

The logo features the word "arriello" in a bold, black, sans-serif font. The letter "a" is contained within a yellow square. The background of the entire advertisement is a composite image showing a man and a woman in a professional setting. The man is on the left, wearing a white shirt, looking at a laptop. The woman is on the right, wearing a dark blazer, also looking at the laptop. Overlaid on this scene are various digital graphics: a world map with regional labels like "EUROPE", "MIDDLE EAST", and "ASIA"; various data charts and graphs; and a list of services including "Investigation", "Public Research", "Accounting", "Finance", "Marketing", "Promotion", "Research", "Development", "Engineering", "Manufacturing", and "Planning".

arriello

From development to market.
Faster. Better. Smarter.

Regulatory Affairs.

Strategic global life-cycle management.

Regulatory Strategy...

Expert Scientific Advice.

Get the right information, first time.

Molecule discovery and creating similar molecules is expensive but rewarding if your products reach patients. We offer consultancy and support services from development to market, developing and realizing tailored strategies that fit your objectives, now and later.

Product development.

Our experts support the development and manufacture of medicines by providing expert advice and creating cost effective and successful strategies to ensure that your products will reach your targeted markets and patients.

That advice comes from years of experience and a deep understanding of ICH, GCP and GMP guidelines.

We can advise and support on:

Our experts support the development and manufacture of medicines by providing:

- Formulation development.
- Manufacturing process development and validation.
- Product specifications development and adaption.
- Dossier development.
- Labeling and artwork creation.

Authority advice.

The contribution of authorities in supporting product development and registration is important, especially when new molecules are developed or submitted.

Our experts regularly engage with authorities around the world, and incorporate our extensive regulatory intelligence resources, to create specific advice and a comprehensive and achievable product development and registration strategy. A smooth collaborative process between manufacturers, MAHs and authorities is usually a strong indicator of success.

We also support you with the preparation of product development documentation “to generate robust evidence on a medicine’s benefits and risks”, ensuring easy and accurate dossier preparation.



...Regulatory Strategy.

Global and Local Regulatory Strategy.

An expert balancing act across many areas.

Regulatory strategy is a sensitive mix of fulfilling current legislation requirements, meeting committed timelines, and keeping the balance between stakeholders.

It integrates and interconnects regulatory objectives, internal and external factors, key milestones and decision points, risks foresight, mitigation and minimization, regulatory precedents- everything to launch and successfully maintain a product on the market.

Considering that regulatory strategy encompasses both science-driven, legal assessment and business purposes, a truly cross-functional team is required to handle the intricacies involved.

Through their extensive knowledge and understanding of applicable legislation, therapeutic areas, product types, and the country or regions involved, our expert team can meet all your global or local regulatory application strategy objectives, with sustainable competitive advantages.

By truly understanding your needs we can make decisions based on individualized target product profiles, making the best use of new regulatory tools to proactively identify challenges and uncover key opportunities.

Regulatory Applications and Submissions...

Product Applications.

- What type of product do I have?
- What type of change must I perform?
- When do I need to make my submission?
- Which documents do I need to support my submission?
- When should I implement and launch?

These are just few of the questions MAHs need to deal with and our consultant experts are ready to advise and support you with all the answers, and the right type of procedure and legal basis considering:

- Type of product.
- Countries of interest.
- Time for approval.
- Cost effectiveness.

Our team offers support at each step, from taking care of administrative actions like slots/appointments booking, fee payments, to fulfilling local requirements on national portals, and through to your successful approval by ensuring the submission and validation of all procedures is done right, first time.

Our deep experience at both the global and local levels, and understanding and communication with National Competent Authorities during your procedure's assessment, drives faster approvals for all your projects.



...Regulatory Applications and Submissions.

Marketing Authorization Holder.

Making the MAH process easy.

A MAH – Marketing Authorization Holder – is responsible for the quality, safety, and availability of a product. This isn't an easy or light responsibility, especially for the first time and considering the particularities and legislation of specific countries.

Arriello supports future MAHs by helping them understand local requirements and register on local portals and global authority databases, and we can also act as a MAH representative on your behalf.

Arriello holds an SME status which means we can offer an alternative process by acting as the applicant for submission or as the Marketing Authorization Holder until the procedure approval is granted.

How can that help you?

- We receive incentives as an SME resulting in smaller fees for our clients.
- We act within the EEA.
- We can hold a license while you are arranging supply routes.
- We can hold the license for a MA duplicate.

Ultimately we can act as an extension of your organization until we perform a Marketing Authorization Transfer to you, making the whole process easy, efficient and pain free.

Regulatory Writing and CMC...

Dossier Development.

Your dossier – the key to success.

