International Journal of Science and Research (IJSR)
ISSN: 2319-7064
Impact Factor 2025: 7.089

Pharmacovigilance Maturity Assessment for High-Impact Business Scenarios: A GVP / ICH-Aligned Framework

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Abstract: ***Pharmacovigilance (PV) organizations are operating in an increasingly complex environment driven by evolving global regulations, diverse data sources (including real-world evidence and digital channels), and more distributed operating models. As a result, PV maturity has become a strategic requirement—not only to demonstrate compliance, but to ensure resilient end-to-end safety oversight, data integrity, and timely benefit–risk decision-making. This whitepaper proposes an industry-focused, corporate PV maturity assessment framework to support high-impact scenarios such as mergers and acquisitions, licensing and partnerships, geographic expansion, outsourcing/vendor transitions, and PV technology modernization (including automation/AI). It also clarifies why regulator-centric tools such as the WHO Global Benchmarking Tool (GBT) do not fully address Marketing Authorisation Holder (MAH) needs. The framework is aligned to GVP/ICH expectations, defines key maturity dimensions and indicative maturity levels, and is supported by illustrative performance indicators and a practical, risk-based roadmap to strengthen inspection readiness and drive continuous improvement.***

Keywords: pharmacovigilance maturity, safety monitoring systems, regulatory compliance in PV, risk based decision making, drug safety data management

1. Introduction

Rapidly evolving regulatory expectations, increasingly complex global operating models, expanding product portfolios, and new data sources (including real-world evidence and digital channels) are raising the bar for Pharmacovigilance (PV). In this environment, PV maturity is not limited to demonstrating compliance- it reflects how consistently an organization can deliver robust end-to-end safety oversight, maintain data integrity, and respond to emerging benefit–risk questions at speed and at scale.

PV maturity becomes especially critical during high-impact business scenarios such as mergers and acquisitions, in-licensing and partnerships, geographic expansion, outsourcing and vendor transitions, and safety technology modernization (including automation/AI). In these situations, companies must assess not only whether core obligations are met, but whether PV governance, processes, technology, and oversight are sufficiently resilient and scalable to prevent reporting disruptions, inspection findings, and avoidable patient-safety risk.

While existing guidance is valuable, the industry lacks a practical, corporate-focused approach to consistently measure PV capability and benchmark progression toward best-in-class performance. For example, WHO's Global Benchmarking Tool (GBT) is designed to assess national regulatory systems rather than a Marketing Authorisation Holder's end-to-end PV operating model. This whitepaper addresses that gap by introducing a GVP/ICH-aligned PV maturity assessment framework that (1) defines key maturity dimensions (governance, organisation and oversight; PV quality management system (QMS) and compliance; end-to-end PV operations; signal management and benefit–risk evaluation; risk minimisation and safety communications; partner/vendor governance and global operations; technology, data integrity and analytics enablement; and patient centricity and real-world safety insights), (2) describes indicative maturity levels, and (3) proposes illustrative performance indicators and a practical roadmap to support continuous improvement and inspection readiness.

Business Scenarios Where PV Capability Assessment Is Essential

PV capability assessment is critical not only during compliance events but across strategic growth, market expansion, operational change, and risk management scenarios. Including new market entry, divestments, and generics-specific challenges ensures the framework reflects real-world industry needs and regulatory realities. Below are real-life scenarios, categorized by business context, where PV capability assessment is essential:

Mergers, Acquisitions, and Divestments (M&A)

- **Pre-Acquisition Due Diligence:** The acquiring company must assess the target's PV system to identify compliance gaps, PSMF integrity, inspection history, open CAPAs, and unresolved safety commitments.
- **Safety Database Integration:** Post-merger, companies must determine database consolidation strategy and ensure compliant migration without data loss or reporting disruption.
- **Transition Services Agreements (TSAs):** When the seller retains PV responsibilities temporarily, the buyer must assess the seller's operational capacity, oversight mechanisms, and handover readiness.
- **Divestments and Carve-outs:** When products or business units are divested, PV capability assessment ensures continued case processing, signal management, and regulatory reporting during ownership transition.

