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*Classification of Quality Management Methods and Tools in  
a Functional Approach*

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### Abstract

**Theoretical background:** The evolution of the instrumentation of quality management makes the list of methods and tools constantly open and inexhaustible. The problems of dividing and classifying quality management instruments are very often discussed in the literature. The need to have a variety of methods and tools is due to the fact that the development of modern competitive strategies, affecting the strengthening of market position, the need for rapid decision-making, as well as progress, mainly in the field of information technology and continuous changes in markets, pose qualitatively new challenges to managers.

**Purpose of the article:** The purpose of this article is to present selected quality management instrumentation by process group.

**Research methods:** In this article, literature review was the starting point for empirical research. Finally, a set of fifty new and classic quality management methods and tools in relation to their main functions was analysed. Based on this, data tables were generated.

**Main findings:** In a large collection of methods, tools and solutions, new concepts appear that are multi-disciplinary and require interdisciplinary knowledge. The choice of appropriate quality instruments is determined by the specificity of the organization and many other variables. The correct use of quality management instruments contributes to solving problems at the management and executive levels of production enterprises, while enriching knowledge about processes.

### Introduction

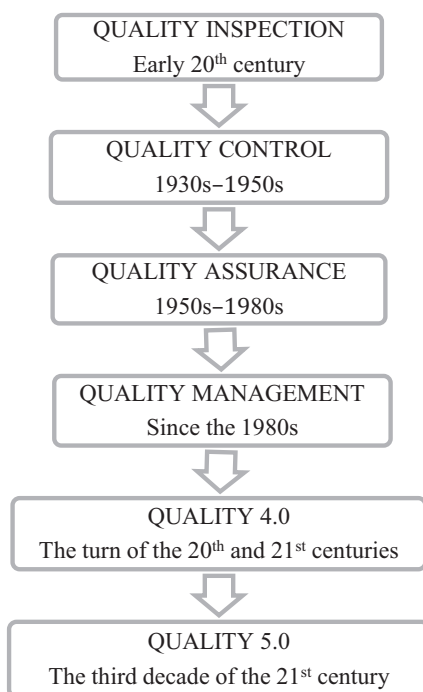
Quality management is timeless, and is rooted in quality being inherent in human development. When considering definitions of the concept of quality, a certain difficulty arises caused by its subjective nature. The premises from which the problems arise concern (Bugdol, 2008):

- quality assessment dependent on experience, knowledge, demand for the product,
- the concept of quality undergoing transformation as a result of the development of mankind and the quality changes taking place,
- the level of awareness of employees and superiors and the degree of implementation of quality concepts in enterprises affecting quality assessment and practical approach to product quality,
- customer requirements determining the level of quality of products,
- multidimensionality and interdisciplinarity.

Management by quality requires the active cooperation of all employees of a company to ensure the highest quality of products and services, and to take care of increasingly better relations based on mutual trust between the manufacturer, the seller and the customer (Hebda-Grodzka, 2002). Hamrol and Mantura point out “that it is difficult to date the various phases of development of quality management, since they proceeded differently in different countries, regions, industries, enterprises, and in theory and practice” (1998, pp. 90–98). Determining the precise dates of the emergence of the various stages of development of management by quality is difficult and conventional. In the literature, until recently, four basic stages of development were most often mentioned: quality inspection, quality control, quality assurance and quality management (Dahlgaard et al., 2004, p. 17), however, the development of new technologies has

changed the approach to quality. In recent years, the concept of Quality 4.0 has begun to appear in the literature as an adaptation to the developing Industry 4.0. The new digitalized quality management takes advantage of modern technologies such as the Internet of Things (IoT), artificial intelligence (AI) and Big Data. What follows is the use of automated sensors, advanced data analysis, and improved communications to monitor production processes in real time, identify defects, and improve productivity. Intelligent systems can automatically and autonomously collect data and consequently obtain information about production cycles, quality requirements and waste production (Salimbeni et al., 2023). They also allow modeling, simulation and forecasting of process and product quality, which supports informed decision-making in this regard (Zonnenshain & Kenett, 2020; Antony et al., 2022).

The reorientation of the world to sustainable development, including a focus on people and the environment with the use of IT and automation, has become the crux of the introduction of Quality 5.0. Optimization of production processes is currently being treated in an expanded scope of influence, as advanced data analysis can help improve production processes, not only reducing production times and eliminating unnecessary waste, but also optimizing the use of raw materials and energy, which corresponds to greener processes (Tadić Stanić, 2022).



