

AN AUTOMATED SYSTEM FOR QUALITY MANAGEMENT IN THE DISCRETE MANUFACTURING OF MEDICAL DEVICES

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Abstract: The purpose of this report the research of modern management approaches dedicated and presented a summary of the characteristics of Bulgarian companies, the opportunities and competitive advantages Total Quality Management application.

Keywords : Total Quality Management, Konkurrenzfähigkeit.

I. INTRODUCTION

The current situation of companies is characterized by intense competition and changing markets. Symptomatic are high pricing pressure, shorter product life cycles, as well as the changing client requirements. For Companies, it is necessary to respond quickly and adapt to the market requirements continuously. For this reason, are the key competitive factors time, cost and quality more and more for the companies uniqueness. [6] The term "quality" has changed considerably in its historical development. Stages of modern quality management case extend substantially from the quality control in the early 20th Century, through quality assurance systems in the 60s and the ISO 9000 standards in the 80s up to the total quality management and the award of the European Quality Award (EQA) since 1992. This new understanding of quality - summarized under the concept of Total Quality Management (TQM) - requires a high organizational commitment of all stakeholders in the company [4,5,6,11].

Besides the traditional quality management systems occur on the one hand more thematic management systems, on the other hand is also a trend towards integrated management systems determined. The ISO 9001 standard was originally operationally oriented detection and documentation tool designed [11]. Modern management systems on the other hand see themselves as controlling and management tools in one, which should primarily support the learning and development capacity of enterprises. The purpose of this report the research of modern management approaches is dedicated, as well as a summary of the characteristics of Bulgarian companies, the opportunities and competitive advantages of Total Quality Management application darzustellen. Eine study on the application of TQM in SMEs was conducted within the research project at the University of Sofia. this paper provides a survey to

II. SCHEDULE

TQM describes a quality concept that goes far beyond an ISO certification and includes products, services and processes, including the interests of all relevant stake holder of the company. This means that in addition to the applicable meeting customer needs and the wishes and opinions of employees and society continuously and are to be taken into account [10]. We should also make the influence of the company on its social environment and thus its image to realize an important marketing factor.

New unlike traditional starting points, it is also recognized that TQM to business success as a quality component and those in the EFQM model even out pretty strong.

The EFQM Model for Business Excellence is a business model that enables a holistic view of organizations. It was developed in Europe in response to the highly valued in the U.S. Malcolm Baldrige National Quality Award and the Japanese Deming Prize by the EFQM. [13] It provides organizations with guidance for the establishment and ongoing development of comprehensive management systems. The companies use it as a tool to determine on the basis of self-reviews strengths and areas for improvement, to stimulate and improve their business. This was in 1992 published by the European Commission together with the European Organisation for Quality (EOQ) and the EFQM and is now

considered the highest European award for outstanding quality management.

Here, the EFQM Excellence Model includes not only traditional quality categories (such as processes or customers), but extends it by strategic components (Policy & Strategy) or "soft" criteria (such as leadership, employee or Company).

The mission of the EFQM

- Europe-Helping organizations to improve measures that ultimately have a positive impact on the company and their social environment and the
- Providing advice to managers of European organizations in the implementation of Total Quality Management (TQM) as a decisive factor for achieving global competitive advantage [6,10], Fig.1.

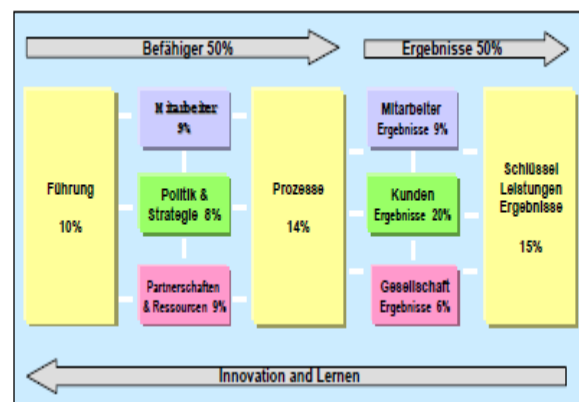


Fig.1 EFQM Excellence Model as a way to TQM

While previously external utility aspects (certificate, secure delivery) were the focus of interest, in addition to winning these beneficial aspects, internal reasons (employee motivation, innovation, etc) important. The aim was to develop a European path for outstanding quality management, which is based on the specific cross-cultural Context. The performance of the original ISO 9000 consisted essentially in the fact that they enabled companies, defined by a systematic approach documented requirements for products and services to erreichen. Nachfolgende approaches such as the ISO 14001 went a step further. For instance, the EFQM model not only outcome measures such as compliance with minimum standards, but the process to achieve top performance and comparisons with other companies (benchmarking) in the foreground. The areas of innovation and learning obtained herein greater importance than in the subject-specific management systems. And models such as the EFQM approach is not certifiable.

