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ON THE WAY TO QMS IMPLEMENTATION: THE MAIN MILESTONES AND ISSUES IN EMERGING ECONOMY

ABSTRACT

The aim of the research is to analyze typical problems in the implementation of quality management systems (QMS) on the basis of private production enterprises which operate in emerging economy context and to develop a rational strategic plan for the design and implementation of such a system, taking into account the experience of successful organizations. The main benefits of implementing QMS are presented. In the article it is recommended to consider the formation of QMS as a project with the appropriate stages of activities. The following positions are envisaged at the initiation stage: formalization of the decision on QMS implementation, appointment of project participants, project team training, as well as development of

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mission, vision, quality policy and QMS process structure. At the implementation stage, it is proposed to develop and approve QMS documents, as well as to implement an internal audit program. At the stage of project closure, it is advisable to put into operation the developed system and pass a certification audit in order to obtain a certificate of compliance with the requirements of ISO 9001. The article presents the structure, content, sequence and estimated duration of all the stages of the project, as well as the division of responsibilities between the project team members. Emphasis is placed on the main issues which can arise at different stages of such a project. In the paper the following range of issues was identified: inconsistency of QMS processes structure with the existing organizational structure of the enterprise; incorrect definition of the performance indicators for processes at different hierarchy levels; erroneous decisions in the internal documentation system organizing. In its turn, in the article the causes for the above-mentioned issues were identified, namely: insufficient motivation of project participants, lack of time or other necessary resources, unwillingness to change the current management system of the company, inconsistency of real goals with the stated ones, etc. In the article it is proposed to divide the main causes of issues into three basic groups: by project participants (personal), bureaucratic (systemic) and leadership (administrative). The authors propose a number of measures to minimize the risks of issues in the QMS implementation, and determine the distribution of areas of responsibility for these measures organizing.

Keywords: Quality Management System, ISO 9001 standard, critical success factors, corporative strategy

1. INTRODUCTION

World market globalization and expansion of enterprises economic activity sets a task of compliance to the International Standards for Quality. One of the tools to improve the company's performance and increase its attractiveness to customers, consumers and other stakeholders is the Quality Management System (QMS) based on ISO 9001 requirements. In recent years, the requirements of Ukrainian manufacturers to their suppliers regarding quality of provided products have caught up with European and world practice. Such trends are observed in the enterprises in food, chemical, machine-building, metallurgical industry and other export-oriented spheres, but they become especially more widespread and cover an increasing number of pharmaceutical businesses.

ISO 9001 standards set out the requirements for Quality Management System of an enterprise (company, institution or any other business entity). Compliance with such requirements involves introduction of a number of measures and streamlining of existing processes at the enterprise. Depending on the level of organization of the enterprise business system, the scale of QMS can be seen as either individual improvements or as large-scale strategic changes, but in most cases it leads to changes in the organizational structure, in the instructions, responsibilities and motivation system of employees, in the regulations of company processes, in the system of documentation. Like any reorganizing, the QMS implementation process, firstly, requires the development of an action plan (projecting), and, secondly, faces a number of challenges which are unexpected for both senior management and employees of the enterprise, and which can not only hinder to obtain the desired results, but also to nullify all efforts in general.

2. LITERATURE REVIEW

Studying of works of numerous authors shows that their researches are mostly concentrated in the following areas:

(1) features of implementation in certain countries and businesses; (Bhuiyan & Alam (2005), Faisal (2016), Almeida et al. (2018), Bravi et al. (2019));
(2) reasons and benefits of QMS implementation and certification as well as an impact on companies' performance (Terziovski et al. (2003), Taylor & Wright (2003), Rahman (2001), Salgado et al. (2015));
(3) procedure and main steps of implementation (Kaidalova et al. (2008), Lysenko and Tavluy (2011), Popovych and Galko (2019));
(4) critical success factors (CSF) for QMS implementation (Taylor & Wright (2003), Jabnoun (2005), Kanapathy (2008), Kumar & Kumar (2011), Rani (2013)).

The similar rank of the most investigated topics noted by Galetto et al. (2017), is as follows: (1) the current diffusion of quality certification and its future trend; (2) the reasons that drive an organization toward the acquisition of the certificate; (3) the benefits and the obstacles/drawbacks; (4) the impact of the certification on the economic/financial performance and on the organizational process.

