

Is Your Organization Ready for a Successful Launch?

Pre-Launch Pharmacovigilance Readiness Checklist



Executive Summary

A positive Phase III readout is only the beginning.

As products move from development to commercialization, pharmacovigilance requirements expand dramatically. New indications, new markets, and new healthcare professional audiences introduce operational complexity that many organizations underestimate.

This self-assessment checklist helps organizations evaluate whether their pharmacovigilance infrastructure is prepared to support a successful launch.

SECTION 1 GOVERNANCE & OVERSIGHT

ORGANIZATIONAL READINESS

Question	YES	NO
Global QPPV responsibilities defined	☐	☐
Local PV contacts identified	☐	☐
Escalation pathways documented	☐	☐
Vendor oversight model established	☐	☐
Governance committees operational	☐	☐

Warning Signs

- Launch activities outpacing PV planning
- Multiple vendors without clear ownership
- Unclear accountability for local markets

SECTION 2 MARKET READINESS

COUNTRY PREPARATION

Assessment Area	Status
Local regulatory requirements mapped	☐
Local reporting timelines documented	☐
Literature monitoring established	☐
Local affiliates trained	☐
Inspection readiness reviewed	☐

Key Question

Can every market demonstrate local PV compliance on Day One?

SECTION 3 SAFETY SYSTEMS

INFRASTRUCTURE ASSESSMENT

Assessment Area	Status
Safety database configured	☐
Product coding completed	☐
Workflows validated	☐
Signal detection plan approved	☐
Reporting pathways tested	☐

Launch Risk

A surprising number of launch delays stem from safety systems that were never fully validated under commercial operating conditions.

SECTION 4 RISK MANAGEMENT

READINESS ASSESSMENT

Risk Management Plan approved	☐
Additional Risk Minimisation Measures established	☐
Educational materials prepared	☐

Safety communications process defined ☐

Escalation procedures documented ☐

Ask Yourself

Can your organization rapidly communicate a newly identified safety concern across every launch market?

SECTION 5 MEDICAL INFORMATION & AE INTAKE

FRONT-LINE READINESS

Assessment Area	Status
HCP inquiry process active	☐
AE intake channels tested	☐
Patient support program reporting established	☐
Contact centre staff trained	☐
Local language support available	☐

Critical Consideration

The first adverse event after launch often arrives through a medical inquiry, not through traditional safety channels.

SECTION 6 LOCAL MARKET COMPLIANCE

Japan

☐ PMDA requirements assessed

☐ Japanese literature monitoring active

☐ Local reporting process documented

GCC

☐ Local representation secured

☐ Country-specific requirements documented

Canada

☐ Health Canada obligations mapped

☐ Bilingual intake capability confirmed

EU

☐ Local language monitoring active

☐ Country-specific requirements assessed

☐ Local safety contacts identified

China

☐ NMPA system established

☐ Safety Representative identified

☐ Reporting pathways tested

SECTION 7 LAUNCH SIMULATION

FINAL READINESS TEST

Conduct a mock launch exercise involving:

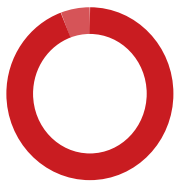
AE Received → Assessment → Reporting → Signal Detection → Escalation

Success Criteria

Can your team complete every activity accurately, compliantly, and within required timelines?



READINESS SCORING



90–100%

Launch Ready



75–89%

Minor Gaps Identified



50–74%

Moderate Risk – Remediation Recommended



Below 50%

High Risk – Significant Readiness Gaps



How PrimeVigilance Helps

PrimeVigilance supports organizations preparing for:

- New product launches
- New indication launches
- Geographic expansion
- First-in-class therapies
- Rare disease commercialization
- Global pharmacovigilance transformation

Our local PV network, regulatory expertise, and scalable operating model help organizations move from clinical development to commercial readiness with confidence.

Ready to Partner? Contact Us Today!

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