SILESIAN UNIVERSITY OF TECHNOLOGY PUBLISHING HOUSE

SCIENTIFIC PAPERS OF SILESIAN UNIVERSITY OF TECHNOLOGY 2021
ORGANIZATION AND MANAGEMENT SERIES NO. 154

APPLICATION OF QFD IN THE PHARMACEUTICAL INDUSTRY

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Purpose: The aim of the paper is to analyze the problems connected with the audit and management review within the organization in the ISO 9001:2015 implementation process.
Design/methodology/approach: Critical literature analysis. Analysis of international literature from main databases and customer research and expert analysis.
Findings: Audits are very useful tool to analyses the organization functioning and improve it's performance. On the basis of the conducted analysis we can say that the main activities needed in the internal audit process are: interview personnel, observe operations, review documents and records and examine records. In the audit process is especially important for auditor to have appropriate qualities. They should be according to ISO 19011 requirements. The best solution for the analysis of the performance of ISO 9001 system can be done when we not only use internal audits but also management reviews in our managerial practice.
Originality/value: Detailed analysis of possibility of use of QFD method in pharmaceutical industry.

Keywords: quality management, ISO 9001:2015, ISO 9001, performance, KPI.

Category of the paper: research paper.

1. Introduction

The QFD method is used to relate customer needs and requirements to the technical features of a product. It has been used in many areas to design products that will be better adapted to customer needs. This article shows the application of the QFD method in the pharmaceutical industry – one of the strategic and very important industries in the modern economy.

The aim of the publication is to analyse the possibility of using the QFD method in the pharmaceutical industry on the example of a tablet.

2. Literature review

The QFD method was developed by Japanese engineers to ensure product quality as early as the product design phase. During the Second World War, the Japanese economy suffered huge losses (Wolniak, 2019). After the war, production was based mainly on making low-quality copies of American products. Then, under the influence of ideas presented by Deming and other quality management specialists who came to Japan, Japanese engineers realised that only innovative products of high quality could ensure their success.

QFD can be defined as: a method of planning and developing a project or service that enables research teams to precisely specify customer needs and requirements and then translate them into the parameters of a product or service, its components and the parameters of the production process itself (Ćwiklicki and Obora, 2008).

The QFD method is often categorised as a marketing research method. However, QFD is more than that, as it is used for structured planning and development of a product or service, enabling research teams to make a precise specification of customer needs and expectations, and then to evaluate each proposed opportunity from the perspective of its impact on satisfying the postulated needs (Łuczak and Matuszak-Flejszman, 2007).

The main element of the method is the so-called "House of Quality". (House of Quality). It is named so because of the specific shape of the diagram. "House of Quality" is defined as the first matrix used in the QFD method (in the basic version of the method the only one), which is used to present the relations between customer needs and technical attributes of the product. QFD is a multi-step planning process aimed at fully satisfying customers, including internal customers, i.e. the company's employees (Francheschini, 2002).

In the figure 1 we present the conception of House of Quality. Particular fields mean parts of information’s used in the QFD conception:

1. Customer specification.
2. Customer importance.
3. Maximization, minimization or optimization of engineering specifications.
4. Engineering specifications.
5. The significance of engineering specifications.
6. Relations between engineering specifications.
7. Comparative assessment of customer specification.
8. Comparative assessment of engineering specifications
9. Importance weight.

The QFD method can be used in many different industries. The basic conception of potential usage of the method was presented in the figure 1. We can find many examples of using this method for example to following problems:

- automotive industry (Wolniak, 2016),
- medical services (Wolniak, 2012),
- machine industry (Zymonik and Wąsińska, 2007; Jiao, 2021),
- sustainable engineering solutions (Rihar and Kusar, 2020),
- proecological analysis (Wolniak and Sędek, 2009; Lin et al., 2010),
- SMEs management (Hwangbo, et al., 2020);
- food industry (Tarczyńska, 2013),
- workplace planning (Wiśniewska, 2006),
- increase of innovativeness (Wolniak, 2016),
- supply chain management, Dai and Blackhurst, 2012).

Figure 1. Areas of application of the QFD method. Source: own study based on: (Raszewska, 2017).

In this paper we concentrate on the usage of QFD in pharmaceutical industry. The topic was described in some publications noted in Scopus database (Karpova and Khomutova, 2018; Nwabueze, 2012; Alinezad et al., 2013). But authors concentrated mainly on supply chain management in pharmaceutical industry not on the problem of pills production. The pharmaceutical industry is a complex processes, operations and organizations involved in the discovery, development and manufacture of drugs and medications. This industry in particular is challenged by constant advancement of its development and production functions.

This industry takes now a second lead among the most profitable industries in the world (Gomez and España, 2021). Because of that is very important and we think worth investigating from various perspectives.

3. Results

In order to perform a QFD analysis for the tablet, 12 customer attributes were selected which are:

- safety of use,
- price,
- effectiveness,
- shape of tablets,
- tablet packaging,
- marketing instruments,
- colour of tablets,
- form of tablets,
- leaflet accompanying the tablets,
- flavour of tablets,
- brand,
- size of tablets.