Although the principles of QMS and the ISO standard are the same for all countries and businesses, there are numbers of studies dealing with development and implementation of QMS in certain regions or types of economic activity (Bhuiyan & Alam (2005), Faisal (2016), Almeida et al. (2018), Bravi et al. (2019)). This may occur because of the cultural, social and economic differences between the countries studied, since they exhibit different industrial and economic characteristics (Almeida et al., 2018). Bhuiyan & Alam (2005) consider problematic issues at Canadian enterprises, and find that, "internally driven companies have less difficulty for certain items. Externally driven companies perceived a higher degree of benefits as compared with internally driven companies". For Ukrainian enterprises, the most influential factors are mainly the requirements of counterparties, especially in the case of entering the external market (Lebedynets, 2014). Krasnokutska & Kruglova (2017) state that introduction of QMS is one of the key factors of effective utilization of the resource potential of a company.

Most mentioned authors consider regions and industries precisely to highlight the benefits of implementing, as well as the most influential factors for successful implementation. However, the results of the QMS implementation do not always meet expectations. Thus, Terziovski et al. (2003) conclude that the ISO 9001 certification is not positively correlated with customer satisfaction; Taylor & Wright (2003) noted, that "many companies were still internally focused" and "ISO9000 certified companies did not perform better than non-certified companies", thus not confirming the statement that the company has achieved better performance under the terms of certification. Rahman (2001) has not found any different results between certified and not certified companies, in terms of organizational and financial variables.

Based on the study developed by Salgado et al. (2015), a positive relationship was found between the "number of issued certificates in each country per 1000 inhabitants and the indicators of economic development (Gross National Income Per Capita)".

We share the view of Jamali et al. (2010) that the failure or non-receipt of benefit from the implementation of QMS connects with gaps in understanding or even ignoring the key

factors necessary for successful implementation: "However, in practice many enterprises fail to adopt and implement TQM. Therefore, there is a need for deeper and more systematic assessment of the factors affecting on QMS implementation".

Alič (2013) describes the problem of bureaucratization due to the large amount of documentation of QMS procedures, and notes that "increasing bureaucracy often prevents companies from deciding to implement ISO 9001".

Taylor & Wright (2003) in a large-scale study about implementation of TQM principles put forward a number of hypotheses, from which the following are confirmed: (1) understanding of the purpose of TQM would be significantly associated with the perceived degree of TQM success; (2) the practice of including specific plans and objectives for quality, as a part of the strategic planning process, would be significantly associated with the degree of success from TQM; (3) the position of the person responsible for leading TQM would be positively associated with TQM success; (4) the firms which have been unable to facilitate or motivate the majority of their employees to become involved in TQM are also less likely to perceive TQM as having been successful.

The vast majority of studies are devoted to finding the causes of failures in the introducing QMS or factors that, conversely, contribute to a successful outcome. The basis for the study of such factors are often the assessment criteria used in ISO 9000 that can be compared to the Malcolm Baldrige National Quality Award (MBNQA). There are seven categories of assessment in the MBNQA which are: (1) leadership, (2) information and analysis, (3) strategic planning, (4) human resource development and management, (5) process management, (6) business results, (7) customer focus and satisfaction. G. Jamali et al. (2010) indicate that four factors, namely (1) top management commitment, (2) strategic quality planning, (3) process management and (4) training are driver factors and need serious attention. Jabnoun (2005) relates the effectiveness of the introduction of QMS with the organizational culture.

Basing on conducted literature review, Kanapathy (2008) generalizes eight critical factors of quality management: (1) top management support, (2) quality information availability, (3) quality information usage, (4) employee training, (5) employee involvement, (6) product/process design, (7) supplier quality, and (8) customer orientation.

Kumar & Kumar (2011), using the Exploratory Factor Analysis (EFA), found nine cross-validated TQM implementation constructs: (1) top management commitment, (2) supplier quality management, (3) continuous improvement, (4) product innovation, (5) benchmarking, (6) employee involvement, (7) reward and recognition, (8) education and training, and (9) customer focus; and one outcome construct (product quality).

Rani (2013) substantiates that the main factors of successful QMS implementation are: (1) top management commitment, (2) quality culture, (3) strategic quality management, (4) design quality management, (5) process management, (6) supplier quality management, (7) education and training, (8) empowerment and involvement, (9) information and analysis, (10) customer satisfaction.

Obviously, the number of factors is growing from the older researches to the newer ones, and depends on the industry, type of business, size of an enterprise. Yusof (2000) provides characteristics of a small and medium business and concludes that it is much easier to introduce QMS in a small business, because fewer people are involved in the process. This conclusion seems quite logical, given that most factors are related to interpersonal communications. Although Taylor & Wright (2003) do not find confirmation of the hypothesis that

the size of the customer base would be significantly associated with the perceived degree of TQM success.

Trang & Do (2020) developed a method based on AHP to determine the percent weightings of eight categories of performance criteria in Vietnamese supporting industries. These criteria include management commitment, role of the quality department, training and education, continuous improvement, quality policies, quality data and reporting, communication to improve quality, and customer satisfaction orientation. They came to the conclusion that "management commitment is the most critical factor; among sub-criteria, supports and responsibilities of top management is the most important".

