Arriello

From development to market.
Faster. Better. Smarter.

Swift support to meet deadline.

National registration in the UK.

Client type:
Pharmaceutical.

Geography:
United Kingdom.

Lifecycle stage:
Post-marketing.

Service area:
Regulatory Affairs.

Summary.

- Dossier, electronic Common Technical Document (eCTD), gap analysis, Marketing Authorization Application (MAA), national registration, Power Of Attorney (POA).
- A lack of licensing to bring the product to the target area together with the submission of Marketing Authorization Application (MAA) in a short time frame.

Challenges.

From ensuring dossier information is up to date to communicating with the appropriate national agency, preparing and submitting a MAA involves many considerations. However, in addition to these difficulties, our UK client faced an additional challenge: a tight internal deadline.

In one short month, we needed to:

- Organize all efforts – both those of our team and those of our client.
- Proactively identify any gaps in the dossier and address them before they created delays.
- Communicate with the national authority and quickly submit a compliant MAA.

Solution.

To provide a smooth process, we obtained a Power Of Attorney (POA), informing the MHRA of our client's intention to submit a MAA as well as the project deadline.

Thanks to our POA, we were able to handle all communications with the agency and respond to any comments, relaying key information to our client.

Afterwards, we created a project plan. This plan outlined the overarching strategy and included key details involved in submitting the MAA – such as who was responsible for what activities; when certain actions were required; and which procedures, instructions, and timelines were involved for each module.

We also identified gaps between our client's documentation and the EU RMP integrated format that would hinder a successful MAA submission – risking rejection of the application and a delay in the initial validation.

As we revised our client's Risk Management Plan (RMP), we discovered areas where the dossier was noncompliant. We knew that – unless we addressed these gaps – our client might experience delays and fail to meet its internal deadline. We acted to correct these disparities quickly.

Thanks to Arriello's expertise, it wasn't long before an updated and compliant eCTD was in the hands of the UK authorities.

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Through our **faster** approach, the UK pharmaceutical company submitted its application before the deadline. Not only that, thanks to Arriello's **better** approach, our **client spotted critical gaps between its dossier and the EU RMP integrated format** – which empowered the organization to execute critical updates to avoid delays.

Finally, with Arriello's **smarter** approach, our client gained a clear project plan, a strategic blueprint that supported a seamless experience for the MHRA. A tight time frame notwithstanding, our UK client successfully completed a MAA submission – and avoided pitfalls in the application process.

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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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