J Pharm Innov (2013) 8:205–211
DOI 10.1007/s12247-013-9159-9

RESEARCH ARTICLE

Quality KPIs in Pharmaceutical and Food Industry

Marianne Torkko · Anu Linna · Nina Katajavuori · Anne Mari Juppo

Published online: 16 August 2013

Abstract
Purpose This study aims to investigate what type of quality key performance indicators (KPIs) companies use and how they utilize the results of these KPIs.
Methods This e-mail survey is aimed at the personnel in the pharmaceutical and the food industries of Finland responsible for quality.
Results Quality KPIs were similar for both the pharmaceutical and food industries with some differences existing in their usage and reporting. In the pharmaceutical industry, the most common quality KPI was rejected batches followed by the number of complaints, product defects, and deviations. The number of complaints was the most common quality KPI for the food industry. The next most common KPIs were the loss during process and the number of deviations. Respondents in both the pharmaceutical and food industries thought that it is important to follow the indicators that describe the quality of a product and operation. Food companies shared their KPIs and their results with their partners and relevant authorities more often than did pharmaceutical companies.
Conclusions The results of this study showed that the food industry was slightly more advanced than the pharmaceutical industry in the utilization of the quality indicators. However, statistical significant differences exist between the pharmaceutical and food industries with regard to one quality indicator, namely, rejected batches on the one hand and in the opinion of respondents on how well quality indicators will help direct operations in the right direction on the other.

Keywords Quality KPI · Quality indicator · Pharmaceutical industry · Food industry · Lean practices

In this study we investigated less published quality indicators in pharmaceutical and food industry. Food industry has been chosen to get important benchmarking data from other area of industry.

Electronic supplementary material The online version of this article (doi:10.1007/s12247-013-9159-9) contains supplementary material, which is available to authorized users.

M. Torkko · A. M. Juppo
Division of Industrial Pharmacy, Faculty of Pharmacy, University of Helsinki, Viikinkaari 5E, P.O. Box 56, Helsinki 00014, Finland

A. M. Juppo
e-mail: anne.juppo@helsinki.fi

M. Torkko (✉)
Orion Corporation, Tengströminkatu 8,
P.O. BOX 425, 20101 Turku, Finland
e-mail: marianne.torkko@orion.fi

A. Linna
Orion Corporation, Orionintie 1, P.O. Box 65, 02101 Espoo, Finland

N. Katajavuori
Faculty of Pharmacy, University of Helsinki, Viikinkaari 9,
P.O. Box 56, 00014 Helsinki, Finland
e-mail: nina.katajavuori@helsinki.fi

Abbreviations

KPI	Key performance indicator
OPEX	Operational excellence
TQM	Total quality maintenance
QM	Quality management
CAPA	Corrective and preventive action
DMAIC	Define-Measure-Analyze-Improve-Control

Introduction

Price pressure and stiff competition are driving the pharmaceutical industry towards higher quality and continuous improvement as a means of sustaining competiveness. ICH guideline Q10 highlights the importance of continuous improvement and states that process performance and product quality system should provide the tools for the measurement and analysis of parameters [1]. There is also pressure on the pharmaceutical industry to transfer from time consuming end-product testing

towards better process design. Real-time analyses during the manufacturing processes have been developed [2, 3].

According to EN-ISO standard, top management is responsible for establishing the quality policy and quality objectives of the company [4]. The achievements of quality objectives have to be measurable, and they may have a positive impact on product quality or operation. Thus, the ISO standards highlight continuous improvement and in ensure these standards the responsibility of management. Management reviews are executed regularly to evaluate the quality management system. These reviews also include identification of the possible actions.

