

# MANAGEMENT SYSTEM SELF-ASSESSMENT OF A DISTRIBUTION COMPANY OF MEDICAL DEVICES

OLTEANU Larina-Georgiana

Faculty of Industrial Engineering and Robotics, Specialization: Quality Engineering, Year of studies: I, Master,  
e-mail: olteanu.larina@gmail.com

Scientific leaders: Prof. dr. ing. Irina SEVERIN, Ş.I. dr. ing. Bogdan DUMITRU

*SUMMARY: The paper presents the self-evaluation of an organization that imports and distributes medical devices for over 25 years on the Romanian market; the self-evaluation was carried out according to the EFQM Excellence Model. The evaluation of the integrated management system implemented at the organization represents an important step in the development/aspiration towards excellence. The sub-criteria were analysed in correspondence with two fundamental concepts, identifying strengths and areas for improvement, with the aim of evaluating the degree of maturity of the integrated management system, as well as identifying priority improvement areas with relevant and motivating potential for the organization.*

*KEYWORDS: self-assessment, management system, medical devices, EFQM excellence model.*

## 1. Introduction

The EFQM model is a globally recognized management framework that supports organizations in managing change and improving performance [1]. Since the organization SOFMED is concerned with the continuous improvement of performance, its evaluation according to the EFQM Excellence Model represents the way in which the improvement areas available at the level of the organization's processes are identified, but also the degree of maturity of the management system implemented in the organization is evaluated. The objectives of the assessment were to identify areas that require actions to maximize the company's efficiency and performance.

To achieve the proposed objectives, the organization was analysed according to the corresponding sub-criteria of two fundamental concepts of the Excellence Model: Management through processes and Adding value for customers. Following the identification of strengths and improvement areas for each analysed sub-criteria, marks were awarded, which were used in the assessment of the organization according to the Model of Excellence.

The abbreviation "EFQM" comes from "European Foundation for Quality Management". The foundation not only gave the concept a name, but also developed it. In general, the EFQM model is considered a comprehensive quality management model. The latest version is based on eight fundamental concepts (taking responsibility for a sustainable future, building partnerships, nurturing creativity & innovation, succeeding through people, managing by processes, leading with vision, inspiration & integrity, adding value for customers, achieving balanced results), which are analysed through the lens of enablers and results, to help understand and analyse the behaviour, thinking and culture of an organization. The instrument used for diagnosing the organization's current strengths and opportunities for improvement is RADAR logic (acronym for Results, Approaches, Deploy, Assess and Define). The goal is always to improve operational performance in all areas and at all levels.

The model provides a holistic view of the organization, identifies areas for improvement, and provides techniques and tools for measuring improvement over time. The determining factor here is the relationship between cause and effect. Companies should analyse what they have done, the results they have achieved and the gaps that still exist. In short, the EFQM model is a quality-focused management

framework that shows where an organization is on the "path to excellence" or what steps need to be taken for improvement [1].

## **2. Presentation of the organization**

The organization SOFMED is a company operating in Europe that provides innovative medical technologies for patients in the fields of minimally invasive surgery, robotics, cardiovascular, intensive care, endoscopy and pneumology.

They make life-saving technologies available to patients in the most remote regions of Europe by empowering healthcare professionals with the most trusted innovation and learning ecosystem.

SOFMED was established in Bucharest in 1994 with the aim of opening new paths and creating opportunities in the Romanian medical system by providing life-saving medical technologies.

During its 29 years of existence, the company has developed in more than 5 countries in Europe, out of the desire to provide innovative medical technologies to as many patients as possible. Since the beginning of the establishment of the company, great attention has been paid to the management system, and currently the company holds three certifications according to ISO 9001:2015, ISO 13485:2016, ISO 14001:2015 standards [2].

