

## On the role of clinical total quality management in clinical research and health care

L. Jakkala\* and M Miraj\*\*

\*MakroCare Clinical Research Limited Makro Towers, Kavuri Hills, Hyderabad-500 033, India

\*\*Director – Operations Inkilab Technologies Private Limited, Hayy Al Wadi, Riyadh 13313, KSA

### ABSTRACT

cTQM known as clinical total quality management is a revolutionary approach in Quality Management. Implementation of cTQM in clinical research is a novel process. 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. Clinical research including trials is an investigation in humans anticipated to decide or confirm the effects of a drug or to identify any adverse reactions with an intention of ascertaining its safety and efficacy. Quality of clinical trials relies on data consistency and subject safety. Quality control and quality assurance are part of quality management. There is an increasing focus on having quality systems in place throughout the planning stages of clinical trials. The regulatory outline for clinical trials has altered in recent years with the addition of thorough controls to guarantee patient protection and data dependability. Clinical research for human health has grown exponentially over the past decade because of cost advantage, treatment naïve patient, qualified doctors conversant in English etc. India has been the second most preferred country to conduct clinical trials outside the US in 2009. However, recent years have witnessed a decline in number of trials in India. The number of drugs entering the Indian markets had been gradually reducing even before the current slump in clinical research activity largely due to quality issues. Thus, the role of quality in clinical research and trials assumes extreme significance, looking to the rapidly developing health care system across the world in future.

### INTRODUCTION

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

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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. There is an increasing focus on having quality systems in place throughout the planning stages of clinical trials. The regulatory outline for clinical trials has altered in recent years with the addition of thorough controls to guarantee patient protection and data dependability.

Clinical research for human health has grown exponentially over the past decade because of cost advantage, treatment naïve patient, qualified doctors conversant in English etc. India has been the second most preferred country to conduct clinical trials outside the US in 2009. However, recent years have witnessed a decline in number of trials in India. The number of drugs entering the Indian markets had been gradually reducing even before the current slump in clinical research activity largely due to quality issues. Thus, the role of quality in clinical research and trials assumes extreme significance, looking to the rapidly developing health care system across the world in future.

In the modern world, TQM has become a part of corporate management on a global scale. Quality is studied under the overall umbrella of TQM. The core philosophy of TQM as it is understood today is that each step in a production or service encompasses the entire organisation from the supplier to the customer, both internal and external to the organisation. Suppliers have to meet customer requirements, both stated and implied, at the lowest cost. Moreover, waste elimination and continuous improvement are ongoing activities (Lakle & Mohanty, 1994; Melan, 1998 and Heizer & Render, 2004).

By adopting a TQM philosophy, managers commit to a continuous company-wide drive towards excellence in all aspects of products and services that are important to the customer (Heizer & Render, 2004). According to James (1996), TQM is essentially about the development of an ideology or philosophy focused on actions designed to satisfy customers completely through continuous improvement. James (1996) thus had identified the principal objectives for an organisation as customer support, customer service and customer satisfaction. Heizer and Render (2004) later on suggested that when TQM is working well, it allows organisations to empower members to make appropriate and reasonable decisions at their level to improve processes or products. It also builds commitment and a sense of belonging. This allows opportunities for upward and downward communication and a free exchange of ideas.

The early development of TQM was influenced by a number of quality 'gurus', or specialists, such as W. Edwards Deming, Joseph M. Juran, Philip B. Crosby, Armand Feigenbaum and Kaoru Ishikawa. These 'gurus'

are the major contributors in the quality discipline. They have similar views on customer satisfaction, leadership, cost reduction, management processes, training and education, teamwork and work culture.

The basic principle of the TQM philosophy for doing any business is to satisfy the customer and the supplier, and to continuously improve business processes (Reed, Lemak & Mero, 2000). Researchers Kruger (2001), Virmani (2002), Scott (2005) and Frederick (2010) reported five key elements of TQM that can be transferred to any business setting. These elements are customer satisfaction, cost reduction, leadership and management, training and education and organisational culture. 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.

Quality assurance is one of the key elements underpinning service quality and customer satisfaction, and can be defined as an effort to change or improve the level of service based upon measures of quality (Krishu, 2011; Camacho & Rubin, 1998; Hall, Epstein, Deciantis, & McNeil, 1993). Furthermore, QA is a systematisation, documentation and assessment of certain evaluation activities, and should be seen as a stimulus that makes business activities as rigorous and pertinent as possible (Varma & El-Kafafi, 2011; Kletz, 2001).