The model supports the internal dynamics, which results in its implementation. The trend is also clear from the conformance testing to comprehensive management systems.

Study on the application of TQM in SMEs.

A study on the application of TQM in SMEs was conducted within the research project at the University of Sofia. It's strengths and weaknesses of the management and in particular the system of quality management were identified, Figure 2

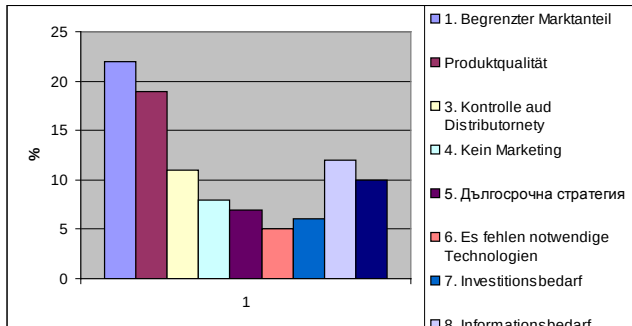


Fig.. 2. Evaluation of competitive advantage

The study also shows that more than 40% of the quality managers have no knowledge of EFQM and claim only 13.7% can be to have more than a superficial knowledge. [13] In practice this very important area, is the satisfaction survey among customers and employees. More than half of the companies studied to analyze or to the satisfaction of its customers nor the motivation of their employees. The positive effects of a successful and comprehensive TQM implementation are numerous:

- motivated employees who take care of the customers and use their creativity to the further development of products and services, the entire company
- satisfied customers who are loyal to the company and are willing to accept moderately higher cost than the competition,
- a positive image of the company, which helps in the long term, to attract new customers and qualified employees and higher corporate profits.

The financial benefit of TQM is questioned again and again. Make the efficiency of the integrated approach and the associated efforts in question. Thus just the key element of TQM is misunderstood, which distinguishes it from all of their business-models. Even if some measures are not directly and in the short term can be attributed to economic benefits, yet the entire corporate culture and the mentality of the workforce is based in the interests of the company and enables entirely new not in a simple cost-benefit analysis accessible effects. If we take a look at the business practices, the individual management systems are very different manifestations Implemented. Information about the new management approaches that companies get in technological exhibitions, at the buyers, consultants and business partners, and 5 percent other, see Fig 3.

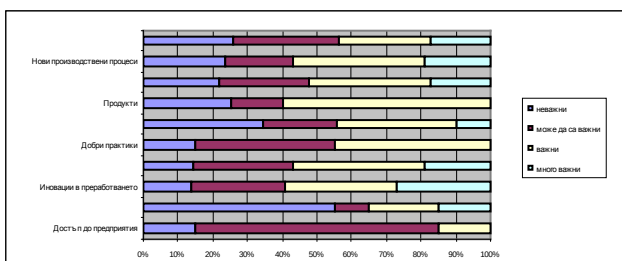


Fig. 3: Respondents' answers to the importance of information in technology, innovation and introduction of new and modern concepts.

The implementation and development of QMs is connected to different QM methods and techniques. Figure 5 shows the proportion of respondents with respect to the QM tools.

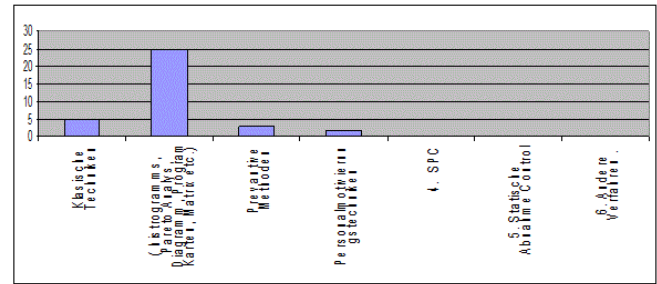


Fig 4.. Applied QM tools

How are companies able to learn?

Besides all this, the question also arises as to what extent the objectives of the increasingly complex management system concepts can be redeemed in practice.