Taylor & Wright (2003) indicate the time-factor, compliance to strategy and the role of top-management and involvements of employees as "deriving success from TQM". Although a lot of attention is paid to the CSF, in our opinion, there is the gap in the methodology of actions to be taken to implement QMS. According to our experience, managers of companies seeking to implement QMS and obtain a certificate of compliance with ISO 9001, often have no idea what actions need to be taken, what measures should be carried out and how long it will take to implement QMS in the enterprise. Nitin et al. (2011) give a whooping comparison of 24 frameworks as given by various NQA's and 14 individual researchers in the light of 26 CSFs of TQM. However, the research focuses on the CSF and not on the process and actions to be performed. There is also a number of issues in the process of QMS implementation, mainly related with the restructuring of the organizational design from functional to processual. But the emergence of other unexpected difficulties can nullify all efforts.

Kaidalova et al. (2008) present a detailed algorithm for implementation of QMS in a pharmaceutical company in accordance with the requirements of ISO 9001 and Good Pharmaceutical Practice. Lysenko and Tavluy (2011) consider the features of QMS in higher education institutions. The authors point to similar problems related to the lack of understanding of the importance or scope of actions for the implementation as well as issues that arise regarding the organizational structure changes (Lebedynets, 2014). Popovych and Galko (2019) describe the risks in the project of QMS implementation, namely the choice of goals, systems and options of quality policy, as well as the risks of leadership and staff involvement. However, in our opinion, creating a universal detailed procedure which would be relevant to a wide range of industrial enterprises is not presented in the mentioned publications, and recommendations for solving problems or risk management are not exhaustive and need to be supplemented.

The aim of the research is to build a detailed plan for the QMS formation at wide range of enterprises: from the pre-project phase to obtaining the ISO certificate. Such an outline will significantly illustrate the project and simplify organizational decisions on QMS, as well as highlight key issues and implementation risks.

3. RESEARCH METHOD AND SAMPLE

Our research is the result of analyzing a number of projects for the practical implementation of the QMS system in 18 Ukrainian enterprises of pharmaceutical (6), food (6), educational (2) and industrial (4: production of packaging, production of chemical compounds, production of printing products) activities of medium and small business. The result of each project was the introduction of TCM, obtaining a certificate of conformity and re-certification in

a year to confirm compliance. The projects were implemented during 2012–2020. The data were obtained from our own practical experience. Observations and recordings of the facts that took place during this project, as well as methods of solving problems became the basis for this material. All stages and problematic moments were fixed in the QMS documentation of the respective enterprises: protocols of meetings of the Quality Project Teams, surveys of needs and expectations of interested parties developed by enterprises, protocols of internal and external audits.

4. RESULTS AND DISCUSSION

Despite the fact that the quality management in a company should be an ongoing process, the implementation of QMS can be considered as a project: from initial decision of CEO and up to implementation of all developed documented procedures and obtaining a certificate of compliance with ISO 9001. These activities have all the properties of the project, namely: (1) the scope is determined by a number of requirements of the standard to which the system must meet; (2) time period means the period from the initiation to getting the first results from implemented procedures and obtaining a certificate; (3) the budget consists of costs a company has to spend. Thus, we consider the implementation of QMS as a project that has the following stages: (1) initiation; (2) planning; (3) implementation; (4) closure.

It is also possible to distinguish the pre-project stage, i.e., analysis of external and internal factors. First of all, there are market requirements in terms of product quality guarantees. The decision to introduce QMS is also prompted by changes in Ukraine's external orientation, namely an increase in the share of EU countries in Ukraine's foreign trade turnover in the first quarter of 2020 to 41.2% (according to Ukraine's foreign trade in goods and services in the first quarter of 2020 (2020)).

These factors lead the top-management or the most active employees of the organization to realize the urgency and feasibility of QMS implemention and certification. Usually there should be collected the data on Certification Bodies and their requirements as well as consideration of resource provision. The pre-project stage can have different duration depending on the degree of influence of factors and the attitude of senior-managers or owners, and ends with an internal meeting (kick-off), which announces the taken decision, formulates the goal and determines the project budget. This is the end of the pre-project stage and the initiation of the project (stage 1).

There are two positions that should be appointed at the internal meeting directly or within a certain period: a project manager (PM); a project team (PT). The previous versions of ISO 9001:2008 required the appointment of a management representative as a special officer responsible for the QMS project implementation and further support. The current version of ISO 9001:2015 does not contain such requirements; thereafter we believe that the latest version of the standard provides the company the choice to appoint one person or a group of people with a specific list of powers and responsibilities to support the QMS. It is good practice to register the decision of the kick-off meeting in organizational documents (such as orders, directives, etc.) in such document as order, indicating the name and position of the project manager, the composition of the project team and a list of its members' authorities and responsibilities.