Some of the company's major achievements in the last 20 years comprise of the first introduction of automatic peritoneal dialysis therapy in Romania (1997), the initiation of the first "Artificial Heart" program in the South East Europe (2001 – Romania), the first video-endoscopy capsule in the South East Europe (2003 – Romania), the first private dialysis treatment in Romania (2005), the first assisted robotic surgery in the South East Europe (2006 – Romania), the first minimally invasive magnetically guided procedure (2015 – Romania) are.

The self-assessment of the organization according to the Model of Excellence is a point of analysis and evaluation that highlights and provides new opportunities for improvement to maximize the efficiency and performance of the company.

## **3. Fundamental concepts of excellence analysed**

In the self-assessment carried out, two of the eight fundamental concepts of excellence were analysed: managing through processes and adding value for customers.

In the organization SOFMED, all activities are driven through processes. The processes and interactions between them are defined in the Quality Manual. Each process has a designated process manager, who, together with the compliance department personnel, implements, monitors, updates and ensures compliance with the procedures and the use of the documents associated with them.

Each process has clear objectives established, with performance indicators, cascading down to the performance indicators of each employee. The desired results are defined both in individual KPIs (key performance indicators) and in the organization's Development/Strategic Plans. Any non-conformity is dealt/treated with by corrective actions and corrections, being considered an opportunity to improve the process and existing procedures, which allows for continuous improvement.

The efficiency and effectiveness of the integrated management system is analysed in the periodic analysis meetings of Management Review. During these meetings, but also as a result of the observed non-conformities and complaints, new risks and opportunities are identified and integrated into the management system. An annual customer satisfaction is carried out annually, through a questionnaire, for collecting customers perception about the organization. In addition, any direct or indirect feedback is recorded in the Feedback Registry and taken into account in Continuous Improvement meetings and beyond.

The organization knows its customer base and adapts its products and services according to their needs and expectations. Through the interactions of clinical support staff, relationships between the organization and clients are built and maintained, based on values such as transparency and integrity. Top-level management is always aware of the latest technologies in the medical field, with the aim of analysing their potential and offering customers the most innovative products and services.

The added value for the customer comes from providing products and services that comply with the applicable legislation in force (compliance for which many actions are taken), along with clinical support and professional development opportunities for the health care professionals. Clinical support personnel not only perform the activities of selling products and services, but also hands-on clinical support, such as in the operating room/treatment, by supporting the health care professionals who operate the products and technologies offered. The personnel have the necessary skills, information and tools to provide clinical support. Any feedback from stakeholders and especially from customers is recorded and considered for continuous evaluation and improvement of the organization. Any complaint about the product or service provided is recorded and its possible cause is identified, with the customer being informed and actions implemented to prevent the recurrence of the complaint.

#### 4. Enablers and results

The EFQM excellence model represented in Fig. 1 is a non-prescriptive framework based on nine criteria out of which five of these are 'Enablers' and four are 'Results'. 'Enablers' criteria cover what an organization does. The 'Results' criteria cover what an organization achieves and how it does it. 'Results' are caused by 'Enablers' and 'Enablers' are improved using feedback from 'Results'.

The arrows emphasize the dynamic nature of the Model, showing innovation and learning contributing to improved enablers that in turn lead to improved results [3].

