

# VIGIVANCE

SCIENCE | COMPLIANCE | IMPACT



A laptop is open on a dark wooden desk in the foreground. In the background, a large window offers a view of a city skyline at sunset or sunrise, with warm light reflecting on the desk and the laptop. The text is overlaid on the right side of the image.

# EXPERTISE THAT CONNECTS. EXECUTION THAT DELIVERS.

VIGIVANCE is an integrated pharmaceutical services and consulting company bringing together scientific, regulatory, clinical, operational and quality expertise to support pharmaceutical organizations across the product lifecycle.

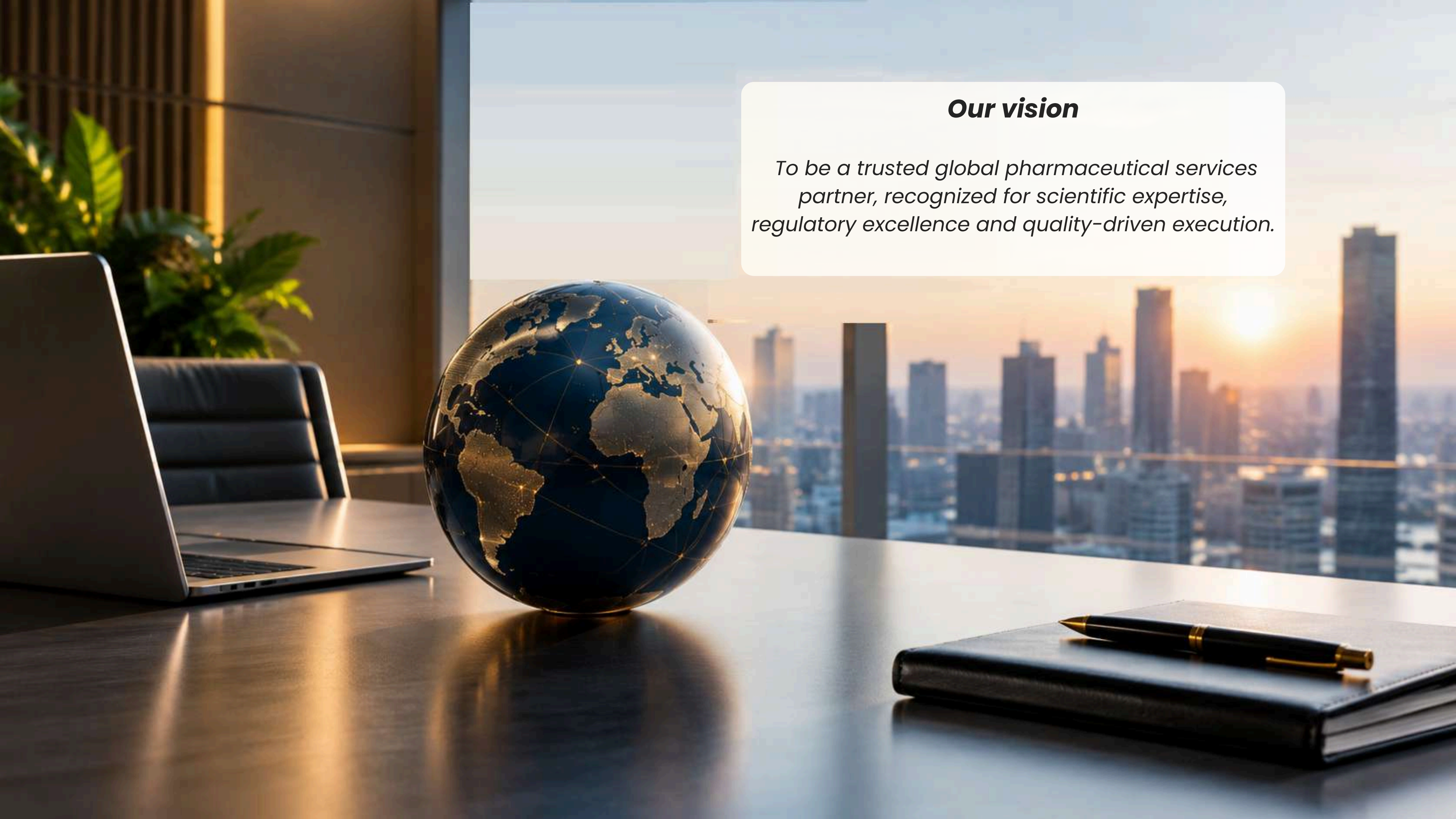
Pharmacovigilance forms the foundation of VIGIVANCE, complemented by specialized capabilities in Regulatory Affairs, Medical Writing, Clinical Study Project Management, and Audit & Compliance.