Market Entry and Geographic Expansion

- **Entering a New Market:** When launching products in new countries or regions, companies must assess whether their PV system can support:
  - Local reporting timelines and formats

- Local QPPV or safety contact requirements
- Language, literature surveillance, and local database interfaces
- Alignment of global PSMF with local annexes

- **Emerging / High-Risk Markets:** In regions with evolving regulatory frameworks, PV capability assessment helps ensure compliance despite regulatory ambiguity or limited authority guidance.
- **Generic Product Market Entry:** For generics, rapid multi-country filings require confidence that PV systems can scale quickly while maintaining reconciliation and reporting accuracy.

Outsourcing and Third-Party Management

- **CRO / Vendor Selection:** Before outsourcing clinical or post-marketing PV activities, companies must assess vendor capability to meet regulatory timelines, data quality standards, and inspection readiness.
- **Distributor and License Partner Oversight:** MAHs must periodically assess partners' ability to exchange, reconcile, and report safety data in compliance with SDEAs.
- **Vendor Transitions:** When changing PV service providers, assessments ensure continuity, data integrity, and regulatory compliance during handover.

Regulatory Inspections and Audits

- **For-Cause Inspections:** Triggered by safety concerns or compliance signals, requiring assurance that signal detection, escalation, and decision-making processes are robust.
- **Routine Inspections:** Regular authority inspections assess QPPV oversight, database integrity, SOP effectiveness, and compliance metrics.
- **Mock / Readiness Audits:** Internal or third-party PV capability assessments are used to identify gaps before regulatory inspections.

Product Lifecycle Milestones

- **New Product Launch:** Prior to launch, companies must confirm PV readiness to manage increased case volumes, aggregate reporting, and RMP commitments.
- **OTC Switch:** An "Rx-to-OTC Switch" in pharmaceutical companies is the strategic, data-driven process of reclassifying a prescription (Rx) drug to over-the-counter (OTC) status, allowing it to be sold without a doctor's prescription. Broader patient exposure requires reassessment of signal detection, consumer reporting intake, and communication strategies.
- **New Indication / Population Expansion:** Adding paediatric, geriatric, or special-population indications requires reassessment of analytical and signal management capabilities.
- **Biosimilar or Complex Generic Launch:** Requires enhanced traceability, product identification, and signal discrimination capabilities.

Specific Safety Situations

- **Emerging or Unexpected Safety Signals:** Rapid assessment of whether tools, governance, and expertise can support timely signal validation and regulatory action.
- **Digital Data Sources:** Introduction of social media monitoring, patient apps, or digital platforms requires assessment of screening, documentation, and regulatory defensibility.
- **Public Health or Crisis Situations:** Pandemics or safety crises test surge capacity, governance, and global coordination of PV operations.

Resource, Technology, and Operating Model Changes

- **AI-Enabled PV Transformation:** Before deploying AI/RPA for case intake or signal detection, companies must assess validation, explainability, and compliance readiness.
- **Safety Database Replacement or Upgrade:** Requires assurance of validated migration, reporting continuity, and inspection defensibility.
- **Operating Model Changes:** Centralization, offshoring, or restructuring of PV teams necessitates reassessment of governance, oversight, and performance controls.

How a PV Maturity Model Supports Current-State Assessment, Gap Analysis, and Prioritised Capability Build-Out

Each business scenario requires a pharmaceutical company (or its affiliate) to maintain specific Pharmacovigilance (PV) business and IT capabilities to ensure the timely and compliant fulfilment of its patient-safety and regulatory obligations. In real-world operating models, a PV organisation (and/or its affiliates) will already be executing a defined set of PV scenarios and processes; however, new or expanded scenarios may arise over time (e.g., new product launches, market expansion, M&A integrations, outsourcing transitions, or new regulatory expectations).

Therefore, it is necessary to determine the incremental PV business and technology capabilities required to support these additional scenarios and to understand the organisation's readiness and capability gaps. A PV maturity model can support this by providing a structured approach to assess the current state, identify gaps versus target maturity, and prioritize capability build-out aligned with GVP/ICH expectations and inspection readiness.