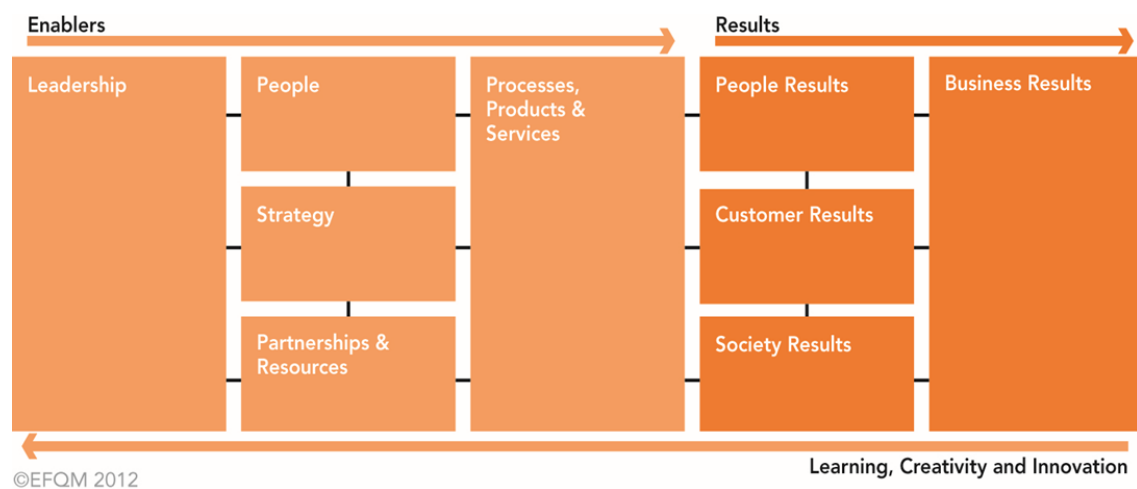


Fig. 1 Enablers and results [3]

Next, the strengths, objective evidence and areas for improvement identified for each enabler and result will be explained.

##### **Leadership** enabler

###### *Strengths*

- The commitment of the Top-level Management - the vision, the mission established for the company and towards the integrated management system → manifested in the meetings at the beginning of the year

- Process results - monitored and analysed in periodic management meetings

- Stakeholder analysis - identifies needs and expectations → periodically reviewed and improved

###### *Areas for improvement*

- Correlating the commitment of Top-level Management with process performance, by identifying tangible elements that will maintain leaders' interest in Integrated Management System

- The introduction of performance indicators to evaluate the commitment of the Top-level Management

- Strengthening the relationship with patient associations

Part of the *objective evidence* that supports the identified strengths includes the periodic implementation of the Stakeholder Analysis and its updating, obtaining, and maintaining the ISO 14001 certificate, establishing quality objectives, establishing and monitoring performance indicators, making reports corresponding to management meetings, completing the Dashboard monthly, drawing up the organization's policy and distributing/promoting it within the company.

### **Strategy enabler**

#### *Strengths*

- The quality policy and the commitment of the Top-level Management - publicly displayed. Policy - communicated to personnel via internal newsletter 2 times per year.

- Stakeholder analysis is carried out and continuously improved. Annual assessments of partners and suppliers.

- Top-level management performs the quarterly analysis of performance indicators

#### *Areas for improvement*

- Evaluation of awareness of the quality policy and strategy, by introducing performance indicators for all levels of the organization

- Personnel awareness of their role in achieving quality objectives and the impact of each individual's activity on service compliance

- Carrying out an evaluation of the performance of competitors in the medical industry, benchmarking.

Part of the *objective evidence* supporting the identified strengths includes drawing up the organization's policy and distributing/promoting it within the company, setting quality objectives and achieving and monitoring action plans to achieve the objectives, conducting periodic review/management meetings, and producing appropriate meeting reports.

### **People enabler**

#### *Strengths*

- Personnel is encouraged to use their skills and knowledge for the benefit of the organisation

- Each employee knows the processes in which they participate and their personal and process performance indicators

- Personnel from different departments collaborate in case of an unexpected/unprecedented situation

#### *Areas for improvement*

- Encouraging commitment and completion of an activity, coordinating an action from start to finish

- Periodic reminder of the mission, vision, and strategic objectives, through internal communications/meetings with management

- Awareness of the importance of each employee in achieving the organization's objectives

Part of the *objective evidence* supporting the identified strengths includes organization-wide recognition of employees whose performance is noted by peers, as well as regular training and retraining of staff.

### **Partnerships and resources enabler**

#### *Strengths*

- Budgets are established for each department, budget allocation plans; every possible expenditure must be approved before its realization.

