



drug safety quality assurance process

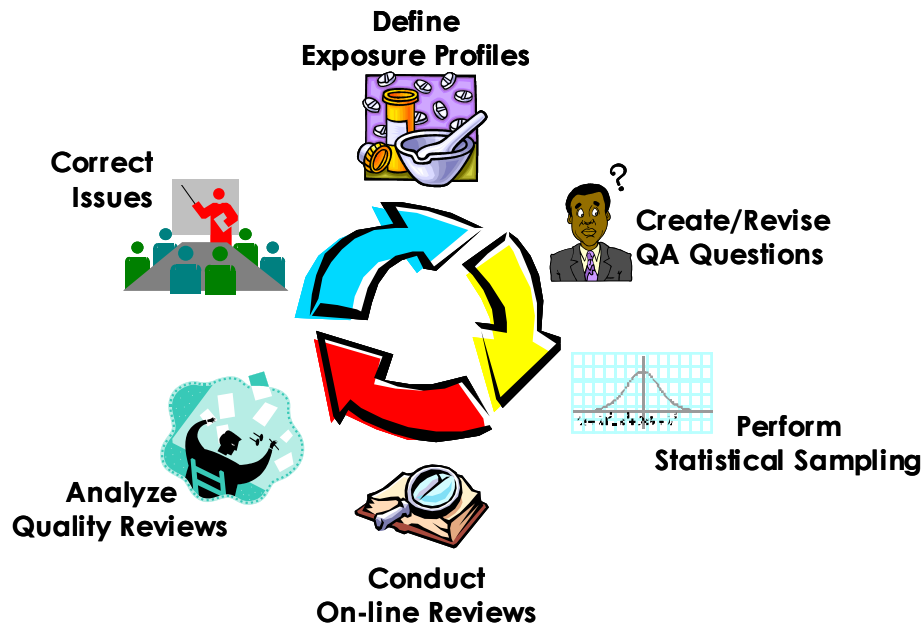
For a large global pharmaceutical company, the Drug Safety division needed a faster and more efficient method to ensure the quality of Adverse Event (AE) information being provided to regulators.

The existing paper-based quality control (QC) process posed numerous business issues:

- Different technologies were being employed in the source and target systems
- The existing QC process was on the critical path for case processing and often was a bottleneck
- QC reviews were high-level in nature due to heavy case loads, which meant many critical variables were not inspected
- Staffing needed to be increased each year to keep pace with the annual growth in AEs
- There was no consistent method to tabulate and then analyze the results of QC reviews
- QC reviews were performed inconsistently across reviewers
- The regulatory group was struggling to resolve data issues missed by the QC group in time to meet regulatory requirements

vision

TCA was engaged by the client to develop and implement a plan to shift the organization from the existing Quality Control process to a new Quality Assurance (QA) process.



TCA developed a new computer system with supporting business processes that leveraged stratified random sampling methods and a



new quality review database to enable fewer AEs to be reviewed and still maintain high quality levels.

Adverse Events were grouped by exposure profile and then statistically sampled for on-line reviews. Exposure profiles accounted for the risk profile of the drug and the seriousness of the Adverse Event. Higher risk profiles were more densely sampled than lower risk profiles. Use of these statistical sampling methods enabled the client to perform quality reviews on a fixed number of cases per exposure profile, per observation period.

Each exposure profile had a unique set of questions to be answered by quality reviewers. Depending upon the answer to a specific question, follow-up questions may be asked. To better ensure consistency across reviewers, question-specific help was also available on-line. The results of each review were stored in a quality review database, which enabled the results to be tabulated and then analyzed.

Continuous process improvement was instituted to perform root cause analysis of issues discovered during QA reviews.

When consistent issues or problems were discovered, corrective action plans were implemented to help prevent the same problems from happening again in the future.

Overall, TCA met and exceeded the client's expectations.

results

Some of the benefits to the client of this project were:

- Headcount associated with quality reviews has been reduced by 50% while AE volume has increased 75%
- The 5-year NPV EVA¹ for this system is over \$10 million
- Cases are now reviewed outside of the case processing workflow, thus reducing overall case processing times and improving compliance
- Quality Assurance reviews are more consistent and in depth than the former paper-based QC reviews
- Metrics now enable executive management to measure the quality of data as well as individual performance
- The tool is generic enough to be used in other departments

value

Consistent and repeatable processes for quality assurance along with applications that decrease the risk associated with processing and managing adverse events.

¹ Net Present Value Economic Value Added accounts for all one-time and on-going costs as well as all quantifiable business benefits over a period. It also incorporates an investment comparison to the same money invested at a fixed rate of return.