

Guerbet Achieves Large Dividends with Integrated, Global Safety System



Guerbet Group

www.guerbet-group.com

Industry: Pharmaceutical, wholly focused on medical imaging

Size: 2009 Sales of €335 million with a total workforce of 1,300 employees

Aris Global® Products:

ARISg™, ARISj™, agXchange ESM™

Key Benefits:

- Helped Guerbet efficiently share safety data from different company/affiliate locations
- Eliminated redundant data entry in a global environment
- Reduced overall case processing time by approximately 40%
- Provided full compliance with the MHLW electronic reporting requirements
- Reduces future outsourcing costs by 50%

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Mr. Nassim Belhadj,

Project Manager, Pharmacovigilance, Guerbet

With a history dating back more than a hundred years, Guerbet Group, headquartered near Paris, France, is the only pharmaceutical group fully dedicated to medical imaging.

Guerbet is considered to be a pioneer in its field, providing comprehensive offerings in x-ray, MRI contrast media and nuclear medicine products that assist medical professionals to better diagnose and treat their patients.

The Guerbet Group's vision of becoming a major global player in the field of medical imaging is backed by a substantial investment in the research and development of new and effective products. Currently, the multi-national company sells its products in over 70 countries and its 20 affiliates and vast network of agents around the world. The trust placed in them by their customers and partners makes patient safety a critical area of focus for the company.

Creating a Unified, Global Pharmacovigilance and Safety System

Up until recently, Guerbet relied on disparate pharmacovigilance systems to manage their safety information in the different regions where its affiliates conducted business.

At their headquarters, Guerbet had been using an old commercial pharmacovigilance system, which enabled it to meet only the basic regulatory requirements of the European Medicines Agency (EMA). The software was not designed to meet worldwide safety regulations and had limited capability to meet the E2B transmission requirements for individual case safety reports (ICSRs), instead using EVWeb to make these submissions to the EMA.

The Challenge

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Adding to the safety disconnect, Guerbet's Japanese affiliate used a different, local pharmacovigilance system that was not integrated with the one used by headquarters. Consequently, while the safety data was entered in Japanese, the same data had to be entered again for submission to EMEA, making the management of worldwide drug safety information a highly inefficient and labor-intensive process.

The absence of real-time, global safety data visibility also increased the company's risk of non-compliance and potentially put patient safety at greater risk.

Guerbet realized it needed a global pharmacovigilance system that offered unified safety information management capabilities. In addition, it was important that the global system offered proven Japanese-language capabilities that would support all the recent MHLW legislation, including all domestic reporting obligations for electronic submission to Japan's Pharmaceuticals and Medical Devices Agency (PMDA).

Selecting a Technology Partner with a Proven Track Record

Guerbet engaged in a rigorous process to evaluate and select a technology partner who could meet its demanding requirements. A steering committee was formed with representation from IT operations, drug safety and quality assurance teams. After reviewing a number of solution providers against their requirements checklist, Aris Global and one other company were short listed to undertake a benchmarking exercise. Pilot projects were undertaken in collaboration with each company, and based on the results and positive feedback of the users involved, Aris Global was selected. Also working in its favor, Aris Global was able to show Guerbet a successful track record that included having the most number of global safety implementations at the top 10 pharmaceutical companies.

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The Solution

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A Structured Implementation Meets with Success

Guerbet followed a structured approach to implementation. They decided to implement the Aris Global solution in each region as strategic projects for the company, depending on the number of cases handled by each of its affiliates. As part of the first project, ARISg, Aris Global's adverse event reporting system, and agXchange ESM, the E2B safety submissions module, were implemented at the headquarters' location since it handled the most number of safety cases. The migration of safety data from the old system to ARISg was handled quickly, and the new safety system went live in early 2010.

Guerbet is the first French life sciences company that finalized successfully the E2B testing with the French Health Products Safety Agency (AFSSAPS) to electronically transmit ICSR data.

The implementation of ARISj, the Japanese language-enabled safety system, and agXchange ESM in Guerbet's Japanese affiliate started in early 2010 and the migration of the Japanese legacy safety data was successfully completed in mid 2010.

ARISg and ARISj are now deployed using one central database, allowing all configurations, including workflow and data entry templates, to only be set up once and easily shared by the affiliates.

Ensuring Regulatory Compliance Worldwide

ARISj has been successfully deployed along with ARISg at Guerbet, enabling it to meet both domestic MHLW and international reporting obligations.

Guerbet is now able to successfully submit the same case (entered in English or Japanese) to the EMEA and MHLW-PMDA without having to completely re-enter the safety data in both company locations.

The ability to manage the risk of safety problems in a global environment can only be accomplished when you have sharing of accurate, timely and complete data about adverse events. The ARISg and ARISj system provides Guerbet with an efficient mechanism for sharing safety data worldwide with its multilingual capabilities in a timely fashion.

Since ARISg and ARISj were deployed, Guerbet now also realizes productivity gains by eliminating double data processing efforts.

The Result

Reduced Overall Case Processing Time

Since its implementation of ARISg, ARISj and agXchange ESM, case processing times have been reduced by approximately 40%. This has been enabled by the advanced workflow capabilities of ARISg and ARISj, which help automate case processing and report distribution. Incoming cases are now automatically placed in the appropriate workflow, and routed based on Guerbet's SOPs and policies. The ability of ARISg and ARISj to enable monitoring of response times for all key activities helps speed up information delivery and prevents any delays in ensuring full compliance across all regions in which Guerbet does business.

Paying Large Dividends Well into the Future

Mr. Nassim Belhadj believes that doing his due diligence in searching for the right solution partner, along with a well-planned implementation strategy, is giving Guerbet the right solution that will continue to pay large dividends well into the future.

While Guerbet is still in the early stages of working with the ARISg and ARISj system, they expect to realize significant cost savings and productivity enhancements going forward.

Guerbet estimates that overall case processing times will be reduced by approximately 60% after its first year of going live. They also expect to reduce much of the pharmacovigilance activities that they currently outsource to third parties by as much as 50%.

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About Aris Global

For more than 20 years, Aris Global has been a trusted and reliable partner of many of the world's leading pharmaceutical, device, biotechnology and clinical research organizations. More than 300 life sciences companies rely on our innovation and advanced technology solutions in pharmacovigilance and safety, regulatory affairs, clinical research and medical information.

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