**Figure 1.** Stages of development of quality management

Fundin et al. (2020) identify five areas that will concern quality in the current decade. These are: system perspectives, stability of change, models of intelligent self-organization, integration of sustainable development and higher purpose as support for quality management. Challenges nato-have included providing systematics and methodologies to explore and understand root causes and diversity, as well as knowledge about developing organizational capacity for learning, change and adaptation (Fundin et al., 2020). The stages of evolution of the quality approach are shown in Figure 1.

## Literature review

The very small number of studies on the classification of quality management methods and tools prompted to focus on this topic in the article. The literature review began with a search for entries in the Scopus database.

**Table 1.** Search results for key terms in the Scopus database in 2024

| Searching   |                               |                                |
|---|-------------------------------|--------------------------------|
| Searched phrase   | Number of results in keywords | Number of results in the title |
| Classification of quality methods and tools                 | 160                           | 1                              |
| Classification of quality management methods and tools      | 20                            | 0                              |
| Functional division of quality methods and tools            | 0                             | 0                              |
| Functional division of quality management methods and tools | 0                             | 0                              |

Source: Authors' own study based on Scopus database.

Analyzing the data from Table 1, it can be concluded that the topic of classification, methods and tools is discussed in the literature. However, the issue of functional divisions is much worse, which is confirmed by the lack of any sources in the extensive Scopus database. For more sources of articles, the Google Scholar and ResearchGate databases were used. In total, the literature review included nearly fifty sources on which the author's own research was based. Most of them were published after 2010.

A review of the literature confirms that the practice of quality management is to be based on scientific evidence that combines the achievements of quality management and management organization science, creating a theory of quality management. This management is supposed to be the study, review, mutual adaptation and growth of the relationship between quality and management issues in organizations. Hence, quality management is titled the realization of management functions according to the quality of the managed system. This management includes the quality of the system taken as a whole, as well as all its components. In the cyber context, quality management functions can be evaluated by comparing the ratio of quality at the output to quality at the input of the process (Hamrol & Mantura, 2005, pp. 99–103).

Moreover, quality management is the substrate of effective leadership implemented through (Łańcucki, 2003):

- a commitment to continuous improvement and management of improvement systems,
- a philosophy of doing things right the first time,
- modern supervised and coached management processes through teamwork,
- training in understanding the nature and essence of the supplier–customer relationship,
- improvement of communication,
- development and systematic implementation of TQM.

The successful implementation of quality management in an organization depends on the fulfillment of many aspects, such as the involvement of top management and all employees, continuous training, education and the use of quality methods and tools (Skrzypek & Hofman, 2010).

The instrumentation of quality management includes quality principles, methods, techniques and tools. The difference is the range of impact of each instrument. The characteristic feature of the principles is the long-term impact and influence on the development strategy of the enterprise. Principles do not provide ready-made solutions or a scheme of conduct, but serve to guide and motivate efforts to improve and enhance quality in enterprises. As for the methods, they make it possible to indicate medium-term impact, shaping the design quality and performance quality of products. On the other hand, short-term in impact are tools, the effective use of which can be seen in combination with other methods. The last group is made up of techniques, which are components of principles, methods or tools and are used to achieve specific goals within the entire instrumentation (Hamrol & Mantura, 2002; Mazur & Gołaś, 2010). The integration of several quality management instruments shows data in different ways while creating a comprehensive analysis of information. Each instrument is equally important because of its diversity (Bamford & Greatbanks, 2005, pp. 378–379).

The evolution of the instrumentation of quality management makes the list of methods and tools constantly open and inexhaustible. The problems of dividing and classifying quality management instruments are very often discussed in the literature (Jękał & Małysa, 2022, pp. 2–6; Tomaszewska, 2022, pp. 117–130; Winkowska & Winkowski, 2018, pp. 370–381; Frąś et al., 2017, pp. 175–188; Hamrol, 2017, pp. 153–206; Wolniak, 2019, pp. 15–23; Marzec, 2017, pp. 79–90; Wawak, 2013, pp. 37–49).

One of the classifications indicated is QT&T (quality tools and techniques) based on the SIPOC (suppliers, inputs, process, outputs, customers) diagram. The first rationale for this classification was the diversity of functioning quality management instruments, i.e. methods, tools, principles, concepts, ideas and approaches. The second was the diversity of environments, as well as the orientation towards the formulation of organizational knowledge resources (Starzyńska & Grabowska, 2010, pp. 515–524).

