VIGIVANCE

OVERVIEW

VIGIVANCE is a specialized services organization focused on Pharmacovigilance, Drug Safety and Regulatory Compliance, supporting clients across the product lifecycle and global regulatory landscape.

Our capabilities are built on multidisciplinary expertise across medicine, pharmacology, pharmaceutical sciences and regulatory operations, enabling a structured approach to complex safety and compliance requirements.

We combine scientific assessment, regulatory expertise, quality-driven processes and technology-enabled solutions to establish robust, traceable and inspection-ready systems that support sustainable regulatory compliance.

OUR OBJECTIVE

To drive sustainable growth through scientific excellence, operational integrity, client-focused delivery, and enduring partnerships creating lasting value and measurable impact for the organizations we serve.

OUR COMMITMENT

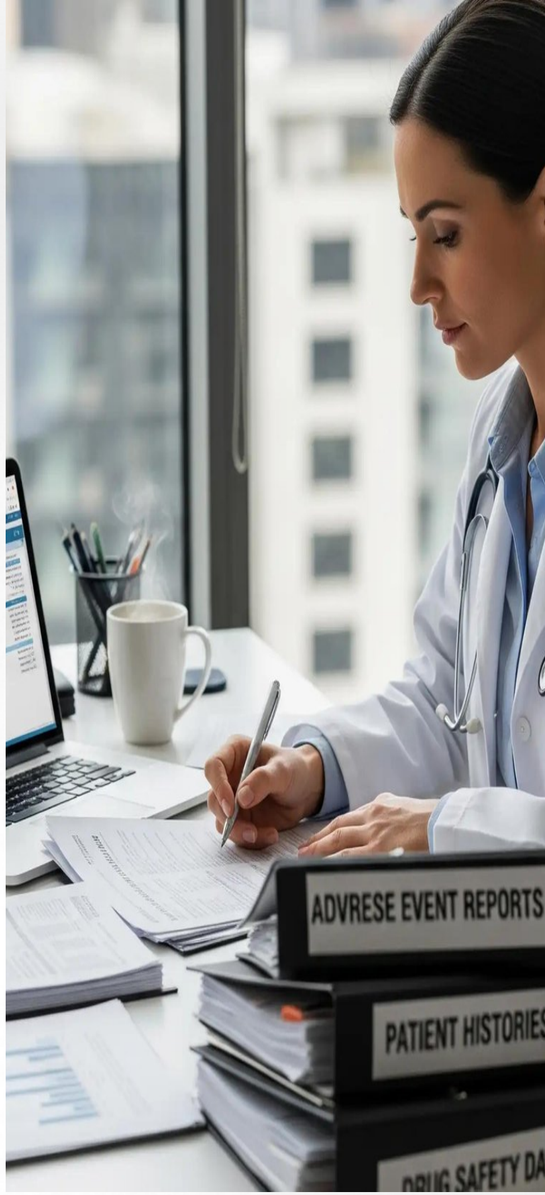
Scientific & Data Integrity

Regulatory Alignment

Quality & Compliance

Transparent Collaboration

We uphold scientific and data integrity, regulatory compliance, operational excellence, and rigorous quality standards, underpinned by transparent collaboration and accountable execution to deliver consistent, reliable, and sustainable outcomes.



OUR FOUNDATION: PEOPLE → PROCESS → TECHNOLOGY → QUALITY

OUR EXPERTISE

INTEGRATED EXPERTISE ACROSS THE PHARMACEUTICAL PRODUCT LIFECYCLE

VIGIVANCE combines pharmacovigilance, regulatory, medical, clinical, and quality expertise to support the establishment, maintenance, and continuous oversight of safety and regulatory compliance frameworks across the product lifecycle.

SCIENTIFICALLY RIGOROUS | REGULATORY-ALIGNED | QUALITY-DRIVEN

01 | PHARMACOVIGILANCE & DRUG SAFETY

End-to-end pharmacovigilance and drug safety support across the product lifecycle,

02 | REGULATORY AFFAIRS

Strategic regulatory support spanning market entry, product registration, lifecycle management, health authority engagement, and ongoing compliance.

03 | MEDICAL & SCIENTIFIC WRITING

Scientifically rigorous writing and documentation supporting clinical, regulatory, safety, and technical requirements across the product lifecycle.

04 | CLINICAL RESEARCH SUPPORT

End-to-end clinical research support covering study feasibility, Study strategy, site and CRO evaluation, coordination, and monitoring.

