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## **First phase of road map from ISO to Six Sigma transformations A case of medical equipment industry**

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## **Abstract**

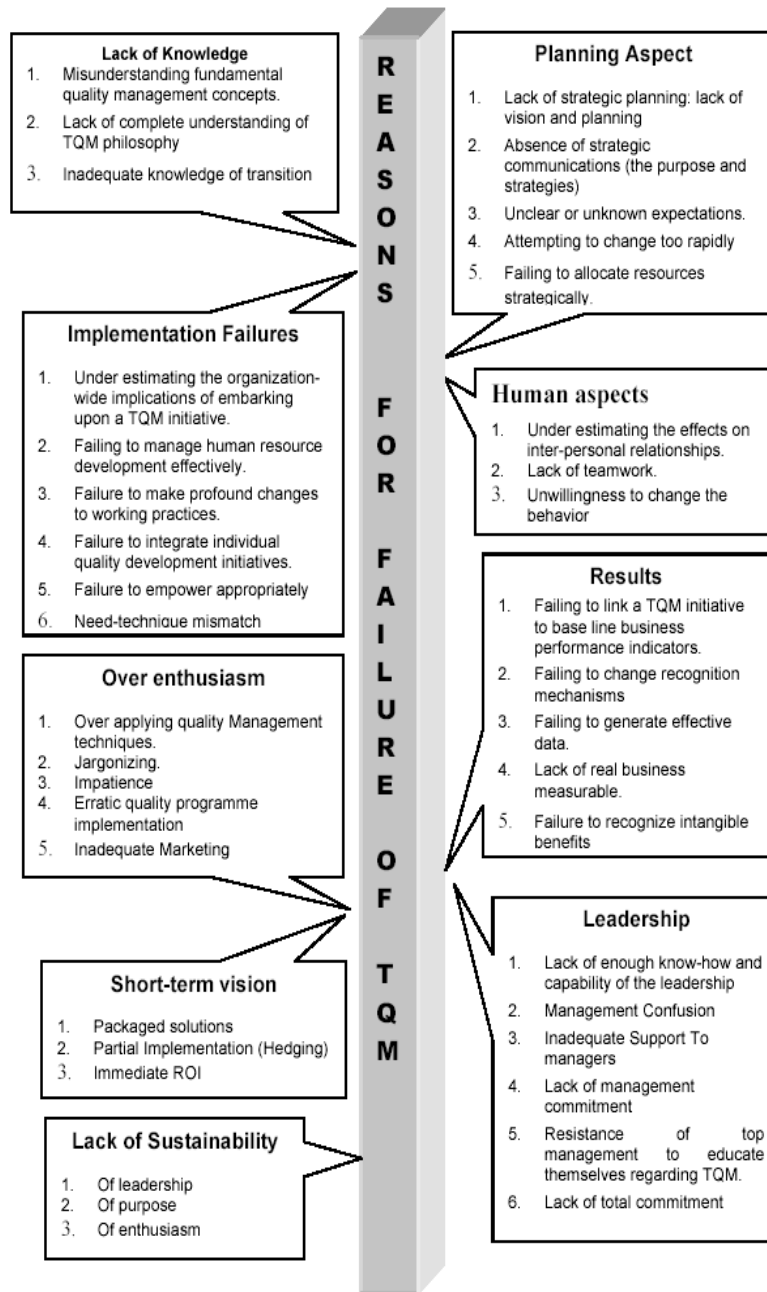
Many companies venture into ISO certification, wish to be TQM company, or wish to apply the recent soft technologies in their system, but very few have been able to capitalize their full potential. This is primarily because of no explicit framework of implementing them. Hence, the purpose of this paper is to devise a robust mechanism for transition of ISO certified company towards six-sigma company and generalize the methodology for the transition viewing it holistically in the context of six-sigma implementation in business organizations. The purpose is envisaged through a case of ISO certified medical equipment industry. The emphasis has been brought out through investment in staff training in these soft technologies in order to promote learning and Continuous improvement.