Another of the classifications that has been popular with employees of companies in various industries for years distinguishes seven new and seven traditional quality tools. It serves to engage in problem solving, promote creative thinking, graphical presentation of results, search for causes of various undesirable events and areas for improvement (Mazur, 2023, p. 106). New management approaches improving the development of new quality concepts and tools are being identified. Some sources state that combining traditional quality methods with the use of Big Data and artificial intelligence will accelerate and improve operations within organizations in the near future (Broday, 2022, pp. 368–382). It is possible to see the positive impact of the use of methods and tools supporting quality management in conjunction with the concept of lean management, which have a significant impact on reducing the occurrence of production problems (Jękał & Małyśa, 2022, pp. 2–6).

The use of quality management instruments contributes to solving problems at the management and executive levels of manufacturing enterprises, enriching process knowledge. Quality management instruments are designed to (Starzyńska & Grabowska, 2010, pp. 515–524):

- collect data and process it into information about events and processes occurring in the production system and its environment,
- support decision-making on the basis of verified data and information,
- improve the work of an individual employee and motivate teamwork.

Among the factors that have led to a huge variety of quality management instruments (especially at the level of implementation of executive processes) are the following (Starzyńska & Grabowska, 2010, pp. 515–524):

- the long history of the development of quality management concepts,
- the dissimilarity of the cultures in which they were developed,
- approaches emphasizing different elements of the concept,
- interpenetration of “quality” concepts with production management concepts,
- assignment to different organizational levels of the enterprise,
- placement in different phases of the product life cycle.

A prerequisite for the effective use of quality management instruments is the understanding of the need for their use and the full involvement and support of top management, the planning and organization of functions related to the implementation of the instruments, the involvement and participation of employees based on teamwork, and a properly conducted training program (Mazur & Gołaś, 2010, p. 28). The need to have a variety of methods and tools is due to the fact that the development of modern competitive strategies, affecting the strengthening of market position, the need for rapid decision-making, as well as progress, mainly in the field of information technology and continuous changes in markets, pose qualitatively new challenges to managers. The implementation of new management principles is a lengthy, difficult, and conflicting process. It is recommended to create programs in organizations for the comprehensive implementation of both concepts and a variety of methods (Pałucha, 2012, pp. 260–261).

## Research methods

The main methodology in this article was a literature review. In addition to quality management methods and tools, the literature review also included those from lean management and contemporary management. The reason is its increasing use in the area of quality management. Based on the indicated attempts to expand the classical approach to quality management methods and tools, a decision was made to use a complex set of instruments in the article. The literature review, as mentioned earlier, involved finding various classifications and divisions of quality management methods and tools (Jękal & Małyś, 2022, pp. 2–6; Tomaszewska, 2022, pp. 117–130; Winkowska & Winkowski, 2018, pp. 370–381; Fraś et al., 2017, pp. 175–188; Hamrol, 2017, pp. 153–206; Wolniak, 2019, pp. 15–23; Marzec, 2017, pp. 79–90; Wawak, 2013, pp. 37–49; Starzyńska & Grabowska, 2010, pp. 515–524). In enterprise quality management, quantitative and qualitative methods, tools and techniques are used to improve key quality elements (Vernon, 2002, p. 172).

The selection of quality management methods and tools that will bring the most benefits are based on various criteria, depending on the needs. They are used both during quality improvement, checking and analysis of results after implementation (Winkowska & Winkowski, 2018, pp. 370–381). A hypothesis was put forward stating that, based on the literature review, a set of quality management methods and tools can be identified, divided into functions.

## Results

The analysis of the literature on quality management instrumentation made it possible to identify directions for their use, and in the next step to subjectively group the fifty instruments selected during the literature review around the functions:

- A) organization of production processes,
- B) product design and improvement,
- C) data identification and analysis,
- D) process management,
- E) organization design,
- F) organizational performance evaluation,
- G) continuous improvement,
- H) engaging employees.

The continuous emergence of new instruments related to TQM, lean, modern process management, knowledge management, enterprise sets a comprehensive basket of 50 methods and tools that serve quality management. It is interesting and valuable to summarize quality management methods and tools from the perspective of their use, where the key is the functions and management processes they support (Tables 2–9). Each instrument has been assigned to a category of functions indicating

the main functions performed. In the case of methods corresponding to more than one function, the primary consideration was their original use.

