PRIMEVIGILANCE

Regulatory Registration and Compliance

Unique Benefits of PrimeVigilance's Registration and Compliance Services

1

Strategic foresight for faster market entry

We guide you through the most effective EU registration pathway – Centralized, Decentralized, Mutual Recognition, or National – with seamless dossier compilation, eCTD authorship and publishing. Our experts also support FDA submissions (NDAs, BLAs) to harmonize global strategies, minimize duplication and accelerate approvals across key markets.

2

Ensuring long-term compliance and market continuity

Our team ensures your products remain compliant and market-ready throughout their lifecycle. From managing Type I/II variations, CBE, PAS, annual reports and renewals to preparing expert statements, we handle every change proactively and efficiently to maintain continuous compliance and regulatory confidence.

3

Consistency, compliance and clarity at every stage.

We deliver globally aligned, locally compliant labeling – from CCDS creation and local adaptation to artwork coordination and mockup reviews. Our integrated process ensures consistency, clarity and compliance across all markets.

4

Local expertise, globally connected

With in-country specialists across regions, we act as your liaison with national authorities. We prepare tailored Module 1 documentation, manage powers of attorney and pre-launch notifications and ensure submission readiness through our coordinated RA&PV network.

5

Confidence through preparation and expertise

We prepare you for successful EMA and FDA interactions with expert briefing packages and inspection-ready documentation. Our approach strengthens compliance, reduces approval risks and builds confidence for every regulatory engagement.

Tailored Solutions for Your Unique Regulatory Affairs Needs

For Startups & Biotechs

Challenge:

- Lack of in-house regulatory expertise
- Need for fast-track approvals & orphan drug support
- Complex regulatory requirements for biologics and gene therapies

Tailored PrimeVigilance Solution

- Regulatory strategy consulting: Early-stage regulatory planning & risk assessment
- Fast-track approval pathway guidance
- (FDA Breakthrough, EMA PRIME, etc.).
- Orphan Drug Designation (ODD) filing & post -approval monitoring

Benefit

Faster regulatory approval timelines, compliance support, and cost -efficient solutions.

For Mid-Sized Pharma Companies

Challenge:

- Managing multiple global submissions (EU, US, APAC, Latin America)
- Need for post-market regulatory compliance and variations
- PV and regulatory compliance handled separately, leading to inefficiencies

Tailored PrimeVigilance Solution

- Integrated RA + PV outsourcing model: One provider for pharmacovigilance & regulatory lifecycle management
- Global dossier preparation & submissions (eCTD, IDMP, PSURs, RMPs, etc.)
- Risk management planning linked with post -market safety updates

Benefit

Reduces regulatory complexity, ensures compliance efficiency, and optimizes cost savings.

For Large Pharma & Generics

Challenge:

- High volume of regulatory submissions & variations
- Need cost-effective post-market surveillance with pharmacovigilance compliance
- Generics and biosimilars regulatory requirements

Tailored PrimeVigilance Solution

- Regulatory lifecycle management (global variations, renewals, line extensions)
- Cost -effective outsourcing model for high -volume submissions
- Specialized biosimilar and generics registration pathway support

Benefit

Optimizes regulatory efficiency while maintaining compliance across global markets.

Why Choose PrimeVigilance for Regulatory Affairs?

Comprehensive Expertise

Access to a wide pool of specialized knowledge and experience across multiple markets, ensuring compliance with diverse regulatory requirements

Global Reach with Local Presence

Ensure that projects are managed with both a global perspective and local execution, providing a balance between broad strategic oversight and regional adaptability

Cost Efficiency and Scalability

Easily scale services to match the project's needs without the overhead costs associated with hiring and training in-house staff

Holistic. Scalable. Compliant.

PRIMEVIGILANCE

Our unrivalled network is trusted across the industry, supported by experienced in-house QPPVs, regulatory professionals, and automation-ready infrastructure.

Ready to Partner? Contact Us Today!

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