Methodology for analytical supply chain management in industrial production

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Abstract. The main purpose of this research is to develop scientific and methodological support for the supplier evaluation process to improve the supply chain management mechanisms for the manufacturing of components. The results of the research can be applied in any light and heavy industry, from medical equipment to aerospace applications. The problem is solved in a few simple steps which are described in the paper, namely: conducting an analysis of procurement legislation for current limitations and assumptions on nonfinancial requirements for suppliers, performing a parametric analysis of global supplier assessment practises, and developing an analytical method for evaluating suppliers with justification of distinguishing characteristics. In conclusion, some practical recommendations can be made.

1 Introduction

The development strategy of the modern world is the quality of life of people in all aspects of its manifestation. Economic development is determined not only by the amount of investment, but also by the qualitative improvements in goods and services, which will allow them to become competitive in domestic and international markets. Modern methods of achieving high quality are based on a methodology developed enshrined in ISO standards, and its implementation is carried out not only by the manufacturers concerned, but also by public organisations, such as the EQO (European Organisation for Quality) [1].

The quality, efficiency, and safety of the products [2] depend directly on the quality of raw materials, semi-finished products, services and, consequently, the work of the suppliers of the production company (manufacturer). The combination of these factors ensures the competitiveness of the manufacturer (producer) of MI on the market. Poor quality raw materials, semi-finished products and services purchased from suppliers or poor quality services provided to them by subcontractors ultimately lead either to the costs of rework/rework of defects or disposal or to dissatisfaction of end users, which may lead to suspension of production with subsequent criminal liability.

In view of the above, the enterprise (manufacturer) faces the task of increasing the reliability of suppliers in order to be able to insure itself against disruptions in terms of deadlines and failures in the performance of the tasks of producing a high-quality, efficient

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and safe product. The solution of this problem can be development by the enterprise of scientific-methodical support of processes of estimation and development of suppliers, aimed at reduction of risks of selection of incompetent/improper quality suppliers and development of suppliers to a certain acceptable level [3].

Using the tool (analytical method) of supplier assessment, in advance they can identify weaknesses of suppliers, risks associated with them and based on these risks decide on the possibility of further cooperation, take actions towards suppliers aimed at reducing or eliminating the identified risks [4].

2 Methodology

It is not feasible for a manufacturer (manufacturer) acting as a purchaser to carry out assessment audits on all potential suppliers, as the costs in this case may exceed the possible financial losses from the actions of incompetent suppliers. Therefore, the risk-based approach consists in defining the audit objects for which the audit is economically justified. The main challenge is to find a balance between the sum of the costs of quality assurance and the benefits (in terms of increased profits) from higher quality [5].

The first step in identifying the audit objects for the manufacturer (manufacturer) is to sort the products procured by value. But this is not enough, as the cost of non-conformance is not always directly related to the cost of the final product. For example, non-compliance with the quality of a minor component of the product's raw material or the failure of a relatively inexpensive part may result in the detection of side effects [6] not declared in the operational documentation, undesirable reactions during its application, facts and circumstances that endanger the life and health of citizens and workers during application and operation, and this may lead to the threat of harm to life and health of citizens, withdrawal from circulation, and reputation risks associated with a change in attitude of consumers and society as a whole, The use of elements of the methodology to analyse the types and consequences of potential design non-conformities has led to the classification of products in different industries in order to apply a differentiated approach to the application of quality management tools [7].

Considering the light industry, for example the sphere of additive technologies [8-9], one can easily say that this "young" industry is currently undergoing the stage of nomenclature sources and standards regulation, but in the medical industry one can see that the risk-oriented approach to the application of quality management tools is reflected in the classification of medical devices in accordance with the risk class (x_1). Assignment of risk class is carried out in accordance with the requirements of Order of the Ministry of Health of Russia 4n [10], GOST 31508 [11], Decision of the Board of UEC No. 173 [12]. However, it should be noted that the assignment of risk classes of medical devices is not based on an assessment of the likelihood of non-compliance of a medical device, but on the potential risk of its use [13]. When classifying medical devices, their functional purpose and conditions of use, duration of use of medical devices, invasiveness of medical devices, presence of contact of medical devices with the human body or interrelation with it, method of introduction of medical devices into the human body (through anatomical cavities or by surgery), use of medical devices for vital organs and systems (heart, central circulatory system, central nervous system), use of energy sources.

