QVIS - Quality & Pharmacovigilance Specialists

Company Introduction

Delivering professional quality assurance and pharmacovigilance services to pharmaceutical and biotech companies worldwide since 2014.

About Us

QVIS was established in August 2014 as the first clinical trial quality assurance company in Korea. We provide professional services by staff who hold prestigious qualifications including Registered Quality Assurance Professional, MedDRA Coder, and US Certified Safety Officer certifications.

Our global reach extends beyond Korea to other Asian countries including China, Japan, Taiwan, Thailand, and the Philippines, as well as the U.S. and Europe. From 2020 to 2024, we performed audits for 49.8% of domestic phase III clinical trials approved by the MFDS.

Core Values

Professionalism

Composed of professionals with diverse experience in quality assurance, pharmacovigilance, and project management, we strive to specialize our services through ongoing training and experience sharing.

Reliability

We pursue the reliability of our services by providing professional services based on a sense of responsibility and ethics.

Independence

Independence in quality assurance, pharmacovigilance, and project management through an independent organizational structure.

Scope of Service

Quality Management

Risk-based QM Service

Perform every aspect of quality assurance for clinical trials and pharmacovigilance utilizing risk-based approach techniques with a dedicated Quality Manager.

- GCP and GVP related Training
- Good Clinical Practice & Laboratory Audits
- Good Pharmacovigilance Audits
- Vendor pre-qualification Audits
- SOP Gap Analysis and Development
- CAPA Management

Pharmacovigilance

Providing comprehensive pharmacovigilance services throughout the life cycle of medicinal products:

- Clinical Pharmacovigilance
- Post-Marketing Pharmacovigilance
- PV Writing (DSUR, RMP, PBRER, PSMF
- development)
- KIDS-KARES database analysis
- Product approval renewal support