The appointment of a project manager and the establishment of his terms of reference rightly entail changes in the organizational structure of the company. A good practice, confirmed by the experience of many companies in Ukraine and other countries, is the creation of a Quality Management Department (QMD) and the appointment of a Deputy Director for Quality (DDQ), who acts as a project manager at the QMS system implementation. There is a common mistake made by many enterprises to substitute QMD with technical-quality control units (TC). The latter are usually present in the structure of any manufacturing enterprise and perform the functions of checkup of raw materials, semi-products or finished goods technical indicators. However, the competence of such units is connected only with evaluating the product quality indicators and does not extend to the managerial, assurance or provision activities (e.g., risk management, internal audits, development of corrective action plans, etc.). Under such conditions, QMS requests from external stakeholders (e.g., customers, contractors, etc.) are often addressed to such units as laboratories, production department, etc., but personnel of these units are usually incompetent to respond to such requests.

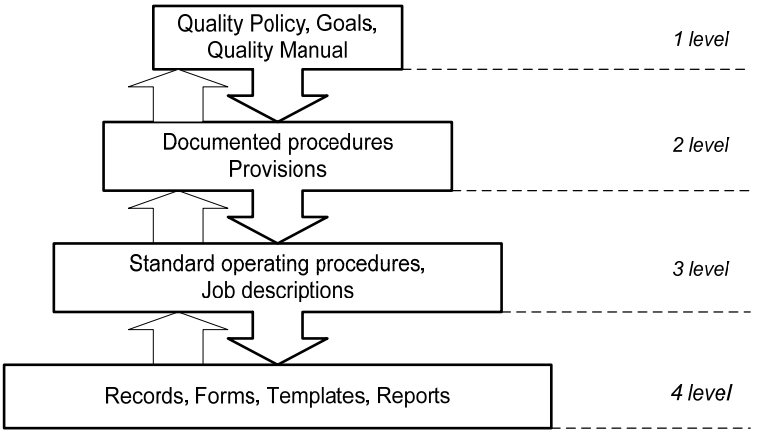
Thus, we consider the appointment of a Deputy Director for Quality to be the best option for electing a project manager. If such a position is not provided, it is advisable to outsource the services and find an external consultant. The project manager and the project team have to carry out a diagnostic audit to identify compliance of the company's actual activities with the requirements of ISO 9001. The report on the results of the diagnostic audit should be considered at the meeting, where the time limits, main stages and budget of the project are adjusted. At this stage, the project initiation is completed.

Project planning (stage 2) is the most time-consuming stage, and involves the following actions: (2A) training the project team; (2B) defining the company's Mission, Vision and Quality Policy; (2C) development of the QMS process structure. The training of PT consists of a series of seminars to study the provisions and requirements of the ISO 9000 standards, and is held in parallel with other processes. Mastering provisions of the ISO 9001:2015 standard will allow to develop the structure of QMS processes, in particular, to make the list of processes necessary for QMS functioning, to define their inputs/outputs, sequence and interaction; determine the leaders (owners) of QMS processes; distribute responsibilities and powers within the QMS.

Defining the goals and performance indicators of QMS processes, methods of their systematic monitoring, as well as identifying and assessing risks and opportunities complete the planning stage. We consider the completion of the planning stage as successful, if the following elements are developed, approved by the company's management and apprehended by employees: (1) mission, vision, quality policy; (2) the scope of QMS; the structure of company's QMS processes (with certain inputs, outputs, resources, management actions) and process-owners; (3) purposes and risks of QMS processes.

Stage 3 of the project can be divided into the following stages: (3A) development and publication of QMS documents; (3B) pre-certification stage; (3C) actual certification. According to DSTU ISO/TR 10013-2003, the set of QMS documentation should consist of four levels (Figure 1).

Figure 1. The typical set of QMS documentation



Source: The authors' own work.

This stage involves:
- determining the structure and content of the QMS documentation;
- creation of a template for documented procedure (DP), then completion of instructions for the DP preparation.

DPs development:
- development and approval of level 3 documents: standard operating procedures (SOP), guidelines, instructions, etc.;
- development and approval of the Quality Manual (not a mandatory document from the standpoint of ISO 9001:2015).

The Quality Manual is the final element in the documentation system. It summarizes the information and essentially presents a "road map" to get an imagination of the whole QMS of the company.

