

MEANING OF THE QUALITY IN THE PRODUCTION OF MEDICAL PRODUCTS

4.1 INTRODUCTION

Each enterprise in contemporary world seeks the methods that help survive in the market and be successful. Vast variety and range of goods offered to customers cause that their quality, apart from price and timeliness, is becoming the main factor of competitiveness in enterprises.

The concept of the quality (Greek *poiotes*) has been present in humanity since Ancient times. Plato, a prominent Greek philosopher, defined quality as 'a kind of perfection'. When a Latin term was being promoted to reflect the Greek concept, Cicero introduced *qualitas*, which started to be used in many languages e.g. in English.

The contemporary concept of quality is defined as meeting or exceeding customer expectations. An important factor in using the above definition is increasing competition and growing richness of a particular part of society.

Quality exists in a number of aspects and approaches [6]:

- quality in value-based approach: humans expect that what they do should be good i.e. should have a particular value. This means that quality is connected with the value, while the value is connected with evaluation. In order to ensure adequate evaluation, one needs the criteria and the basis for criteria are particular reasons,
- quality in market approach – degree of consistency of the properties of the product with customer expectations. The attempts of balancing demand and supply occurs through quality,
- quality in systematic approach, considered much wider than merely at the level of the enterprise,
- quality in process approach: a process is regarded as an ordered and interrelated chain of events which transform inputs into the final products. With this approach, quality is not a single act but it results from different activities which caused that the obtained effect matches the expectations.

4.2 CHARACTERISTICS OF ENTERPRISE

The enterprise analysed in the study was established in 1988 and is a leading supplier of solutions in the sector of manufacturing wheelchairs for the disabled. The enterprise deals with production of parts and assembly of a lightweight version of wheelchairs.

The wheelchairs are used by patients who are unable to move independently or partially

independently with the help of another person. The modular structure of the wheelchairs and wide range of optional equipment offered (the basic version is equipped in fleece seats, cane holder, support for lower extremities after amputations) allow for adaptation of wheelchairs to the persons with limited opportunities of moving or persons with the lack of these chances due to degeneration and deformation of body parts, contractures and joint diseases, muscle and nerve damage, balance disturbances or human body emaciation due to cancer, lost limbs or paralysis.

In the case of individual orders, the following factors should be considered: body size and weight, physical and psychical condition, age of the patient and their housing and environmental conditions.

The wheelchairs are manufactured in the enterprise studied according to the requirements of the Directive 93/42/EEG that concerns medical products. According to the classificatory criteria for medical products, these wheelchairs were classified as class one. This means that the wheelchairs manufactured by the enterprise ensure a high level of utility and safety.

4.3 DESCRIPTION OF THE RESEARCH SUBJECT

The product analysed in the study is a wheelchair presented in figure 4.1. It features an aluminium frame, which ensures that its weight is relatively low. It is easy to fold and has a wide range of optional equipment.



Fig. 4.1 Wheelchair

Source: Material provided by the analysed enterprise

With high quality of the parts used and modular construction, the wheelchair can be adjusted to individual needs and preferences of customers. The model presented in the study

is dedicated to more active users due to the material and constructional solutions which reduce its weight and allow for an independent moving and active enjoying the life.

Technical specifications of the wheelchair:

1. seat width: 40.5 - 48 cm,
2. depth of the seat: 40 - 46 cm (original setting: 43 cm),
3. back height: 42.5 cm (possible change to 47.5 cm),
4. weight: from ca. 15 kg,
5. maximum load: 125 kg.

4.4 RESEARCH METHODOLOGY

BOST questionnaire (principles of Toyota management in questions) was created by Prof. Stanisław Borkowski, director in the Institute for Production Engineering in the Faculty of Management in the Częstochowa University of Technology and is based on the principles of Toyota manufacturing system. The name BOST comes from the first initial letters of the professor's first name and surname and is a proprietary name [1, 2, 3]. The questionnaire is universal and can be used in both manufacturing and service-providing enterprises (e.g. banks, hospitals, schools, shops).