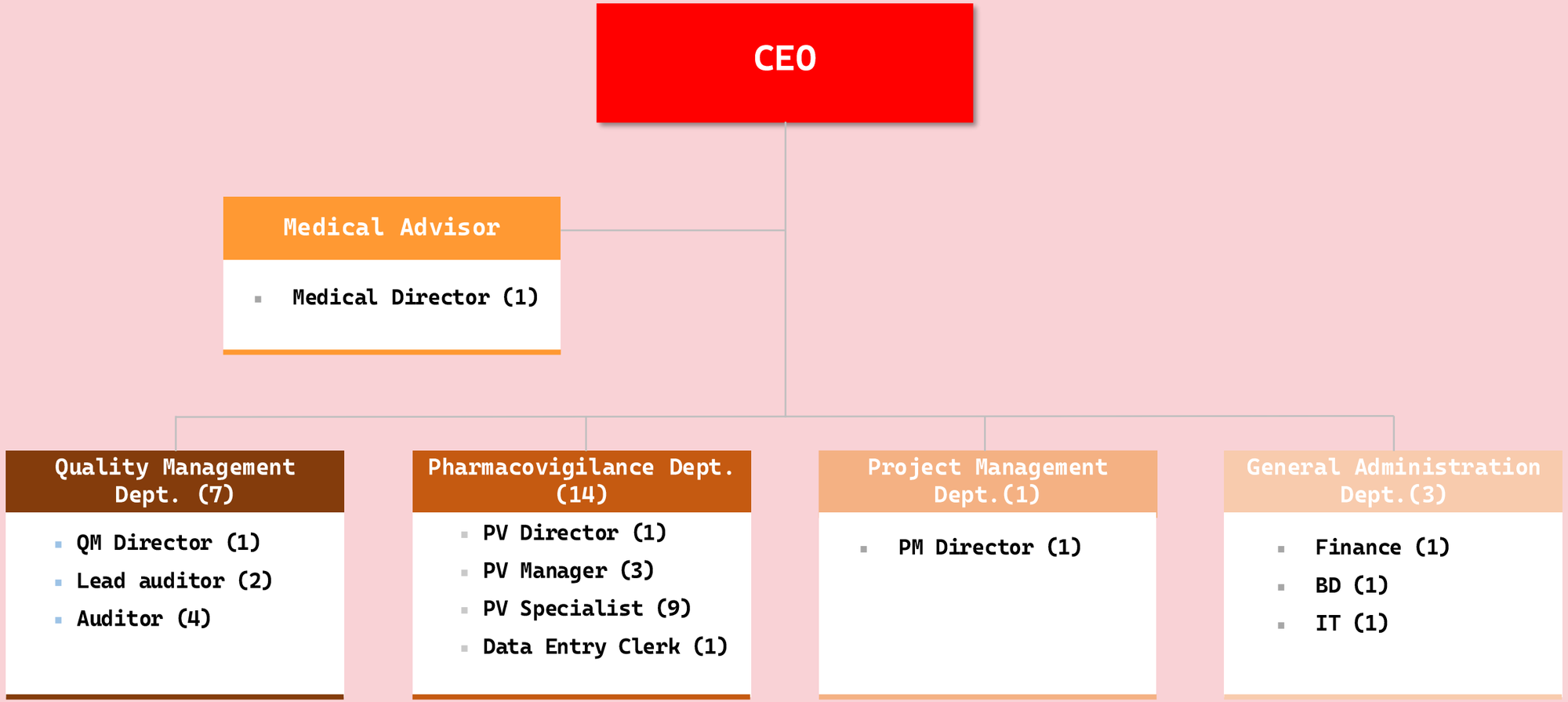
Project Management

Provide dedicated project managers to conduct regulatory mandated active surveillance and long-term follow-up study

Additional Services:

- QM Consultation - Evaluate quality management systems
