Arriello

From development to market.
Faster. Better. Smarter.

A proactive approach to passing a PV audit.

Expert support for an imminent PV audit.

Client type:
Pharmaceutical.

Geography:
Sweden.

Lifecycle stage:
Post-marketing.

Service area:
Quality/Auditing.

Summary.

- Proactive consultancy, robust project management, gap analysis and documentation.
- Arriello onboarded a new-in-post deputy EUQPPV with support for a pharmacovigilance audit with only a week's notice.

Challenges.

A personnel change at our client took place just before a scheduled PV audit. A new deputy EUQPPV was appointed to manage the umbrella of Local Persons for Pharmacovigilance (LPPVs) as well as the upcoming PV system audit.

Our attentive and knowledgeable team quickly spotted that the new deputy would benefit from expert support to prepare for the audit.

It became clear that there was a need to mitigate any risk associated with the audit and that we would need to take a proactive approach to highlighting the issues and supporting the EUQPPV.

Solution.

Arriello had to act fast, as we were informed of the audit at short notice. First, we brainstormed on how we could best support the client before the audit. The Arriello project team decided to share our audit experience and the key documents required including: quality management system documents, latest reconciliation documents, and training records.

We earned the trust of the new deputy EUQPPV by being hands-on. We had already set up EUQPPV – LPPV meetings, guiding the new deputy EUQPPV through the process. We added value by taking a more active role in steering the meetings, including offering to attend and contribute to any audit calls necessary.

We organized an audit preparation meeting and prepared a recommended list of documents that, from our experience, we knew might be requested. In addition, our consultants prepared an audit guide and invited the client to a webinar about the lessons we have learned during audits.

Faster. Better. Smarter.

Arriello's faster, better, smarter approach, allowed us to help our client at very short notice. We stepped up to support the client with expert support for their audit at a crucial time.

Our team realized there was an urgent need for a **proactive approach to risk mitigation** and that there was no time to waste in taking control of the audit preparation.

Arriello's long experience with similar audits put us in a good position to offer knowledgeable and expert support.

We were able to share key documents including a dedicated **audit guide** that we had readily available – **ensuring the client passed the audit successfully**.

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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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