The findings suggest that the learning process is characterized by measurement, detection and correction of errors, and cost reduction. In six-sigma implementation, learning is a single-loop type of learning. It is an incremental change process, which reminds a technical variant of the learning organization. Continuous improvement occurs through procedural practices (the DMAIC-cycle) which forms a structure for sustaining learning. The paper emphasizes a gradual evolution, which gets effectively integrated in the system for its sustained effect. Making the employees have faith in the soft technologies is feasible only when the system becomes a learning organization or an entity, it should become the prime objective to avoid all the soft technologies ending up as fad. The paper discusses only the inception phase of road map of transition from ISO to Six sigma.

**Keywords:** Six sigma, Learning organizations, Continuous improvement.

**1.0 Introduction-** Six sigma is a powerful business strategy that employs a

disciplined approach to tackle process variability using the application of statistical and non-statistical tools and techniques in a rigorous manner. Six Sigma has been well recognized as an imperative for achieving and sustaining operational and service excellence. While the original focus of six sigma was on manufacturing, today it has been widely accepted in both service and transactional processes. Six sigma has made a huge impact on industry and yet the academic community lags behind in its understanding of this powerful strategy. It will therefore be incumbent on academic fraternity to provide well-grounded theories to explain the phenomena of six sigma.



**Fig.1 various reasons for failure of TQM**

TQM & six sigma work in the service and production industry helping to increase motivation, leadership, and creativity. These are factors that are vital for the productivity, efficiency, profitability and quality of work in organizations. It is important to realize that not all quality improvement techniques will lead to improved quality, since every organization has to face different pressures and obstacles from different stakeholders and environment. However, TQM & Six sigma cannot be accomplished overnight.

Six-sigma methodology utilises the tools and techniques for fixing problems in business processes in a sequential and disciplined fashion. Each tool and technique within the six-sigma methodology has a role to play and when, where, why and how these tools or techniques should be applied is the difference between success and failure of a six-sigma project.

Taking a cue from the series of TQM debacles for more than a decade, it is necessary to take cautious but a sustainable route towards effective implementation six sigma, so that it does not fall the same line of TQM as another fad. This is of prime importance, as employees shouldn't lose faith on these soft paradigms. Most quality improvement initiatives have been a failure in the past and six sigma is no exception to it. Therefore, it is essential to know some of the important reasons for TQM debacle as compiled in the Figure.1 (Bhushi, 2003), this should facilitate in robust introduction of soft technologies so that they are launched on a firm footing.

From the above figure one can feasibly get over if the organizational learning is initiated to overcome most of the causes spelt out in the diagram. Having understood the lacunae of effective TQM implementation, it is essential to nurture an effective methodology of integration through Learning organization.

## **2.0 Organizational learning, continuous improvement, and six sigma: Defining and examining the main concepts**

**2.1 Organizational learning:** During the last 40 years, that the concept of organizational learning (OL) has existed, a number of approaches and definitions have been produced. In this paper, Huber's (1991) definition is applied as follows: an entity learns through the processing of information, potential behaviour changes and acquiring knowledge that it recognizes as potentially useful to the organization.

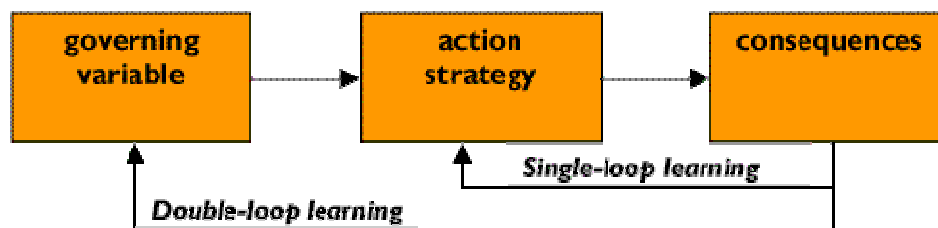
Three main views in OL can be identified according to Easterby-Smith and Araujo (1999) the technical, social and cycle views. The effective processing, interpretation of and response to information inside and outside the organization characterize the technical view. Argyris and Schön (1978) make distinction between two types of learning – single-loop learning and double-loop learning. The former, which reminds the type of learning the six-sigma approach represents, is the detection and correction of errors within a given set of governing variables. Double-loop learning involves changing those variables.