- Mock Inspection - Risk assessment for inspection readiness
- Inspection hosting and support

Organization Structure



*Effective date: 01-June-2025

Pharmacovigilance Service

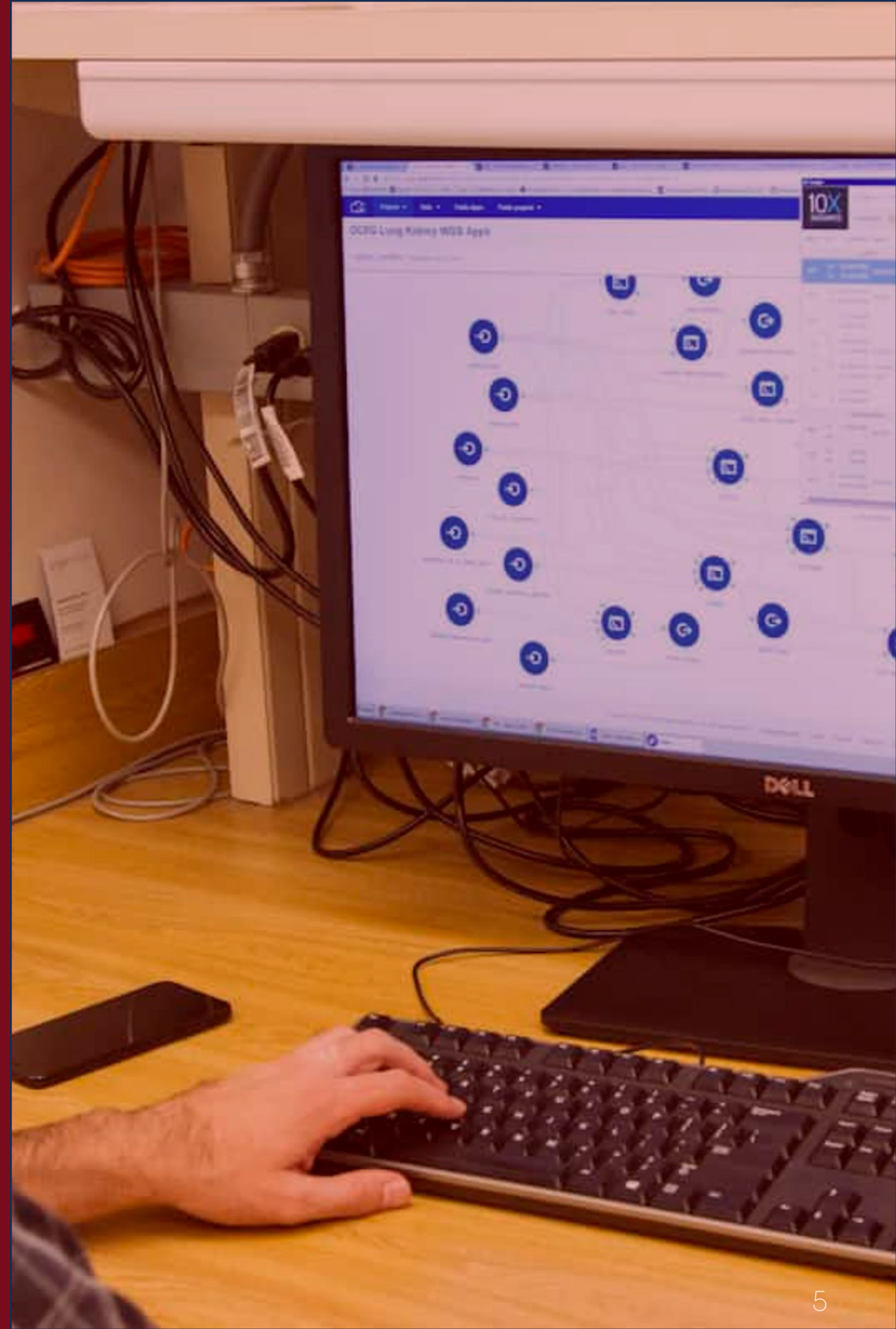
Comprehensive Safety Monitoring Throughout the Product Lifecycle