Lean practices that historically originated from Japanese manufacturing techniques have been applied to many types of industries [5]. The overall idea of lean practices is continuous improvement as in the ISO standards and doing things right the first time. The principles of lean practices are the identification of value for the customer, the elimination of waste, and the optimum generation of flow [6]. Value definition means that manufacturing process is a way to deliver value to the customer and any activity that does not add value to the customer is a waste [5]. Lack of time and concerns about the impact to regulatory compliance are reasons that may prevent the implementation of lean thinking and manufacturing practices [5]. Antony and Banuelas investigated critical success factors in the implementation of Six Sigma projects in different companies [7]. Six Sigma is methodology for defining, measuring, analyzing, improving, and controlling processes. There have to be clear metrics used to measure process. Accurate data are also required for analyzing root causes. Management commitment and involvement was the most important factor in the success of the implementation of the Six Sigma Program following understanding of its methodology, tools, and techniques. Other critical success factors were: linking quality initiative to business strategy, customers and suppliers, quality project selection, reviews and tracking, organizational infrastructure, cultural change, quality project management skills, training, and linking quality initiative to human resources.

The pharmaceutical industry can be considered as a special case because of good manufacturing practices (cGMP) guidelines. However, lean manufacturing practices have been successfully combined with cGMP in the pharmaceutical industry [8–10]. The purpose of a previous case study of the pharmaceutical manufacturer was to analyze a company's manufacturing problems and investigate and eliminate waste [8]. In this study, problems of certain production line were analyzed. Lean practices such as "5-whys root cause analyzing technique" and "5S housekeeping tool," by which every tool has its own place, were successfully used in the actual manufacturing site.

Friedli et al. [11] investigated implementation levels of operational excellence (OPEX) as a target state for lean manufacturing in the pharmaceutical industry and OPEX's effect on key performance indicators (KPIs). They carried out the survey in pharmaceutical production sites in 2004 and 2009. OPEX includes four subsystems: total productive maintenance, total quality maintenance (TQM), just-in-time, and effective maintenance system. Quality-related KPIs in TQM were the complaint rate (customer), rejected batches, and the complaint rate (supplier). The results of these quality KPIs were better in 2009 than in 2004 except that the suppliers' complaints increased slightly. This study showed that pharmaceutical companies successfully implemented tools and methods towards continuous improvement processes within the 5-year period. However, there is still a lot of work to do in the area of pharmaceutical industry because pharmaceutical companies are still far away from having "a continuous flow." Gebauer et al. [12] investigated the effect of lean manufacturing practices on operational performance in the pharmaceutical industry. They also concluded that lean practices have a positive effect on operational performance in the pharmaceutical industry. They found that company size and type have an effect on the implementation of lean practices. Larger plants are more likely to implement lean practices than smaller plants. Contract and generic manufacturers are more likely to implement lean practices than research-driven companies. There are similar results in the implementation of TQM in the food industry [13]. Belay et al. [13] investigated the effect of quality management practices and concurrent engineering on business performance in one of the brewery companies. The results of their study showed that QM practices improved overall business performance, and it indicated that companies that do not have continuous improvement philosophy may not improve their business performance in the long term.

It is necessary to have the tools to measure the quality. Not many studies could be found in the literature on the use of quality KPIs in the pharmaceutical industry. Benchmarking data from other industries are also very important. This type of study on the comparison of quality indicators of different industries has not previously been published.

KPIs have longer history in the food industry than in the pharmaceutical industry. The purpose of this study was to compare current situation between pharmaceutical and food industry. The aim of this study was to investigate to difference of quality metrics and utilization of them between pharmaceutical and food companies. The aim of this survey was to investigate what type of quality KPIs companies use and how they utilize the results of these KPIs.

Materials and Methods

This study was performed as an email survey of pharmaceutical and food companies in Finland. The food companies were chosen because benchmarking data were needed from other industry and the food industry has some similarities with the pharmaceutical industry. The e-mail questionnaire was designed and compiled to get a general idea about less-published quality

indicators. The questionnaire was designed to cover four themes: what kind of quality KPIs companies have, reporting of quality KPIs, respondents' opinions about the importance of quality KPIs, and utilization of quality KPIs. The survey consisted of 22 questions including both open-ended questions and alternative questions. The responses to those questions in which the opinion of the respondent was asked were graduated according to a 5-point Likert scale. Anonymity was required due to sensitivity issues to the relating pharmaceutical and food industries. Therefore, the anonymity of the respondents was preserved in this survey.