When classifying medical devices, each medical device [14] can only be assigned to one class:

($x_{1.1}$) class 1 - low-risk medical devices;
($x_{1.2}$) class 2a - medium risk medical devices;
($x_{1.3}$) class 2b - high-risk medical devices;
($x_{1.4}$) class 3 - high-risk medical devices.

An indicative classification of medical devices according to risk of use is shown in Table 1.

Table 1. Classification of medical devices by risk of use.

Class	**Nature of the products**	**Example of a product type**
1	Low-risk products	Non-automated blood pressure meters, microscopes, binocular and stereoscopic vision instruments, test lens and prism sets, medical equipment in terms of manual and hydraulic hospital beds, operating tables, chairs, dental chairs, some glassware, etc.
2a	Products with a medium degree of risk	Audiometers, laboratory equipment, special dressings, spirometers, thermal imagers, electromyographs, rigid and flexible endoscopes, echoophthalmoscopes, echosinusoscopes, hearing aids, etc.
2b	High-risk products	Pulse and heart rate monitors, pulse oximeters, cardiac analysers, electrocardiographs etc.
3	High-risk products	Circulatory and other life-sustaining organ replacement equipment

However, defining the scope of quality assurance requirements based on the risk class of a medical device does not fully take into account the impact of non-conformities on project economics and timing. GOST R 50444 "Medical devices, apparatus and equipment. General technical requirements" [15] classifies medical devices:

- (x_2) depending on the perceived mechanical influences;
- (x_3) depending on the possible consequences of failure in use.

Medical devices are divided into five groups depending on the mechanical forces they are subjected to:

$(x_{2.1})$ 1 – stationary;

$(x_{2.2})$ 2 – Wearable, portable and movable, not intended to be carried and moved within a stationary room;

$(x_{2.3})$ 3 – Wearable, portable and mobile, designed to be carried and moved within the confines of a fixed installation;

$(x_{2.4})$ 4 – transportable, as well as permanently installed on mobile medical devices, not intended for transport or on-the-go work;

$(x_{2.5})$ 5 – transportable, as well as permanently installed on mobile medical installations designed to work in transport or on the move, mobile medical installations.

Products are divided into classes according to the possible consequences of failure during use:

$(x_{3.1})$ A – products whose failure poses an immediate risk to the patient's life;

$(x_{3.2})$ B – products whose failure, while not immediately life-threatening, may have harmful effects on the patient's health;

$(x_{3.3})$ C – items whose failure reduces efficiency or delays the treatment and diagnostic process in non-critical situations, or increases the burden on medical or care personnel;

$(x_{3.4})$ D – products whose failure does not cause disruption of essential functions, but only changes in additional characteristics that do not cause consequences for the patient.

It should also be borne in mind that when considering the risks associated with use, the medical device manufacturer prepares a "Risk Management File" at the design stage, which accompanies the product throughout its entire life cycle. The risk analysis was carried out in accordance with the requirements of [15]. The risk concept includes two components:

a) (x_4) likelihood of harm;

b)(x_5) the consequences of the harm caused, i.e. its severity.

When using the method of probability of harm analysis, product categories are determined on the basis of an assessment of the following criteria:

- $(x_{4.1})$ very high risk;

- ($x_{4.2}$) high risk;
- ($x_{4.3}$) medium risk;
- ($x_{4.4}$) low risk;
- ($x_{4.5}$) remote risk.

As a result of the assessment, it is proposed to assign numerical values to the criteria (from 0 to 5) and add up the scores to calculate the final rating. The criterion "very high risk" has priority and is therefore multiplied by 2 when calculating the rating. Depending on the final rating, it is recommended to classify the product to enable a differentiated approach to the application of quality management tools.

When using the method of analysis, the consequences of the harm caused, i.e. its severity, product categories are determined on the basis of an assessment of the following criteria:

- ($x_{5.1}$) of occurrence - probability of occurrence;
- ($x_{5.2}$) significance - the effect of a product not conforming to safety;
- ($x_{5.3}$) detection - the ability to prevent and detect non-compliance in a timely manner.

3 Discussion

In recent decades, the sourcing process has played an increasingly important role in procurement activities. The growing importance of supply chain management is leading manufacturers (producers) to review and improve their procurement activities, a change that benefits all market participants: consumers, suppliers, producers (producers) acting as customers.