Pre-Marketing

- Safety Management Plan Development
- AE/SAE case processing
- Safety DB set-up and maintenance
- CIOMS Generation
- Regulatory Reporting
- Medical Writing (DSUR, RMP)

Post-Marketing

- PV SOP Development
- Medical Writing (PSMF, PBRER/PSUR)
- Spontaneous ICSR processing
- Literature Search
- PV Audit
- Safety Report Development for Drug Renewal



PV Staff Qualifications

Our pharmacovigilance team consists of highly qualified professionals with specialized training and extensive industry experience.

Medical Advisor

- Medical Doctor (Surgeon)
- Over 20 years of practitioner experience
- Medical advisor experience for clinical trials
- Experience in Medical Assessment of ICSR

Pharmacovigilance Manager

- Korean QPPV Training
- US Certified Safety Officer
- Minimum 10 years of experience in Pharmacovigilance or Pharmaceutical industry
- Certified MedDRA coder

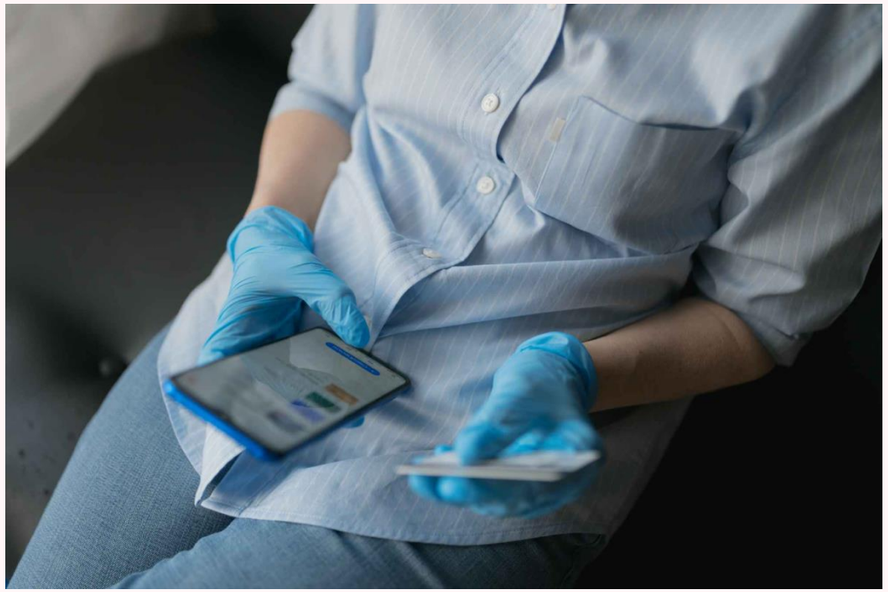
Pharmacovigilance Specialist

- Korean QPPV Training
- Complete 24 hours QVIS Pharmacovigilance Induction Course
- Minimum 1 year of experience in Pharmacovigilance or Pharmaceutical industry
- Certified MedDRA coder
- US Certified Safety Officer

Continuous Professional Development

All QVIS pharmacovigilance staff receive continuous training to maintain cutting-edge knowledge of global regulations and industry best practices.

Pre-Marketing Pharmacovigilance Activities



Our comprehensive pre-marketing pharmacovigilance services ensure patient safety during clinical development phases while maintaining regulatory compliance.

Foundation Setting

Development of PV SOPs and Safety Management Plans

Establishment and management of safety database

Case Management

Complete case processing workflow from intake to closure

Medical assessment of SAEs and medical coding

Reporting & Analysis

Preparation of ICSR Reports (ICH E2B(R3))

Regulatory reporting via Gateway

Signal detection and periodic safety data review

Preparation of periodic safety reports (e.g., DSUR)

Post-Marketing Pharmacovigilance Activities

Once your product reaches the market, QVIS provides comprehensive post-marketing safety surveillance to identify and mitigate risks while maintaining regulatory compliance.

Risk Management

- Preparation and management of Risk Management Plans (RMPs)
- Implementation of risk minimization measures
- Development of Pharmacovigilance System Master Files (PSMF)

ICSR Processing & Reporting

- Efficient case processing and regulatory reporting of Individual Case Safety Reports (ICSRs) from solicited and unsolicited source to meet global regulatory requirements

Periodic Reporting

- Preparation of RMP implementation reports
- Periodic Benefit-Risk Evaluation Reports (PBRER)

We also provide ongoing PV system management, including SOP development, pharmacovigilance training, PV system audits, and Safety Data Exchange Agreements (SDEAs) preparation to ensure comprehensive safety oversight.

Post-Marketing Pharmacovigilance Activities

- **Literature Monitoring**

  Systematic literature search for safety information relevant to your products, including screening, assessment, and incorporation into signal detection activities

- **Partner & Regulatory Support**

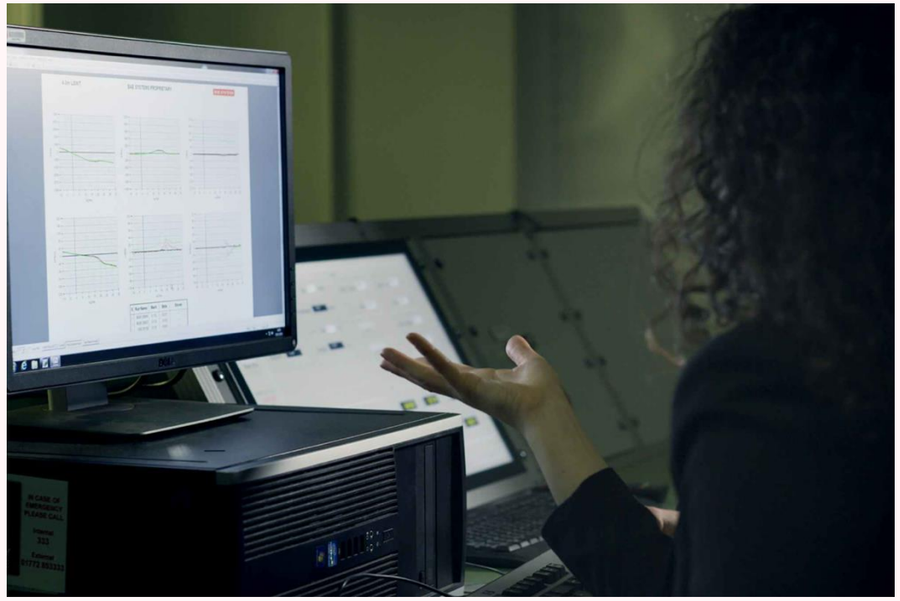
  Support for business partner audits and regulatory inspections, ensuring readiness and compliance with all safety requirements

