

Japan Pharmacovigilance Readiness

Supporting Growth in One of the World's Most Demanding Regulatory Markets



Why Japan Matters

Japan is a strategically important market for global biopharmaceutical companies. Marketing Authorisation Holders (MAHs) must comply with Good Vigilance Practice (GVP), Good Post-Marketing Study Practice (GPSP), and broader PMD Act requirements while maintaining local safety governance and post-marketing oversight.

Key Pharmacovigilance Requirements for MAHs in Japan



Local Safety Governance Structure

Marketing Supervisor General (Soseki / 総括製造販売責任者): Responsible for oversight of quality and safety activities and supervision of key PV functions.

Safety Control Manager (Anseki / 安全管理責任者): Responsible for pharmacovigilance operations, safety oversight and implementation of safety measures. The role operates independently from sales and commercial functions and is generally expected to have local Japanese language capability.

Post-Marketing Safety System Requirements



Operational Challenges

Challenge	→	Risk	→	PrimeVigilance Solution
Japanese AE intake		Delayed reporting		Local language support
Literature monitoring		Compliance gaps		Local monitoring
EPPV support		Inspection findings		Local expertise

How PrimeVigilance Supports Success in Japan

- Local PV infrastructure and governance support
- Japanese-language safety operations
- Literature monitoring and safety intelligence
- Post-marketing surveillance support
- Risk management and EPPV support
- Flexible specialist resources that complement existing global operations

Conclusion

PrimeVigilance helps organisations navigate Japan's unique pharmacovigilance environment through local expertise, operational flexibility and scalable global support.



**Ready to Partner?
Contact Us Today!**

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