The pre-certification stage begins with the implementation of provisions of QMS documentation into the practice of company's processes, and then the initial registration of data on the effectiveness of the QMS processes. There should be a certain period for data collection. During this period, internal auditors (IAs) should be selected and trained.

The cycle of pre-certification internal audits presents a mini-project, as it requires:
- initiation as selection and training of internal auditors described in detail in ISO 19011:2018 Guidelines for auditing management systems (subsections 5.5.4 and 7.2);
- planning as development of audit program and plans as well as preparation of questionnaires (check-lists) and forms of protocols;
- implementation consists of carrying out internal audits, preparation of reports on the results;
- closure means determination and taking of necessary corrective actions (CA) to eliminate the causes and consequences of the identified nonconformities and preventive actions (PA) to minimize or eliminate of identified risks, preparation of reports on audit results.

The most important element of the post-audit activities is the correction of processes in accordance with the recommendations, monitoring the execution of CA and PA, improving the QMS documentation, etc.

A meeting to assess the QMS's readiness for certification completes this phase. In the case of a positive decision on readiness, the company proceeds to the third step of the implementation stage. The components of this step are following:

- initiations as a selection of a Certification Body and submission of an application;
- planning consists on coordination of the audit plan with the certification body and appointment of a responsible person;
- implementation presents cooperation with auditors, elimination of discrepancies (if any);
- closure consists on obtaining a positive decision of the Certification Body auditors.

The duration of stage 3C will depend on the Certification Body. This paper presents data from common practice.

The closing of the stage almost coincides with the closing of the project. However, any project cannot be considered closed until it has been analyzed and recommendations for further action have been identified. Therefore, the closure of the project involves a report of the project manager at the general meeting of the company, the formulation of recommendations for the future.

The project stages are clearly presented in Table 1. According to our own research, the duration of the project in a medium-sized business is usually from 25 weeks, and traditionally planning and implementation takes 90% of the time. For better understanding later the landscape diagram can be built (Polančič et al., 2020).

Table 1. Step-by-step plan for QMS implementation

№	Stages and content of the main activities	Preliminary act	Start, week	Duration, weeks	Result	Responsible
	1. PROJECT INITIATION					
1A	Initial (kick-off) meeting		1		The order of QMS implementing, PM and PT appointment	CEO (director)
1B	Establishing a QM department or an external consultant attracting (if necessary)	1A	1		The order to specify duties and responsibilities	CEO (director)
1C	Diagnostic audit	1B	1	1	The report of results	PM
1D	Approving of report and recourse assurance	1C	1	1	Project budget	CEO (director)

Table 1. Step-by-step… (cd.)

№	Stages and content of the main activities	Preliminary act	Start, week	Duration, weeks	Result	Responsible
	2. PROJECT PLANNING					
2A	Project Team training	1D	2	4	Evaluation protocol	PM
2B	The development of key QMS documents					
2B1	Establishing a Quality Policy	1D	2	1	Quality Policy	PM / CEO
2B2	Determination Company's context and relevant issues	2B1	2	1		PT/PM / CEO
2B3	Formation of purposes and risks	2B2	3	1	Register of risks and opportunities	PM / CEO
2C	The development and regulation of set of QMS documentation					
2C1	Defining set of QMS processes, as well as their inputs, outputs, sources and receivers	2B3	4	2	QMS process model	PT / PM / CEO
2C2	Defining of process owners	2C1	5	1	Matrix of responsibility	PT / PM / CEO
2C3	Correction of organizational structure and Project Team composition	2C2	5	1	The order of set an organizational structure	PM / CEO
2C4	Determination and approving the purposes and KPI of processes	2C3	6	1	Purposes register	PT / PM
2C5	Identifying risks and opportunities	2C4	7	1	Risks register	PT / PM
2C6	Coordinating the purposes, risks and opportunities of processes throughout the system	2C5	8	1	QMS process model corrected	PT / PM / CEO
	3. IMPLEMENTATION					
3A	The development of QMS documentation					

Table 1. Step-by-step… (cd.)

№	Stages and content of the main activities	Preliminary act	Start, week	Duration, weeks	Result	Responsible
3A1	Determining the structure and content of the QMS documentation	2C2	6	1	DP Management of documented information	PM
3A2	Creation of a template for documented procedure (DP), then completion instructions for the DP preparation	3A1	7	1	Standard form	PM
3A3	Appointment a persons responsible for DPs preparation	3A2, 2C6	9	1		PM / CEO
3A4	Actually DPs development.	3A3	9	3	Set of Processes DPs	PT / PM
3A5	Creation of a template for documentation of 3-d level (SOP etc.), completion instructions	3A2	8	2	Standard forms	PM
3A6	Development and approving documentation of 3-d level	3A2, 3A5	10	3	Set of 3-d level documents	PT/PM
3A7	Development and approving Quality Manual	3A6	13	1	Quality Manual	PM / CEO
3B	Implementation of QMS documents. Launch and monitoring of QMS operation					
3B1	Performance data registration	3A7	14	2	Protocols	PT / PM
3B2	Selection and training internal auditors	3A7	14	1	The order	PM / CEO
3B3	Development of audit program and plans as well as preparation of questionnaires and protocols	3B2	15	1	Set of IA documentation	BA/PM
3B4	Internal audits carrying out	3B1, 3B3	16	2	Reports of IA results	BA

Table 1. Step-by-step… (cd.)

