Qinecsa Case Study

Cost-effective drug safety systems and solutions

Challenge

A small pharma client with limited budget had several clinical compounds in Phase I and II, and one globally approved commercial product.

Multiple stakeholder reviews and incorrect document versions impacted compliance and quality.

Following a regulatory inspection, the client required robust processes for evaluation of single and aggregate data to strengthen stakeholder review and documentation management associated with serious adverse events (SAEs).

Approach

Roles and responsibilities were clearly defined through product specific project plans, focusing on accountabilities per stakeholder.

A streamlined process was introduced to ensure formalized version control for the management of reference safety information.

A QMS was introduced to independently assess the effectiveness of change throughout a three-year period.

Outcome

The validated PV system established to support accurate and timely safety report generation met the requirements of the regulator and the client.

Compliance for both single and aggregate submission of safety data was consistently met in line with client and regulatory expectations.

The client's ambitious development strategy was successfully progressed to commercialization in line with client budget.