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Quality Management in Clinical Trials

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cTQM is a revolutionary approach in Total Quality Management. Implementation of TQM in Clinical Research is a novel process, and is also known as cTQM. In the clinical research domain, cTQM is solely responsible and is focused on customer satisfaction.

In future, cTQM is the way of managing quality in the clinical research, and is far wider in its application than just assuring product or service quality – it is a way of managing people and business processes to ensure complete customer satisfaction at every stage, internally and externally. cTQM, combined with effective leadership, results in an organization doing the right things right, first time.

Total Quality Management

Total Quality Management (TQM) is a business management strategy aimed at embedding awareness of quality in all organizational processes. TQM has been widely used in manufacturing, CROs, education, government, and service industries, as well as NASA space and science programs.

TQM Compared to ISO 9001

ISO 9001 is a Quality System Management Standard. TQM is a philosophy of perpetual improvement. The ISO Quality Standard sets in place a system to deploy policy and verifiable objectives. An ISO implementation is a basis for Total Quality Management implementation. Where there is an ISO system, about 75 percent of the steps are in place for TQM. The requirements for TQM can be considered as an ISO plus. In short, implementing TQM is being proactive—concerning quality—rather than reactive.

cTQM

Implementation of TQM in Clinical Research is a novel process, and is also known as cTQM. Successful implementation of cTQM in various industries and in existence for several years can be expanded to clinical research. Here is an overview and a model on how cTQM can be adapted in clinical research. The cTQM steering committee should be wholly responsible and dedicated to customer satisfaction. The committee will be headed by Country Head Operations/Regional Head Operations. The cTQM will comprise of members from all functional departments (i.e Clinical Operations, Biometrics, Pharmacovigilance, and Drug Safety, Medical Writing, Medical Affairs, Regulatory Affairs, PMO (Project Management Office) and, QAU). The cTQM committee will meet once in a month and will be responsible to improve the quality standards, root cause analysis, and prevention of problems and also conduct of preventive trainings. The cTQM committee will also be responsible for the conduct of staff training on quality management, in order to meet customer needs, intended expectations, and improve quality standards of the company. Head-QAU is responsible for the implementation of changes in association with functional departments.

TQM Role in Clinical Research

The cTQM committee plays a vital role in the success of the Clinical Research department, and can make an impact on other business operations of a company, while meeting client needs and expectations. When queries or issues are raised by clients, sponsors, or investigators with respect to functional services/clinical research services, the process flow will generally be as follows:

Primary analysis of the query is conducted by the respective functional department HODs/Managers. If the query is not solved, the cTQM representative from the respective functional department will escalate the issue to the cTQM steering committee. The cTQM steering committee will then discuss, based upon the complexity of the issue/problem and will arrange a meeting on priority basis to take appropriate decision/corrective measures to resolve the same. The updated information will be communicated to the client, sponsor and/or investigator through Project Manager, while the PM is responsible to collect feedback/comments from the client, sponsors, and/or investigators.

cTQM-Activities

- Defining the process
- Measuring process performance (metrics)
- Reviewing process performance
- Identifying process shortcomings
- Analyzing process problems
- Making a process change
- Measuring the effects of the process change
- Communicating both ways between supervisor and user

Improvement Ideas

A company can establish a program to receive suggestions on process improvement called "Opportunity for improvement". This program will allow a staff member from any level to submit an idea of a process improvement through an e-mail to cTQM help desk. cTQM steering committee will review and discuss on the suggestions given by the staff members in a monthly meeting. Once in a month, appreciation awards or letter of appreciation will be given to the best ideas on.

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