The above-mentioned customer attributes were grouped into 3 categories, which are shown in Table 1.

Table 1.
Grouped customer attributes

Performance features	Appearance characteristics	Other features
Safety of use, effectiveness, form, taste	Shape, colour dimension, size, tablet packaging	Price, brand, marketing instruments, leaflet accompanying tablets

Source: own study based on: (Raszewska, 2017).

In the next step, a survey was carried out in which customers rated the importance of the individual attributes. Table 2 shows the results of the survey.

Table 2.
Survey results

Lp.	Customer attribute	1	2	3	4	5	6	7	8	9	10	Sum
1	Price	5	10	10	10		20	25	20		20	120
2	Safety of use	22	20	15	10		25					92
3	Packaging of tablets	18	10		10		5		5			48
4	Effectiveness	20			20	50	30	5	30		45	200
5	Shape of tablets		15	25	10			40		60	20	170
6	Marketing instruments		30		5	10			5			50
7	Colour of tablets				10	10			10			30

Cont. table 2.

8	Tablet form	10	5	40	5	25	15	20		25	5	150
9	Leaflet accom-panying the tablets	5						10	10	5		45
10	Flavour of tablets				15		5		10		10	25
11	Brand name				5	5			10			20
12	Tablet size	20	10	10						10		50
	Total	100	100	100	100	100	100	100	100	100	100	1000

Source: own study based on: (Raszewska, 2017).

Table 3 shows the hierarchical customer attributes by assessment.

Table 3.
Hierarchical customer attributes by evaluation

Customer attribute	**Assessment**
Effectiveness	200
Tablet shape	170
Tablet form	150
Price	120
Safety of use	92
Marketing instruments	50
Size of tablets	50
Tablet packaging	48
Leaflet accomanying the tablets	45
Colour of tablets	30
Flavour of tablets	25
Brand name	20
Total	**1000 points**

Source: own study based on: (Raszewska, 2017).

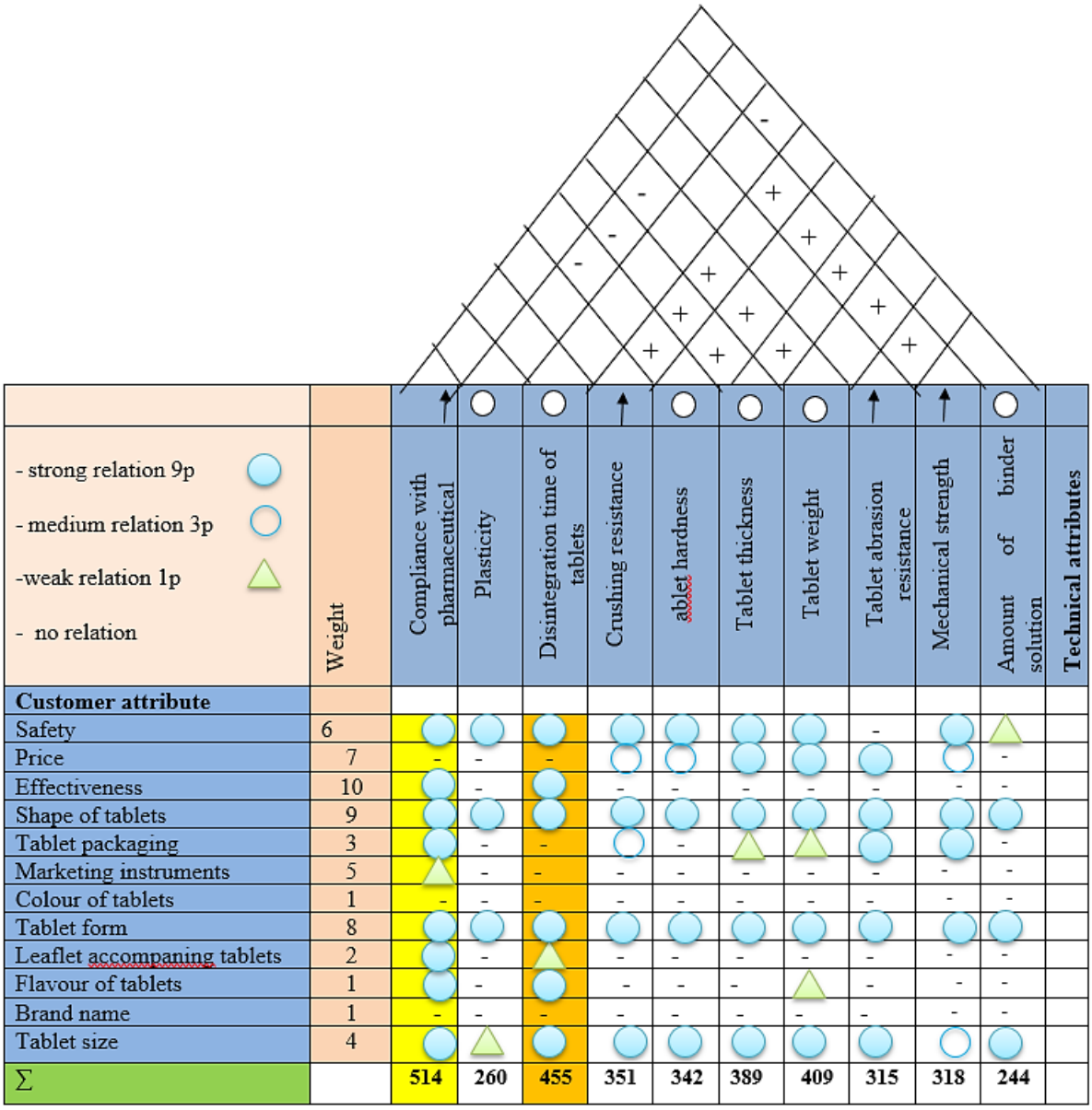
Table 4 shows the weights for each customer attribute. The weights were evaluated on a scale of 1-10 and given hierarchically from 10 for the highest customer evaluation value to 1 for the lowest values. Since for the lowest rated attributes the ratings were similar it was considered possible to assign a value of 1 for the three lowest rated attributes.

