

Expert support delivered.

Internal Quality audit.

Client type:
Biotechnology.

Geography:
USA.

Lifecycle stage:
Post-marketing.

Service area:
Quality/Auditing.

Summary.

- Audit support, documentation collection and preparation, internal audit, mock interviews.
- Their Russian affiliate faced an urgent internal audit inspection.

Challenges.

Timeline. Arriello received the request for help with just one week before the audit. We had little time to ready the affiliate, or collaborate with its departments to prepare and share the extensive documentation list.

Experience. Our client's affiliate had no prior experience with audits. In fact, this was the team's first audit, and they didn't know what to expect or how to prepare.

They lacked information on what documentation they needed, how the auditor would interview them, and what questions the auditor would ask.

Language. While our client's affiliate was Russian, the auditor spoke English, further complicating the situation.

Solution.

Through a series of teleconferences we gathered the agenda and the documentation the auditor required, including all records: trackers, standard operating procedures (SOP), contracts, program overviews, and curricula vitae (CV), formatted and organized in a cloud-based system to make them available to the auditor.

Two days before the audit we arrived in Russia and immediately prepared the client by querying the regulatory teams, medical affairs teams, and sales representatives with strategic mock interview questions based on our extensive knowledge of prior audits.

During the audit, we established fluent communication between the auditor and the affiliate, and assisted the organization with answers when needed.

Faster. Better. Smarter.

Our client achieved **faster results thanks to Arriello's proactive measures**. We allocated resources and organized all pre-audit preparation well before the audit commenced. This provided the necessary time to review all the processes and make any changes so our client avoided mistakes before the final report.

Our results were also qualitatively better. Because we take a personal approach to client interactions, the affiliate **gained an improved understanding of the audit process**, preparing the team for questions the auditor would ask.

Another benefit of our better approach was the project's organization and planning, helping the affiliate understand the agenda and become familiar with the audit process through mock interviews.

Finally, by partnering with Arriello, our client benefited from our smarter approach. When the request for help came, we didn't panic at the one-week timeline. Instead, **we leveraged the collective expertise** of our team-sharing responsibilities to quickly meet our client's objective.

Our faster, better, smarter approach empowered our client to turn a lack of preparation into a successful inspection outcome.

arriello

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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