Pharmacovigilance services.

Full PV System and Global PV Network.

Full PV System.

Minimize your risk and stay compliant. Arriello's Full Pharmacovigilance System and services.

Take the **faster, better, smarter** approach and discover how we can provide a total solution to all your Pharmacovigilance needs.

Failing to properly monitor, assess and report safety concerns puts patients as well as your investment in your Marketing Authorization at risk. That's why it's essential to have a proven and robust Pharmacovigilance System in place.

Arriello has been a leading supplier of Global and Local Pharmacovigilance services, since 2008. Our team has a combined experience of over **75 years** across the **EU, US, LATAM, MENA, CIS, APAC** regions and **South Africa**.

Our Full Pharmacovigilance System and services have been developed and refined over several years and is maintained by our in-house European Union Qualified Person Responsible for Pharmacovigilance (EUQPPV) and Deputy QPPV, backed up with the support of a range of medical specialists.

Whatever your pharmacovigilance needs, our experts can advise, implement and continue to minimize your risks and keep you fully compliant.

Core services.

Monitoring of authorities' websites.
We constantly monitor the EMA (European Medicines Agency) and HMA's websites for global PV regulatory intelligence applicable for the whole EU and use our findings to advise and update your procedures.

EudraVigilance maintenance.
Your EudraVigilance profiles for production and testing are registered and maintained by our experienced EU QPPV (Responsible Person) and Deputy EU QPPV (Trusted Deputy). We make sure your medicinal products are entered and updated in the Article 57 database accurately and on time.

PV System setup and maintenance.
We are fully responsible for the creation and update of your Pharmacovigilance System Master File (PSMF).

Global Literature Monitoring.

Global Literature Monitoring is a key part of a full Good Vigilance Practice (GVP) based Pharmacovigilance system and at Arriello, we screen using Embase with Medline database.

Using broad and narrow literature queries, we search for ICSRs, published studies and information relevant for the safety of your products. We make sure we've fully assessed any available information that may impact on patient safety or require further investigation.

Risk Management.

An effective Risk Management System and the development and update of Risk Management Plans, mandatory in the EU, are a critical part of Pharmacovigilance and patient safety.

If you don't effectively monitor for important identified and potential risks or missing information your Marketing Authorization or Application is itself at risk. Arriello's in-house risk management expertise can identify new safety concerns and propose appropriate risk minimization measures, keeping you compliant and improving patient safety.

Pharmacovigilance Signal Management.

Rely on Arriello for signal management, and gain peace of mind knowing our experts have the in-depth knowledge you need to stay compliant. From keeping tabs on adverse events in EudraVigilance to helping your organization follow Good Pharmacovigilance Practices (GVP), our team members will help you follow the right regulatory guidelines.

Pharmacovigilance training.

In addition to our in-house Pharmacovigilance services, we can also provide Pharmacovigilance training for your specific project or as a standalone service.

Comprehensive Management of ICSRs.

Managing your individual case safety reports (ICSR's) accurately and efficiently is critical to an effective PV system and Arriello provides full support for each step of the ICSR handling process.

From confirmation and translations to data entry and archival, we'll manage your safety data and meet all your ICSR requirements.

Our capabilities include MedDRA coding, case assessment, and electronic reporting through EudraVigilance.

Aggregate Safety Reports.

We can handle all your Aggregate Safety Reporting obligations throughout the life-cycle of your product with the creation of Development Safety Update Reports (DSURs) and Periodic Safety Update Reports (PSURs).

From compiling your DSUR information to preparing your PSUR for the EMA (European Medicines Agency), we have the knowledge and expertise you need to stay compliant with requirements.

Global PV Network.

Risk management and compliance in 143 countries around the world.

A poor translation can lead to a misunderstood critical report. An article on an adverse reaction buried in a local scientific journal can go undetected.

A follow-up on a case isn't carried out. All these errors can lead to serious repercussions for you, and for patient safety.

It's an undeniable fact; an ineffective Local PV service can lead to a significant level of risk with non-compliance of regulatory requirements, major or critical inspection findings, and patient safety.

And that's why the quality and efficiency of the processes and management of your Local PV System is critical.

Arriello has been a leading supplier of Global and Local Pharmacovigilance services, since 2008. Our team has a combined experience of over **75 years** across the **EU, US, LATAM, MENA, CIS, APAC** regions and **South Africa**.

We are constantly expanding our global coverage and currently operate in **143 countries**, with the ability to expand this as required.

Our global network of external PV vendors currently spans **128 companies** in **92 countries**, enabling us to offer a completely tailored Local PV service.

Drug Safety Officer.

A major and growing role in Pharmacovigilance is that of the Drug Safety Officer (DSO). This role is often connected/interchangeable with the titles Local Safety Officer (LSO), Local person Responsible for Pharmacovigilance (LRPV) and others which can differ country by country and client by client.

The DSO role objective is primarily the same regardless of title; to have a dedicated knowledgeable and efficient technical service at the individual country/territory level.