Our approach combines specialized expertise, structured processes, technology-enabled execution and quality-focused oversight to help pharmaceutical organizations manage complex requirements with greater clarity, control and consistency.



### ***Our purpose***

*To simplify and strengthen pharmaceutical operations through specialized expertise, structured processes and coordinated execution creating a stronger foundation for sustainable growth, lasting success and long-term business progress.*

The background image shows a professional office environment. In the foreground, a dark wooden desk holds a silver laptop on the left, a small globe in the center, and a black leather notebook with a pen on the right. A large window in the background provides a panoramic view of a city skyline at sunset, with the sun low on the horizon and its light reflecting on the buildings and the desk surface. A potted plant is visible on the left side of the desk.

## ***Our vision***

*To be a trusted global pharmaceutical services partner, recognized for scientific expertise, regulatory excellence and quality-driven execution.*

# EXPERTISE, ACROSS PRODUCT LIFECYCLE.

Pharmacovigilance as our core specialization, VIGIVANCE extends its expertise across Regulatory Affairs, Medical Writing, Clinical Study Project Management, and Audit & Compliance to support organizations across the product lifecycle.

This breadth enables us to address varied pharmaceutical needs through connected functional expertise and coordinated execution.



YOUR PRODUCT.  
EVERY STAGE.  
ONE PARTNER.

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# OFFERINGS



## **PHARMACOVIGILANCE**

*End-to-end safety system operations, ICSR management, regulatory reporting, risk management, PSMF, QPPV & LQPPV support, PSUR, RMP, SDEA, Literature review, and PV quality oversight.*

## **REGULATORY AFFAIRS**

*Regulatory strategy, submissions, market authorization and post-approval, Dossier & Lifecycle support across markets.*

## **MEDICAL WRITING**

*Scientific, clinical, safety and regulatory documentation with structured authoring and quality review.*

## **CLINICAL STUDY**

*Feasibility, site selection, study coordination, monitoring documentation and project oversight.*

## **AUDIT & COMPLIANCE**

*GxP assessment, audits, gap analysis, CAPA, quality risk management and inspection readiness.*

# FLEXIBLE ENGAGEMENT MODELS

The right expertise, exactly where it is needed.

From building in-house systems and strengthening existing teams to accessing specialized expertise, transferring operational activities and scaling capacity, flexible engagement models provide the freedom to choose the right level of support, maintain control where it matters and expand capabilities without the burden of building every resource internally.

## **BUILD or STRENGTHEN**

*When need a inhouse PV system*

## **EXTEND or MANAGE**

*When need additional expertise or operational support*

## **OUTSOURCE or SCALE**

*When need to transfer a complete activities or expand capacity*





**SET UP**  
YOUR PV SYSTEM

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**STRENGTHEN**  
YOUR EXISTING  
FUNCTION

---



**EXPAND**  
INTO NEW  
MARKETS

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**OUTSOURCE**  
PV OPERATIONS

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**PHARMACOVIGILANCE**

YOUR SAFETY.  
OUR FOCUS.

# A MULTIDISCIPLINARY TEAM TO RELY ON



VIGIVANCE integrates multidisciplinary expertise, defined functional responsibilities and quality oversight within a coordinated structure to ensure consistent, accountable and quality-driven service delivery.

## The Expertise Behind Our work

- Medical & Pharmacology Expertise
- Pharmacovigilance & Regulatory Specialists
- Clinical Operations & Project Coordination
- Medical Writing & Scientific Support
- Quality, Compliance & Leadership



## Pharmacovigilance

Safety Today. Health Tomorrow

- Case Intake & Triage
- Medical Review
- Regulatory Submission
- Signal Detection
- Risk Management



### ICSR Trends



### Safety Signals





# OUR STRENGTH IN PHARMACEUTICAL EXPERTISE

**Not Just Consulting. We Deliver Solutions.**

We deliver tailored pharmaceutical solutions aligned with product, process, market and regulatory requirements.

