The Complex Safety Review Project Team Became Productive on time and More than 50% Under the Budget.

Customer and Industry: A leading biopharmaceutical company & the global leader in rare diseases.

Services Provided: Medical review & Signal detection resources.

Company: A global, bio-pharmaceutical specialty company working closely with physicians, pharmacists and other life-sciences professionals, to develop and market drugs that focussed to improve quality of life of patients.

Challenge: Customer believes in expertise rather than experience. With increasing demand for medical company's drug safety review team in North America saw a need for qualified physicians with a specialized degree in medicine (MD) to meet rising demands for Individual Case Summary Reports (ICSRs) and aggregate reports submissions. The major challenges they faced were resource crunch and highly paid human resources.

Value Creation

- Work-load management

- Timely submissions

- This complex safety review project team became productive on time and more than 50 % under the budget.

The management concluded that recruitment of resources would best be achieved by substituting recruitment of in-house permanent resources with external resources from the existing vendors.

Solution: The organization decided to take advantage of available & trained resources in drug safety, medical review and signal detection to achieve optimum efficiency and productivity.

They have approached GPT to provide resources to the project; initially for one year. The drug safety team management believes in expertise rather in experience. The trained & skilled resources with advanced medical degrees were placed at the customer location within two weeks of time.

Our resources were trained and tested according to the industry norms on various in-house projects (simulations/models). GPT immediately expected responsibility for building and managing the safety review team, which consisted of three distinct components:

- Train, build, and nurture
- ICSRs Medical review & Triaging
- Contributions to aggregate reports and Signal detection team

There was a liaison between GPT and the customer facilitating effective communications. The parameters for service level agreement penalty were based on service availability and service quality. Any quality issue or non-compliance will be bringing penalty over GPT.

Results

The resources became productive on schedule and more than 50% under the budget. The biggest achievements form this implementation were quality, low costs and increased productivity.

The initial short-term contract has been extended. This successful project laid the foundation for subsequent contract agreement with customer placing resources at the client's locations in the USA.