**A) organization of production processes** (purpose: to ensure appropriate process conditions)

**Table 2.** Set of methods/tools/techniques assigned to functional group A

| No. | Method/tool/technique                | Action  |
|-----|--------------------------------------|---|
| 1   | 5S                                   | Systematic and sustainable order at workstations                          |
| 2   | Kanban                               | Inventory control   |
| 3   | Poka Yoke                            | Detection and elimination of errors                                       |
| 4   | SMED (single minute exchange of die) | Reducing changeover times of machines, equipment and production processes |
| 5   | TPM (total productive maintenance)   | Use of available machine time to produce products                         |
| 6   | Process validation                   | Confirmation by providing proof of meeting a specific requirement         |
| 7   | JiT (just in time)                   | On-time production, reduction of inventory                                |
| 8   | Statistical quality control          | Observation of processes, response to nonconformities                     |

Source: Authors' own study based on: (Salwin et al., 2019, pp. 137–151; Szwedzka & Jasiulewicz-Kaczmarek, 2015, pp. 408–414; Osada, 1991; Konieczka & Konieczna, 2019; Langowska, 2008, p. 7; Chan et al., 2005; Belu et al., 2015, Danielak & Pujer, 2017; Kołakowska, 2018, pp. 91–92).

In the first area organization of production processes there is a huge amount of management-related instruments, but not all of them are related to quality. A limited number of management methods, tools and techniques related to quality are indicated here. Some of them were developed in Japan for the purpose of improving production processes while maintaining the highest quality standards. They constitute the basis for techniques and detailed solutions used in the design of work stations, cells and production lines.

**B) product design and improvement** (purpose: to transform input assumptions into product specifications and then manufacturing processes, taking into account the possibility of achieving design quality within existing technical and financial constraints, analyzing performance, identifying opportunities and making incremental changes)

**Table 3.** Set of methods/tools/techniques assigned to functional group B

| No. | Method/tool/technique                    | Action   |
|-----|--|--|
| 1   | FMEA (failure mode and effects analysis) | Identify potential risks and impacts that may occur during project implementation  |
| 2   | QFD (quality function deployment)        | Transmission of information from the market on consumer requirements, technical parameters used by designers in the organization     |
| 3   | SERVQUAL                                 | Service quality assessment combining service quality design simultaneously from the point of view of the enterprise and the customer |
| 4   | Valuing quality                          | Evaluating product quality and solving decision-making problems  |
| 5   | Taguchi method                           | Designing parameters aimed at finding optimal values for controllable factors  |

Source: Authors' own study based on: (Macura et al., 2022, pp. 103–118; Taguchi & Clausing, 1990, pp. 65–75; Mazur & Golaś, 2010; Urbaniak, 2013, pp. 29–38; Mantura, 2012, pp. 37–24).



Within the design and improvement function, methods and tools related to material products, design and improvement of services have found their place. The oldest of the methods mentioned in this function is FMEA, which identifies potential threats and effects that may occur during the implementation of the project/process.

**C) data identification and analysis** (purpose: to generate knowledge about a given phenomenon, to check, organize, transform and model data in order to gain useful information, develop conclusions)

**Table 4.** Set of methods/tools/techniques assigned to functional group C

| No. | Method/tool/technique | Action  |
|-----|-----------------------|---|
| 1   | Control chart         | Monitoring and control of process variability   |
| 2   | Affinity diagram      | Arranging information in groups   |
| 3   | Relationship diagram  | Demonstrating the relationships that exist between factors that affect difficulties   |
| 4   | Matrix diagram        | Showing the relationships between selected elements in the form of a matrix   |
| 5   | Pareto–Lorenz diagram | Solving problems by prioritizing them according to the most important causes  |
| 6   | Analysis sheet        | Collecting data with simultaneous ordering of data  |
| 7   | Histogram             | Detecting outliers, skewness, bimodality and other shape features in the distribution, as well as for comparing subgroups in the data |
| 8   | Ishikawa diagram      | Identifying problems and their causes   |
| 9   | Scatter diagram       | Investigating relationships between two factors   |

Source: Authors' own study based on: (Kowalik, 2018, pp. 15–17; Detyna, 2011, pp. 164–165; Bachman, 2017, pp. 46–47; Mazur-Dudzińska & Dudziński, 2015; Łuczak, 1994, p. 11; Miller, 2011, p. 449; Stefanów, 2007; Krechowicz, 2022; Łuczak & Matuszak-Flejszman, 2007, pp. 248–249).

The quality management instrumentation includes methods and techniques that use statistics, observation, and reasoning. Also, in the first half of the 20<sup>th</sup> century, the first production quality control systems were introduced, along with methods that are still popular today.