- **Training & Knowledge Transfer**

  Comprehensive pharmacovigilance training for your team, ensuring knowledge transfer and capability building

- **Product License Renewal**

  Analysis of KIDS database and reporting



Our post-marketing services provide comprehensive safety oversight while ensuring regulatory compliance across all markets where your products are distributed.

Case Processing Timeline

QVIS adheres to strict case processing timelines to ensure regulatory compliance with expedited reporting requirements for Suspected Unexpected Serious Adverse Reactions (SUSARs).

1. **Initial Case Receipt**
   Case intake and initial assessment
2. **Day 3**
   Medical assessment completed
3. **Day 5 (Fatal/Life-threatening)**
   Regulatory authority reporting for fatal/life-threatening SUSARs
4. **Day 7 (Fatal/Life-threatening)**
   Archiving with acknowledgment for fatal/life-threatening SUSARs
5. **Day 9 (Non-fatal)**
   Regulatory authority reporting for non-fatal SUSARs
6. **Day 12 (Non-fatal)**
   Archiving with acknowledgment for non-fatal SUSARs

Sponsor Review: Case QC, Final review of ICSR within 5/8 Calendar day

Roles & Responsibilities in Safety Management

Sponsor

- Maintains overall accountability for trial conduct and regulatory compliance
- Performs final medical evaluation and decision-making
- Ensures timely submission of SUSARs and regulatory reports
- Communicates with Investigator through CRA

Investigator

- Detects and documents AEs/SAEs at site level
- Reports SAEs and special cases to QVIS within 24 hours
- Provides follow-up clinical information and clarifications
- Ensures patient safety through continuous monitoring

PV Specialist (QVIS)

- Receives and processes SAE/AESI from Investigators
- Validates case, enters data into safety database, performs MedDRA coding
- Conducts QC and medical assessment with PV Manager
- Submits SUSARs to Regulatory Authorities within required timeframes
- Notifies Sponsor and Investigators (CIOMS, line-listings)

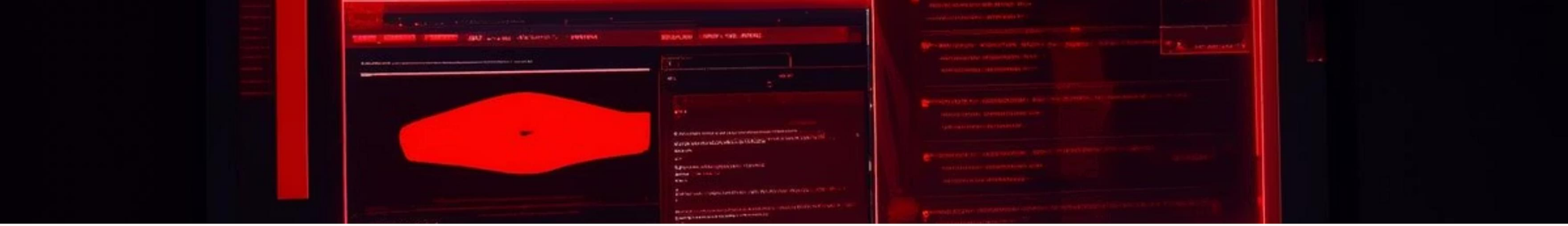
Medical Advisor (QVIS)

- Provides independent medical oversight throughout the trial
- Reviews QVIS assessments for medical accuracy
- Conducts final medical evaluation of causality, seriousness, and expectedness
- Confirms adequacy and completeness of ICSR documentation

CRO (Data Management)

- Provides clinical database outputs for SAE reconciliation processes
- Forwards SAE-related data to QVIS including dates, outcome, severity, causality
- Ensures data consistency between Clinical Database and Safety Database

This interconnected workflow ensures comprehensive safety monitoring throughout the clinical trial, with clear lines of responsibility and communication channels to maintain compliance with ICH-GCP guidelines and regulatory requirements.