A PV maturity model helps because it turns "Are we compliant and ready?" into a repeatable, evidence-based assessment that is directly traceable to GVP/ICH expectations and typical inspection focus areas (governance, QMS, data integrity, oversight, and end-to-end process control). Concretely, it supports three linked steps:

1) Assess the current state (baseline, fact-based)

A maturity model provides defined dimensions, criteria, and evidence requirements (e.g., policies/SOPs, PSMF elements, KPIs, audit trails, system validation evidence). This enables a structured review across People–Process–Technology–Data, such as:

- Governance & oversight (e.g., QPPV oversight model, SDEAs, vendor governance)
- Core PV processes (ICSR intake/triage, case processing, reporting, reconciliation)
- Signal & risk management (signal detection/validation, RMP/PBRER processes)
- Quality system (deviations, CAPA, audits, training, document control)
- Technology & data integrity (validated safety database, interfaces, access controls, ALCOA+)

Output: a baseline maturity score/profile by domain, with supporting evidence—useful for internal leadership and defensible in audits/inspections.

2) Identify gaps vs. target maturity (what must improve and why)

Because maturity levels are defined (e.g., ad hoc → defined → managed → optimized), you can set a target maturity appropriate to the scenario (e.g., new market entry may require stronger local compliance controls; M&A may require integration readiness and reconciliation robustness).

The model then highlights:

- Compliance gaps (missing/weak controls vs GVP/ICH expectations)
- Capability gaps (insufficient resourcing, unclear RACI, fragmented workflows)
- Technology gaps (manual steps, poor traceability, weak integrations)
- Inspection readiness gaps (lack of documented oversight, incomplete evidence packs, poor metrics)

Output: a gap register mapped to impacted regulations/modules and the specific inspection risk (e.g., late reporting, poor oversight, inadequate signal documentation).

3) Prioritize capability build-out (risk-based roadmap)

A maturity model supports prioritization by combining:

- Patient-safety and regulatory risk (severity/probability of noncompliance)
- Business impact (launch timelines, partner obligations, scalability)
- Effort/complexity (process change, system validation, change management)

This results in a practical roadmap of capability build initiatives (e.g., strengthen vendor oversight and SDEA governance; implement reconciliation controls; improve case quality review; enhance signal tracking; upgrade/validate safety system; define KPIs and management review), typically staged as:

- Immediate inspection-risk mitigations (0–90 days)
- Stabilize and standardize (3–6 months)
- Optimize and automate (6–18 months)

Output is a prioritized implementation plan that is explicitly aligned to GVP/ICH, backed by metrics, and oriented toward inspection readiness (i.e., demonstrable control, traceability, and continuous improvement).

Existing PV Maturity Frameworks & Guidance – Scope and Relevance

Comparison of the key existing PV maturity frameworks and guidance explicitly brings out what each provides and whether it is relevant to pharmaceutical companies or to National Regulatory Authorities (NRAs/NCAs).

WHO Global Benchmarking Tool (GBT)

- A formal maturity benchmarking framework to assess national regulatory systems, including vigilance functions, across the full medical-product lifecycle.
- Uses maturity levels (ML1–ML4) adapted from ISO concepts to rate how advanced a national PV system is—from basic existence to continuous improvement. [who.int]
- Evaluates governance, legal frameworks, quality systems, signal detection, reporting, inspections, and national PV coordination through structured sub-indicators.
- Designed to support capacity-building and institutional development plans for regulators.

Conclusion: *The WHO GBT is a regulator-focused benchmarking tool. While it can provide useful context on national PV expectations and system components, it is not designed to assess an MAH's end-to-end corporate PV operating model (e.g., QPPV oversight, global/local governance, partner/SDEA oversight, safety database validation, and managed services delivery) or to support scenario-driven capability prioritization for a company.*

EFPIA International Pharmacovigilance Group (IPVG) Recommendations

- It provides consensus-based recommendations for the stepwise development of effective PV systems, aligned with ICH and EU-GVP principles.
- Focuses on core PV capabilities such as: ICSR management, Signal management, Safety communication and Governance and oversight.
- It explicitly acknowledges variability in national PV maturity and proposes pragmatic, scalable approaches suitable for diverse regulatory environments.

