

5 WAYS

Interim Leaders Accelerate Performance in Pharmacovigilance

Inspection readiness, governance
clarity, and operational continuity
when it matters most

WittKieffer

The Pharmacovigilance (PV) Landscape is Shifting

Regulatory expectations across FDA, EMA, MHRA, and PMDA continue to intensify. Pharma companies manage increasingly complex product portfolios, global vendor ecosystems, and high-volume data flows. At the same time, leadership turnover – particularly in PV, medical safety, and QPPV roles – creates vulnerability at moments when oversight must be strongest.

In this environment, no organization can afford gaps in safety governance, documentation, decision traceability, and inspection narrative continuity. Interim leaders and on-demand PV experts provide immediate stability, specialized expertise, and the operational rigor required to maintain compliance and withstand regulatory scrutiny.

When Interim PV Leadership Becomes Critical

- Escalating regulatory risk exposure (inspection findings, commitments, delayed CAPAs)
- Approaching critical milestones (FDA/EMA inspection, NDA/BLA filing, product launch)
- Sudden or planned leadership transitions (QPPV, Head of PV, Medical Safety)
- Audit failures, control breakdowns, or vendor oversight gaps
- M&A activity and post-merger integration impacting global safety models
- IPO or public-company readiness requiring inspection-defensible PV infrastructure
- Board and investor pressure following safety events or compliance signals

PV failures destroy value. They increase regulatory exposure, damage organizational credibility, undermine trust with regulators and investors, and, most critically, elevate patient risk.



FIVE WAYS Interim Leaders Accelerate Performance in PV Processes and Operations

The interim PV leadership journey from rapid assessment to sustainable capability – how interim and on-demand leaders deliver impact across every phase.

PREPARE

Rapid risk diagnosis and inspection-focused stabilization

OPTIMIZE

Assessment, prioritization, and best-practice implementation

GOVERN

Inspection-defensible oversight, decision rights, and escalation

INTEGRATE

Embed capability, leadership depth, and sustainable ownership

01

Strengthen Inspection Readiness

02

Conduct Independent PV and Safety Operations Assessments

03

Establish / Optimize PV Governance

04

Provide Team Leadership

05

Build PV Leadership Depth

01 Strengthen Inspection Readiness

Interim PV leaders rapidly elevate preparedness for FDA, EMA, MHRA, and PMDA inspections – closing gaps before inspectors arrive and ensuring teams can respond confidently.

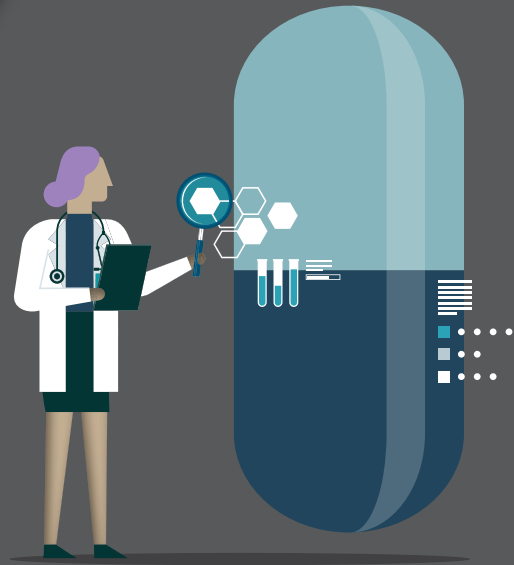
- **DEFINE INSPECTION ROLES AND OPERATING MODEL.**
Define inspection-day roles, including front-room/back-room governance and daily response cadence.
- **RUN MOCK INSPECTIONS AND DEVELOP GAP ASSESSMENTS.**
Simulate interviews and document requests; identify gaps in SME readiness, documentation, and process execution.
- **AUDIT SOPs, VENDOR OVERSIGHT, AND DOCUMENTATION PRACTICES.**
Review SOPs, work instructions, database management, and document storage for consistency and compliance.
- **PREPARE TEAMS FOR REAL-TIME INSPECTION NEEDS.**
Train SMEs, build inspection “war rooms,” and develop storyboards, response templates, and document trackers.