FDA ESG NextGen AS2 & EU EudraVigilance Integration: Successful Electronic Reporting Implementation

FDA ESG NextGen AS2 Implementation

- Successfully completed AS2 account setup for direct electronic reporting to FDA
- Prepared digital certificates, completed USP registration
- Configured AS2 profile and validated with test submissions

EU EudraVigilance Gateway Integration

- Connected to EMA's centralized electronic reporting hub
- Supports multiple transmission methods including AS2
- Completed profile registration and public key exchange
- Enabled real-time safety reporting after connection testing

Successful FDA Reporting

Upon successful submission, we now receive Message Delivery Notifications (MDN) and final acknowledgments (ACK) from FDA, confirming successful receipt of safety reports.

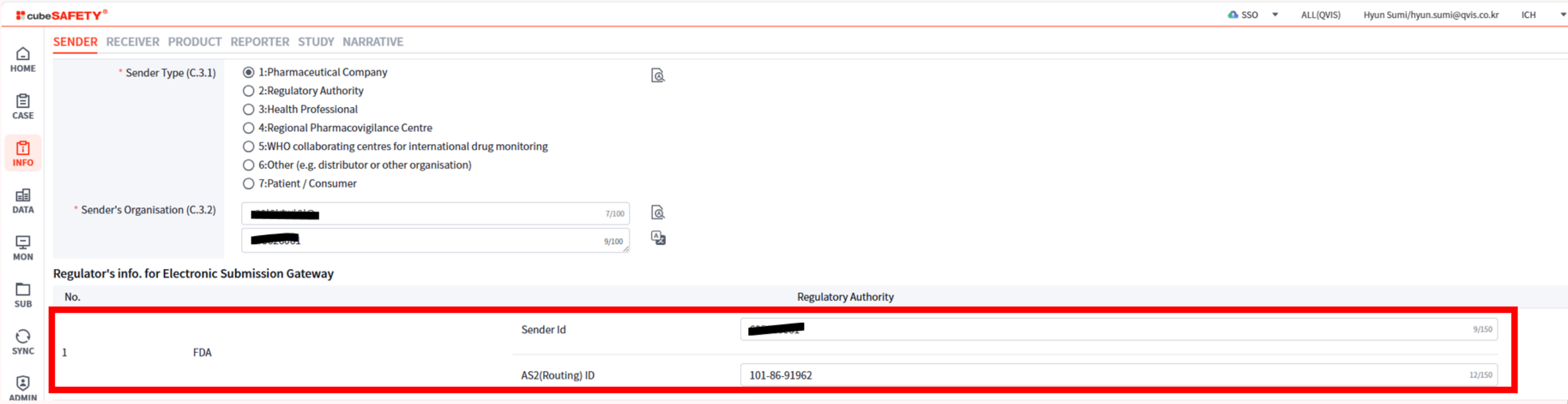
Automated EU Reporting

The EudraVigilance system now automatically exchanges safety reports and confirmation messages, streamlining the entire European reporting process.