The BOST questionnaire is dedicated to both managers and employees and the questions correspond to the Toyota's principles and the Toyota house roof [4]. Furthermore, the questionnaire allows for the evaluation of the managers according to the Toyota's principles, respondent's profile and specification of the enterprise's/institution's activities.

The BOST questionnaire is comprised of 12 sets of factors. The version for the employees includes a set of factors which determine the elements of the Toyota house roof and the principles 1, 2, 3, 4, 6, 7 and 14, whereas the version for the employers includes a set of factors that describe all the principles of management in Toyota and the elements of the Toyota house roof. The questionnaire contains a ranking of importance and the respondents evaluate the importance of each factor on a particular scale.

The first set of factors in the questionnaire for employees (area E1) represents Toyota house roof (quality, costs, lead time, work safety, employees' motivation) and respondents evaluate, on a scale of 1 to 5, which of the factors are the most important in the enterprise studied. Another group of factors (customer's good, independence and responsibility of employees, innovativeness of product, development of technology, cooperation with partners, care for the enterprise's culture, trust in relationships with employees) is denoted as the area E2 and relates to the principle 1 of Toyota ("Base your management decisions on a long-term philosophy, even at the expense of short-term financial goals") - the respondent evaluate, on a scale of 1 to 7, which of the factors they regarded as decisive in the concept of development in the enterprise.

The area E3, connected with the principle 2 of Toyota management ("Create a continuous process flow to bring problems to the surface"), concerns the factors which, according to the respondents, are the most important to the production process. The respondents can chose from the following factors: continuous system of detecting problems, stopping production after detection of the quality problem, standard tasks, processes and documents, delegating authority, using only reliable technologies, using visual control (on a

scale of 1 to 6).

Another set of factors is a set regarded as the area E4 and connected with the principle 3 of Toyota management ("Use the pull systems to avoid overproduction") and the respondent, on a scale of 1 to 4, evaluated which of the factors (production to order of customers, rational utilization of machines, people, generation of the product stock, short lead times) is ensured during organization of the manufacturing system.

The principle 4 of the Toyota management, i.e. "Level out the workload (heijunka)" is connected with another set of factors (equal workload for employees, equal load to machines, short series of products, regularity of deliveries) i.e. the area E5. The employees answer to the question of: Which factors are the most important to the production process? The above factors are evaluated on a scale of 1 to 4.

The area E6, which is comprised of such factors as time for performance of a single time, process, three-part warehouses, documents, training, flow of information or employment, is connected with the principle 6 of Toyota management ("Standardized tasks and processes are the foundation for continuous improvement and employee empowerment"). The respondents were asked to choose from the above set of factors and answer to the following question: Which type of standardization is the most important in ensuring continuous improvement of the processes in your enterprise (scale of 1 to 7) ?

Another set of factors relates to the principle 7 of Toyota management ("Use visual control so no problems are hidden"), denoted as E7. The respondents answered to the question: "Which factor is the most important to visual control". They used a scale of 1 to 6 and chose from the following factors: cleanliness, order, flow, information boards, participation in production places, monitoring, graphical presentation of the results.

The BOST questionnaire was carried out in the enterprise studied (wheelchair manufacturer) among the employees. The last set of factors (area E8), which related to the principle 14 of the Toyota management was also analysed in detail. ("Become a learning organization through relentless reflection (hansei) and continuous improvement (Kaizen).") and it included such factors as: the employment of workers – ZT, relations between employees and bosses – RE, motivation system – SM, documentation – DA, technology portfolio – PT, information flow – PN, quality – JK, cooperation with customers – WS, maintenance – UM, cooperation with suppliers and partners – WD. The employees in the enterprise studied focused on the above factors and responded using a scale of 1 to 10 to the question: Which area will produce best effects after its improvement ? [5].