- The analysis of risks and opportunities is carried out periodically, with the identification, analysis, and estimation of risks, to treat, monitor and reassess the risk.

- The analysis of partners and suppliers is carried out annually.
- Specialized sources of amendments to the legislation in force, official sources of publication of public tenders are consulted daily, in order to participate; Monthly internal newsletters are prepared with the most relevant news in the medical field, with new devices approved in the EU.

*Areas for improvement*

- Realization of finance courses for non-finance personnel to understand the basic financial indicators

- Digitization of the evaluation process of partners and suppliers

Part of the *objective evidence* that supports the identified strengths includes the completion of the risk registry and its updating, the preparation of the monthly internal Newsletter with the newest products and innovative technologies in the medical field, the completion and continuous updating of the Tender Registry, the preparation and implementation of a Policy of decision-making, as well as the preparation of the annual evaluations of the partners.

**Processes, products, and services Enabler**

*Strengths*

- All processes - the basis of an integrated management system, certified according to ISO 9001:2015, ISO 13485:2016 and ISO 14001:2015 standards.
- Processes are periodically improved, through corrective actions and through the analysis and implementation of employee suggestions/proposals for improvement
- Before introducing a new technology/business group - assessing the impact of the change
- The business model - defined in the Quality Manual, with the mention of key capabilities, processes, partners, and value propositions.
- All products are checked to ensure that the organization supplies only compliant products.

*Areas for improvement*

- Carrying out market studies, customer questionnaires to anticipate and identify market needs.
- Comparing the performance of the organization's products and services with competitors.
- Identifying the company's market position and using it as a competitive advantage in promoting the products and services offered
- Increasing awareness of quality as a company's competitive advantage and maximizing its promotion

Part of the *objective evidence* that supports the identified strengths includes obtaining and maintaining ISO 9001, 13485 and 14001 certificates, drawing up and updating the Quality Manual, completing, and updating the Register of non-conformities, as well as carrying out Impact change assessments.

**Clients Result**

*Strengths*

- Customer perception - assessed in the satisfaction rating questionnaire (Net promoter score - NPS). Based on the answer to a first question, customers fall into one of the following categories: promoters, detractors, or passives.
- All interactions between health care professionals and clinical support specialists are documented through meeting reports, with any spontaneous feedback recorded.
- Following each complaint regarding the products or services provided, letters are sent to customers identifying the causes of the defect/complaint, together with actions that aim to prevent the recurrence of these situations.

*Areas for improvement*

- Introducing a satisfaction evaluation questionnaire following the purchase of products and services.
- Conducting Focus Group meetings (customers, partners, invited suppliers) to have free discussions/ Q&A/ different discussion topics.

- Making an annual comparison of the organization against other companies with similar activities, comparison at the level – size/object of activity/financial data/customer satisfaction, in order to be able to analyse the place of the organization in the Romanian market.

- Measuring customer retention by analysing existing partnerships.

Part of the *objective evidence* supporting the identified strengths includes submitting the customer satisfaction survey and achieving the NPS score, completing the Feedback Registry, requesting, and receiving root cause analysis letters, and completing the Complaints and Non-conformities Registry.

### **People Result**

#### *Strengths*

- Each employee - individual performance indicators derived from process performance indicators, as a measure of meeting process objectives. Annually - evaluate individual performance indicators.

- Every employee should take at least one annual development course, after which they share what they have learned with the relevant people.

- All initiatives and improvement proposals communicated by the employee are mentioned in the annual evaluation.

- At the organization level, every quarter and annually, the Employee of the quarter/year is chosen following the proposal of the people by the management and their voting by all the employees of the company.

#### *Areas for improvement*

- Personnel involvement in decision-making and their commitment to the management system - number of improvement proposals, active participation in meetings, number of observations/corrective actions.

- Introduction of performance indicators to evaluate the fulfilment of the obligation to share with interested persons the information/new knowledge acquired following the development courses.

