Arriello

Listen. Advise. Implement.

Scaling Local Affiliate Support. Across 25+ Countries.

Client type:
Pharmaceutical.

Geography:
Worldwide.

Lifecycle stage:
Post-approval.

Summary.

A pharmaceutical client transitioning from clinical development to post-marketing operations needed to establish **sustainable pharmacovigilance (PV) support across more than 25 countries**. This transition introduced increased reporting obligations, the need to manage legacy safety data, and the requirement for consistent oversight across global and local operations.

Key focus areas included:

- **Compliance:** Ensuring alignment with global PV regulations and local requirements
- **Process:** Establishing scalable, repeatable affiliate support workflows.
- **Data:** Migrating and maintaining the integrity of legacy safety case data.

Challenges.

- Migration of approximately **1,200 legacy safety cases** into a new safety database.
- Expansion from clinical trial activity to full post-marketing PV obligations.
- Requirement to **support 25+ countries with localized PV responsibilities**.
- Need to establish inspection-ready governance, oversight, and documentation.

Arriello's extensive experience in supporting similar global PV transitions was a key factor in the client's decision to engage.

Solution.

Arriello implemented a **scalable and integrated affiliate support model** designed to align global strategy with local execution. Key elements included:

- Deployment of a hosted safety database, including structured migration and validation of legacy data;
- Establishment of local PV coverage across all relevant markets, ensuring compliance with national requirements integration of:
  - » Local case processing and expedited reporting;
  - » Regulatory intelligence and ongoing compliance monitoring;
- Active participation in regulatory inspections alongside the client, providing operational and compliance support;

The model reduced inefficiencies by **minimizing hand-offs between global and local teams** while improving visibility and control.

Our solution brought the following **outcome**:

- Successful migration and stabilization of safety operations within the new system.
- Strong performance during regulatory inspection, demonstrating robust compliance and governance.
- Enhanced oversight and coordination between global and affiliate-level activities.
- Expansion of the partnership into broader regulatory and PV support services.

Our Holistic Approach.

Arriello delivered a fully integrated transition, combining data migration, affiliate support, and governance into **a single operating model that minimized risk at a critical lifecycle stage**.

Rather than working in silos, we aligned global strategy with local execution across 25+ countries, ensuring consistent compliance while adapting to country-specific requirements. Our team operated as an client's extension.

By embedding best-practice processes, validated data migration, and scalable affiliate workflows from day one, we created an **inspection-ready framework that worked in practice, not just on paper**.

The result was a stable, efficient, and scalable model that supported immediate operational needs while positioning our client for long-term growth.

Arriello

Integrated Regulatory,
Pharmacovigilance, Quality & Compliance.

Why choose Arriello for Regulatory, PV and Quality Compliance?

At Arriello our ethos is simple: to be more than just a service provider – to act as an extension of the client, providing expertise and tailored solutions to improve compliance while also improving efficiency. We believe in supporting our clients at every stage of a project, starting with strategic support and advice and then transitioning to providing any support necessary to help clients meet their goals.

We believe that project delivery should go beyond the provision of services, but bring with it our extensive knowledge, experience, and expertise to not only support immediate needs, but also anticipate future requirements and opportunities.

Our team has a global footprint. Our regulatory, pharmacovigilance and quality compliance services are underpinned by a robust regulatory intelligence framework and broad industry experience enabling us to anticipate and proactively manage changes in regulation or industry best practice throughout your project.

About us.

Arriello is a leading life sciences consultancy, offering expert guidance in regulatory affairs, pharmacovigilance and quality compliance.

Our global services span the product lifecycle from clinical to post-submission regulatory affairs, pharmacovigilance, and quality & compliance.

Headquartered in Ireland and with operations across Europe, we provide services and solutions globally.

With decades of experience, ISO:9001 and ISO/IEC 27001 certification, and a friendly, diverse team, we've been a trusted partner to the life sciences industry, primarily with pharmaceutical and biotech companies since 2008.

ISO 9001 certified

ISO 27001 certified

Global headquarters

Arriello Ireland
Dublin, Ireland

European locations

Arriello
Prague, Czech Republic

Arriello
Lisbon, Portugal

US locations

Arriello USA (East Coast),
Boston, USA

Arriello USA (West Coast),
San Francisco, USA

For help and advice or any service inquiries: solutions@arriello.com

linkedin.com/company/arriello_group

www.arriello.com