Table 4.
Weight of customer attribute

Customer attribute	**Assessment**	**Weight**
Effectiveness	200	10
Tablet shape	170	9
Tablet form	150	8
Price	120	7
Safety of use	92	6
Marketing instruments	50	5
Size of tablets	50	4
Tablet packaging	48	3
Leaflet accomanying the tablets	45	2
Colour of tablets	30	1
Flavour of tablets	25	1
Brand name	20	1
Total	**1000 points**	

Source: own study based on: (Raszewska, 2017).

From Table 4, it can be concluded that the most important customer attribute is the effectiveness of the tablets with a total score of 200. The second most important customer attribute is the shape of the tablets.



- strong relation 9p - medium relation 3p -weak relation 1p - no relation	Weight	Compliance with pharmaceutical	Plasticity	Disintegration time of tablets	Crushing resistance	ablet hardness	Tablet thickness	Tablet weight	Tablet abrasion resistance	Mechanical strength	Amount of binder solution	Technical attributes
Customer attribute												
Safety	6								-			
Price	7	-	-	-							-	
Effectiveness	10		-		-	-	-	-	-	-	-	
Shape of tablets	9											
Tablet packaging	3		-	-		-					-	
Marketing instruments	5		-	-	-	-	-	-	-	-	-	
Colour of tablets	1	-	-	-	-	-	-	-	-	-	-	
Tablet form	8											
Leaflet accompaning tablets	2		-		-	-	-	-	-	-	-	
Flavour of tablets	1		-		-	-	-		-	-	-	
Brand name	1	-	-	-	-	-	-	-	-	-	-	
Tablet size	4											
Σ		**514**	**260**	**455**	**351**	**342**	**389**	**409**	**315**	**318**	**244**	

Figure 2. QFD analysis of tablets attribute. Source: own study based on: (Raszewska, 2017).

Links between customer attributes and technical attributes:

- Taste of tablets and tablet disintegration time – Drug Formulation Technology article, Orally disintegrating tablets. Research directions, technologies. The rapid disintegration of a tablet depends on the correct choice of excipients. This is achieved by the use of bulking agents, binders, bursting agents, glidants, hydrophilisants and flavour enhancers. Due to the need to develop formulations with short disintegration times, particular attention is paid to the selection of substances with disintegrating properties.

- Tablet size and disintegration time – article Drug Formulation Technology, Orally disintegrating tablets. Research directions, technologies. Disintegration time dependent on tablet size and shape.
- Content of drug substance, uniformity of drug substance, stability, rate of drug substance release, amount of impurities – Doctoral dissertation from Jagiellonian University. The criticality of the influence of process operating variables on product quality depends on the technological procedure used. In the case of high-speed granulation, the criticality of the influence of the following operational parameters was found: amount of binder solution, main stirrer rotational speed, granulation time. In terms of the research carried out, no criticality of the influence of fluidised bed granulation variables on product quality was found.

On the basis of the conducted QFD analysis it can be concluded that the most important attributes of a tablet according to the customer are its efficacy and shape. Apart from that, the results of the analysis carried out show that such technical parameters of tablets as compliance with pharmaceutical law requirements and tablet disintegration time are the most important. The disintegration time of tablets is directly connected to the size and shape of tablets. The rapid disintegration of the tablet also depends on the appropriate choice of excipients. This is achieved by the use of bulking agents, binders, bursting agents, glidants, hydrophilising agents and flavour enhancers. Due to the need to develop formulations with short disintegration times, particular attention is paid to the selection of substances with bursting properties. Figure 3 shows the innovative design of a tablet shape for heart disease.

Figure 3. Heart disease tablets in a blister socket. Source: own study based on: (Raszewska, 2017).

4. Conclusion

The analysis conducted in this publication has shown that the QFD method can be successfully used in the pharmaceutical industry for analysis related to the design of customised tablets. The conducted research showed that the most significant parameters of a tablet from

the point of view of customer needs are its effectiveness and shape. After the analysis and linking of customer parameters with technical parameters, it turned out that the most important technical parameters are: meeting the requirements of pharmaceutical legislation and tablet disintegration time. It is also worth noting that the disintegration time is related to the size and shape of the tablet.

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