QACAL
PROFESSIONAL SERVICES

Safety and Pharmacovigilance Services

The **evolving** regulatory environment and the progressive globalization of the industry is causing pharmacovigilance to change.

Smarter collection and reporting of adverse reactions have provided an opportunity to access more, high quality data to create **alternative approaches** within pharmacovigilance.

At QA CAL, we understand that there is no "one-size fits all" implementation of a safety and pharmacovigilance system and offer **'out of the box' and bespoke solutions** tailored to your specific needs.

Supporting Patient Safety Throughout Your Product's Lifecycle

Outsourcing pharmacovigilance services to QA CAL allows you to manage your end-to-end product lifecycle activities with continued assurance of quality and timeliness, allows your internal teams to re-focus on new assets and serves to:

- Provide premier **global safety strategies** for drug and device development
- Elevate **quality, overall economies and productivity** of service delivery
- Furnish a cost-effective, predictable spend through **competitive pricing** while driving financial and operational efficiencies
- Supply you a **trusted partner, take ownership of quality** and does what is needed to achieve the right outcomes
- Actively **streamline services** through simplified oversight and reduced communications noise
- Yield ascendant support of pharmacovigilance programs by **experienced and well-trained teams globally**
- Deliver **value-added, catered solutions** supported with **mature technologies** driven by well-established and tested processes
- Supply top-notch, compliant, data-driven expertise that is **flexible to changing needs**

> **"Quality errors within safety can increase the risk of the product to the patient and have a negative effect on company reputation."**

Safety & Pharmacovigilance

QA CAL offers the following safety and pharmacovigilance services to support Phase I, through product authorization to post-marketing to ensure quality and compliance.

Clinical Trial Safety. Phase I-IV, full processing from data entry to case closure, including aggregate report writing and submissions.

Post-Marketing Safety. Case processing, reporting, signal detection, literature search and review, safety writing (e.g. PBRER, PADER, RMP), EU QPPV, PSMF creation and maintenance, risk management strategy and minimization, local safety support.

Safety Submissions. Dedicated subject matter experts in safety regulatory legislation and submissions with access to a regulatory intelligence database.

Safety Physician. Dedicated/trained physicians in all aspects of the life cycle of safety and pharmacovigilance, including risk-management expertise.

Safety Database. Dedicated support team with in-house Oracle Argus expertise and experience with client safety systems.

Safety Call Center. Provides services for ADR intake, product quality complaint intake, medical information request handling and outbound phone call follow-up.

Full Life Cycle Support

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Case Processing and Submissions

Quality, compliant, data-driven delivery flexible to your changing needs.

Communication and Collaboration

- Clear and transparent communication with our clients on planning
- Routine status update and addressing of any comments and concerns collaboratively

Prioritization and Workflow Management

- Cases prioritized to ensure compliance timelines
- Closely monitored workflow management to ensure productivity and turnaround time

Built-in Flexibility

- Resourcing model flexes during buffer, leave, and holidays to allow for unanticipated spikes
- Cross-trained resource pool within the project and department

Centralized Submissions Structure

- Centralized structure following global processes to ensure compliance
- Submissions tracked in centralized system (PV Hub) for consistency and oversight

Resource Management

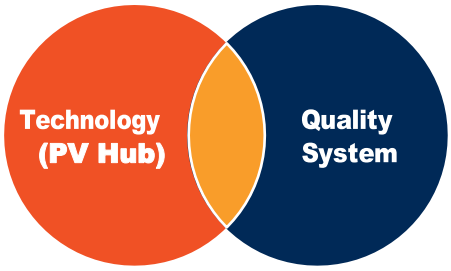
- Clear communications about resourcing planning
- Resource movement within department to address immediate needs
- Long term needs addressed with recruitment

Case Quality

- Robust training, accreditation, mentorship and on the job support programs
- Centralized system to assess case quality at both project and individual employee level

Technology Integration with and our Quality Framework

Technology assists the quality assessment at the departmental, project and individual employee level.



Standard Operating Procedures, work instructions and training are actively updated.

Define

- Do it right the first time
- Clear process flow and quality expectations
- Training requirements

Collect

- Data collection plan
- Quality management plan

Measure

- PV Hub tool
- Retrospective QC
- Team quality
- Individual quality

Analyze

- Trend analysis
- Root cause analysis (RCA)
- Identification of training needs and preparation of action plan

Report

- Regular feedback
- Case presentation
- Focus group
- Review actions

Recognition

- Quality chamion
- Spotlight awards
- Maintain good quality

Literature Search and Review

QA CAL is a core provider of literature services to multiple customers, providing access to first-hand knowledge of best industry standards and practices.

