Creating a winning approach.

Pharmacovigilance Inspection.

Client.
Global Biotechnology Firm, USA. Est.: 1992. Size: 2,400.

Project.
Creating multi-party collaboration for a successful inspection in Croatia.

Summary.
Inspection preparation, inspection support, collaboration, communication, LPPV.

Acting as the Local Person Responsible for Pharmacovigilance (LPPV) for a US biotechnology firm, our local vendor had a complex task on its hands.

The Croatian National Health Authority (HALMED) had contacted and tasked them with performing an on-site audit for all our client's pharmacovigilance activities in Croatia to see whether our client met all local regulations and requirements. Requiring support, the vendor turned to Arriello, and we were soon preparing both the vendor and its client for the audit.

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. Coordination was critical. For instance, when authorities requested information, we had to pull data from all parties and synthesize it.

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. We thought outside the box and predicted potential questions, creating a checklist of possible problems and a checklist of 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 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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