Conclusion: *EFPIA-IPVG provides valuable best-practice recommendations to design and strengthen PV systems; however, it is not a formal maturity model. It does not define standardized maturity levels, scoring criteria, or evidence-based benchmarking measures that would enable consistent cross-organization assessments or quantitative tracking of improvement over time.*

WHO & Global Fund – Minimum Requirements for a Functional PV System

- Defines baseline ("minimum") requirements for establishing a functional national PV system, particularly in low- and middle-income countries.
- Covers essential elements such as: National PV centre, ADR reporting mechanisms, Basic signal detection capability and Sustainable funding and governance
- It is designed to ensure existence and sustainability, not optimization or innovation.

Conclusion: *This guidance is designed to establish baseline ("minimum viable") PV system functionality—primarily in resource-constrained settings—and therefore focuses on presence of essential elements rather than performance, scalability, and optimization. It does not address a corporate MAH's advanced maturity needs (e.g., global operating model design, vendor governance, validated safety-system architecture and integrations, data integrity/ALCOA+ controls, or readiness for automation/advanced analytics).*

Key Elements of an Industry PV Maturity Framework

A robust industry PV maturity framework provides a structured, evidence-based lens for assessing how an organisation's safety capabilities evolve—from meeting baseline regulatory obligations to delivering proactive, scalable, and inspection-ready end-to-end pharmacovigilance. Grounded in EU GVP and ICH expectations, the framework should reflect real operating-model complexity (global/local delivery, partners and service providers, multiple systems and interfaces) and support scenario-driven decisions such as M&A, licensing, market expansion, outsourcing transitions, and PV technology modernisation.

As highlighted in the prior section, existing resources (e.g., WHO GBT, WHO/Global Fund minimum requirements, and EFPIA-IPVG recommendations) are valuable but do not provide a consistent, corporate-focused maturity measurement approach that spans governance, PV QMS, end-to-end operations, technology and data integrity, and strategic readiness. This reinforces the need for an industry PV maturity framework that complements regulator-centric tools while enabling a Marketing Authorisation Holder (MAH) to assess its own capability and prioritise improvements.

1) **Governance, Organisation & Oversight:** Clear accountability (including QPPV/PV leadership), defined roles and RACI, and effective oversight across global and local PV delivery. This includes management review and decision governance (e.g., safety governance forums), escalation pathways, and documented oversight of outsourced activities and partners.
2) **PV Quality Management System (QMS) & Compliance:** A fit-for-purpose PV QMS aligned to GVP/ICH, including controlled documentation (SOPs/WIs), training and role qualification, deviation and CAPA management, change control, audit programme and supplier audits, inspection readiness activities, and continuous improvement through metrics and periodic management review.
3) **End-to-End PV Operations (Processes & Controls):** Consistent, well-controlled execution of core PV processes such as case intake and triage, case processing and medical review, expedited and non-expedited reporting, literature monitoring, reconciliation (including partner and database reconciliations), and aggregate reporting deliverables. Emphasis should be placed on role clarity, handoffs, cycle-time control, and business continuity/surge capacity.
4) **Signal Management & Benefit–Risk Evaluation:** Robust, traceable signal management aligned to GVP Module IX (detection, validation, confirmation, analysis/prioritisation, assessment, and recommendation for action), supported by appropriate epidemiology/biostatistics and medical expertise. Includes benefit–risk evaluation through RMP and PBRER processes, clear decision documentation, and timely implementation of agreed actions.
5) **Risk Minimisation & Safety Communications:** Implementation and lifecycle management of risk minimisation measures (e.g., RMP activities and, where applicable, REMS), including safety variation/labeling change processes, DHPC/safety communications governance, and evaluation of risk-minimisation effectiveness using defined measures and real-world insights.
6) **Partner/Vendor Governance & Global Operations:** Effective governance of third parties (CROs, vendors, affiliates, distributors, and license partners) through SDEAs/quality agreements, oversight KPIs, audit and issue management, data exchange controls, and periodic reconciliation. Includes capability to meet diverse global/local regulatory requirements (e.g., local safety contacts, language needs, submissions formats/timelines) with clear handoffs and escalation.
7) **Technology, Data Integrity & Analytics Enablement:** Validated safety systems and controlled interfaces (e.g., safety database, RIM, clinical, quality, and master data), with strong data integrity (ALCOA+), access controls, audit trails, backup/restore, and migration controls. Includes fit-for-purpose reporting capabilities (E2B), analytics for operational control and signal detection, and a governed approach to automation/AI (validation, change control, monitoring, and documentation of model performance).
8) **Patient Centricity & Real-World Safety Insights:** Structured intake and assessment of patient-reported information across channels (including digital), incorporation of real-world data where appropriate, and transparent communication approaches that improve accessibility and trust—while maintaining traceability, privacy, and regulatory defensibility.
9) **Maturity Levels:** Across the dimensions above, maturity typically progresses through five levels. The intent is to describe not only "what exists" (documents and tools) but "how well it works" (control, oversight, performance, and inspection readiness):
   - **Level 1 – Ad Hoc:** Activities performed inconsistently; limited documentation; heavy manual effort; high dependency on individuals.
   - **Level 2 – Reactive/Basic:** Core processes in place to meet key timelines, but controls and oversight are inconsistent; limited metrics; issues addressed after escalation.
   - **Level 3 – Defined:** Standardised procedures and roles; established PV QMS; consistent execution across products/regions; validated core systems with documented interfaces.
   - **Level 4 – Managed/Proactive**: Performance is actively managed using KPIs and trend analysis; strong oversight of partners; integrated workflows and reconciliations; routine inspection readiness practices.
   - **Level 5 – Optimised**: Continuous improvement is embedded; advanced analytics/automation are governed and validated; predictive insights support

