

## quality assurance

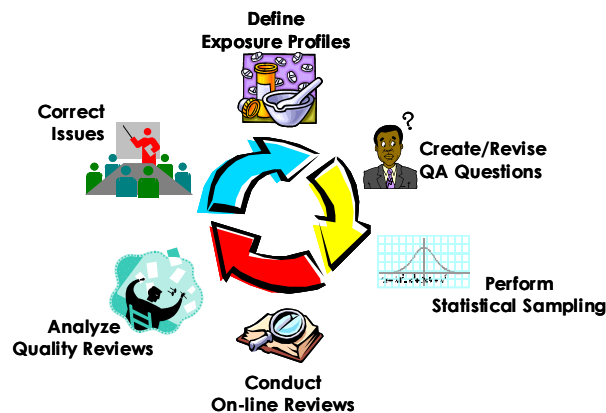
At a large global pharmaceutical company, the Drug Safety division needed a faster and more efficient method to ensure the quality of Adverse Event (AE) information being provided to regulators. The existing paper-based quality control (QC) process posed numerous business issues:

- The existing QC process was on the critical path for case processing and was often 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 method in place to tabulate and then analyze the results of QC reviews
- QC reviews were performed inconsistently across reviewers
- The regulatory reports 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 then 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 and supporting business processes. This system 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 question,

additional follow-up questions may be asked. To better ensure consistency across reviewers, question specific help was made available on-line. The results of each review were stored in a quality review database. This enabled the results to be tabulated and then analyzed.

Continuous process improvement was instituted for 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.

**Project Approach:** TCA worked with the client's business and IT staff to develop a strategy, business case, and phased approach to implementation that fit their needs.

A number of business executives within the client's Drug Safety department were concerned about the validity of using statistical sampling techniques versus the existing method of QC reviewing 100% of all AEs. To address these concerns, TCA worked with statisticians within the client's epidemiology department to develop a valid statistical sampling approach.

Over the next 4 months, TCA gathered requirements, designed the system, defined business processes, and then constructed a pilot version of the new system. In addition, TCA worked with the client's business representatives to provide guidance on the structure of the questions to ask for each quality review.

The system was piloted for 3 months with a small number of users and for two exposure profiles. Feedback from the pilot was used to revise the user interface of the system, to modify the questions, and to refine the new business processes. A second pilot was conducted for an additional 3 months before the system went live with all exposure profiles.

Total duration from inception to the completion of the business pilots and production implementation was under 12 months. TCA was responsible for system development, validation, and end-user training. In addition, TCA defined and documented the new business processes.

## results

TCA produced tangible results quickly and ensured realization of measurable business benefits – a system, business processes, and adoption.

TCA was selected because of our unique blend of industry experience, IT knowledge, and our ability to deliver results quickly. TCA professionals:

- Have extensive experience within Drug Safety
- Have extensive business process modeling experience
- Understand the FDA's 21 CFR Part 11 regulations
- Deliver end-to-end consulting services
- Leave behind and invest their knowledge in your staff

### value

TCA was able to meet, and in some cases exceed, the client's expectations. TCA was able to deliver the solution on time, within scope and on budget. Some of the benefits to the firm of this project were:

- Headcount associated with quality reviews has been reduced by 50% while AE volume has increased 75%
- The 5-year NPV EVA<sup>1</sup> 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 exist, which enables executive management to measure the quality of data and also individual performance
- The tool is generic enough to be used in other departments; sampling rates can be adjusted per type of review; questions can be changed to interrogate any subject matter

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<sup>1</sup> Net Present Value Economic Value Added. Accounts for all one-time and on-going costs, and all quantifiable business benefits over a period. Measures investment comparison to the same money invested at a fixed rate of return.