- Awareness of improvement initiatives/proposals and their promotion.

- Creation of Career path to motivate personnel to exceed.

Part of the *objective evidence* that supports the identified strengths is the annual evaluation of the employees by the direct manager, the recognition in front of the whole organization of the employees, evidence of the necessary skills of the personnel, as well as surveys conducted at the personnel level.

### **Key performance indicators Result**

#### *Strengths*

- The organization annually establishes the desired financial results, based on the needs and expectations of the stakeholders, considering the analysis of the performances and results obtained in the past and anticipating them for the next year.

- Each process has established process performance indicators, consistent with the company's mission, vision, and strategy, which cascade down to individual performance indicators.

- All process performance indicators are monitored and analysed quarterly, to take actions to achieve the proposed targets. The analysis of the indicators was carried out in the last 3 years, with the fulfilment of the targets for more than  $\frac{3}{4}$  of the indicators.

#### *Areas for improvement*

- Identifying and protecting intellectual property

- Risk assessment in the field of information security, followed by the planning and implementation of vulnerability control measures

Part of the *objective evidence* supporting the identified strengths includes completing and monitoring the Dashboard, establishing annual financial objectives, conducting partner and supplier evaluations, establishing and monitoring process and individual performance indicators, as well as conducting an analysis of previous years' results.

## **5. Outcomes**

Following the analysis of the below mentioned sub-criteria of enablers and the results (first line of Fig. 2), scores were given in accordance with the RADAR logic of the EFQM model, the outcomes obtained being shown in Fig. 2.

Enabler	1B	1C	2B	2D	3C	4B	4E	5A	5B	5C	5D	5E	6A	6B	7B	9B
Score	72	58	53	60	48	63	45	83	60	56	73	63	44	58	39	66