At Arriello we offer a unique blend of in-house resource and expertise, combined with local in-country staff who fully understand local regulations.

This includes but not limited to:

Individual Case Safety Reports (ICSR) intake and local level processing.

Local submissions (aggregate reports, RMPs, ICSRs, etc.).

Compliance monitoring.

The implementation of Local PV requirements in relevant procedures and systems.

Providing PV/product-specific training.

Health Authority inspections and many more!

As the role is flexible depending on individual client needs and Local PV regulations, the exact mix of capabilities and requirements varies.

Whatever your Drug Safety Officer requirements, we can propose and deliver a **faster, better, smarter** solution to meet them.

Local Person Responsible for Pharmacovigilance (LPPV).

Through consultation and our extensive experience and knowledge of Local PV requirements, we know what is required in each market and how that matches your requirements. We can then provide either a Local Qualified Person for Pharmacovigilance service (LQPPV), or a Local Contact Person for Pharmacovigilance service (LCPPV).

We can do this in all your markets through our comprehensive global vendor network which is qualified and audited by our dedicated vendor management department.

Local Literature Monitoring.

Literature Monitoring specifically at the individual country level is a key part of our local pharmacovigilance system at Arriello. Using broad and narrow search strategies and keywords, we search local medical and scientific journals including published study results, literature reviews, meta-analysis, etc.

We make sure we've fully assessed any available information that may have an impact on patient safety, or require further investigation or changes required in specific markets.

Regulatory Intelligence.

Our **faster, better, smarter** approach extends right down to the requirements from our local vendors. They provide us with regular updates on changes to local regulatory requirements and legislation by monitoring official sources such as their National Competent Authority, Health Ministry websites and others. Then, all this information is double-checked by another vendor to ensure all it is correct.

This depth of research and monitoring, with a double-checking process, means you can be confident that you're completely compliant in that market. Plus, you'll gain country-specific insights that could reduce your risk and allow ample forward planning of changes and implementation that can impact your PV System or your product.

Local level Case Management.

We offer complete support in management of ICSRs on local level, including but not limited to.

Safety mailbox management.
We can monitor, assess, track, process and forward any correspondence and information received in the local safety mailbox.

Local case submission.
We can process all local submissions to the National Competent Authorities according to the country specific requirements (e.g. on format, timelines, route of submission, etc.).

Case follow-up.
We ensure that all cases that require additional information after initial review are rigorously followed-up back to their sources.

Safety Reports.

Whatever the specific requirement is for writing and developing safety reports, you can trust Arriello's pharmacovigilance experts to gather the right data, use the right formats, and follow the right processes to comply with local regulatory requirements.

Pharmacovigilance Translations to/from Local Languages.

Clear communication is critical for maintaining your MA and protecting lives. We provide translations specifically for Life Sciences materials across all therapeutic areas.

From ICSRs to abstracts and articles from local literature screening, translations are available in virtually any language and at any scale.

Our network is based on a mix of certified translators, or local translators that meet a minimum three criteria of medical background, local language plus English knowledge.

Vendor Vetting and Management.

Our global network of external PV vendors currently spans **128 companies** in **92 countries**, but that doesn't mean they aren't subject to the demands of our **faster, better, smarter** culture.

When you partner with Arriello you can be sure quality extends right through to our vendors thanks to the robust processes our vendor management department has in place for vetting and management including:

Qualification for selection.
Using a balanced scorecard, our department assesses and monitors potential vendors based on predefined criteria.

Reporting.
We regularly require our vendors to provide reports on their performance, which are then checked internally by our PV project managers and specialists. We also monitor all reporting timelines are adhered to for compliance too.

Compliance monitoring.
To ensure our vendors are fully compliant, we conduct on-site and off-site audits based on the frequency identified in the approach to risk planning or Risk Management Plan.

Risk Minimization activities.

At Arriello, we provide support several risk minimization activities targeted at increasing patient safety close to the source.

These can include documents that may help physicians properly prescribe your drug or patients and doctors to properly use it (e.g. Direct Healthcare Professional Communication (DHPC), educational materials and other communications) – all according to the guidelines and requirements of the national competent authorities in that location.

from development to market.
faster. better. smarter.

arriello

About us.

Arriello has been a leading provider of risk management and compliance services to the Life Sciences sector since 2008.

These include Market Consultancy, Global Regulatory Affairs strategy and implementation, Full and Local Pharmacovigilance solutions, Clinical Drug Safety, and Quality and Compliance auditing and systems.

Our brief is simple; to make the process from development to market faster, better and smarter.

Headquartered in Ireland, with European operations in Central Europe, we provide expert Market Access guidance across the EU, US, LATAM, CIS, MENA, Asia and South Africa.

With our extensive global vendor network, ISO 9001 certification, years of experience and satisfied clients, including Global Originators, Biotechs, Generics and CROs, you can be confident in our ability to deliver.

However complex or simple your requirements, you can rely on us as a trusted partner.

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