A draft questionnaire was compiled based on literature and practical information from the pharmaceutical industry. The draft questionnaire was then pretested with academics and a pharmaceutical industry expert to check its content validity, and the questionnaire was modified based on their comments. The modified questionnaire was then piloted to check its suitability and appropriateness for the target population. The questionnaire was piloted by four experts: one an expert from the food industry and three from the pharmaceutical industry. Small changes, such as the correction of writing errors and a justification section were deleted from two alternative questions on the recommendation of the experts.

The survey was carried out in Finland during the spring of 2012. Data collection took place between April and June. The survey was sent by e-mail to personnel responsible for quality in the companies. They were asked to forward it to the responsible person if they considered that they were not the relevant persons to answer the survey. The survey respondents had titles such as Vice President, Responsible Pharmacist, Quality Manager, QP, R&D Manager, Production Manager, Technician, and Quality Responsible of Department. The survey was sent to all pharmaceutical companies that had a manufacturing license from the Finnish Medical Agency (Finnish Authorities) (12 companies) and also the 30 biggest food companies in Finland. Respondent data are presented in Table 1. The list of the biggest food industry companies was received from the Finnish Food and Drink Industries' Federation. Two e-mail reminders were sent to nonresponders. Finally, nonresponders were contacted by telephone. The final response rate was 57 % for the food industry and 75 % for the pharmaceutical industry. The survey was sent to 42 companies and the number of responses was 26. The results were initially analyzed as a whole and then on a case-by-case basis. Answers to the open-ended questions were content analyzed by grouping similar themes and ideas [14]. Some well-described answers from the open-ended questions are presented in the results section. Pearson's Chi-square test was used in analyzing the statistical differences of the responses between pharmaceutical and food companies.

Table 1 The size of companies

Number of employees	Pharmaceutical companies (number of included 12)	Food companies (number of included 30)
10–99	56 % (n=5)	12 % (n=2)
100–499	11 % (n=1)	47 % (n=8)
>500	33 % (n=3)	41 % (n=7)

Results and Discussion

Quality KPIs

Every company taking part in this survey used quality KPIs. Most of the companies had six to ten quality KPIs in concurrent use.

In the pharmaceutical industry, the most common quality KPI was rejected batches followed by the number of complaints, product defects, and deviations (Table 2). The number of complaints was the most common quality KPI for the food industry. The next most common KPIs were the loss during process and the number of deviations. There was a significant difference (p<0.05) between the food and pharmaceutical industries for only one KPI, namely: rejected batches. One reason for this difference may be that rejection of a batch is a big issue for a pharmaceutical company because of the associated costs. Raw materials are usually more expensive in the pharmaceutical industry than for the food industry. There were also open-ended questions in the questionnaire in which respondents were asked if their respective companies have other quality indicators or they were planning to use other quality indicators. There were 12 answers to the question about which

Table 2 The quality KPIs in both the food and pharmaceutical industries

KPI	Food industry	Pharmaceutical industry
Right first time for example batches without deviations	12 %	44
Number of deviations	82 %	89
Errors found at final inspection of product	47 %	22
Rejected batches	65 %	100
Reprocessed/repaired batches	29 %	22
Cost of bad quality	35 %	22
Loss during process	82 %	67
Number of complaints	100 %	89
Number of product defects	59 %	89
Observations from audits of partners and authorities	47 %	33
Corrective and preventive actions has been done in target time	24 %	33

other quality indicators companies have. There were six answers to the question concerning planned use of other quality indicators. Other KPIs, which were in use or planned to be used by the pharmaceutical industry, were the efficiency of corrective and preventive actions (CAPAs), batches delivered within target times, and the achievement of validation and qualification. By contrast, the respondents of food companies also mentioned: errors observed during the process, deviation handling times, the number of deviations in internal audits, the plant/raw material quality index, comparing with the competitors, the biggest customers best supplier evaluation, recalls, and also batches delivered within target times.