05 | GVP & GCP AUDITING

Independent audit and compliance support covering GVP/GCP systems, service providers, CAPA effectiveness, and inspection readiness.

CORE EXPERTISE

End-to-End Pharmacovigilance Support Across the Product Lifecycle

PV SYSTEM & GOVERNANCE
PV System Setup & Oversight, QPPV/LQPPV Support, PSMF, SOPs, SDEA, Training

CASE MANAGEMENT
ICSR Processing, Medical Review, MedDRA Coding, Follow-up, E2B Reporting

SAFETY SURVEILLANCE
Literature Surveillance, Signal Detection, Signal Management, Safety Evaluation, Benefit–Risk Assessment

AGGREGATE & RISK MANAGEMENT
PSUR/PBRER, DSUR, RMP, Risk Assessment, Risk Minimisation

QUALITY & COMPLIANCE
PV Audits, Inspection Readiness, Gap Assessment, CAPA, Compliance Monitoring

REGULATORY & TECHNOLOGY
Expedited Reporting, Safety Labelling, PV Database, Automation

Global Compliance | Quality-Driven Delivery

OUR SOLUTIONS

Pharmacovigilance Built Around Your Requirements

Every organisation has different products, markets, volumes, regulatory obligations, and internal capabilities.

VIGIVANCE provides fit-for-purpose PV support that can be scaled to meet specific operational and compliance requirements.

YOUR PV CHALLENGE - OUR EXPERTISE

Need to establish a PV system? We establish a robust PV framework designed for regulatory compliance, controlled, and sustainable operations

Facing gaps or compliance challenges? We assess your system and strengthen processes, quality controls, and compliance.

Need additional expertise or resources? We extend your team with specialised PV capabilities and scalable operational support.

Looking to optimise resources and focus on your core business? We manage your PV activities with structured governance, quality oversight, and regulatory compliance.

"Audit & Compliance, Market Expansion, Regulatory Change, Resource Constraints, Cost Optimization or Business Focus whatever is your need
We delivers scalable, fit-for-purpose Solutions and operational support aligned with your evolving requirements"

Build what you need | Strengthen what you have | Extend when required | Outsource when preferred

TECHNOLOGY & INNOVATION

SAFETY SYSTEMS & AUTOMATION

Technology-enabled safety systems and controlled workflows support ICSR intake, case processing, quality review, follow-up, reconciliation, and regulatory reporting.

DATA, QUALITY & REPORTING

Controlled data processes support data quality, reconciliation, traceability, compliance monitoring, performance metrics, dashboards, and safety reporting.

SAFETY INTELLIGENCE

Structured surveillance and analytical capabilities support literature monitoring, signal detection, safety evaluation, trend analysis, and ongoing safety assessment.

OUR APPROACH

Scientific Judgement. Regulatory Discipline. Controlled Execution.

Every engagement is driven by the right expertise, clear processes, active oversight, and accountable delivery bringing together People | Process | Technology | Quality to deliver dependable Pharmacovigilance outcomes.

Expertise → Control → Confidence

GLOBAL PRESENCE

VIGIVANCE supports Marketing Authorisation Holders, Manufacturer, Distributors in fulfilling and maintaining their Pharmacovigilance and regulatory obligations across diverse international regulatory environments.

Experience across 100+ countries, our geographic exposure spans
EU | EAEU | CIS | MENA | GCC | LATAM | SEA | ROW, providing an informed understanding of varied regulatory & operational requirements.

Product & Safety Expertise
Pharmacovigilance | Cosmetovigilance | Materiovigilance, supported by diverse product experience across innovator and branded products | Generics | Biosimilars | Hybrid Medicines | Diagnostic Agents | Contrast Media | Injectables & Parenterals | ODS | Paediatric & Geriatric Products | Oncology Therapies | Veterinary Products | Cosmetics | Medical Devices.

Supporting MAHs Across Markets. Across Products. Across the Lifecycle.

PROVEN EXECUTION

Our experience is reflected in the work we deliver, across diverse products, markets, and regulatory environments.

100+
Countries
PV & Regulatory
operational experience

15+
PV System Established

20+
GVP Audits &
Compliance assesment

Decades of
PV Expertise, Product
Registration & Market
Entry

YOUR REQUIREMENT-OUR EXPERTISE

LET’S DISCUSS THE RIGHT SOLUTION FOR YOU

Pharmacovigilance | Regulatory Affairs | Medical Writing | Clinical Support

LET’S CONNECT

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“VIGIVANCE”

Specialized Expertise. Regulatory Discipline. Operational Excellence.