In addition area E8, an analysis of the respondents structure, denoted as area E12 area was done. In BOST questionnaire we have six features of respondents: gender – MK, education level – WK, age – WI, job seniority – SC, mobility – MR, type of employment – TR) in order to determine the structure of human resources in the organizations studied.

4.5 ANALYSIS OF THE RESULTS

Table 4.1 and figure 4.2 present the respondents characteristics in the company studied (area E12 in the BOST questionnaire), which manufactures wheelchairs, divided into:

- gender (MK) – 1 – Man, 2 – Woman,
- education level (WE) – 1 – basic, 2 – professional, 3 – secondary, 4 – higher,

Table 4.1 Features of respondents. Number characteristic. It concerns enterprise, which produces wheelchairs

Symbol	Features' marking and their numerical characteristic					
	MK	WE	WI	SC	MR	TR
1	23	1	4	9	2	19
2	7	3	13	13	8	4
3		9	6	1	10	7
4		17	4	2	6	
5			3	2	3	
6			0	1	1	
7			0	2		
8				0		

Source: own study

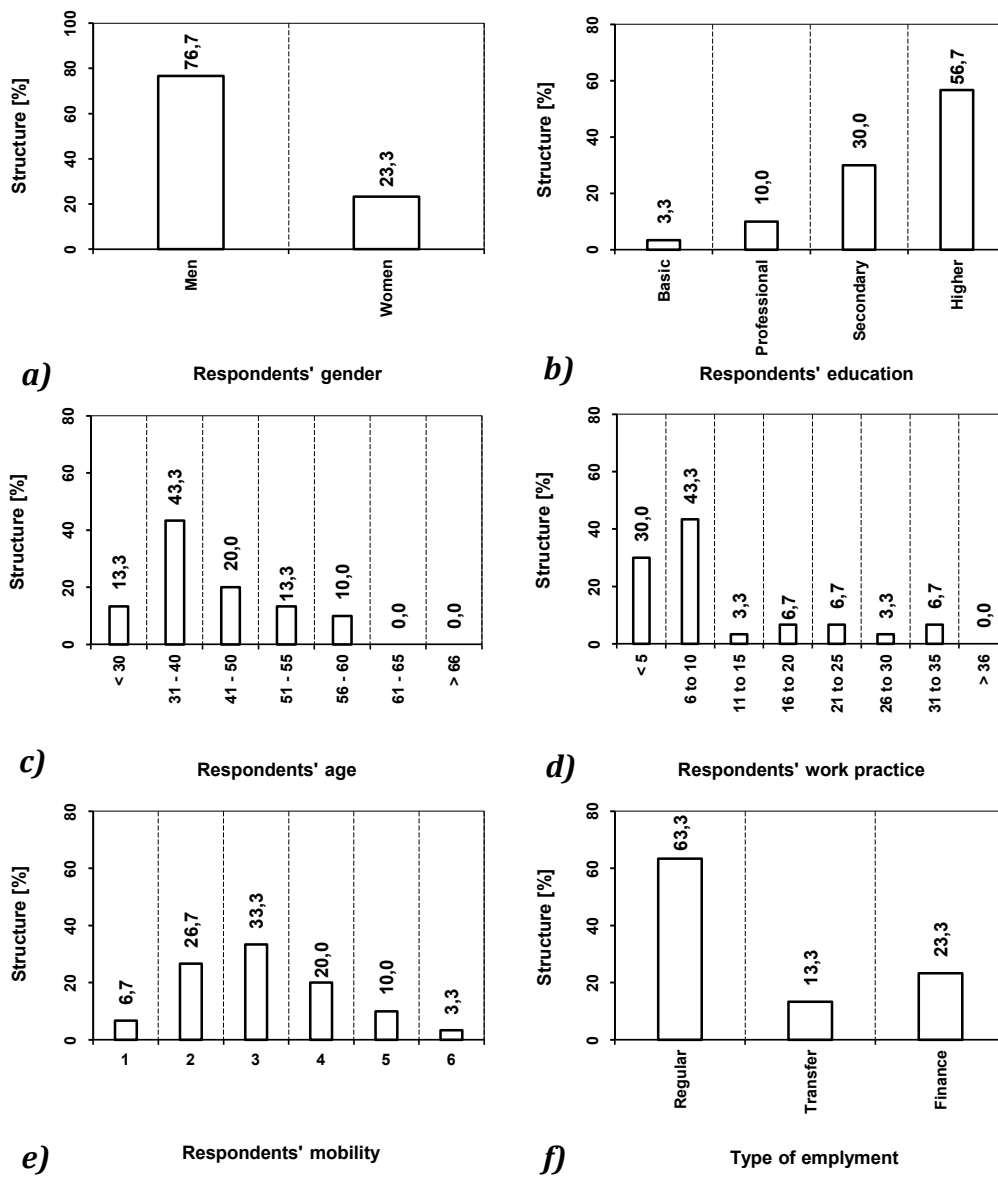


Fig. 4.2 Histograms. Respondents characteristic with consideration of: a) gender, b) education, c) age, d) job seniority, e) mobility, f) type of employment. It concerns enterprise, which produces wheelchairs

Source: own study

- age (WI) – 1 – to 30 years, 2 – 31 to 40 years, 3 – 41 to 50 years, 4 – 51 to 55 years, 5 – 56 to 60 years, 6 – 61 to 65 years, 7 – more than 66 years,
- job seniority (SC) – 1 – to 5 years, 2 – 6 to 10 years, 3 – 11 to 15 years, 4 – 16 to 20 years, 5 – 21 to 25 years, 6 – 26 to 30 years, 7 – 31÷35 years, 8 – 36 years and more,
- mobility (MZ) – current employment is: 1 – the first, 2 – second, 3 – third, 4 – fourth, 5 – fifth, 6 – further place of work,