Our multidisciplinary expertise ensures scientifically sound, practical and quality-driven execution.

# CLIENT RELATIONSHIPS. OUR CREDIBILITY.

We proudly serve a wide range of Renowned Pharma Manufacturers, Medical Device Manufacturers, Cosmetic Manufacturers, Marketing Authorization Holders, Pharmaceutical Distributors



Multi domain Eepertise,  
Broad Therapuetic Knowledge  
Deep Product Insight



| EXPERIENCE THAT SPANS MARKETS, SYSTEMS & PRODUCT LIFECYCLES. |                         |  |  |
|--------------------------------------------------------------|-------------------------|--|--|
| 60+                                                          | 20+                     |  |  |
| Countries                                                    | PV Systems              |  |  |
| 20+                                                          | 100+                    |  |  |
| GVP Exposure                                                 | Aggregate Reports       |  |  |
| 100+                                                         | 15+                     |  |  |
| Product Registrations                                        | Clinical Study Projects |  |  |
| SPECIALIZED EXPERTISE. CONNECTED EXECUTION.                  |                         |  |  |

# TECHNOLOGY THAT STRENGTHENS EXECUTION.

VIGIVANCE integrates people, processes, technology and quality to deliver pharmaceutical operations with greater efficiency, visibility, traceability and control.

**PEOPLE • PROCESS • TECHNOLOGY • QUALITY**

**ViGenIQ™**

**Purpose-built digital workflows for controlled, efficient pharmaceutical operations.**

**Explore ViGenIQ™ →**



# SMARTER DIGITAL INFRASTRUCTURE. SIMPLER OPERATIONS



Introducing ViGenIQ™ A smarter solution for complex PV operations,

Purpose built digital workflows designed to simplify PV operations, reduce manual work and strengthen visibility, traceability and control.

It helps simplify complex activities, improve traceability and strengthen operational oversight, without the cost and complexity of building and maintaining an extensive in-house technology infrastructure.

Enterprise-ready capabilities. Flexible subscriptions. Technology that works around your operational needs.

*Currently available across three key PV processes:  
ICSR MANAGEMENT, LITERATURE SCREENING, PSMF MANAGEMENT*