Inspection outcomes are driven by clarity, consistency, and confidence under scrutiny – areas interim leaders address before inspectors arrive.

The Value of Interim PV Leadership

Interim leaders provide operational depth with strategic foresight. They step in quickly, assess the landscape objectively, and implement improvements that strengthen both near-term readiness and long-term capability.

Their impact is most visible in five areas that consistently determine inspection outcomes, organizational resilience, and safety performance.



02 Conduct Independent PV and Safety Operations Assessments

Interim leaders provide an external lens to identify blind spots internal teams may have normalized and accelerate targeted remediation.

- **AUDIT CORE PV PROCESSES.**
Evaluate end-to-end PV processes, including case intake and processing, signal detection, aggregate reporting (PSURs and PADERs), risk management, and quality oversight.
- **REVIEW OUTSOURCING STRATEGY AND VENDOR OVERSIGHT.**
Assess CROs, call centers, and commercial partners against inspection expectations, with a focus on oversight effectiveness and accountability.
- **EVALUATE GLOBAL PV OPERATING MODELS.**
Review role distribution, escalation pathways, and handoff points across global PV organizations to identify operational and inspection risks.
- **BENCHMARK AGAINST INDUSTRY PRACTICES.**
Compare processes and KPIs against established, inspection-validated practices, including automation where appropriately validated.
- **DELIVER PRIORITIZED REMEDIATION PLANS.**
Provide targeted remediation plans aligned to regulatory risk, operational feasibility, and anticipated inspection timelines.

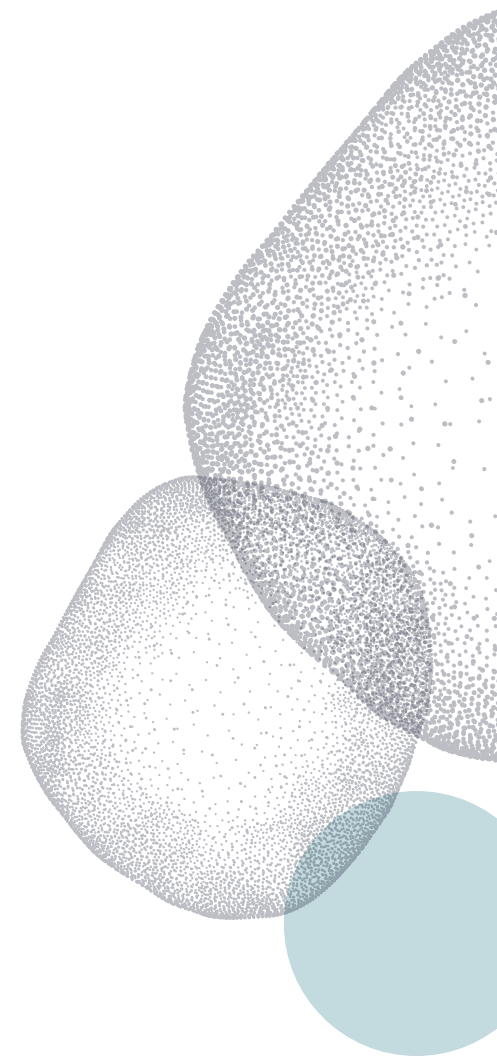
Independent assessments surface hidden regulatory risks and create a defensible remediation path before inspectors do.

03 Establish / Optimize PV Governance

As organizations grow, governance often becomes fragmented. Interim leaders translate governance models into inspection-defensible decision ownership.

