Arriello

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Delivering a full solution.

DCP regulatory strategy for an EU registration.

Client type:
Pharmaceutical.

Geography:
United Kingdom.

Lifecycle stage:
Post-marketing.

Service area:
Regulatory Affairs.

Summary.

- DCP, EU market authorization, SmPC, Medical literature search, CMS, RMS, therapeutic indications, APIs Suppliers, Local QP, local literature searching, ICSR processing, local HA, regulatory intelligence.
- Needing guidance, research, and a regulatory strategy, Arriello created a Decentralized Procedure (DCP) regulatory strategy, and provided support for everything from analyzing medical literature search to giving advice on selecting the right API vendors.

Challenges.

With no experience in EU submissions, regulatory processes and which countries they wanted to target the firm needed the full range of Arriello's regulatory expertise.

From direction on how to conduct their bioequivalence studies to advice on which therapeutic indications were right for each country, this UK firm relied on Arriello's expertise to comprehensively meet its informational and strategic needs.

Additionally, our client also requested help finding Active Product Ingredient (API) suppliers within the EU. Arriello needed to source the most cost-effective vendors, with no sacrifice in quality, so our client could purchase APIs for their drug.

Solution.

Arriello crafted a DCP regulatory strategy, with the recommendation that our client's Reference Member State (RMS), was the Netherlands. This choice would be supportive and efficient thanks to the country's experienced personnel, good communication and respect for timelines.

Through research we knew the Dutch Medicines Evaluation Board had already approved a similar API drug to our client's, and had assessed similar dossiers to our client's.

For our client's Concerned Member States (CMS), our DCP strategy targeted Spain, Belgium, and Poland. The Arriello team knew that the composition of our client's drug was similar to products already approved in these countries.

We provided further safety advice, researching scientific articles and analyzing internal Summary of Product Characteristics (SmPC) documents, and hand-selected three GMP-certified companies who could supply the APIs ingredients required locally.

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Our DCP regulatory strategy allowed our client to apply to the EU countries where a faster MA approval was most likely. Selecting **the right countries through good regulatory intelligence** created a much better experience, characterized by good communication and collaboration. And we went the extra mile researching local API suppliers.

Finally, we chose the smartest route for success. Instead of wasting effort learning EU regulatory intricacies by trial and error, our client tapped into **our team's combined expertise** – charting the most efficient path toward its long-term goals.

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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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