Successful applications start with an accurate, compliant, and smart dossier and Arriello offers full 'hands on' support with creating your complete EEA, dossier, starting right from the raw manufacturing and expert data.

Through the extensive use of our regulatory intelligence, we ensure fully compliant content, using experience, analysis of precedents and new regulatory tools to create smart dossiers.

We know this proven approach contributes to faster approvals, and reduces the number of changes with regulatory impact, throughout your product's life cycle.

Our experts have extensive backgrounds in manufacturing and clinical environments, which also makes them excellent regulatory writers.

And we always consider the integration of authority feedback to improve dossier content and reduce the number of deficiency letters.

We also know from experience that collaboration between MAHs and manufacturers is also critical to ensure that the presented dossier information is both correct and supports each section efficiently.

Throughout the dossier creation process, we are your active partner, able to identify gaps in your documentation and propose the best solution.



...Regulatory Writing and CMC...

CMC Consultancy.

Smart dossier planning for production and beyond.

New product submissions, extensions or changes in manufacturing (manufacturing or analytical transfer changes in quality parameters, etc.) require the creation or up-date of the chemical manufacturing and control (CMC) module (M3) of your dossier.

Our consultants can offer all the advice and support you need to create or change all the relevant CMC documents to support submissions.

Our team have extensive experience working directly in manufacturing plants and understand exactly what is required in your dossier regarding quality, manufacturing, and supply processes.

Combining regulatory intelligence with GMP guidelines creates compliant and smart documentation that is designed to meet authority requirements and reduce the level of impact from future changes.

We do this by:

- Translating legislation into clear requirements specific to the type of product.
- Apply our latest knowledge to continuously improve dossier content.
- Create smart content to avoid additional requests from authorities and to minimize changes with possible regulatory impact throughout the lifecycle of your product.
- Ensure that all dossier sections contain compliant information which adequately supports your application.

Regardless of whether your dossier needs to be created from raw data (raw materials specifications and monographs, process validation or batch records, finished product specifications and stability data), or your dossier already exists and just requires updates, you can be sure our regulatory team has the expertise and experience to find the right solutions for success.



...Regulatory Writing and CMC.

Technical Writing.

Ensuring experienced input to your dossier.

Effective technical writing requires expertise in many areas including scientists, pharmacists, and medical doctors. As all parts of your dossier are equal in importance this essential knowledge and medical practice experience comes together in our expert advice and creation of the clinical and nonclinical modules of your dossier (M2.4, M2.5, M2.6, M2.7, M4, and M5), and environmental risk assessments (M1.6.1 and 1.6.2).

Our team can prepare these modules for full or abridged dossiers depending on the type of application and product nature, including biologic products that are non-GMO or GMO based.

We can also provide this expert support with the creation of product information based on product indications and provide extensive consultation regarding the preparation of promotional materials.

Regulatory Operations...

Agency Interactions.

Good communication is important.

Communication with competent authorities is very important at any stage of your product's lifecycle, whether your strategy for submission still needs to be prepared, or submission has already taken place and your dossier is under evaluation.

We have both the local communication networks and the global communications experience required to work with authorities worldwide.

We can lead communication on your behalf, exchange high level opinion with authority experts, identify and discuss potential risks and propose alternative options to successfully reach mutually acceptable solutions.

We also monitor regulators' initiatives to develop new communication channels with stakeholders for harmonized decisions, focusing on scientific development and relevant regulatory frameworks, especially for innovative products or therapeutic concepts.

Regardless of whether you're an innovative drug developer who wants to optimize your development program early, or you need to redesign an already marketed product, the earlier you contact us the easier it will be to create faster, better, smarter communications solutions.



...Regulatory Operations...

Lifecycle Management.

Protecting your investment.

After your product receives approval, multiple changes can occur which may or may not have an impact on its registered details.

Our expert consultants can advise you if you need to act to remain compliant and within the change management process identify the change impact, the change classification, and advise on submission strategy and support documentation. **Failure to do this puts your marketing authorization investment at risk.**

Through our deep understanding and expertise, and the use of extensive regulatory intelligence we can help you protect your investment by ensuring your products are compliant and on the market throughout their life cycle.

We closely monitor all submissions and approvals and follow-up quickly with authorities. Our aim is manage your change implementation while ensuring no interruption to product supply or out of stock situations.

Variations and national phase.

Variations can always be required following various exercises like a gap analysis for example, or changes in:

- Raw materials specification and suppliers/ manufacturers
- Manufacturing site
- Manufacturing process
- Finish product specifications
- Shelf life
- Legislation
- Product safety profile, etc.

Our team of experts are focused on maintain the compliance of your product, and can support you with predicting changes, understanding change complexity, and designing the best regulatory strategy for submissions and change implementation, all geared to ensure your product remains available on the market uninterrupted.