The development of quality management methods has deep roots. The formation of the system approach to quality management is based on scientific developments in the field of metrology, standardization, certification and general quality theory. The general theory of product quality is formed in the works of famous scientists, such as V.V. Boytsov, B.V. Boytsov, O.P. Gludkin, V.A. Komkov, A.B. Glichev, etc. [16] Theoretical foundations of standardization have been considered in the works of V.V. Treyer, A.P. Shalaev, G.I. Elkin, Y.V. Budkin, etc. A.F. Feigenbaum, G. Taguchi devoted to the study of quality management methods. Significant contribution to the study of certification problems, as well as conformity assessment has been made by such researchers as Y.I. Deniskin, A.R. Deniskina, M.L. Rakhmanov, V.A. Shulov, etc. [17].

G. Dixon [18] concluded that the more complex the goods/works/services to be purchased, the more important the non-financial selection criteria become and vice versa, in the procurement of simple goods/works/services the price remains the main selection criterion. He therefore concluded that the nature of the goods/works/services to be procured had a significant impact on the criteria to be considered when selecting a supplier.

In 2011. S. Hossein Cheraghi from Wichita State University and M. Dadashzadeh from the University of Auckland in their paper "Critical criteria for supplier selection: an update" [19] revised the criteria outlined by G. Dixon in 1966 [19] revised the criteria outlined by G. Dixon in 1966. Based on an analysis of over 110 scientific papers, the authors conducted a study that showed a significant change in the relative importance of different sourcing criteria between 1990 and 2001, compared to 1966-1990. Increased competition, globalisation of markets, and the development of innovative technologies have combined to change the relative importance of different sourcing criteria and the emergence of new ones. In addition to traditional criteria such as: quality, on-time delivery, price, service, technological capability, production capacity, new criteria have become important - reliability, desire to build long-term partnerships, continuous improvement, supply chain management. Based on their research, the authors conclude that supplier selection criteria will continue to change.

4 Result

As a result of the evaluation of these criteria, they are assigned numerical values (on a 10-point scale). Multiplication of these values results in risk number (RN), depending on the value of which the product is classified in one of the quality assurance categories. The number of categories and their PD boundaries may be determined by any organisation at its discretion. In doing so, the values of the "Significance" and "Detection" criteria shall be determined by expert judgement. To assess the frequency of "Occurrence", available statistical data on similar products (frequency of failures over a certain period of time) are used. If such data are not available, it is permissible to give subjective expert assessments.

It seems advisable to use the second of these methods of product classification, used in accordance with GOST ISO 14971, because of its simplicity and the possibility of taking into account many risk factors without taking into account the contamination of workplaces [20-21]. To determine the category of the product we will consider the following characteristics (Fig. 1):

- safety (including technical, electromagnetic, biological, radiological (as applicable));
- impact of delay (consideration of possible loss of profit, e.g. due to delayed delivery/performance, etc.);
- completeness of development (need for developmental work);
- complexity (complexity of manufacturing, assembly, maintenance, replacement);
- product value;
- time limits (for production/performance of work/services);
- transportability in standard containers and without special transport [22-39]

It is proposed that the specified characteristics of the products be evaluated on a 3-point scale. The conditions for assigning points to the product characteristics are shown in Table 2.

Table 2. Criteria for assigning numerical values to product characteristics.

Feature[1]	Point		
	0	**1**	**2**
Safety (a)	Failure does not cause disruption of basic functions, but only changes in additional characteristics that do not cause consequences for the patient (risk class 1)	Failure of items that reduce efficiency or delay the treatment and diagnostic process in non-critical situations, or increase the burden on medical or care staff (e.g. risk class 2a)	Failure will result in a risk of harm to life and limb (e.g. 2a,2b and 3)
Effect of a delay (b)	Delayed delivery is not critical to the production process	Delayed delivery will result in a stoppage of the production process or a delay in the performance of the revenue contract (the timing of the key event will be compromised), with compensatory measures to address the delay possible	Delayed delivery will result in stoppage of the production process (e.g. key delivery/construction/scheduled preventive maintenance events will be missed) or delayed performance of the revenue contract (any compensatory measures are ineffective)
Complexity (c)	• A standardised product and/or a product designed to perform simple (elementary) functions. • A small number of process steps. Simple technological process[3]. • High processability (production, operation, maintenance)	• The product includes a number of assemblies with specific functions, but is designed to assemble more complex products. • Several technological operations. A complex technological process[4].	• The product includes a number of assemblies with specific functions and is designed to be used independently. • Many technological operations. Complex technological process. Application of STP for production. • Comprehensive supplier procurement-delivery of equipment and construction works to fulfil customer requirements • Low manufacturability (production, maintenance, repair)
Development (d)	Production according to customer specifications	The customer has design documentation and prototype documentation. Development of design documentation for a series production product is required.	A new product needs to be developed according to customer specifications
Cost (e)	Less than RUB 10 million per unit of product/work or service worth less than RUB 50 million	More than RUB 10 million per unit of product/work or service costing more than RUB 50 million and less than RUB 100 million	More than 50 million roubles per unit of a product/work or service worth more than 100 million roubles
Timeline (f)	Less than 3 months	3-6 months	More than 6 months (long lead time equipment)