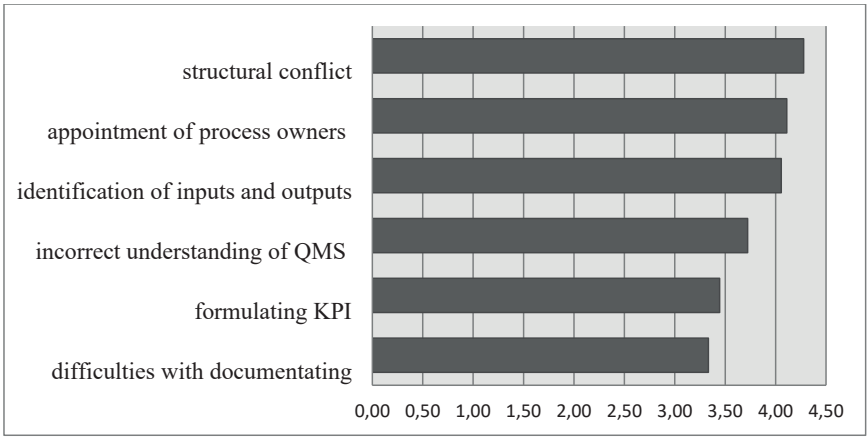
№	Stages and content of the main activities	Preliminary act	Start, week	Duration, weeks	Result	Responsible
3B5	Determining and taking the necessary corrective and preventive actions (CA and PA)	3B4	18	1	Reports of CA and PA results	PT/PM
3B6	Meeting to assess the QMS's readiness for certification	3B5	19	1	The order to organization and conducting certification procedure	CEO (director)
3C	QMS certification					
3C1	Selection the Certification Body	3B6	20	1	Application for certification	PM
3C2	Coordination of the certification audit plan and appointment of a responsible person	3C1	20	1	Program of audit	PM
3C3	Cooperation with auditors	3C2	21	3	Recommendations	
3C4	Elimination of nonconformities and their causes (if any)	3C3	25	1	The report on CA	
3C5	Getting certificate	3C4	26	1	Certificate of compliance to ISO 9001:2015	Certification Body
4. PROJECT CLOSURE						
4.1	The report of PM on results and developing further recommendations	3C5	27	1	Report Recommendations	PT/PM
4.2	Creation or re-approval of the PT as a permanent Quality Council	4.1.	27	1	Order on the establishment of the Quality Council	CEO (director)

Source: The authors' own work.

The next direction of our study is to cover problem areas and difficulties in the process of QMS implementation.

As mentioned above, the research results are based on the practical experience of implementing TCM. During the ongoing processes of QMS implementation projects, a number of difficult issues were recorded, as well as a survey of project team participants was conducted. The participants were asked to identify the most problematic points and assess the difficulties on a 5-point scale. Estimates of the most problematic areas are shown in Figure 2.

Figure 2. Identification of problem areas in QMS implementing



Source: The authors' own work.

Thereafter, according to our experience, the most problematic area is the construction of the QMS process structure.

Firstly, the coordination of processes often comes into conflict with the existing organizational structure, where there are numerous working issues at the junction of areas of responsibility of different divisions of the enterprise. Such coordination in the chain "receipt of the order – purchase – production – sale" is especially important as formulating of inputs and outputs of processes which are the core in value-formation; the selection of processes should be based on their strategic contribution to the company performance (Brin et al., 2020).

Secondly, the appointment of process owners can be not so easy. The existing structure establishes a range of responsibilities, and the need to change the number or the nature of actions leads to the creation of new units rather than to the revision and change of responsibilities in the existing ones.

Another complication is the unification of terms, especially in the names of inputs and outputs. The output of the vendor process is called differently with the input of the client process, possibly because the vendor and the client pay attention to different characteristics of the object, which is being the output for the first and the input for the second. Such complexity is often the consequence of the existing system of internal documentation (rules, job descriptions, etc.). The existing documentation system can be useful, but it can also hinder the compilation of new QMS documentation for the same reason, namely the stability of the existing structure.