Respondents were also asked to give their opinion about which company's quality indicator is best to describe the quality of the product and quality of the operation. This question was an open-ended question, and there were 19 answers to this obtainable. According to the respondents in the pharmaceutical industry, the most important KPIs were rejected batches (5), deviations (3), and the loss during process (3). In the food industry, the most important KPIs were complaints (8), deviations (5), and rejected batches (3). Customer orientation was highlighted especially in the answers of food companies; for example, one respondent from a food company wrote: "Our main quality KPI is our biggest customer's best supplier evaluation in 3-month intervals. We see our position compared with our competitors …" The information from customers is the most important factor in the success of the company. Do not measure only for your own purposes" (respondent 21). Previous research also highlighted that measures should not only measure the efficiency of internal processes but that their impact on the customers have to be taken into account too [15] because the customer defines the quality of the manufacturer [10]. According to Kaplan and Norton, also balanced scorecard includes customer perspective [16]. Customer metrics answers the question how customer see the company. Financial perspective, internal business perspective and innovation, and learning perspective are other perspectives of balanced scorecard. The idea of a balanced scorecard includes combined traditional financial and nonfinancial measures.

Reporting of the Results of KPIs

Respondents were asked how often they report their quality indicators. All companies of food industry that answered this question reported their quality KPIs monthly or more often (Fig. 1). There was a wider disparity among the pharmaceutical companies. In the pharmaceutical industry, 11 % reported KPIs weekly, 33 % monthly, 22 % two to four times a year, and 33 % yearly.

In Fig. 2 the reporting of KPIs according to the size of company is presented. All the biggest companies (more than 500 employees) reported their KPIs two to four times a year or more often. Most of the middle-sized companies (100–499 employees) reported their KPIs monthly. Most of the smallest companies reported their KPIs yearly.

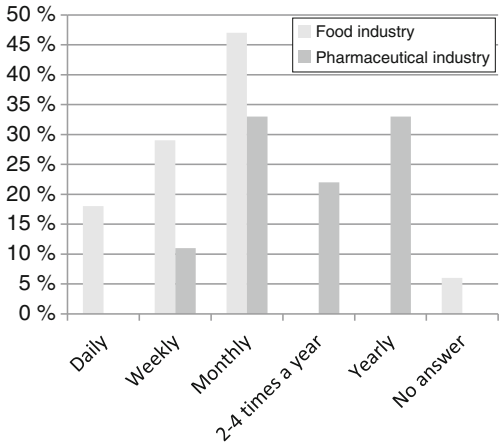

Fig. 1 Reporting of KPIs in food and pharmaceutical industries

Attitudes and Opinions

The proposition that states: "It is important to follow the indicators that describe the quality of a product and operation" was agreed by 100 % of respondents of the food industry who strongly agreed and by 78 % of respondents of the pharmaceutical industry who strongly agreed and 22 % of whom somewhat agreed. Thus, the respondents in both the pharmaceutical industry and the food industry thought that the quality KPIs are important. There was also the opportunity to give justification of their opinions about statement. There were six comments to the proposition. According to the comments, it is necessary to have the tools to measure the quality; for example, one respondent wrote: "It is the only way to get the general impression of the quality" (respondent 2, food industry).

Most of the respondents of the food industry strongly agreed and 29 % somewhat agreed with the proposition: "It

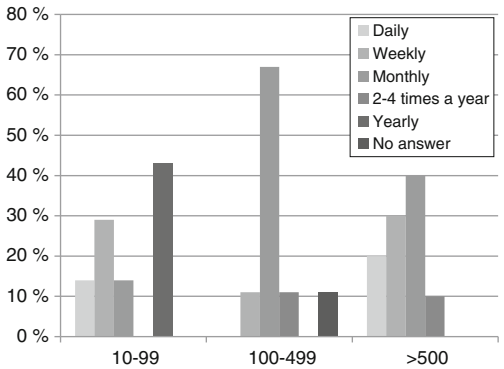

Fig. 2 Reporting of KPIs according to company's size (number of employees)

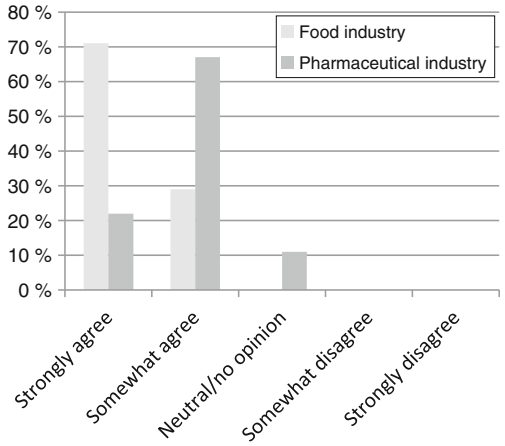

Fig. 3 Answers to the proposition: it has been noticed that the indicators that describe the quality of a product and operation will direct operation in the right direction