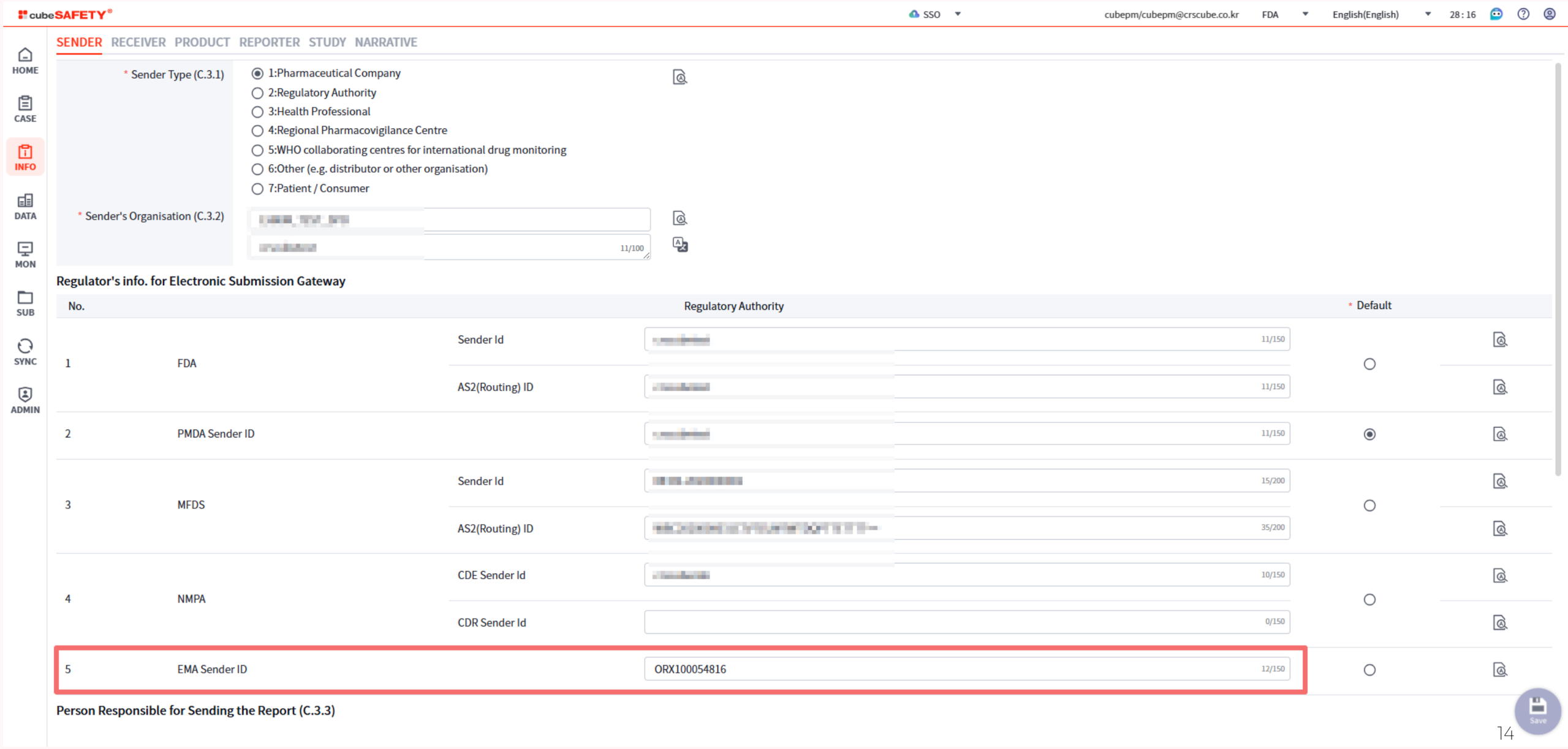
Result: We've established a rapid, secure ICSR submission system for both FDA and EU regulatory authorities, enabling direct reporting through automated channels.

QVIS QUALITY & PHARMACOVIGILANCE SPECIALISTS

SUSAR submission via CubeSAFETY (FDA)



SUSAR submission via CubeSAFETY (EMA)_1



SUSAR submission via CubeSAFETY (EMA)_2

HOME
CASE
INFO

SUBMISSION HISTORY CASE HISTORY

No.	Receiver	Sender	Batch No.(ACK.A.1)	Status	ACK	ICSRs	Comments	Submission Date	Acknowledged Date	Data File
3	EMA(EVCTM)	[redacted]	IO-2025-36845	ACK Accept		1		2025-08-14 10:17:30+09:00	2025-08-14 11:06:22+09:00	
2	EMA(EVCTM)	[redacted]	IO-2025-36761	ACK Accept		1		2025-08-13 17:50:45+09:00	2025-08-13 17:53:04+09:00	
1	EMA(EVCTM)	[redacted]	IO-2025-36182	ACK Accept		2		2025-08-11 11:48:33+09:00	2025-08-11 12:11:18+09:00	

