

## 23 countries in two months.

### Complex pharmacovigilance local support.

#### Client type:

Consulting.

#### Geography:

European Union.

#### Lifecycle stage:

Post-marketing.

#### Service area:

Pharmacovigilance.

#### Summary.

- Pharmacovigilance, local PV, recruiting and training local contact persons for pharmacovigilance (LPPV), regulatory strategy, regulatory intelligence.
- The client had previously partnered with another consulting firm who lacked the organization and expertise to manage this complex project resulting in a failed initiative.
- During a previous local PV project, Arriello's faster, better, smarter approach had previously made impression on this client and they turned to us for support.

## Challenges.

While the scope of the project was the same, the process would differ for each country, with different requirements and regulations for a LPPV. Not following these guidelines could result in an Authority rejecting the LPPV and losing Marketing Authorization.

Differing country-specific guidelines also made literature screening complex. Helping our client take the smartest route for each country required both in-depth knowledge and effective local vendor management, adapting to different processes and conditions whilst remaining under budget and on time.

## Solution.

We hand-selected LPPVs for each country based on their PV, IT, Quality systems, Project management skills and more. All details of the project were fully assessed for responsibilities, timelines and documentation. LPPVs then notified their local Authorities where needed and we delivered a project management plan detailing everything from our client's high-level objectives to the roles and responsibilities of project managers team members.

A comprehensive PV manual provided LPPVs with guidance on their responsibilities and all training documents.

Our proactive approach meant we went beyond simply managing multiple teams, preparing documents, or LPPVs oversight, we also scanned for information and intelligence that could impact our client such as the latest regulatory requirements, and adapted our services as needed.

## Faster. Better. Smarter.

Partnering with Arriello meant our client successfully accomplished its objectives, implementing a local PV network that was faster, better, and smarter.

**Faster.** 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.** 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.** 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.

The logo for Arriello, featuring the word "Arriello" in a bold, sans-serif font. The letter "A" is white and set against a yellow square background, while the remaining letters "rriello" are black.

From development to market.

**Faster. Better. Smarter.**

## 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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