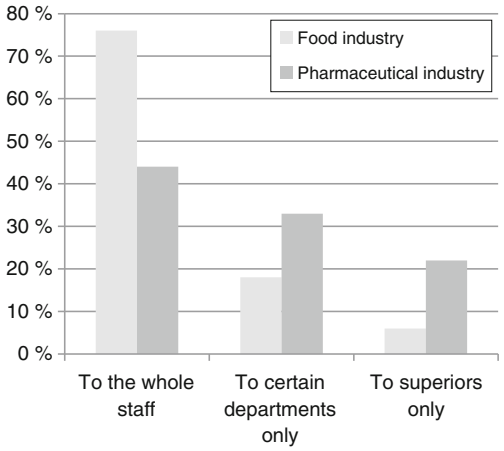

Fig. 5 Sharing KPIs and their results within the company

has been noticed that the indicators that describe the quality of a product and operation will direct the operation in the right direction" (Fig. 3). Moreover, 22 % of respondents of the pharmaceutical industry strongly agreed and 67 % somewhat agreed with this proposition. Thus, according to this survey respondents of the food industry thought that quality KPIs help responsible personnel direct the operation in the right direction more often than did respondents of the pharmaceutical industry. There was a statistically significant difference in the opinion of respondents between food industry and pharmaceutical industry ($p<0.05$). One explanation for this difference may be that measuring is more familiar in the food industry which follows ISO standards than for the pharmaceutical industry which follows GMP. Lean practices have already been implemented in many types of industry. However, lean practices with the continuous improvement objective and measurement are still new for the pharmaceutical industry. The aim of lean thinkers is perfection with a never-ending improvement cycle, and this culture change is a most difficult change for many companies [5]. It may be that this culture change is still ongoing in the pharmaceutical companies.

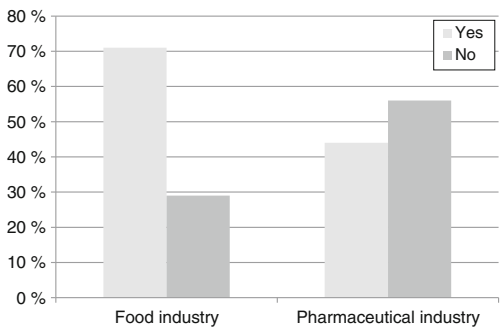

Fig. 4 The sharing KPIs and their results out of company

The respondents were also asked why their quality indicators were chosen. This was an open-ended question and there were 14 comments to this question. According to the comments, the reasons were the importance to the operation, requirements of the authorities, easy of obtaining information and developing an operation, and continuous improvement of the process. One illustrative comment: "The indicators have developed over 15 follow-up years. With their help, we strive for continuous improvement" (respondent 19, food industry). Previous research also highlighted that there must be a periodical re-evaluation of the performance system in the firm [17]. Other reasons may be that the processes are quite complicated in the pharmaceutical industry and changes take time to implement because of regulatory requirements. One reason that may prevent the implementation of lean practices is concerns about the impact to regulatory compliance [5]. However, ICH guideline Q10 highlights the importance of continuous improvement and process performance which

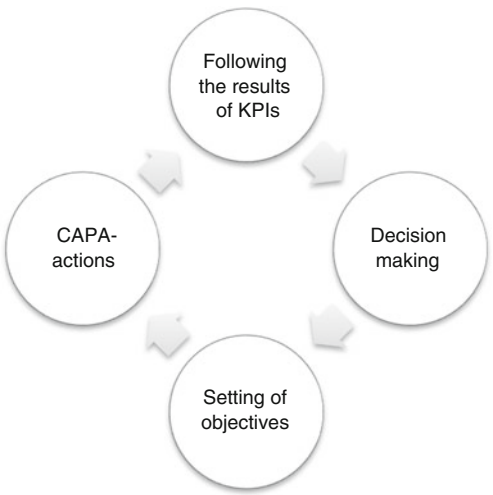

Fig. 6 Continuous improvement process

drives pharmaceutical industry towards continuous improvement and higher quality.