The social view focuses on how people make sense of their experiences at work. Organizational learning is seen as a political process, which is not recognized as important in the technical view. The social view involves also cultural aspects. As the processual change approach has gained ground since the 1980s, the social view in organizational learning has, in turn, emerged and spread more widely in the late

1990s. Moreover, individual vs. Organizational learning is one of the main topics of the discussion and research in the field.

An important issue is what form and type of change are associated with learning. Single-loop learning is linked to incremental change, where an organization applies new methods, and finds new ways of action and attempts to get feedback on their consequences in order to be able to make adjustments and adaptations. Double-loop learning is linked to radical change involving major (strategic) changes (Easterby-Smith and Araujo, 1999). Discussion about the learning organization as a whole “entity” is also characterized by the technical and social variants. Cyclical models have been developed as well. The technical orientation examines interventions based on measurement and learning curves. The social orientation focuses on the human side, i.e. the ability of individuals to learn from their experiences, from or with each other in work settings. A number of linear (stage based), hierarchical progress models, and cycle models of the learning organization have been developed. Kolb’s (1984) experiential learning cycle has formed an inspiration for many of the models. Learning is seen as a continuous process. It goes through several stages involving generation of information, the interpretation of information, and development of actions on the basis of interpretations, and iteration between individual and organizational learning.

It is during this phase of single loop learning confidence of employees is garnered and they start appreciating the soft technology, its purpose and also perceive some effects in day to day chore work and is feasible when they are aware of why is change needed, how it is helping them and the organization. Once the faith is restored, it is the double loop learning will facilitate from the strategic intent, initiating in the perspective that fosters higher return. So an apt linkage needs to be established between the two loops, giving suitable gestation period for the concepts to be ingrained in the culture or blood of an employee.



**Fig.2 Single loop & Double loop Learning**

**2.2 Six sigma:** The six-sigma methodology is a structured tool with techniques of quality management, and it can achieve strategic business results through its applications on a project basis (Wang et al., 2004). The process improvement methodology was first developed in the 1980s in Motorola (Breyfogle, 1999). A number of books and articles provide the basic concepts of six sigma (see, for example, Harry and Schroeder, 2000; Hahn et al., 2000). Recently, six sigma has been applied in wider areas of organization, such as human resource management (Wyper and Harrison, 2000). Six sigma is a process improvement methodology that aims to increase business performance through a solid and accurate business focus (Haikonen et al., 2004). It is a systematic approach to achieving continuous process

improvements. More specifically, six sigma focuses on eliminating variation by detecting and reducing the sources of variation. Six sigma's target is to achieve less than 3.4 defects or errors per million opportunities – hence the name. The higher the sigma, the more consistent the process output or the smaller the variation.

Successive and simultaneous improvement projects are selected based on the impact on the bottom-line business performance. The major purpose of the method is to search for opportunities for improvement that have the maximum effect on the bottom-line compared to the net-expenses of the project. Six sigma links customer requirements and process improvements with financial results.

The six-sigma methodology incorporates five stages of implementation in process improvement. The stages are called the DMAIC-cycle of define-measure-analyze-improve-control. These steps guide the improvement process and help detect root causes of the failures in a single improvement project. It is possible to concentrate on the process failures causing most of the variation and, thus, have the greatest impact on the existence of output failures. Craig (1993) presents the key steps in six sigma as follows:

- (1) Defining product characteristics that affect customer satisfaction.
- (2) Using a failure mode and effect analysis to identify and control parameters to meet customer specifications.
- (3) Employing a reproducibility and repeatability study to measure the control parameters.
- (4) Estimating the process capability of the prototypes and thereby being able to correct individual defects immediately.
- (5) Developing the quality control plan and training material.

The idea of continuous improvement and learning are involved in the implementation of six sigma projects through the DMAIC-cycle. The cycle includes basically searching for improvement opportunities, which requires commitment to learning. The increasing need for performance improvement tends to invalidate existing answers in an organization and requires continuous learning (Dixon, 1994). Knowledge is attained through learning; learning generates improvements that can lead to learning and again to further improvements. Organizational learning occurs on a continuous basis. It functions as a dynamic mechanism for improvements. And the organization's capabilities to learn more quickly are likely to enhance and sustain competitiveness. Continuous improvement. Continuous improvement (CI) is defined as "an organization-wide process of focused and sustained incremental innovation"(Bessant et al., 1994). According to Bessant and Francis (1999), organizational capability of CI provides dynamic mechanisms for involving the organization in learning processes.