- type of employment (TR) – 1 – in the regular mode, 2 – on the basis of the transfer, 3 – due to better financial conditions.
- table 4.1 and figure 4.2 shows that the majority of the respondents in the enterprise studied are men (76.7% i.e. 23 people). Regarding the education level (WE), the most of the employees have higher education level, which means 17 people (56.7%) and secondary education level (9 people, 30%). With respect to age (WI), the majority of the employees surveyed are those aged 31 to 40 years and from 41 to 50 years. This group includes 19 respondents, which constitutes 63.3% of the whole group. Job seniority (SC) in over 70% of the respondents is 5 to 10 years and, for 24 employees the enterprise represents the second, third and fourth workplace (MR). The most of the employees who participated in the survey i.e. 19 people (63.3%) were employed (TR) in the regular mode.
- another set of factors (E8) in BOST questionnaire, which was analysed in detail in the enterprise studied contains the areas which were supposed to be evaluated by the respondents in terms of the effects obtained after improvement. One of these factors is quality (JK).
- the numerical comparison of the scores for the factors from the area E8 is presented in the form of a table (see table 4.2) and bar charts (fig. 4.3).

Table 4.2 Principle 14. Numerical combination of the factors' importance evaluation for E8 area. It concerns enterprise, which produces wheelchairs

Evaluation	Factors indicating									
	ZT	SM	PT	JK	UM	RE	DA	PN	WS	WD
1	12	1	3	1	2	3	3	3	2	0
2	7	3	3	0	4	4	2	2	1	4
3	3	8	1	2	2	2	2	4	3	3
4	0	3	2	0	5	3	4	3	6	4
5	4	0	2	2	2	5	4	4	6	1
6	2	5	3	2	2	5	4	1	2	4
7	1	1	6	2	3	3	4	5	2	3
8	1	8	6	2	3	3	4	1	0	2
9	0	1	2	13	3	1	3	1	5	1
10	0	0	2	6	4	1	0	6	3	8

