Regulatory Affairs.

Strategic global life-cycle management.

Regulatory Affairs.

How, when and where.
The smarter approach to Pharmaceutical Regulatory Affairs.

The decisions you make about Pharmaceutical Regulatory Affairs can fuel your growth, or create unnecessary obstacles between you and your objectives. Initially launching your drug in one country can speed up its launch in another, but it might potentially cap your pricing in other countries, or across an entire regulated market! That means successfully navigating regulatory requirements is more than simply following the rules, it's about understanding the complexities and implications of different procedures and requirements across international markets, and developing the best strategy for your current and future needs around them.

With over **55 years** combined experience, Arriello has the in-house expertise to develop and execute that strategy worldwide across the **EU, US, LATAM, MENA, CIS, APAC** regions and **South Africa**.

It doesn't matter if you're a US-based biotech looking to reach specific or all markets, or you need guidance for OTC authorization.
From preparing and maintaining dossiers to providing translation services, we make sure our clients can achieve their goals **faster, better, smarter**.

Where our Regulatory services start in a typical product life-cycle.

Pre-Submission Support.

Set your CTD up for success with expert strategic guidance, and leverage over 55 combined years of experience in Regulatory Affairs. Explore the comprehensive services we provide, including:

Gap analysis.
We'll evaluate your dossier and pinpoint what's missing, as well as the steps you should take to correct it.

Dossier updates.
Your dossier is a living document – keep it updated with the information you need for successful submission.

GxP inspection support.
From Good Manufacturing Practice (GMP) inspections to Good Distribution Process (GDP) inspections, we'll provide the guidance you need for inspection approval.

WDA application support.
Rely on Arriello to shorten your WDA application timeline so you quickly reach your target market.

Electronic Common Technical Dossier (eCTD) support.
Remain ICH compliant, and tap into our expertise in submitting eCTDs. Our comprehensive support includes Readability and User Testing (RUT), preparing all Module 1 documents, and providing expert overviews as well as artwork and labeling among other activities.

Submission Support.

Submitting an eCTD is no longer an option, it's a necessity. At Arriello, we'll publish your eCTD and can convert older NtA or NeeS dossiers quickly and accurately.

To expedite the process, allow us to submit your dossier and follow up with the appropriate agencies until you've successfully received your Marketing Authorization (MA) approval.

When you partner with Arriello, we can also act as your:

Applicant or authorized representative.
Let us handle all the administrative tasks of your application and communication with Authorities, and take the headache out of securing your MA.

Market Authorization Holder.
If you lack a presence in your target market, let our team become an extension of your own organization. We'll hold your Market Authorization and transfer it to you afterwards.

Post-Submission Support.

Submitting your CTD is only part of reaching your goals and realizing continued success. Arriello's continued support includes:

National phase management.
Gain targeted support for navigating individual countries' pharmaceutical Regulatory Affairs requirements.

Translation.
Let us connect your organization to the linguistic expertise you need to translate your texts into the local languages of your target markets.

Market Authorization Transfer (MAT) support.
When it's time to transfer your MA, we'll walk you through the process, step by step.

Product whole life-cycle maintenance.
Your dossier undergoes constant changes. Rely on Arriello for renewals, extensions, and variations to your CTD.

from development to market.
faster. better. smarter.

arriello

About us.

Arriello has been a leading provider of risk management and compliance services to the Life Sciences sector since 2008.

These include Market Consultancy, Global Regulatory Affairs strategy and implementation, Full and Local Pharmacovigilance solutions, Clinical Drug Safety, and Quality and Compliance auditing and systems.

Our brief is simple; to make the process from development to market faster, better and smarter.

Headquartered in Ireland, with European operations in Central Europe, we provide expert Market Access guidance across the EU, US, LATAM, CIS, MENA, Asia and South Africa.

With our extensive global vendor network, ISO 9001 certification, years of experience and satisfied clients, including Global Originators, Biotechs, Generics and CROs, you can be confident in our ability to deliver.

However complex or simple your requirements, you can rely on us as a trusted partner.

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