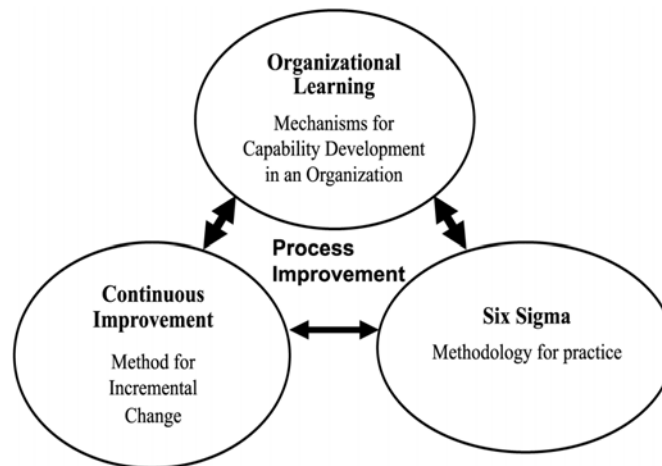
The six-sigma methodology is linked to continuous improvement, due to the systematic selection and continuing implementation of improvement projects. Zinkgraf and Snee (1999) present the following key elements in the selection of six sigma projects. First, project selection starts with the clarification of the "Big Picture" using strategic plans and an annual business operations plan. Second, the plant's productivity baseline needs to be established. Third, the projects need to be prioritized based on customer value, resources required, and schedule. Finally, key projects with leadership support need to be selected. This includes also the checking

of accountability. Traditionally process measurements have been made to support financial systems and identify customer needs. The six-sigma methodology differs in that it emphasizes the need for measurements that are focused on process improvements. Thus, new measurement systems with associated data collection, analysis, and reporting are needed. The systems need to be linked and integrated at different strategic, managerial, and operational levels in the organization to ensure fact-based decision making in the improvement process.

There are several different managerial and operational roles in the six sigma methodology and its implementation; Executives, Champions, Master Black Belts, Black Belts and Green Belts. Executives are representatives of the senior management who are in charge of the company's overall strategy. They are usually trained one-to-two days to give an overview about the philosophy.

Champions are vice presidents, superintendents, directors and group managers, who are expected to take a five-day training session about the philosophy and methodology. The champions are leaders who are responsible for leading six sigma projects, i.e. selecting appropriate projects, resourcing them and taking responsibility for other details related in the improvement project management. Black Belts are team leaders who are responsible for measuring, analyzing, improving and controlling key processes that have influence on customer satisfaction and/or productivity growth. A Black Belt is a person who has the potential to have a synergistic expertise between their work areas and the six sigma methods and tools. They are supposed participate in extensive four-week education on the methodology. The Black Belts are usually working full-time within six sigma. Master Black Belts are teachers who also review and mentor Black Belts. Selection criteria for Master Black Belts are quantitative skills and the ability to teach and mentor. They take additional one-week training session after working a few years as a Black Belt. Green Belts are six sigma team members who are trained approximately two weeks to understand the philosophy and the use of basic quality tools (Haikonen et al., 2004).

### 3.0 Linking the main concepts



**Figure 3. Integrating the frameworks of the main concepts**

### **3.1 Case study:**

This paper attempts to suggest a methodology for transition from ISO 9001-2000 certification to six sigma implementation in a surgical instruments manufacturing industry named “Adler Mediequip Pvt. Ltd., Muradpur, Devrukh”, by integrating the frameworks of three main concepts of organizational learning, continuous improvement & six sigma.

Finally, the main concepts discussed above are linked in a framework (Figure 3). Several links can be found between learning, CI, and six sigma. In the context of six sigma, continuous improvement is based on learning. Procedures and practices are mentioned above that facilitate the achievements of major process improvements, and of financial gains. As is prescribed in the six-sigma philosophy, it involves structures that enable basic problem finding and solving. Mechanisms that facilitate learning include an idea management system, extensive training, and reward and recognition system. Practices of continuous improvement focus on strategy and strategy deployment with a bottom-up systematic monitoring and measurement system. These practices are prescribed to be important in the six-sigma approach. In the implementation of six sigma, continuous improvement and learning are linked through the DMAIC-cycle. The cycle is closely linked to the Deming’s PDCA cycle (see, for example, Deming, 1986) showing a structure for dynamic continuous improvement process through learning.