earlier risk detection and faster benefit–risk decisions; operating model scales efficiently.

2. Performance Indicators

To measure progress, the maturity model should include a balanced set of indicators covering compliance outcomes, operational performance, quality, and technology enablement. Illustrative indicators include:

- **ICSR compliance and timeliness**: on-time submission rates by region, late cases with root-cause trends, and rework rates.
- **Signal management performance**: cycle times by stage (detection → validation → assessment → action), quality of documentation, and decision traceability.
- **Inspection readiness and PV QMS health**: audit coverage, deviation/CAPA recurrence, CAPA effectiveness and closure time, training compliance, and supplier oversight outcomes.
- **Technology enablement**: degree of workflow integration, reconciliation automation, data-quality indicators, and (where used) validated automation/AI coverage with ongoing performance monitoring.

3. Conclusion

This whitepaper demonstrates that pharmacovigilance maturity is no longer a "nice to have" compliance exercise- it is a strategic capability required to protect patients and to sustain regulatory confidence across high-impact business scenarios such as M&A, licensing, geographic expansion, outsourcing transitions, and PV technology modernization. As organizations grow and operating models become more complex, hidden weaknesses in governance, quality systems, data integrity, and signal/risk management can translate into inspection findings, business disruption, and avoidable patient-safety risk.

Existing guidance (e.g., WHO GBT, WHO/Global Fund minimum requirements, and EFPIA-IPVG recommendations) is valuable but does not provide a complete, corporate-focused maturity assessment mechanism that spans end-to-end PV operations, technology, and strategic readiness. The proposed GVP/ICH-aligned PV maturity assessment framework closes this gap by enabling a repeatable current-state assessment, target-state definition, gap identification, and risk-based prioritization- supported by practical performance indicators (timeliness, signal cycle time, audit readiness, and automation adoption) and a staged improvement roadmap.

- Establish a defensible baseline of PV capability across governance, processes, technology, data integrity, partner oversight, and patient centricity.
- Identify and quantify inspection and compliance risk through evidence-based maturity scoring and gap mapping.
- Prioritize investments and remediation initiatives based on patient-safety impact, regulatory exposure, and business criticality.
- Accelerate PV modernization (including automation/AI) while maintaining validation, traceability, and auditability.

By adopting such a maturity model, companies can move from reactive compliance to proactive, measurable, and continuously improving safety operations- strengthening inspection readiness today while building a scalable foundation for future portfolio and geographic growth.

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