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 medicinal product in one country can speed up its launch in another, but it might potentially affect your pricing in other countries, or across an entire 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 world markets and developing the best strategy for your current and future needs around them.

With over **72 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're a more established European company needing guidance for OTC authorization, wherever you are and your target market is, we can make sure you can achieve your goals **faster, better, smarter**.

Comprehensive support for all your submission requirements.

Your Common Technical Document (CTD) dossier plays a critical role in bringing your medicinal product to market. When you partner with Arriello, you'll gain comprehensive support across all stages for your dossier whether that's a pre-submission gap analysis or post-submission activity like variations and dossier maintenance.

Pre-Submission Support.

Through a full dossier preparation or gap analysis, our experts can find and resolve technical issues and problems in advance, avoiding costly delays and deficiencies that allow you **faster, better, smarter** access to your target market.

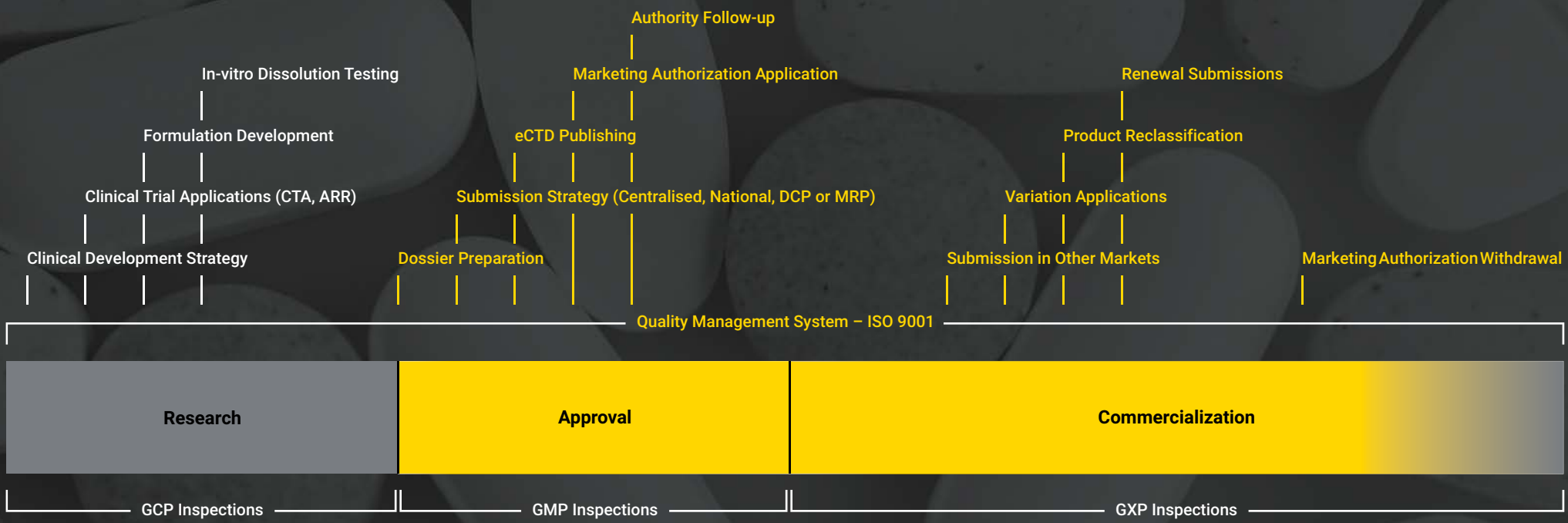
Submission Support.

When we publish your dossier and submit it to the relevant authorities, we monitor its progress, keeping you fully informed on your application status, and follow up with authorities to ensure that any dossier deficiencies are addressed and your Marketing Authorization is granted as fast as possible.

Post-Submission Support.

Submitting your dossier is only part of reaching your goals and realizing continued success. We also support you in maintaining regulatory compliance through variation submissions and other regulatory processes for simple and cost efficient lifecycle management.

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



Arriello offers Regulatory Affairs services in the areas marked in yellow.

Pre-Submission Support.