Fig. 2 The score obtained for each enabler/result analysed

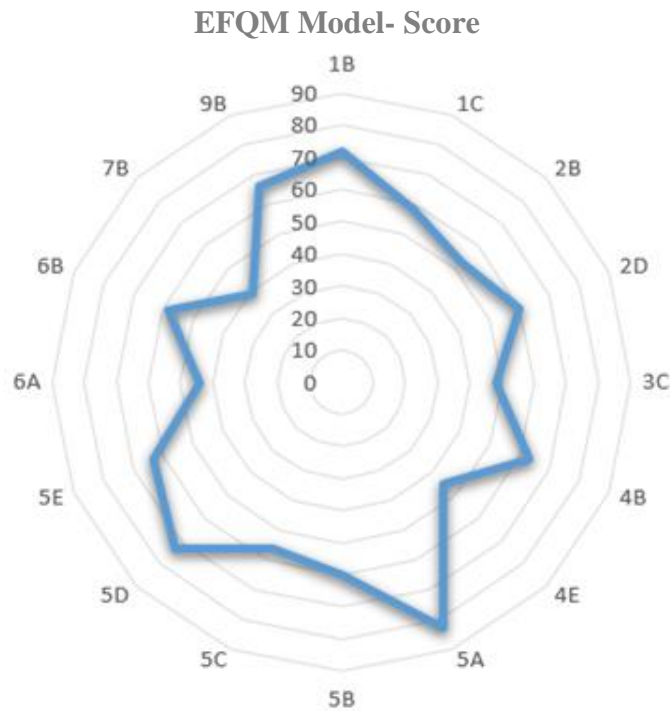


Fig. 3 Chart of scores to identify areas for improvement

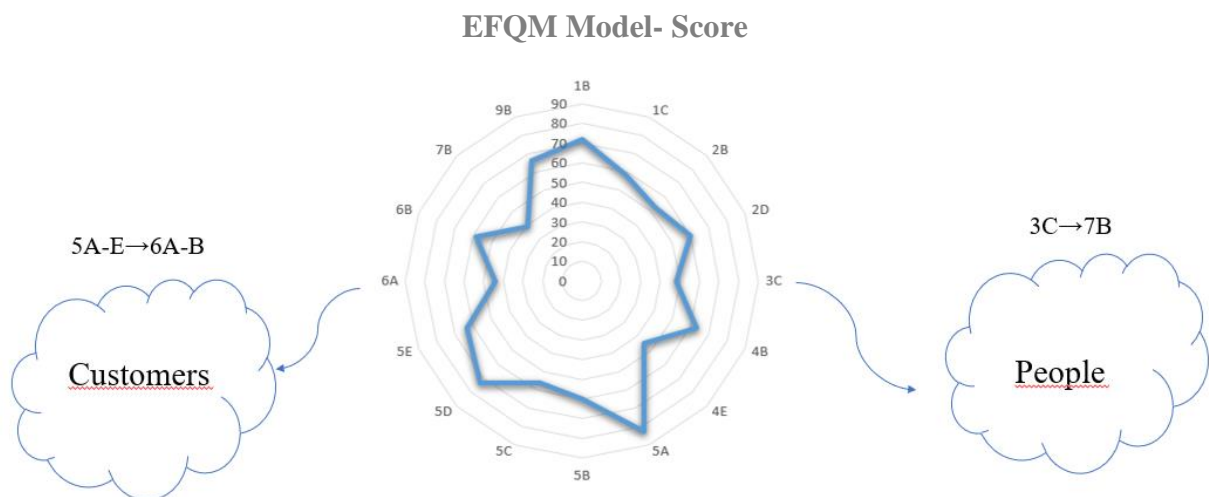


Fig. 4 Graph of scores obtained along with identification of areas for improvement.

The self-assessment of the integrated management system according to the EFQM excellence model allowed the identification of two improvement areas, according to the scores obtained on the enablers and results for people and customers.

Improvement strategies may start with the following:

- Awareness of the importance of each employee in achieving the organization's objectives
- Personnel involvement in decision-making and their commitment to the management system
- Introducing a satisfaction evaluation questionnaire following the purchase of products and services
- Carrying out an annual comparison of the organization against other companies with similar activities, comparison at the level – size/object of activity/financial data/customer satisfaction
- Increasing awareness of quality as a company's competitive advantage and maximizing its promotion

## 6. Conclusions

The self-evaluation of the integrated management system implemented at the organization SOFMED according to the EFQM Excellence Model highlighted the following aspects:

- ✓ It was identified a model that helps the organization to correlate the company's results with the enablers that determine these results, highlighting the correspondence between enablers and results;
- ✓ It was identified a structured way of analysis that allows the correlation of objective evidence with the strong points of the organization's efforts and areas for improvement were easily identified;
- ✓ Two fundamental concepts of the Excellence Model were analysed, which led to the identification and argumentation/substantiation of the improvement projects that the company can develop. At the same time, the identified strengths can be exploited even more in order to be used as a competitive advantage over other organizations with similar activities on the market.

Improvement projects target two broad groups of enablers and results, people (personnel) and customers. The areas of improvement identified will be developed and applied in this regard in the next project to improve the integrated management system.

## 7. Bibliography

- [1] “The EFQM Model - EFQM.” <https://efqm.org/the-efqm-model/> (accessed May 02, 2023).
- [2] “SOFMEDICA Romania - Life Saving Innovation – SOFMEDICA.com.” <https://sofmedica.com/ro/> (accessed May 15, 2023).
- [3] “My first step with the EFQM Excellence Model.” <https://sites.google.com/site/myfirststepwithefqmmodel2010/> (accessed May 11, 2023).
- [4] “SOF MEDICA SRL din BUCURESTI - CUI 6719715.” <https://termene.ro/firma/6719715-SOF-MEDICA-SRL> (accessed May 16, 2023).
- [5] “Sistem de management integrat” <https://moodle.com/upb.ro> (accessed May 11, 2023).