

Creating a winning approach.

Pharmacovigilance inspection.

Client type:
Biotechnology.

Geography:
USA.

Lifecycle stage:
Post-marketing.

Service area:
Quality/Auditing.

Summary.

- Inspection preparation, inspection support, collaboration, communication, LPPV.
- The Croatian National Health Authority (HALMED) contacted our vendor who was acting as the Local Person Responsible for Pharmacovigilance (LPPV) for a US biotechnology firm. They required an on-site audit for all our client's pharmacovigilance activities in Croatia. Requiring support, the vendor turned to Arriello.

Challenges.

Preparing for the inspection meant navigating the various roles and responsibilities of Arriello, the vendor, and our client. Numerous individuals from different locations and time zones were involved, raising the risk of miscommunication and information being delayed, so good coordination was critical.

The project also necessitated meetings over agreements, outstanding data, and standard operating procedures. These communication challenges didn't just appear during the preparatory phase, they also surfaced during the actual inspection.

Communication obstacles also impacted documentation requests. When auditors asked for information, we needed to act as a mitigator between our client and our local vendor to prepare, provide and support the flow of documentation whilst overcoming time and location differences, ensuring all parties function efficiently.

Solution.

We executed a set of oversight activities, such as holding weekly preparation meetings, defining roles and responsibilities, and more. Predicting potential questions, we created a checklist of possible problems and other preparation activities.

Months in advance, we also began collecting the required documentation, placing records in the cloud for quick retrieval during the inspection. Throughout all this our trademark strong communication skills ensured that everything was in place.

With the agenda from HALMED, we assigned the roles and responsibilities for individuals needing interviews. Additionally, we gathered intelligence on similar inspections from other clients – such as the inspecting style of the health authority and frequently asked questions – sharing this data with our local vendor and our client, creating a plan of action.

Faster. Better. Smarter.

With Arriello's faster, better, smarter approach, the vendor successfully passed the audit.

Our team fostered collaboration, strong project management, a quality system, and adherence to processes – delivering **faster results that avoided delays in the inspection timeline**. Our client also enjoyed a better experience during the inspection process. While the project was complex, our communication and

partnership with all parties empowered us to achieve a common goal together.

Finally, the client benefited from our smarter mindset. Keeping our client's larger interests in mind, we considered the big picture and thought outside of the scope of work for better preparation. This winning approach went beyond a successful inspection, creating **an experience our client called "phenomenal."**



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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