Source: own study

Table 4.2 and figure 4.3 demonstrate that the employees in the enterprise studied, who are expected to generate the highest effects after improvement, pointed to the area which concerned the quality factor (JK). This factor was given the scores 9 and 10 by 19 respondents, which means that nearly 63% of the employees regards this factor as the factor which should be improved first. The importance of this factor is even higher since none of

other factors in the E8 area scored more than 50% of 9 and 10 points. Furthermore, the above table and the figure demonstrate that the group of factors which were given higher scores (7, 8, 9 and 10) contains the factor concerning technology profile (PT) – 16 respondents evaluated this factor with 7, 8, 9 and 10 scores, of which only 4 people used 9 and 10 points, and the factor related to cooperation with suppliers and partners (WD) – 8 respondents gave the highest score (10) to this factor.

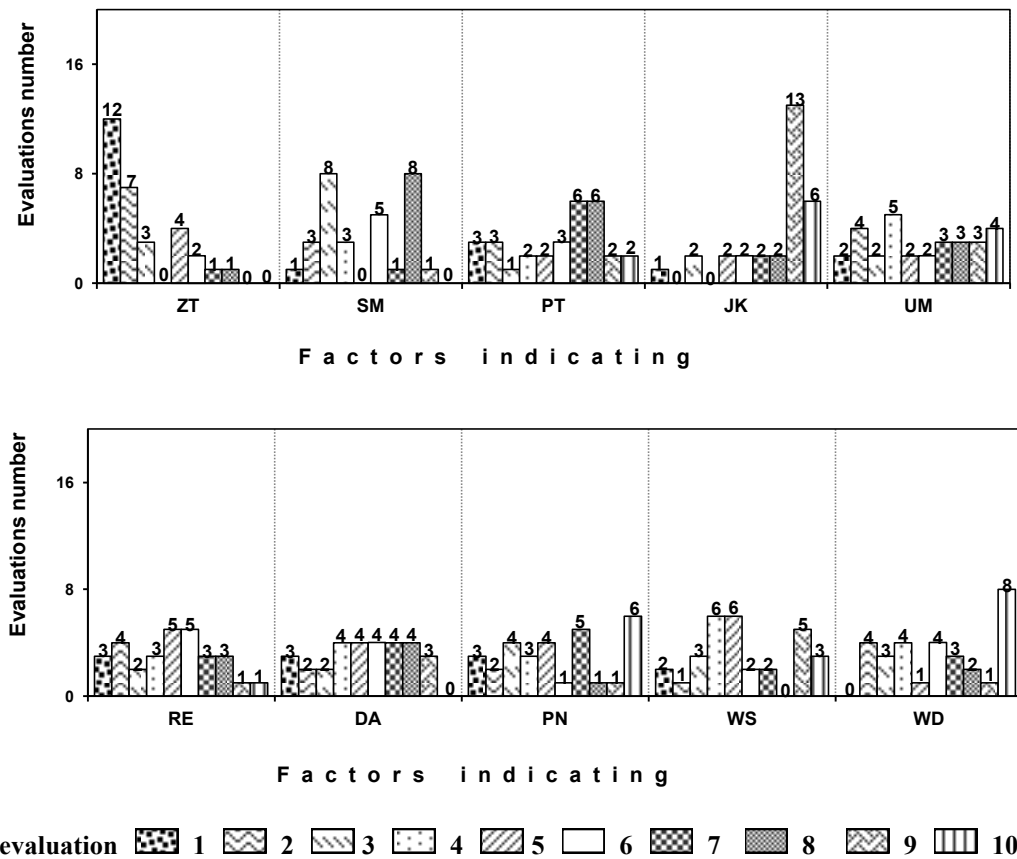


Fig. 4.3 Principle 14. Distribution analysis of evaluations E8 area factors. It concerns enterprise, which produces wheelchairs

Source: own study

The factor which was evaluated as a factor which does not produce or might produce the lowest effects after improvement is employment (ZT). Compared to the quality factor, an opposite pattern can be observed: 19 employees (63% of the respondents) gave this factor the lowest scores (1 and 2).