**D) process management** (purpose: to increase the efficiency of the organization)

**Table 5.** Set of methods/tools/techniques assigned to functional group D

| No. | Method/tool/technique             | Action   |
|-----|-----------------------------------|--|
| 1   | Six sigma                         | Monitoring and continuous control to eliminate nonconformities in processes and products |
| 2   | SPC (statistical process control) | Observation of processes and response to nonconformities                                 |
| 3   | Process capability analysis       | Determining the degree to which quality requirements are met                             |
| 4   | Skills matrix                     | Charting the existing and missing skills in the team of employees                        |
| 5   | Bernaténé–Grün chart              | Analysis and evaluation of procedures  |
| 6   | Clark chart                       | Analysis of the entities of the procedures   |
| 7   | Network diagrams                  | Presentation of interconnections between entities reducing the process execution time    |
| 8   | Flowchart                         | Presentation of the next steps in the algorithm  |

Source: Authors' own study based on: (Parab et al., 2016, pp. 85–97; Szerszunowicz, 2013, pp. 153–161; Bielińska, 2017, pp. 155–169; Czekaj, 1975; Ćwiklicki & Alcouffe, 2013; Grześ, 2014, pp. 196–214).

The process management function includes methods for describing processes and research tools that take into account statistics and improvement. The 20<sup>th</sup> century first brought statistical methods, and then diagrams, on the basis of which IT solutions are proposed. In the past, these systems were implemented in large corporations, now there are generally available applications for smaller and medium-sized enterprises on the market.

### **E) organization design** (purpose: to identify elements of structure and ties)

**Table 6.** Set of methods/tools/techniques assigned to functional group E

| No. | Method/tool/technique          | Action  |
|-----|--------------------------------|---|
| 1   | Process decision program chart | Analyze events using simulations, determine preventive actions  |
| 2   | Quality planning               | Identify and implement actions necessary to ensure that customer expectations for a product or service are met                      |
| 3   | Benchmarking                   | Comparison of processes and practices used by own organization to those used by organizations considered best in a particular field |
| 4   | Decision tree                  | Graphic decision support  |

Source: Authors' own study based on: (Hamrol & Mantura, 2005; Małyshko & Wielgosz, 2016, pp. 318–323; Podgórska, 2013, pp. 325–337; Xu et al., 2018, pp. 79–102).

Over the years, a number of methods and techniques have been developed to support the design of organizations. Some of them were created for dedicated management fields.

### **F) evaluation of the organization's performance** (purpose: to evaluate the effectiveness and efficiency of the organization)

**Table 7.** Set of methods/tools/techniques assigned to functional group F

| No. | Method/tool/technique                          | Action   |
|-----|--|--|
| 1   | The Deming Application Prize                   | Evaluating the organization according to the criteria: organization's policies and goals, organization and its operational activities, knowledge education and dissemination, data collection, communication and its use, analysis, standardization, control, quality assurance, results, future plans |
| 2   | Malcolm Baldrige National Quality Award        | Evaluate the organization according to criteria: leadership, strategic planning, customer and market focus, information, analysis and knowledge management, human resource management, process management, business performance  |
| 3   | The European Foundation for Quality Management | Identification of where the organization is on the path to excellence  |
| 4   | Customer Satisfaction Survey                   | Identification, diagnosis and classification of stakeholders   |
| 5   | ISO 9004 Self-Audit                            | Charting guidelines for self-assessment and improvement  |
| 6   | Cost of quality                                | Presentation of progress and quality issues in the organization  |

| No. | Method/tool/technique | Action   |
|-----|-----------------------|--|
| 7   | Management review     | Collection, summary of information and analysis made on the basis of the process measurements made |
| 8   | Internal audit        | Independent advisory and verification activities, improving the organization                       |

Source: Authors' own study based on: (Sułkowski & Wolniak, 2013; Kacała & Kołaczyk, 2013, pp. 145–154; Czernyszewicz, 2012, pp. 57–70; Imai, 2007; Szczęśniak, 2016; Kolman et al., 1996, pp. 24–25; Szczęśniak, 2016; Nowicki, 2015, pp. 284–315).

The group of methods indicated here allows for the collection of feedback on the functioning of the enterprise, some of them concern the current assessment, while the rest assess the entire organization. The first part consists of internal audits, management reviews, customer satisfaction surveys, the second part defines self-assessment models and the assessment of the organization according to the criteria of national and international awards.