The next range of issues is the lack or insufficient or vague formulating of Key Performance Indicators (KPIs). The majority of companies focuses on the final financial results, as well as the second level considers the dynamics of sales. For internal business processes which have as the client not the end user, but other processes, performance indicators are not formulated, or are formulated very vaguely. At the same time, performance indicators for internal business processes, such as warehousing, manufacturing, quality control, laboratory research, etc., are often not formulated or are formulated very vaguely.

A number of issues arises due to incorrect understanding or unconscious attitude of the leaders of the organization towards QMS. We do not consider cases where top management deliberately distrusts QMS, considering it only as a means of obtaining a certificate. But it is common for the company's CEO to assign all responsibilities to the PM and either:

a) not to participate in the formation of the process structure and/or in the preparation of the first-level documentation; or
b) not to demonstrate to employees their own interest in the QMS realization. The result of such actions (or inaction) is lack of understanding of QMS feasibility by employees, lack of both internal and external motivation to make additional efforts.

Quite often there are difficulties with the formation of the documentation system. Such difficulties can, firstly, lead to excessive time, and thus to the cost of the project, and secondly, to formation of poor-quality "formal" procedures that will not be viable and will not allow QMS to be actually implemented.

The reasons for such difficulties can be:

– misunderstanding of the essence of the processes and subprocesses to be described. This situation is a consequence of difficulties in the formation of the QMS structure, the defining of inputs, and outputs and processes interconnections;
– lack of PT members experience in drafting such documents, or purely technical difficulties in verbal formulation;
– lack of time or heavy workload with the main duties.

The same difficulties arise at the stage of developing a program and documents for conducting internal audits.

Identification of existing problem areas and generalization of issues leads the authors to the following conclusions.

In our opinion, the areas of issues can be divided into three groups: personal, system and administrative (or leadership).

The first group represents issues related to certain characteristics of people involved in the process of creating and implementing QMS: the level of knowledge and competencies, available experience, as well as habits and internal motivating factors.

The second group is the issues raised by the existing management system of the organization, primarily – the organizational structure, the current distribution of powers and responsibilities, the degree of centralization, the principles of planning, measuring results and reporting. This group can include issues related to organizational culture. Quite often there is a simple "overlay on the top" of a new system on the old one, instead of replacing the old system with a new one. As a result, the "old" rules are not repealed and continue to operate, and thus, there is an increase in the burden on participants in the process.

The third area of issues is the position of leaders. As noted, the motivation of process participants depends on organizational decisions and communication with top and middle man-

agers, whose behavior should be a role model. Next, the processes structure and the system of measuring effectiveness depend on the correct formulation of goals.

The results and consequences of the problematic moments can be summarized as follows.

1) The delay of the project due to the greater cost of time at certain stages, and as a consequence, the additional costs are the "least evil" on this list.
2) The overloaded and the overloaded, cumbersome nature of presenting information in QMS documentation difficult to perceive QMS documentation makes its really application impossible, and then the system just "does not work", the company remains in the same condition as before the QMS implementation.
3) Incorrect hierarchy of goals, ill-considered interaction of processes, incorrect KPI lead to erroneous prioritization and deterioration of the company's performance.

Covering the causes, nature and scope of issues allows us to make recommendations for overcoming them.

To overcome the problems caused by lack of experience and unprofessionalism of the project participants, the following measures are appropriate:

– training should be accompanied by examples of good practice;
– use of benchmarking, i.e., QMS materials of another enterprise;
– creation of the most detailed templates for the generated documents;
– individual consultations of participants by the project manager.

To avoid congestion and lack of time, it is advisable to allocate special time for: a) holding PT meetings; b) individual consultations with MP; c) independent work.

Another important measure is the delegation of part of the scope of work performed by PT members to other employees.

Overcoming the resistance of the system is the most difficult process and requires the greatest effort. Among those the most needed are:

– determination of the status and wide range of powers and responsibilities of the project manager and the PT at least for the time of project implementation;
– determining the interaction of process owners and heads of structural units, if they are not the same persons;
– accompanying the project review of the record keeping system and removal of "old" requirements and forms of documentation as they are replaced by new ones.