# ViGenIQ™

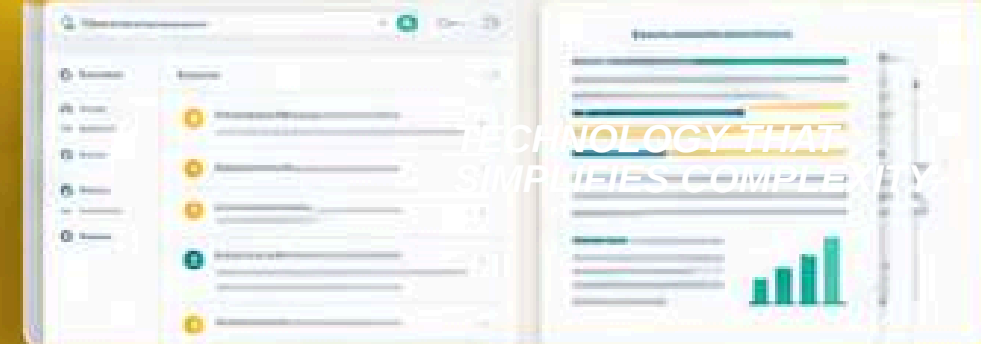


ICSR  
DATABASE

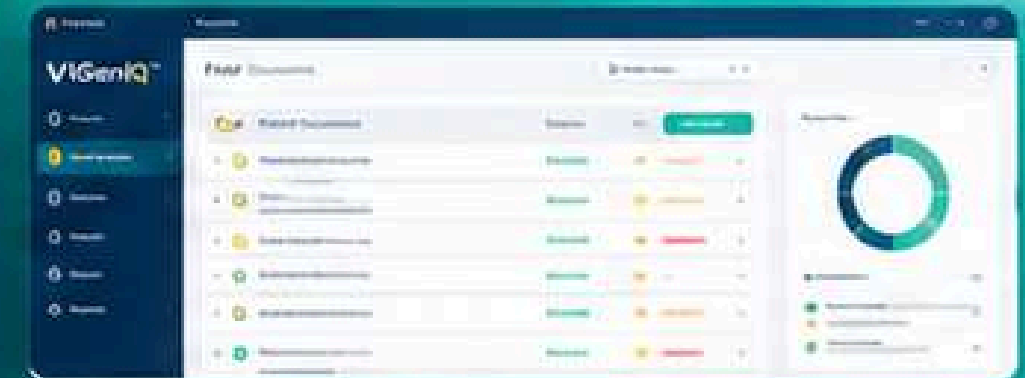
| Case ID | Case Name | Case Type     | Case Status | Case Action |
|---------|-----------|---------------|-------------|-------------|
| 1       | Case 1    | Adverse Event | Open        | View        |
| 2       | Case 2    | Adverse Event | Open        | View        |
| 3       | Case 3    | Adverse Event | Open        | View        |
| 4       | Case 4    | Adverse Event | Open        | View        |
| 5       | Case 5    | Adverse Event | Open        | View        |
| 6       | Case 6    | Adverse Event | Open        | View        |
| 7       | Case 7    | Adverse Event | Open        | View        |
| 8       | Case 8    | Adverse Event | Open        | View        |
| 9       | Case 9    | Adverse Event | Open        | View        |
| 10      | Case 10   | Adverse Event | Open        | View        |



LITERATURE  
REVIEW



PSMF  
MANAGER



ViGenIQ™

Dashboard

ICSR

Literature

PSMF

Reports

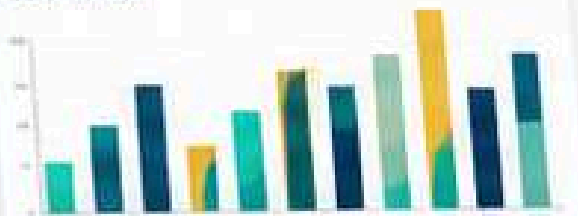
Settings

ICSR  
1,248

Literature  
852

PSMF Documents  
36

Case Trends



Safety Signals



Recent Activities

| Date       | Module | Activity |
|------------|--------|----------|
| 2023-10-27 | ICSR   | Case 1   |
| 2023-10-27 | ICSR   | Case 2   |
| 2023-10-27 | ICSR   | Case 3   |
| 2023-10-27 | ICSR   | Case 4   |
| 2023-10-27 | ICSR   | Case 5   |
| 2023-10-27 | ICSR   | Case 6   |
| 2023-10-27 | ICSR   | Case 7   |
| 2023-10-27 | ICSR   | Case 8   |
| 2023-10-27 | ICSR   | Case 9   |
| 2023-10-27 | ICSR   | Case 10  |

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# MEET THE VISIONARY BEHIND THE EXPERTISE

VIGIVANCE is guided by a multidisciplinary leadership team whose scientific expertise, pharmaceutical industry experience and strategic oversight drive service excellence, regulatory compliance and quality-focused execution.

## **Mr. M. S. Naveed**

*Founder & Chief  
Executive Officer*

A visionary pharmacologist connecting scientific knowledge, regulatory expertise and strategic thinking to build an integrated pharmaceutical services organization.

## **Ms. Sofiya Khan**

*Director – PV &  
Operations*

A pharmaceutical professional with 16 years of experience, driving pharmacovigilance operations through regulatory understanding, operational discipline and quality-focused delivery.

## **Mrs. Rumi. S**

*Quality Lead*

A quality professional strengthening pharmacovigilance quality systems, compliance oversight and inspection readiness through structured, quality-driven processes.



# LET'S MOVE YOUR ORGANIZATION FORWARD.

One trusted destination. Connected capabilities.

Confidence at every step. Whether the requirement is clearly defined or still taking shape, our team is ready to listen, advise and work towards the right solution. The right expertise is closer than you think.

REGULATORY  
PHARMACOVIGILANCE  
GLOBAL MARKETS  
COMPLIANCE

**Your Goals. Our Expertise. A Stronger Way Forward →**

# Get in Touch

WE'RE HERE TO HELP

✉ [info@vigivance.com](mailto:info@vigivance.com)  
🌐 [www.vigivance.com](http://www.vigivance.com)  
in LinkedIn / VIGIVANCE

