

Regulatory Affairs Excellence with Global Reach and Local Expertise

Discover our step-by-step guide to global regulatory affairs. Learn how to accelerate EMA/FDA submissions, ensure compliance, and streamline approvals.

Why regulatory affairs excellence matters?

In an increasingly complex regulatory landscape, pharmaceutical companies need more than just technical support – they need a partner who understands both the global picture and the local details.

Whether you're entering a single country or launching globally, we deliver the strategic insight and operational precision to get your products to patients faster.



Our Regulatory Affairs team combines worldwide regulatory intelligence with deep local knowledge to support every stage of your product's lifecycle.



From early development through approval and post-marketing maintenance, we provide tailored, end-to-end solutions that ensure your submissions meet regulatory expectations in every market.

Strategic Planning and Regulatory Pathway Selection

Effective regulatory planning begins with selecting the right strategy for each market. Our team helps you identify the most appropriate regulatory routes, whether you're seeking approval in a single country or launching across multiple regions. We specialize in both global development planning and region-specific regulatory pathway selection, ensuring your strategy aligns with product type, timelines, and commercial goals.

Our services include:



Regulatory landscape assessments and feasibility analysis



Global regulatory strategy development and alignment



Risk-based planning to accelerate timelines and reduce rework







Coordination of global development plans with local market entry requirements

Initial Submissions: EMA, FDA and beyond

We provide expert support for initial marketing authorization applications (MAAs) across major markets, including the EU (via Centralized, DCP, or MRP procedures), the U.S. (via NDA/BLA routes) and other key regulatory jurisdictions worldwide. Our team helps you compile and submit technically sound, regulator-ready dossiers that stand up to review.





We support:

-  Preparation and submission of NDAs, BLAs, and MAAs
-  Coordination of scientific advice meetings and pre-submission discussions with health authorities
-  Harmonization of submission content to satisfy both EMA and FDA requirements
-  Strategic gap analyses and remediation for clinical, non-clinical, and CMC data

Post-Approval Lifecycle Management

After approval, ongoing regulatory maintenance is critical to ensure continued compliance and market availability. We manage all aspects of post-approval regulatory support, including product updates, safety-driven variations and labeling changes.






Key services include:

-  Authoring and submission of Type I/II variations and renewals in the EU
-  Submission of FDA supplements and annual reports
-  Maintenance of labeling, CMC content and risk management plans
-  Integration of regulatory intelligence and structured change control processes to maintain global alignment

Dossier Preparation: Non-Clinical, Clinical and CMC Expertise

We provide integrated regulatory support across all critical scientific areas required for successful submissions. Working closely with trusted experts in non-clinical, clinical and CMC disciplines, our team oversees the preparation and review of dossier content to ensure that each module is presented clearly, consistently and in full alignment with the highest scientific and regulatory standards.

We offer:

-  Authoring and review of CTD Modules 2.4–2.7: clinical and non-clinical summaries and overviews
-  Review and adaptation of existing data to meet EMA, FDA and ICH requirements
-  Preparation of responses to authority questions during review
-  Development and harmonization of Module 3 content, ensuring completeness and technical accuracy
-  Coordination of scientific input to support robust, regulator-ready documentation across all modules

Module 1 Preparation & Local Marketing Authorization (MA) Support




Getting your submission over the finish line requires attention also to local detail. Our local regulatory specialists act as a direct link between you and national health authorities, providing hands-on support throughout the Module 1 preparation process and beyond.

We ensure that all region-specific Module 1 documentation is accurately prepared, adapted and submitted in line with local expectations.

This includes:

-  Cover letters, application forms, declarations and powers of attorney
-  Customization and linguistic review of product information, including label mockups and artworks
-  Country-specific formatting, terminology and compliance alignment

Our services also cover:





-  Pre-launch activities, including portal access, national notifications and submission readiness
-  Direct liaison with authorities during the national phase of EU procedures (DCP/MRP)
-  Preparation and submission of supplements, variations and amendment packages
-  Quality control and publishing as required

Through our established network of local PV and RA contacts (QPPVs, LCPPVs), we coordinate in-market regulatory activities with full visibility and accountability. From portal submissions to inspection-ready documentation, we ensure your product information is locally compliant, up to date and aligned with global strategy.

Labeling Strategy and Product Information Management

We integrate labeling strategy into your global regulatory plan, ensuring consistent, compliant messaging across all markets.

We offer:

-  Creation and maintenance of Company Core Data Sheets (CCDS)
-  Coordination of local implementation and linguistic adaptation
-  Support for SmPC, PIL and labeling updates in line with regulatory changes
-  Artwork and mockup review to ensure accuracy and compliance

Why Partner With Us?

When you choose us as your regulatory partner, you gain the advantage of a team that combines global reach with deep local insight. We deliver seamless coordination across regions while providing tailored, country-specific guidance to navigate the complexities of local regulatory environments.

With end-to-end regulatory support spanning the entire product lifecycle, we help pharmaceutical and biotech companies:



Accelerate approvals across key markets



Ensure sustained compliance with evolving requirements



Optimize submission strategies and reduce regulatory risk



Achieve efficient, successful market access



Our proven track record, integrated approach, and commitment to quality make us a trusted extension of your team — wherever your products are headed.

Ready to accelerate your regulatory success?

Partner with PrimeVigilance for tailored regulatory consulting, global submission expertise, and sustainable compliance.

Contact our Regulatory Affairs experts today to discuss your project

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