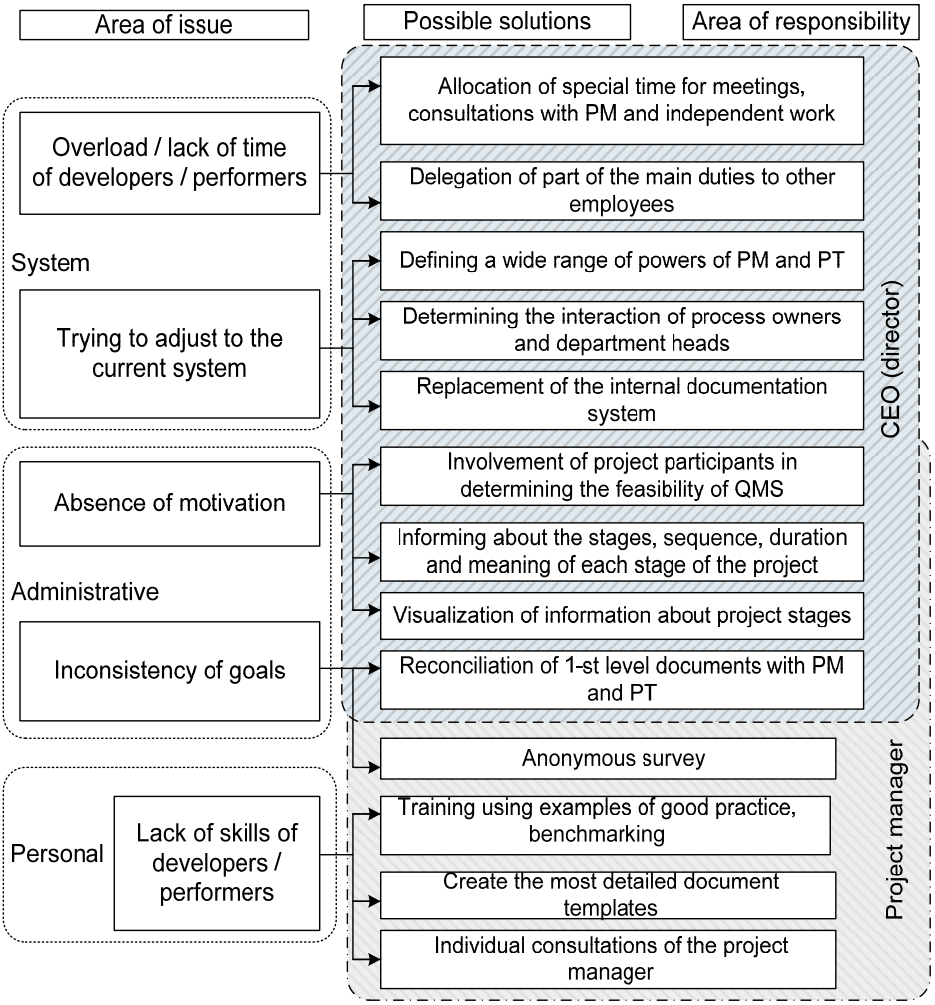
Issues related to motivation of participants involve a very wide range of solutions. But we consider it is necessary to focus on measures not material incentives, but on internal levers aimed at understanding the importance of the project. But we consider it is necessary to focus not on material incentives, but on internal levers aimed at understanding the importance of the project. To explain the feasibility of QMS, the participants should be asked to determine for themselves why QMS may be important to the Company and to them personally, or what effect they expect from the introduction of QMS. It is essential for motivation to inform the project participants about the stages of the project, their sequence, duration and feasibility. It is also possible to ask participants to determine what the appropriateness of a particular stage is. Project management methods also emphasize the expediency of visualizing information and marking the completed stages of the project, as well as "celebrating milestones", i.e., the completion of certain stages.

Top-level discussions and positions with PT members (or with the project manager) as well as an anonymous survey of PT members will help to achieve the alignment of goals by senior management.

Based on the revision of these measures, we propose the following division of areas of responsibility for the organization of these activities (Figure 3).

The figure 3 shows that in the field of competence of the leaders of the organization is overcoming systemic and motivational problems. At the same time, in the area of competence of the project manager should be overcoming unprofessionalism, prevention of inconsistencies in the formation of a higher level of QMS. At the same time, the area of competence of the Project Manager should include overcoming the unprofessionalism of employees, preventing inconsistencies in the formation of a higher level of QMS. In the field of motivation, the competencies of the Director and the Project Manager intersect.

Figure 3. The most common issues and areas of responsibilities in QMS implementation process



Source: The authors' own work.

5. CONCLUSIONS

Introducing QMS at the enterprise represents a project with the specific scope, time-limit and budget, and it consists of traditional project phases. Each phase has a number of stages, each of which ends with a specific result that must be documented.

The proposed detailed step-by-step plan allows us to constitute the QMS implementation project and identify the necessary resources.

Problematic issues that arise in the process of QMS implementation are based on personal, systemic or leadership factors. Overcoming issues based on systemic and partly on leadership factors belongs to the competence of the CEO or top-management of the company. Overcoming issues based on personal and partly on leadership factors is the responsibility of the project manager.

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