Set your dossier up for success with expert strategic guidance, and leverage over **72 years** combined experience in Regulatory Affairs.

Explore the comprehensive services we provide, including:

Full dossier gap analysis.
We can evaluate your dossier against industry standards and regulatory requirements and pinpoint exactly what's missing for successful submission, advising and supporting you with all the steps needed to correct it.

Your corrected dossier will be fully compliant with the requirements of the specific market where the application is made, making validation faster, and with far fewer, or no letters of deficiency issued during the evaluation process, resulting in a much faster time to market.

Full dossier preparation – Modules M1-M5.
We can create each section of your dossier from scratch with the raw manufacturing documentation provided. Our experts challenge and collaborate with manufacturers to ensure that all the presented dossier information is both correct and supports each section efficiently.

CMC – Chemistry, Manufacturing and Control.
We can write the CMC part of the dossier for your medicinal product based on the information that defines the raw materials chemical characteristics, the manufacturing process, the quality control testing, the finished products specifications and its stability together with additional information.

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.

Medical Writing.
Our team at Arriello combines the essential regulatory, medical, clinical, and practical knowledge to provide comprehensive services in pre-clinical and clinical Medical Writing.

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.

Beyond your dossier there's the full range of submission services we provide including:

Applicant or authorized representative.
Let us take the headache out of securing your MA by handling all the administrative tasks of your application along with communications with National Competent Authorities to ensure your project is successful and runs as smoothly as possible.

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.

National phase and life cycle management.
We can help you protect your marketing authorization investment, ensuring your products are compliant and on the market throughout their life cycle.

Local Regulatory Intelligence.
Get the latest local regulatory changes from our on-the-ground network around the world to assess any implications for your products in specific markets.

Artwork management.
Make sure your packaging is up to date and fully compliant with our artwork management service, successful in all markets since 2008.

Translation.
Our global network of certified translation specialists is always ready and at your disposal.

Pricing and reimbursement.
We can support you with product reimbursement based on local country legislation, ensuring the pricing of your products satisfies both regulation and your expectations.

Internal team support.
We can support your internal regulatory and market access teams by proactively supplementing any missing capacity or capability with a fast, agile and responsive service or strategic solution.

Post-Submission Support.

Post submission approval, we can help you efficiently monitor and manage your products throughout their life cycle by ensuring any applicable changes are always submitted on time.

In short, we can create a **faster, better, smarter** life cycle strategy for any post approval situation, adapting to changes driven by manufacturing, commercial or legislation to keep you fully compliant at all times.

Arriello's continued support includes:

Variations.
Stay one step ahead. We can help you define and implement your strategy for the preparation and submission of any type of variation.

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

Reference Member State (RMS) Transfer.
As part of your product life-cycle market strategy you may need to switch to another RMS. No problem, we can guide you and provide a full support service to make switching easy.

Readability and User Testing (RUT).
Arriello has offered a full RUT and labelling service including mock-up creation since it's conception, and we are considered as global industry experts.

Readability User Testing is of course an integral part of product compliance and is designed to ensure that product leaflets are "legible, clear and easy to use" for patients, so we take this extremely seriously for patient safety.

We also offer Bridging studies, with or without focus testing, for any European country. Our test reports are prepared in English, but we can also conduct user testing in local languages.

"I'd like to personally thank you for the high quality of Regulatory support you've given us so far, especially Gabi and Maria and your local partners. We're very satisfied with the service."

Jaya Ramakrishnan
General Manager – Regulatory Affairs, Bluefish Pharmaceuticals, India

With over 72 years combined experience in Regulatory Affairs, we've the depth and expertise to help you with any project.

Arriello's Regulatory Affairs team can provide a range of efficient, expert services from development to lifecycle management.

Whatever your strategy requirements and challenges are, we can help you overcome them, **faster, better, smarter**.

"I'm proud to lead an experienced, passionate and enthusiastic team at Arriello.

We are focussed on providing quick, effective and strategic regulatory solutions for our clients, guiding them through implementation, or acting as their extended regulatory team."

Gabriela Marton
Regulatory Affairs Director

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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