

Quality & compliance

Qinecsa provide quality and compliance services to support clients in audit and inspection readiness, SOP writing, data privacy adherence, pharmacovigilance training, PSMF maintenance and CAPA management. Our diverse range of clients benefit from an operating model strengthened by a pharmacovigilance quality system that meets the evolving global Regulatory obligations while protecting our clients and their systems.

'All-time' audit readiness

Deep-rooted experience in managing pharmacovigilance inspections and audits in line with both client and Regulatory expectations.

Keep your project 'green'

Robust quality management system helps identify and address gaps within pharmacovigilance processes so that all quality and compliance parameters are in accordance with global Regulatory requirements.

Keep up with evolving Regulatory requirements

Highly experienced Quality and Compliance team that supports clients to proactively adapt to the changing Regulatory landscape.

Service

Qinecsa

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Inspection readiness

Certified auditors, equipped with quality management systems to help plan, execute, and close inspections in line with the requirements of applicable regulations, guidelines, and standards, and ensure our clients are always inspection-ready.

Audit support

Development and implementation of strategies to support a risk-based approach to client audit requirements. Complete range of GxP audits undertaken across geographies with recommended CAPAs & audit certificate.

CAPA management

Established CAPA management process to ensure delivery of the complete life cycle in line with client pharmacovigilance conventions.

Pharmacovigilance training

Integrated, compliant training framework established by our highly qualified team, including development of Standard Operating Procedures & Work Instructions in accordance with PV quality requirements.

Global Regulatory inspection experience



Japan USA EU UK Canada India UAE

Highly experienced global team

Average experience of 12 years in PV audits and inspections

Experience in ISO 9001 and 27001 standards

Experience of conducting audits across the EU, US, Canada, Asia

Find out more qinecsa.com Contact us contact@qinecsa.com