

Your Trusted Partner for Quality and Inspection Readiness in Pharmacovigilance

At PrimeVigilance, we empower our partners with tailored **Quality Assurance (QA)** solutions that ensure regulatory compliance and inspection readiness. Our team of **PV-focused QA consultants** brings deep industry expertise, offering a **holistic approach** to maintaining and improving your safety system. From targeted gap analyses to full-system audits, we deliver measurable results with proven success **across the product lifecycle**.

Core Offerings in Inspection Readiness

We support biopharma clients across every phase of development with tailored services such as:

- **SOP Gap Analysis:** Evaluation of current PV documentation against industry and regional best practices.
- **Inspection Readiness Program Design:** Strategic preparation plans, including mock audits and internal training.
- **Full PV System Audits:** Expert assessments to uncover system gaps and establish remediation priorities.
- **Audit Universe Set up and Management:** Deliver a full set of audit-related procedures and a risk-based Tactical Audit Plan, both fully compliant with requirements for MAH PV systems and PV audits.



Tailored QA Services – Built Around Your Product Milestones

Whether launching your first product or entering a new market, our QA consultants provide:

Service	Purpose	Ideal Timing	Deliverable
 SOP Gap Analysis	 Assess system compliance vs. regulations	 Pre-launch or system changes	 Gap Analysis Playbook
 Inspection Readiness Audits	 Prepare for authority inspections, identify risks	 Before scheduled or triggered audit	 Audit Report + CAPA Guidance
 Regulatory Affairs Integration	 Align PV SOPs with regulatory filings	 New region entry or submission prep	 Regulatory Alignment Report

Built for Compliance. Designed for You.

PrimeVigilance is proud to support biotech, pharma, and generics clients worldwide. Our tailored QA programs are structured around your product's milestones and regulatory obligations to ensure readiness, visibility, and efficiency.

Ready to Partner? Contact Us Today!



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