The product category is determined on the basis of the safety effect of the product and

the resulting rating, which is calculated according to the following formula:

$H = K_1 \times a + b + c + d + e + f$ – total generalised decision-making criterion,

where *a, b, c, d, e, f* - points assigned to product features.

K_1- severity factor. $K_1 = 2$.

Depending on the product category, the applicability of the audit tool in the procurement procedure is determined (Table 3).

Table 3. Applicability of the audit tool according to product category.

Final ranking	**2a, 2b, 3 risk class**	**1 risk class**
0-3	-	as decided by the customer
4-5	recommended	as decided by the customer
6-7	recommended	recommended
8-9	by all means	recommended
10-14	by all means	by all means

Where:

– Category B-C, the use of a tool is compulsory;

– Category A-B, the use of the tool is recommended;

– Category 0-A, the tool is applied at the customer's discretion.

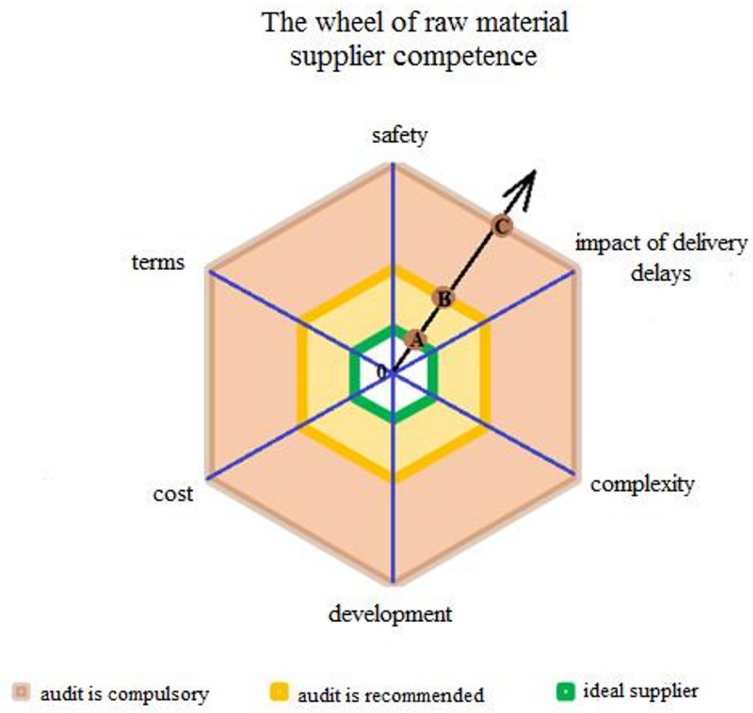

Fig. 1. Leaf diagram "Scope of tolerance of raw material suppliers". The area of the 'ideal supplier' (0-A) from 0 till 3; Area "recommended audit" (A-B) from 3 till 7; The area of "mandatory audit" (B-C) up to 7.

5 Conclusions

It should be noted that using the category system in conjunction with the failure type and consequence analysis method, based in addition to relevance on the probability of occurrence of a nonconformance and the ability to prevent and detect a nonconformance in a timely manner, the automation of initial selection allows a faster process of identifying nonconformances. In the absence of an industry-wide unified non-conformance management system and sufficient statistical data on non-conformances, the reliability of assigning the probability of occurrence of a non-conformance is low. At the same time, if the industry has a classification based on the potential risk of a medical product and a differentiated approach to the application of quality assurance tools, the ability to prevent and detect non-conformities in a timely manner is high for a quality product. Thus, when a category system is used in the medical device industry, a sufficiently low priority risk number can be assigned to the safety of the final medical device. The validity of a category system for medical products using the assessment of product characteristics is currently higher, however, the application of both methods, as well as the combination of their elements, seems to be possible.

It is not enough to classify the products procured in order to define the audit object, because the evaluation tool can have its own nuances at different stages of the interaction with suppliers.

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