- **DEFINE GOVERNANCE FORUMS AND DECISION AUTHORITY.**
Establish benefit risk committees, safety review boards, QPPV councils, and cross functional escalation bodies.
- **CLARIFY ROLES AND RESPONSIBILITIES.**
Delineate responsibilities across PV, clinical, regulatory, medical affairs, and vendors.
- **DEFINE ESCALATION PATHWAYS.**
Ensure consistent handling of safety signals, risk management issues, and compliance concerns.
- **ALIGN THE QP ROLE AND QPPV OFFICE.**
Ensure global and local regulatory requirements are met with appropriate oversight and documentation.

Interim leaders translate fragmented governance into inspection-defensible decision ownership, clarifying authority, escalation, and accountability.



04 Provide Team Leadership

Leadership gaps in PV can quickly escalate into compliance risk. Interim leaders stabilize teams, maintain continuity, and guide teams through periods of change, vacancies, or transformation.

- **STEP INTO QPPV, HEAD OF PV, MEDICAL SAFETY, OR OPERATIONS ROLES.**
Assume full accountability for safety oversight and regulatory compliance during leadership transitions.
- **MAINTAIN PATIENT SAFETY DECISION CONTINUITY.**
Ensure continuity of patient safety decision-making during leadership transitions, with no degradation in signal escalation or benefit-risk oversight.
- **MANAGE THROUGH CRITICAL INFLECTION POINTS.**
Navigate complex organizational change such as M&A, reorganizations, product launches, or market expansion while maintaining operational stability.
- **ENSURE CONTINUITY OF ADVERSE EVENT REPORTING AND CRITICAL SUBMISSIONS.**
Maintain timely and compliant adverse event reporting, including PSURs, PADERS, RMPs, and DSURs during leadership transitions
- **REBUILD MORALE AND CLARITY DURING PERIODS OF TRANSITION.**
Provide steady leadership and clear direction when teams need it most.

Interim leaders provide immediate leadership presence by stabilizing teams, maintaining decision continuity, and preventing safety risk from escalating during transitions.

05 Build PV Leadership Depth

PV leadership pipelines are often thin, especially when companies promote from within or transition from clinical or regulatory backgrounds. Interim leaders build long-term capability.

- **SUPPORT FIRST-TIME HEADS OF SAFETY OR QPPV SUCCESSORS.**
Provide hands-on guidance during critical early months in new leadership roles.
- **COACH LEADERS ON STAKEHOLDER MANAGEMENT.**
Develop skills to navigate complex multi-stakeholder environments effectively, including teams, regulators, and vendors.
- **ADVISE ON BEST PRACTICES.**
Transfer decades of expertise in regulatory preparedness, safety strategy, inspection management, and governance.
- **BUILD SUSTAINABLE PV LEADERSHIP PIPELINES.**
Develop the next generation of PV leaders by accelerating readiness for senior safety roles through structured exposure, coaching, and progressive accountability.

Interim leaders leave organizations stronger through coaching emerging PV leaders and embedding leadership capability that endures beyond the engagement.

Pharmacovigilance Optimization and FDA Preparedness for a Publicly Traded Commercial Biopharma

THE SITUATION

A commercial biopharma company anticipating an FDA inspection experienced the unexpected departure of its Head of PV. The Executive Director of Patient Safety stepped in as acting Head of PV, but the organization required external expertise with deep PV and inspection experience to prepare for a potential inspection and ensure operational continuity.

THE INTERIM SOLUTION

WittKieffer deployed an experienced management consultant – a former Accenture professional with deep expertise across PV, clinical, and quality functions. Over three months, the consultant:

- Established governance structures
- Developed inspection storyboards and documentation
- Ran mock inspections and SME readiness sessions
- Updated and organized processes and SOPs
- Provided ongoing support to the newly appointed PV leader

THE IMPACT

The organization entered the inspection period with stronger governance, clearer documentation, and a more confident safety team.

- Inspection ready documentation and governance model
- Strengthened SME confidence and preparedness
- Improved process consistency and documentation quality
- Seamless transition to the new PV leader

