Qinecsa Case Study

Enabling product commercialization

Challenge

A global pharma company needed pharmacovigilance expertise following a European Medicines Agency (EMA) inspection which resulted in several critical findings.

Their portfolio contained clinical products, one of which was on the cusp of commercialization in US, Canada, and Europe.

The company required a robust pharmacovigilance system that is compliant with the requirements of Food and Drug Administration (FDA), EMA and other national health authorities.

Approach

Qinecsa implemented a fully compliant pharmacovigilance framework in line with US, Canadian, and European regulatory requirements.

This included the design, validation and implementation of a new safety database and the migration of a large volume of cases.

The engagement was supported by a strengthened program management and governance infrastructure to ensure adherence to challenging timelines.

Outcome

Client successfully hosted EMA inspection with no critical finding as a direct result of Qinecsa's support.

All milestones met within the required timeframes, despite a challenging transition from the incumbent service provider.

Qinecsa have subsequently implemented a robust knowledge retention process to ensure sustained delivery of high-quality output.

Qinecsa