### 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

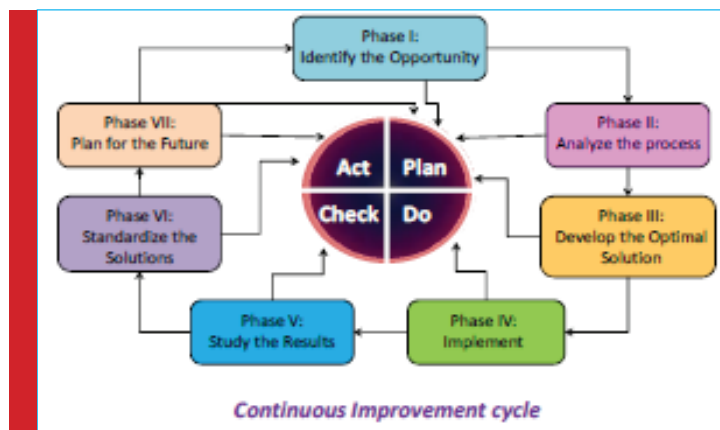
Implementation of TQM in Clinical Research is a novel process, and is also known as cTQM. Successful implementation of cTQM in various industries and in existence for several years, can be expanded to clinical research. Here is an overview and a model on how cTQM can be adapted in clinical research. 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.

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

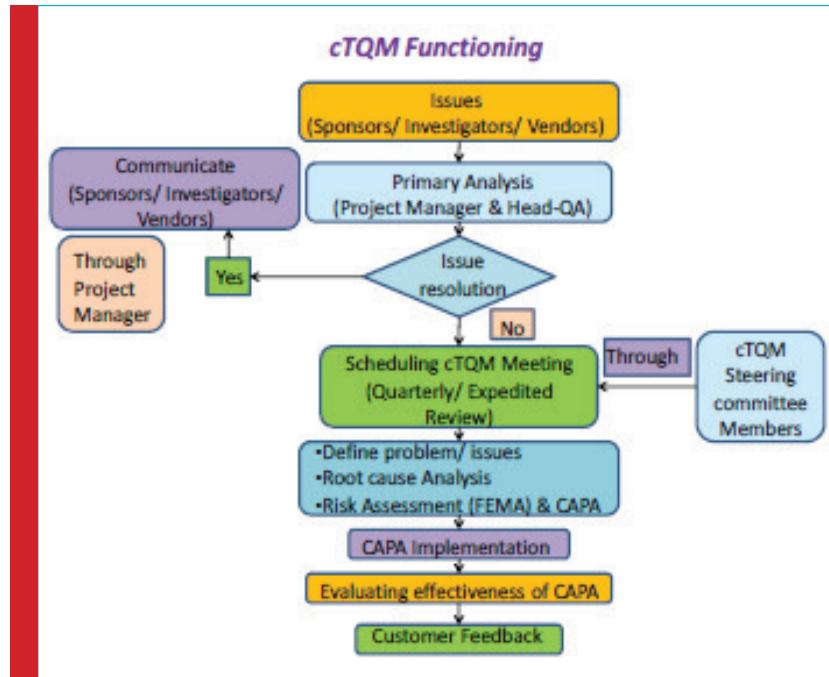


### TQM ROLE IN CLINICAL RESEARCH

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

### 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



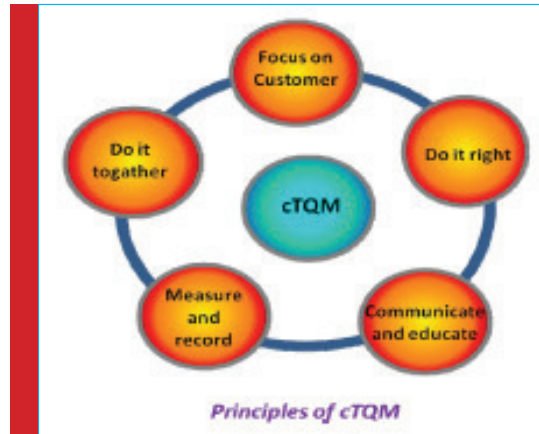
from any level to submit an idea of a process improvement through an e-mail to cTQM help desk. cTQM steering committee will review and discuss on the suggestions given by the staff members in a monthly meeting. Once in a month, appreciation awards or letter of appreciation will be given to the best ideas on improvement. Appreciation is probably one of the most effective ways to encourage perpetual quality.

**CTQM OBJECTIVES**

- Meeting customer requirements/expectations and customer satisfaction
- Reducing cycle times to meet customer timelines and targets
- Providing training and improve performance quality
- Reducing service costs
- Delivering higher quality services

**STEPS TO IMPLEMENT CTQM**

1. Pursuing new strategic thinking
2. Knowing your customers
3. Setting true customer requirements



4. Concentrating on prevention, not correction
5. Pursuing a continuous improvement strategy
6. Using structured methodology for process improvement
7. Reducing variation
8. Using a balanced approach
9. Applying to all functions

## CTQM PROCESS IMPROVEMENT AND PROBLEM SOLVING SEQUENCE

1. Defining the problem
2. Identifying possible causes
3. Evaluating possible causes
4. Making a change
5. Checking and observing the effects\
6. Taking action and embedding the fix into the process for good, taking permanent action

## CONCLUSION

cTQM applied to clinical research can improve quality that will be evident in increased speed and efficiency that ultimately benefits all stakeholders. cTQM efforts will help the organizations to attain integrated results in day-to-day operations. An organization must go beyond “good enough” as we strive for continuous improvement in our performance. This commitment will be used as guide and inspiration for all research organizations when we make “cTQM as way of life”.

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