, boosts efficiency, ensures compliance, and lowers total cost of ownership through multi-tenancy.

Headquartered in the United States, ArisGlobal has regional offices in Europe, India and Japan. For more information, visit [arisglobal.com](http://arisglobal.com) or follow ArisGlobal on LinkedIn and Twitter.

## Regulatory Reporting formats

LifeSphere Vet Safety provides the capability to create veterinary safety reports with all data elements mandated by global, and local regulatory authorities including EMA and US FDA. The system supports electronic submission and exchange of veterinary safety data in XML format as defined in the Eudravigilance access policy for medicines for veterinary use. LifeSphere Vet Safety supports all major regulatory reports based on CVMP and VICH guidelines.

## Powerful workflow

LifeSphere Vet Safety provides a powerful and configurable workflow that can be setup according to the organization's business needs. Inbound cases are automatically placed in workflow and routed based on company SOPs and policies. Based on user roles and privileges, cases are routed to users for specific actions such as data assessment, coding and reporting for full compliance while the integrated communications and tasks modules allow the user to track all follow-up activity.

## Intuitive dashboard, charts and reports

LifeSphere Vet Safety's powerful query and reporting tools allow instant access to all the data eliminating the tedious and time-consuming process of compiling the data manually for analysis. Standard reports and charts provide trending and analysis, while an intuitive dashboard provides a comprehensive view of the critical metrics and compliance data related to user's role. Capability to trigger alerts and notifications for activities that are due ensures immediate attention to high priority tasks. Reports can be generated in a variety of formats including PDF, Microsoft® Word, Excel or PowerPoint.

## A proven solution from the market leader

ArisGlobal, the leading provider of pharmacovigilance solutions and regulatory compliance in human drugs has now extended its expertise also in the field of veterinary pharmacovigilance. LifeSphere Vet Safety is the all-in-one solution specifically designed to address the veterinary safety and regulatory reporting needs of the veterinary industry. The robust adverse event reporting system expedites the process of obtaining market authorization contributing towards company's profitability and better animal as well as human health and safety arising out of direct or indirect exposure to veterinary medicines.