Variations could be under European procedures, where we will act immediately after RMS approval to ensure smooth implementation, or during national procedures, and in either case we are here to fully support you every step of the way with extensive regulatory intelligence and local representation in your countries of interest.



...Regulatory Operations...

Market Authorization Transfer (MAT) support.

Changing Marketing Authorization Holder (MAH) is a key part of your commercial strategy and our consultants have extensive experience with the considerations and processes involved.

We can identify suitable partners to hold your MA in a particular territory, or we can support a transfer of your portfolio between companies.

Our experts will carefully plan your transfer process by engaging an interdepartmental team to assess and manage your supply and marketing needs.

Drawing on our extensive regulatory intelligence capabilities, we will identify all the activities and timelines associated with your MAT, ensuring there is no disruption to supply and the immediate introduction your product on the market.

We've packaged our tips for tackling the challenges of Marketing Authorization Transfer in Europe, in this easy to understand Arriello guide.

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.



...Regulatory Operations...

Regulatory Intelligence.

Knowledge is power.

Local regulatory intelligence is one of the essential requirements of an effective regulatory strategy and is incredibly valuable for anticipating change.

Knowing where to search and what to look for is not sufficient, which is why we obtain and maintain a wealth of information related to submission procedures, MAH responsibilities, GMP requirements and regulatory fees.

Our experts stay one step ahead through our global network of trusted partners to keep fully up to date on any changes that could positively or negatively affect your products.

Publishing.



The advantages of expert publishing.

The eCTD format has been standard for more than ten years, yet the process of creating and managing regulatory submissions on a global scale remains complex and costly.

Whilst at first glance dossier publishing seems like a simple technical task, it has its own challenges, especially with intricate dossiers, and this highlights the value of using a trusted partner over a simple service provider to obtain fast Health Authority approval.

Our experienced eCTD publishing team can reduce processing time and the risk of human error, to a minimum.

Using the latest scalable, all-in-one submission management software, which meets the requirements for both electronic and paper submissions, allows us to maintain a comprehensive overview of an unlimited number of products across multiple countries, requirements, and conditions and assures accuracy and security across the life cycle of your dossiers.

...Regulatory Operations...

Artwork / Labeling.

Design that does more than please the eye!

Our packaging team has managed the design and compliance of all our client's artwork and labelling requirements across all markets since 2008.

We can create well designed product packaging that meets all your brand ID guidelines, whilst ensuring it remains perfectly compliant and fulfils all authority requirements, or we can simply implement your desired changes in your existing artwork.

Our designers can creatively extend your brand image through to user friendly packaging, and our labelling support team can guide you through the sheer volume of legislation and

guidelines to find the best solution for your manufacturing equipment, without affecting product information legibility.

And of course, any graphic design project that requires multiple local variations is open to mistakes in translation or context, in addition to the safety implications, so we make full use of our local partners to ensure all artwork is fully compliant with the approved product information.



...Regulatory Operations...

Translations.

We speak your language, and theirs.

In the strictly regulated field of life sciences, translation cannot be seen as a separate, stand-alone activity, but as an integral part of a successful and efficient regulatory process.

Our regulatory team follows a fully integrated approach to translations and linguistic solutions for all your needs including pharmaceutical texts, medical devices, clinical trials, scientific papers, case reports, marketing materials, legal documents, inspection reports or quality documents.

Our global network of native language experts has been carefully selected and vetted, based on professional background in the industry and/or years of experience in the field.

All your translation requests are handled by dedicated project managers that are trained in regulatory processes and understand the regulatory requirements that apply to translations.

Our in-house expertise and deep understanding of these areas, together with our pool of trusted language experts make Arriello your perfect one-stop shop.



...Regulatory Operations.

Readability/User Testing.

If patients can't read it, it isn't safe.

Arriello has offered a full RUT and labelling service including mock-up creation since its conception, and we are considered global industry experts.

Readability User Testing is an integral part of product compliance and is designed to ensure that product leaflets are "legible, clear and easy to use" for patients, in accordance with Directive (2004/27/EC).

Our readability test services include:

- Review of the text and layout of the proposed PIL (Product Information Leaflet), and suggestions for improvement.
- Questionnaire preparation.
- Recruitment of participants.
- Pilot test + Full readability test performed by an experienced interviewer.
- Project management/administration.
- Test protocol development and writing of the final report, including all results.
- Support in addressing readability testing related deficiency letters.

Our test reports are prepared in English, but we can also conduct user testing in local languages, such as French, Spanish, German, or Dutch. Contact us for more information.

Bridging Studies.

We also offer Bridging Studies, with or without focus testing, for any European country, and can help you by assessing if bridging is appropriate for your submission.