Companies are not always really adaptive and flexible as postulate advanced management models. And not always associated with the management systems business objectives are transparent. So it is not surprising that far not every company, for example, is with total quality management and the EFQM model employed, indeed a culture of openness and development capability has. Often for the first new system approaches from top management are virtually ordained without the willingness to lasting changes in the organization is modeled. The second is that in companies often underestimate the time factor, which is in social change processes is of great importance. The introduction of effective management systems takes time. Can be done during the construction of the formal procedures within half a year, increasing innovation and learning ability of companies is a long-term process. Thirdly, companies often lack basic experience with the plan-do-check-act cycle management, which forms the foundation of any functioning management system and taught in the standards ISO 14001, EMAS and ISO 9001-2008 is

All companies surveyed have information self-assessment models and methods for the development and monitoring of quality control. Only 10 percent of the surveyed companies have information on the EFQM model. However, effective at the European and national frameworks tools to improve the competitiveness of the Bulgarian economy is necessary to develop the players of the Bulgarian economy, SMEs and research institutions and authorities koordinierte measures. It is important to be specific, measurable, appropriate, demanding, relevant and timed objectives shall be defined so that both employees and managers know how their performance will be evaluated and Riskio [8]. For successful practices apply qualitatively and quantitatively measurable criteria. This allows the evaluation of the achieved and concentrate. The manner in which it was obtained This is a desirable economic performance with the establishment of the desired corporate culture in the company represents To this end, indicators of TQM examines how TQM culture and organization in Figure 5

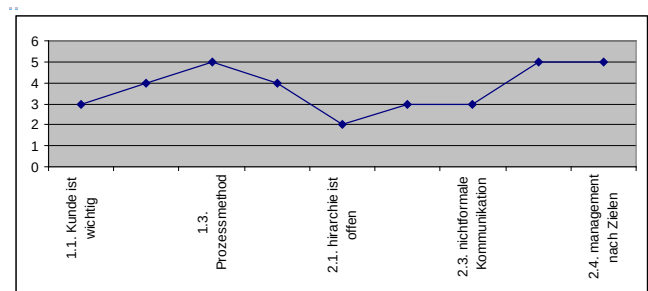


Fig. 5 TQM - Culture and Organization

Respondents cited a number of proposals to improve the quality, most of them expressed their willingness to help by providing information and / or participate in voluntary work. In such an environment, it soon becomes clear that TQM is too important to let fail, an implementation project. Success factors for successful implementation are: comprehensive support through seminars, consultants or software, the full support of management and the timely preparation of the practical problems of TQM implementation.

Conclusion

Although Total Quality Management is one of the most important management concepts and many of the newcomers are the EFQM Bulgarian firms, it appears that the self-assessment according to the EFQM Excellence Model in particular in Bulgaria not to have become established as an accepted instrument for strategic quality management.

The implementation of TQM can lead to high economic benefits, such as to increase efficiency, to reduce costs and to higher motivation and job satisfaction of employees and managers.

LITERATURE

- [1] Dukendjiev, PhD, D., R. Yordanov, control and quality management Softrade, Sofia, 2008
- [2] Lazarov, I., Quality Management, Softtreyd, Sofia, 2000
- [3] Stefanov, N., R. Radev, I. Burov, V. Stancheva R. Vodenicharov, Quality Management, "Labour and the Law", Sofia, 2004
- [4] Deming Prize Committee: Deming Prize Guide for Overseas Companies. Tokio, Union of Japanese Engineers and Sciences(JUSE), 1994
- [5] Feigenbaum, A. V. Total Quality control, McGraw-Hill, New York, 1949
- [6] Kamiske, G. F. / Malorny, C.: TQM - ein bestechendes Führungsmodell mit hohen Anforderungen und großen Chancen,,Carl Hanser Verlag München, Wien, 1998
- [7] Juran, J., Juran's Quality Handbook, Fifth Edition, McGraw-Hill, 1999
- [8] Николова, И. Управление на качеството, 2010
- [9] Pfeifer, T.: Qualitätsmanagement, 2., vollständig überarbeitete und erweiterte Auflage, Carl Hanser Verlag München Wien 1995,
- [10] Zink, Klaus J.: TQM: Begriff und Aufgaben - ein Überblick, Schriften zur Unternehmensführung - Total Quality Management I Herausgeber: Dieter B. Preßmar Wiesbaden 1995
- [11] www.iso.org
- [12] <http://www.tqm.dewww.vdi.de/Ludwig-Erhard-Preis-Auszeichnungen> fuer Spitzenleistungen im Wettbewerb
- [13] Report des TU Forschungberichts 08013ни-15/2008