As a part of this, training programmes have been conducted on various soft technology applications like Kaizen, Poka Yoke, Lean Manufacturing, TQM, Quality cost and like for all the staff separately for managerial cadre and one for the working class in their language, which has boosted their affinity for the tools and they have been asked to find areas of these application in their work area with in the given explicit time framework, which has resulted in enhanced thought processes, interaction at all levels, asked them to quantify their value addition. They have been given monthly targets in their area. In essence Management by Objectives has been applied and involvement in the work area is enhanced.

The fundamental purpose of the six-sigma methodology aims to support the growth and profitability of business enterprises. Continuous improvement of process performance require effective implementation of systematic quality methods, such as six sigma. Effective use of quality methods requires appropriate organizational learning strategies (see, for example, Hyland et al., 2000; Gieskes and Ten Broeke, 2000; Mitki et al., 1997). In summary, the “integrating” framework in Figure 3 incorporates several learning mechanisms and CI practices illustrating the dynamics between the two, and their links to six-sigma implementation, for which DMAIC methodology is followed as explained below.

### **3.2 The DMAIC Methodology**

#### **Phase I: Define**

During this phase, the training is given on various techniques to facilitate team members on how to select project of biggest priority, define the problem, make the charter, select the team, calculate financial benefits etc.

After the training, project is selected and detailed charter is made.

## **Phase II: Measure**

Training on the Measure phase is given to each team member. After the completion of the project, the team members are able to collect data related to their projects, carry out measurement system analysis and determine the current sigma level of the process. The reviews of Measure phase is done and support to each team is given as required.

From this phase onwards, the participants are getting exposure of statistics and use of software like MINITAB along with fundamental understanding of various statistical tools and techniques.

## **Phase III: Analyze**

After completion of Measure phase, training is given on various tools and techniques used for analyzing the problem. Special focus is given on tools and techniques specific to the projects in the organization.

After the training, data analysis for each project is done. The required support to all the team is given to analyze the data and deriving the statistical solution of their problems.

## **Phase IV & V: Improve & Control**

Training is given on Improve and Control phase. The participants after training are able to derive the practical solution from the statistical solution, validate the solution and would be able to implement the controls needed to sustain the improved performance of process.

The support is given to each team for deriving the solution and implement right controls for their processes.

## **4.0 Results & Conclusion:**

Six-sigma implementation seems to reveal mainly technical, single-loop type of learning. It is a problem-based learning process, an incremental change process starting with problem finding and proceeding to producing solutions. The analytical and step-based implementation methodology of six sigma involves structures and procedures that support continuous improvement. Support is shown, for example, the identification of major reasons in the beginning of the process improvement. This can be seen as a built-in type mechanism for single-loop learning at the operational level, which facilitates continuous improvement practices. Since the training was initiated taking employees into confidence and also the purpose was clearly made explicit the employees have been actively involved in the learning process.

### **4.1 Managerial implications:**

Finally, the findings imply that managerial commitment is the foundation for improving continuously and creating sustaining learning. Top management needs to define, promote, and launch the six-sigma philosophy in the entire organization. The investments in executive training should be made on a continuing basis to overcome crucial barriers. Creating the six-sigma council is also recommended. Organizing and resource allocation are some of the key managerial responsibilities. Management should invest in, and allocate resources to staff training in order to promote learning and CI. On the level of operational leadership, the role of the leaders needs to be more

clearly defined and leaders should be empowered. The development of information systems is initially a managerial responsibility. As the ultimate goal is the best possible utilization of existing information in monitoring and decision-making, the development of information systems is a necessity for supporting CI structures and for progressive learning. The organization may enhance learning and support to continuous improvement by organizing a forum for knowledge dissemination where successes and failures are shared. Dissemination is seen as essential by many researchers of learning (Kolb et al., 1984, Senge, 1990, Garvin, 1993, Dixon, 1994, among others). Sharing of knowledge would lead the organization towards collective, social learning and a more advanced level of development activities.

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