Skilled pool of literature management trained professionals

- **>5 Million literature reviews,** with quality and timeliness KPIs exceeding **99%**
- **~90,000 abstracts** reviewed per month
- **Flexible resource model** to provide dedicated support to low and high volumes

Safety Writing

PBRERs, DSURs, ASRs, PADERs, ACOs, Clinical Overview Safety Updates, CCSI, CCDS, RMP

Safety Surveillance

Benefit-Risk Assessment

- Creates the initial risk class assessment using our template
- Reviews the risk class assessment annually (at minimum) and on ad-hoc basis
- Dedicated physicians and qualified persons

Safety Signal Review Meetings

- Schedules and chairs safety signal review meetings
- Issues identified and related recommendation for actions raised
- Evaluation and endorsement risk assessment

Signal Detection

- Signal detection, triage, validation, prioritization and assessment
- Reviews of adverse events, clinical data, literature, authority databases and websites
- Recommendations of actions and communicates to regulatory authorities

Safety Review Suite

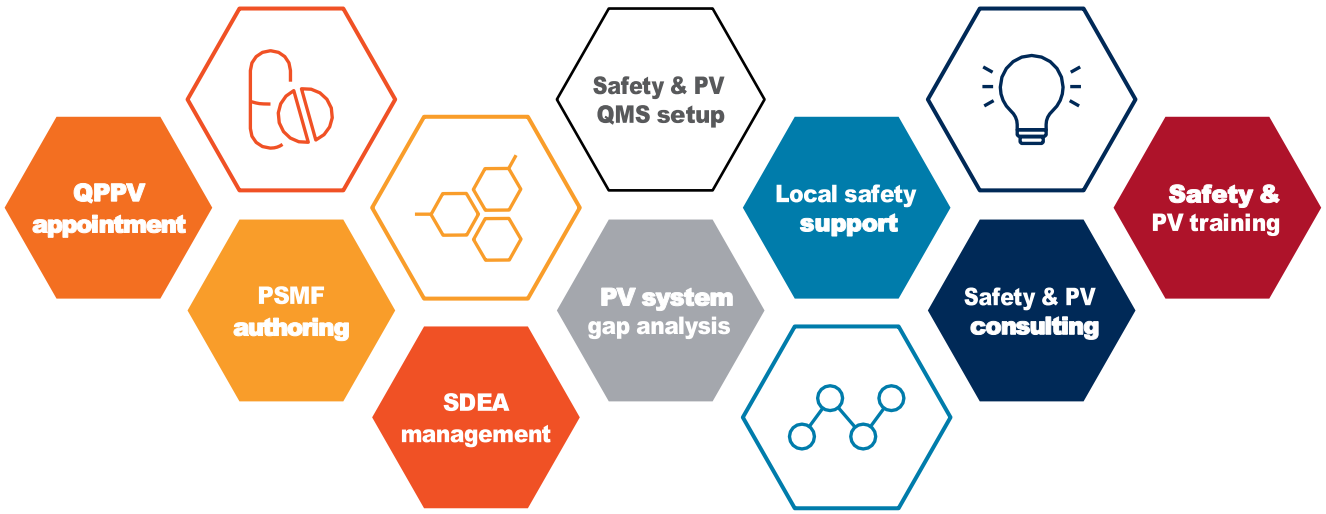
Spotfire-based in-house developed system that aggregates data from multiple sources.

Users access data interactively in customized dashboards.

Qualified Person for Pharmacovigilance (QPPV)

QA CAL, we can provide you a QPPV who possesses a breadth of qualities and deliverables:

- Recruited from our **competent, well-seasoned** staff located in the EU and UK
- Experienced with **acting as QPPV** within various outsourcing models
- Strong **knowledge of EU PV requirements** and capability to build Global PV Quality Management Systems
- **PV system Gap analysis** to help you build or refine your PV System
- **KPIs** and reports to monitor compliance and performance



Strong proficiency in EU and UK for local **PSMFs, SDEAs** writing and negotiation, **RMPs, Inspection Readiness,** Deviation Management and PV Root Cause Analysis.

We can support you with **PV training,** and **CAPA management.**

We work with you to support pharmacovigilance quality projects or act as an extension of your internal pharmacovigilance staff.

Why Choose QA CAL Safety and Pharmacovigilance Services?

Highly qualified safety scientists and skilled healthcare professionals with experience and deep knowledge in pharmacovigilance.

Our culture of openness high communication and flexibility to provide solutions to best fit your needs.

Our ‘PV academy’ ensures our staff are appropriately trained in relevant areas of pharmacovigilance.

Want to learn more?

Please contact our Safety & Pharmacovigilance: qacal.in

About QA CAL

QA CAL is a leading fully integrated biopharmaceutical solutions organization built to accelerate customer success. We translate unique clinical, medical affairs and commercial insights into outcomes to address modern market realities.

Together we share insights, use the latest technologies and apply advanced business practices to speed our customers' delivery of important therapies to patients. We support a diverse, equitable and inclusive culture.

To learn more about how we are **Shortening the distance from lab to life®**, visit qacal.in.

Contact us

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