QVIS ICSR Submission Regions

QVIS enables direct ICSR submission capabilities across five key global regions, ensuring efficient pharmacovigilance reporting worldwide:

Korea

China

Japan

Europe

United States

Global Network

QVIS has established strategic partnerships with leading pharmacovigilance organizations worldwide, allowing us to provide seamless global services to our clients.

PrimeVigilance

Global

Insuvia

Global

PhamEng

Asia Pacific

Why QVIS?

Choose QVIS as your trusted partner in pharmaceutical quality management and pharmacovigilance for unmatched expertise and proven performance.

1

Unparalleled Expertise

Team members hold prestigious qualifications including US Registered Quality Assurance Professional and US Certified Safety Officer certifications

2

Regulatory Leadership

MFDS Inspector Trainer (2022-Present) and contributor to 'Standard Clinical Trial SOP Development' (2014)

3

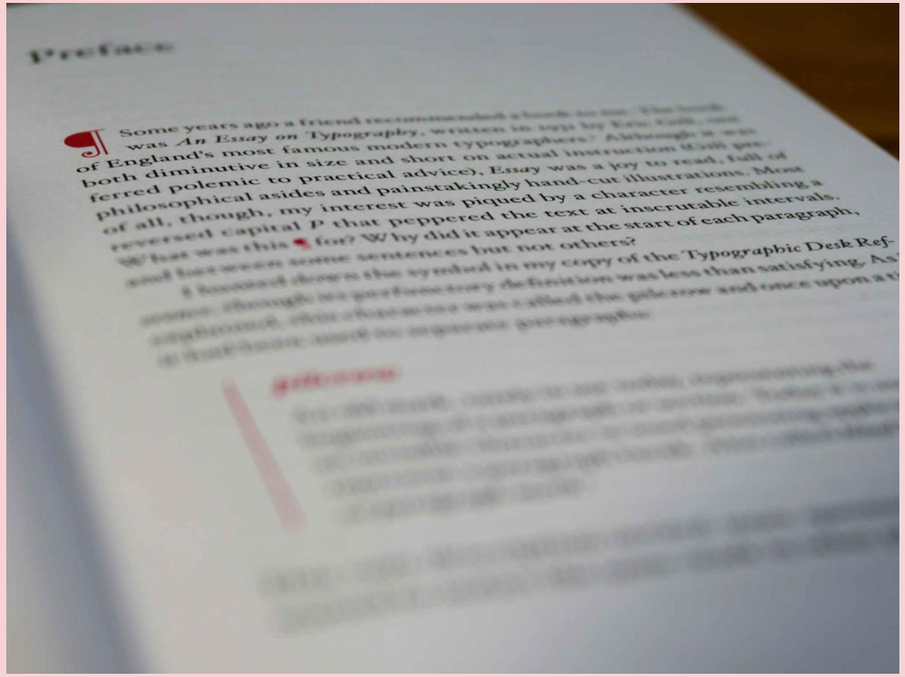
Inspection Excellence

Host for 10+ MFDS GCP inspections annually with exceptional pass rates

4

Government Recognition

Selected by Ministry of Health for ‘Inspection of New health technology assessment' (2015-Present) and Korea Disease Control for ’GCP Inspection and Pharmacovigilance (2024-Present)’



Trusted by 250+ pharmaceutical and biotech companies

Our proven track record of excellence has made us the preferred partner for quality assurance and pharmacovigilance services across the industry.

Contact QVIS

Partner with the Leading Quality Assurance and Pharmacovigilance Specialists

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Contact us today to schedule a consultation and discover how our services can enhance your regulatory compliance and patient safety initiatives.