Strategic planning for effective results.

Local Pharmacovigilance in 50 countries.

Arriello

From development to market.
Faster. Better. Smarter.

Client type:
Pharmaceutical.

Geography:
European Union.

Lifecycle stage:
Post-marketing.

Service area:
Local PV.

Summary.

- ICSRs, local literature screening, PV manual and training, regulatory intelligence, safety mailboxes.
- Having established its worldwide product in several international markets, this Danish pharmaceutical company was conducting in-house pharmacovigilance (PV) in LATAM, the EU, and Canada – a total of 50 countries.
- After shifting its approach to outsourcing, the organization decided to transfer its PV activities to Arriello.

Challenges.

Our client faced a tight timeline. Additionally, a scope of 50 countries meant that clear communication required working around differences such as time, language, culture, ways of doing business, and local regulations. Collaborating with vendors was also a challenge. Each vendor followed its own system, and we would need to align vendors to a common goal, ensuring compliance and effective management to meet the deadlines.

Solution.

Our first step was identifying a LCPPV for each country, screening candidates with a qualification process. After preauditing potential LPPVs, we gave them a questionnaire and evaluated their curriculum vitae. Candidates' quality management systems, pharmacovigilance systems, experience, and expertise also came under our scrutiny. After a kickoff meeting, we introduced the LPPVs to a PV manual we created exclusively for their support and provided kick-off. This detailed manual empowered our LPPVs with instructions on what, how, and where to report safety information.

Our client's local PV system also included local literature screening. If new safety information or adverse events were detected, our client would quickly receive a report. Local ICSR case processing was another way we helped our client mitigate risk. Each country accessed the PV safety mailbox including important ICSR findings in a monthly report for our client to follow up on.

Our local PV services would not have been complete without regulatory intelligence, compiled in a monthly report to keep our client up to date. If the information was urgent, our client would receive an alert within one business day.

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By the end of the project, we complied with our client's requirements and delivered a comprehensive local PV network for 50 countries **in nine months when it should have taken over a year**. Despite the urgent deadlines our client realized full implementation without encountering major obstacles.

Faster meant the entire process only took about two months. Arriello's collective expertise expedited the LPPV recruitment and training process as well as other goals. But **our speed didn't compromise quality**, the client's local PV network stayed fully compliant with EMA requirements. **Better** meant our client enjoyed a process marked by communication and collaboration. The Arriello team's project management skills ensured we successfully met deadlines, effectively managed vendors, and established a wide-reaching local PV network.

Smarter meant we took the best strategic route for our client. Leveraging an adaptable, proactive approach to regulations, laws, and updates, we empowered our client to avoid pitfall.

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About us.

Arriello is a leading consultancy and solutions provider of risk management and compliance services to the pharmaceutical industry. We've been making the development-to-market process faster, better, and smarter since 2008.

Our global services span the product life cycle from Clinical to post-submission Regulatory Affairs and Pharmacovigilance, Quality Assurance and Auditing, and innovative automation solutions.

Headquartered in Ireland, with operations across Europe, we consult and create solutions across the EU, North America, LATAM, CIS, MENA, Asia, and South Africa.

With our extensive global network, decades of combined experience and ISO:9001 certification, we are a trusted partner primarily to pharmaceutical and biotech companies.

Our valued clients rely on our ability to deliver, however complex their requirements, through our proven expertise, global coverage, and technology.

ISO 9001 certified

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