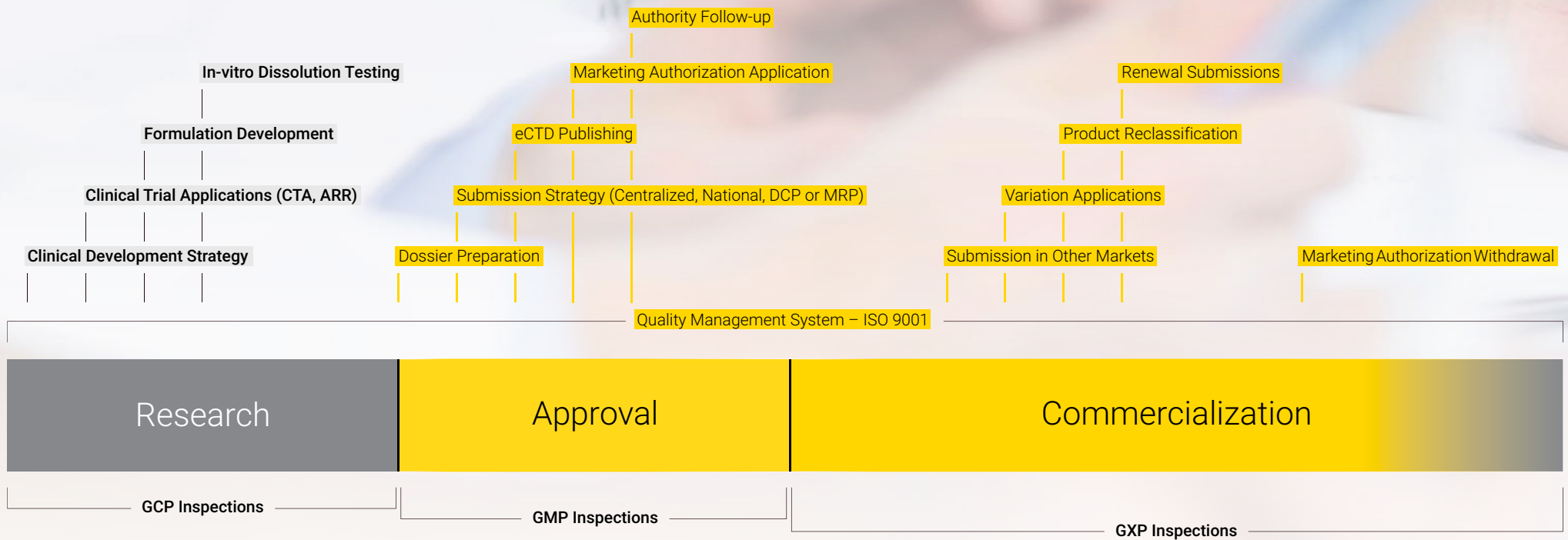
In bridging, a successful user test on one PIL (the "Parent" PIL) can be used to support a justification for not performing a full test of a similar leaflet (a "Daughter" PIL).

When a Bridging Report is not enough to support your project needs, we will help you outline a "Focus test" concentrating on the significant changes, in compliance with a QRD template as well as relevant guidelines.

Bridging includes:

- Review of the text and layout of the proposed PIL and suggestions for improvement, in compliance with a QRD template as well as relevant guidelines.
- Review of previous consultations/readability tests.
- Comparison of the "Daughter" and "Parent" leaflets in content, structure, and design.
- Writing of a Bridging Report containing the rationale for bridging for submission to regulatory authorities.
- Support in addressing readability testing related deficiency letters.

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



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



**Bluefish
Pharmaceuticals
India**

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

Jaya Ramakrishnan

**General Manager – Regulatory Affairs,
Bluefish Pharmaceuticals, India**

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

“ Clear communication and deep understanding of our clients’ needs enable us to work as true partners. This is what makes a difference and sets us apart from other solutions providers.”



Sandra Lourenço

Head of Regulatory Affairs

arriello

From development to market.

Faster. Better. Smarter.

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

Service inquiries: sales@arriello.com

 [linkedin.com/company/arriello_group](https://www.linkedin.com/company/arriello_group)

Global headquarters

Arriello Ireland Limited
No. 51, Bracken Road,
Sandyford, Dublin D18 CV48,
Ireland
+353 1 293 6755

Prague office

Arriello s. r. o.
Olivova 2096/4,
110 00 Prague 1,
Czech Republic
+420 222 367 765

Lisbon office

Maleo Saldanha Offices,
Av. da República 18,
1050-191 Lisbon,
Portugal
+351 21 053 4240

USA office

Arriello USA
One Marina Park Drive
Suite 1410, Boston,
MA 02210, USA
+1 617 807 7016

www.arriello.com