**G) continuous improvement** (purpose: continuously achieving small improvements in process quality, product quality, delivery capability and service quality)

**Table 8.** Set of methods/tools/techniques assigned to functional group G

| No. | Method/tool/technique                                    | Action  |
|-----|--|---|
| 1   | Zero defects   | Identification of nonconformities and formulation of improvements for nonconformity level 0                 |
| 2   | Kaizen   | Continuous improvement of product and organizational quality  |
| 3   | PDCA (plan, do, check, act) cycle                        | Optimization of processes, seeking solutions to increase operational efficiency and financial effectiveness |
| 4   | DMaic (define, measure, analyse, improve, control) cycle | Problem solving, identification of requirements   |

Source: Authors' own study based on: (Nowosielski, 2014; Szczęśniak, 2016; Gupta, 2021, pp. 79–81).

Moving on to discuss the instruments of continuous improvement, it is important to note the multiple changes and evaluations of this concept. Currently, continuous improvement is identified with the Japanese philosophy of kaizen, which assumes the improvement of social, personal and work life.

**H) engaging employees** (purpose: to build trust in superiors, the organization and co-workers, appropriate working conditions and a well-thought-out incentive system)

**Table 9.** Set of methods/tools/techniques assigned to functional group H

| No. | Method/tool/technique | Action   |
|-----|-----------------------|--|
| 1   | Quality circle        | Group identification and development of an effective way to improve the studied phenomenon |
| 2   | Hoshin Kanri          | Goal planning and implementation by all employees  |
| 3   | Quality Audit Meeting | Group solution of current problems   |
| 4   | Empowerment           | Increasing employee empowerment  |

Source: Authors' own study based on: (Rodriguez et al., 2021, pp. 105–111; Konieczka, 2021, pp. 227–237; Kolman et al., 1996, p. 138; Krawczyk-Brylka, 2012, pp. 313–330).

Another of the indicated functions is engaging employees – a key factor in the success of pro-quality programs. Without employee engagement in quality improvement activities, one cannot count on the success of implementing a quality management system. Considering the individual functions of the methods/tools/techniques in Tables 2–9, there is no doubt that all the indicated instruments in such a view can be used to a greater or lesser extent in different enterprises. The requirement to improve quality management processes implies the selection of various concepts, methods or techniques of organization. The selection of appropriate quality instruments is determined by the specifics of the organization and many other variables. In addition to well-known solutions, new concepts are emerging that have a multidisciplinary character and require interdisciplinary knowledge.

## Discussions

Over fifty analyzed sources allowed to identify important quality management methods and tools. Eight basic functions were identified, i.e. organization design, process management, data identification and analysis, product design and improvement, organization of manufacturing processes, engaging employees, continuous improvement, and evaluation of organization performance. In the case of methods and tools corresponding to more than one function, the primary consideration was their original application. Some of them were indicated in other previously mentioned classifications, such as QT&T or seven new and seven traditional quality tools. However, none of the analyzed sources contained a functional division that could constitute a starting tool for working with quality management instruments.

The use of appropriate methods and tools of quality management is intended to maintain the correct quality of the product, as well as to reduce defects and inconsistencies already at the stage of production, and not during operation. When choosing an instrument or set of instruments to implement in the organization, it is worth paying attention to the indicated classification of functions, on the basis of which it is easy to adapt the desired instruments to the current needs of the organization.

## Conclusions

The article analyzes a set of new and classic quality management methods and tools around their main functions: organization of manufacturing processes, product design and improvement, data identification and analysis, process management, organization design, evaluation of the organization's functioning, continuous improvement and employee involvement. The hypothesis was confirmed, and a set of quality methods and tools defined by function was created.

In a large collection of methods, tools and solutions, new concepts appear that are multi-disciplinary and require interdisciplinary knowledge. The choice of appropriate quality instruments is determined by the specificity of the organization and many other variables. The correct use of quality management instruments contributes to solving problems at the management and executive levels of production enterprises, while enriching knowledge about processes.

The considerations presented in the article contained a comprehensive analysis of the problem and theoretical considerations. It should be emphasized, however, that this article does not completely exhaust the issue of divisions and classification of quality management methods and tools. It, therefore, seems reasonable to continue research on this multi-aspect and multi-dimensional issue. Mainly in the direction of an attempt to examine the application and usefulness of these quality management methods and tools. Another important aspect of further research that should be undertaken in the future should be to determine the boundary conditions for the use of quality management methods and tools for manufacturers of medical devices. An interesting direction also seems to be the examination of forms of support for the possibility of electronic improvement of the functioning of quality management methods and tools.

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