Another figure 4.4 shows Pareto-Lorenz diagrams that represent the importance of the factors from the area E8 for individual scores.

As results from the Pareto-Lorenz diagrams presented in figure 4.4, the quality factor (JK) takes the first place in the ranking of importance for the score 9 (over 40% of the scores) and the second place in the ranking of importance for the score 10 (20% of the scores). On the other hand, the factor of cooperation with suppliers and partners, was given the first place in the ranking of importance for the score 10 (over 20% of these scores), but the penultimate (9th) place for the score 9. It is noticeable that the factor of technology portfolio was given the

first place in the ranking of importance for the score 7, the second place in the ranking of

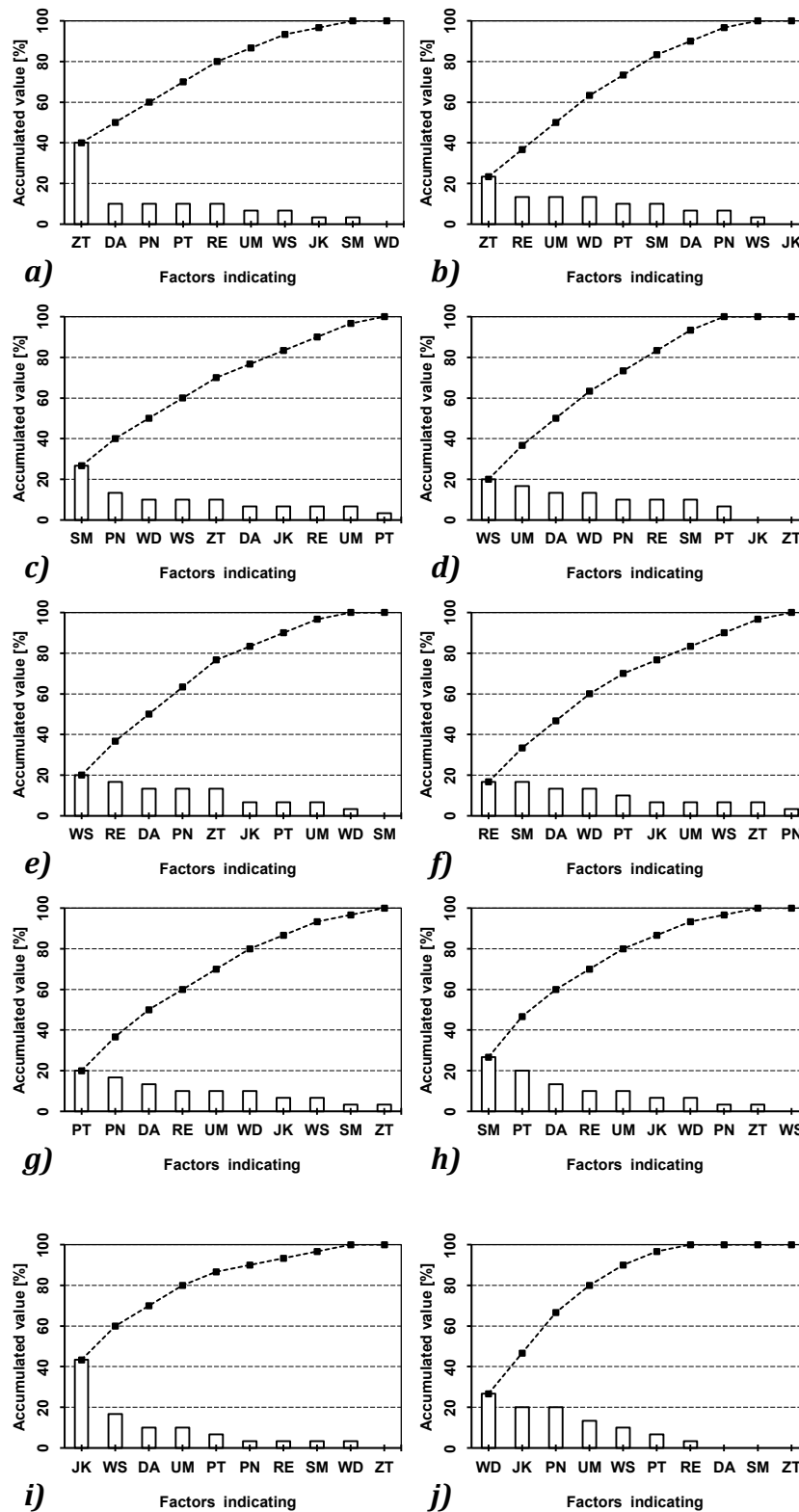


Fig. 4.4 Principle 14. Pareto-Lorenz diagrams of the factors' importance E8 area for evaluations:

**a) „1”, b) „2”, c) „3”, d) „4”, e) „5”, f) „6”, g) „7”, h) „8”, i) „9”, j) „10”.
It concerns enterprise, which produces wheelchairs**

Source: own study

importance for the score 8 but, in the case of the highest scores (9 and 10), it was given further places in the ranking of importance (the fifth place for the score "9" and 6th place for "10"). The first place in the ranking of importance for the lowest scores (1 and 2) was taken by the factor connected with employment.

SUMMARY

As results from the presented analysis, the employees who responded to the BOST questionnaire pointed to the quality as the area which is likely to produce the highest effects after improvement. Over 60% of the respondents assigned 9 and 10 scores to this factor, which demonstrates the importance of this factor. Quality, which is meeting customer expectations and even exceeding these expectations in the enterprise studied (wheelchairs), is given the first place in the enterprise. Improvement in the product quality (wheelchairs) is likely to help increase the patient's comfort and adjust wheelchairs to their individual needs. It is essential when manufacturing wheelchairs to be oriented toward production of high-quality parts, which in effect allows for long, maintenance-free, safe and convenient use of the wheelchairs by the disabled people.

