Arriello

From development to market.
Faster. Better. Smarter.

Moving fast on a MHRA application before Brexit deadline.

Full regulatory support for MHRA application.

Client type:
Pharmaceutical.

Geography:
United Kingdom.

Lifecycle stage:
Post-marketing.

Service area:
Regulatory Affairs.

Summary.

- Gap Analysis, documentation preparation, cloud storage system and additional consultancy.
- Arriello was approached to help with an MHRA application with a very short six-week preparation phase.
- Our proactive and talented team not only completed the contracted gap analysis on the scope (M1 and M3) but went beyond (M1–M5 inclusive) to ensure a successful submission.

Challenges.

With Brexit looming large on the horizon, we were tasked with package preparation and submission in just six weeks – a very tight deadline that required our unique expertise. The first challenge was the gap analysis for the M1 dossier: some documents had expired and/or contained incorrect information.

A subsequent check of the M2, M3, M4 and M5 documents revealed certain issues. For example, whilst reviewing the M3 dossier, we realised some excipients tradenames were stated, and in order to prevent filing additional variations when those wanted to be changed, we recommended to remove the extra details from the dossier.

The quick turnaround made open and responsive communication vital to success, but unfortunately an already tight schedule on the client-side made getting the answers we needed difficult, forcing us to accept that further delays were inevitable.

Solution.

With a proactive team, unfazed by the time frame and committed to delivering excellent attention to detail, our gap analysis looked beyond the scope of work (M1 and briefly M3) and extended to all documentation (M1-M5 inclusive) that could have been unvalidated, expired and/or inaccurate.

Full transparency of all documentation from the start meant our follow up quickly identified what was required and allowed for teleconferences or additional project demands to be swiftly set in motion.

To speed up the information exchange, our team uploaded all documentation to Arriello's cloud-based storage system. Being remotely accessible made storage not only easy for the client to share what was needed as it became available to them, but helped track files as and when they were added – allowing a more open workflow for all involved.

Although more gaps were identified than originally expected, our team updated all dossier sections and worked with the client to set realistic targets and expectations.

Faster. Better. Smarter.

Arriello's faster, better, smarter approach, allowed our client to submit before the deadline, and successfully meet the MHRA (UK) requirements.

We identified not only the scope, but what would be needed across the MHRA application, to ensure that preparations kept moving at the **faster** pace Arriello is known for.

Our outstanding attention to detail and proactive team put into place a 'best approach' thinking from the outset, which meant an overall **better** outcome for the client (the final MHRA resulted in only one comment). And Arriello's cloud-based system once again proved the **smarter** way to share and access information in a transparent and timely manner.

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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