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Abstract: *This chapter presents the definition of the quality and basic concepts of quality. An enterprise which manufactures the lightweight wheelchairs of the disabled was analysed. The methodology used in the study was BOST questionnaire – their principles of Toyota management in questions. The chapter contains a detailed analysis of the two selected areas of BOST questionnaire: the area E8, connected with the 14th principle of Toyota management and the area E12, i.e. respondent's characteristics. It was found that the quality in the enterprise studied is considered as an area in the enterprise which might produce the greatest effects if it is improved. The analysis used bar charts and Pareto-Lorenz diagrams.*

Key words: *BOST poll and, Toyota's management principle, diagram Pareto-Lorenz*

ZNACZENIE JAKOŚCI W PRODUKCJI WYROBÓW MEDYCZNYCH

Streszczenie: *W rozdziale zaprezentowano definicję jakości oraz podstawowe ujęcia jakości. Przedstawiono przedsiębiorstwo zajmujące się produkcją lekkich wózków inwalidzkich. Metodyka badań to charakterystyka ankiety BOST – zasad zarządzania Toyoty w pytaniach. W rozdziale dokonano szczegółowej analizy dwóch wybranych obszarów ankiety BOST- obszaru E8, związanego z zasadą 14 zarządzania Toyoty i obszaru E12 czyli charakterystyki respondenta. Stwierdzono, że w badanym przedsiębiorstwie jakość postrzegana jest jako obszar przedsiębiorstwa, który może przynieść największe efekty po udoskonaleniu. Do analizy użyto wykresów słupkowych i diagramów Pareto-Lorenza.*

Słowa kluczowe: *ankieta BOST, zasada zarządzania Toyoty, diagram Pareto-Lorenza*

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