Utilization of KPIs

It was asked if companies showed their quality KPIs and their results out of their company, for example, to partners and to the authorities. Most of the food companies shared KPIs and their results with relevant partners or the authorities (Fig. 4). Pharmaceutical companies shared this information less than did food companies, i.e., they did not utilize this information as much as food companies. However, there was no statistically significant difference between food companies and pharmaceutical companies in sharing such information. In the food industry, KPI data were shared with partners, customers, authorities, auditors, and suppliers. In the pharmaceutical industry, KPI information was also shared with partners and authorities. It is important that companies have good cooperation with suppliers and other partners. Fynes et al. [18] investigated the effect of supply chain relationships such as trust, commitment, adaptation, communication, and collaboration on quality performance. They found that supply chain relationships had a positive effect on design quality. This suggests that by developing good partnerships with suppliers, suppliers become more proactive in the design and new product development processes. It appears that based on this survey, pharmaceutical companies did not utilize their KPI information by sharing it with partners and suppliers as much as possible.

Information about the results of KPIs was regularly shared with the whole staff in 76 % of food companies and 44 % of the pharmaceutical companies (Fig. 5). The KPI information was shared with certain departments for only 18 % of the food companies and 33 % of the pharmaceutical companies. The results of KPIs were shared only superiors in 6 % of food companies and 22 % of pharmaceutical companies. In some cases, the results of KPIs were initially reported to superiors and the information was subsequently made available to the whole staff on the company intranet, for example.

Respondents were also asked how the results of quality indicators were handled in their companies. This question was open-ended and there were 20 answers given. The results of KPIs were handled in different meetings and training sessions in both the food industry and the pharmaceutical industry. There was no difference between responses of pharmaceutical and food industry. The reasons for any changes in KPI results were analyzed also. A responsible pharmacist of one pharmaceutical company pointed out: “The indicators are regularly gone through paying attention to how the result can be influenced by oneself in various departments” (respondent 16).

There was also an open-ended question about the utilization of the results of quality KPIs and there were 18 answers to this question. The KPI results were utilized in the development of operations for both the food industry and the pharmaceutical industry. “Continuous improvement” was highlighted especially in the answers obtained from the food companies. Respondents of food industry pointed out also that processes have been changed based on the results of KPIs. Changes of processes are easier to carry out in food industry than pharmaceutical industry because of their different effect of regulatory impact. It was also mentioned that trends of KPI results were followed and CAPAs were implemented based on results of KPIs. In Fig. 6, continuous improvement based on the results of quality KPIs is presented. It is important to utilize the KPI results; for example, a case study of a brewery company [13] showed that QM practices improved overall business performance by eliminating problems at their sources before they caused big problems to develop and by motivating workers to do things right the first time. Lam and Robertson [19] investigated factors that had effects on employees’ willingness to participate in continuous improvement projects. They found that organization culture had effects on the willingness to participate in continuous improvement projects.

Limitations

One limitation of this study is that the companies of the food industry tended to be big companies compared with the companies of the pharmaceutical industry. This factor may have an effect on the results of the study. The sample size was also small. However, the survey covered all pharmaceutical companies that concurrently have a manufacturing license in Finland and the biggest food companies in Finland. This survey covered only the pharmaceutical and the food companies in Finland. The results might be slightly different from global point of view. It would be interesting to compare the results of pharmaceutical and food companies of other countries despite the fact that some companies taking part this survey have their headquarters in other countries. However, this survey presents important information about the less-published quality KPIs and their utilization by the pharmaceutical industry and the food industry. Companies can thus utilize this information for the implementing and developing of their own quality indicators in the future.

Conclusions

Based on these results, every company used quality KPIs. Quality KPIs were quite similar for both the food and pharmaceutical industries but some differences existed in their use and reporting practices. The results of this study showed that the food industry was slightly more advanced than the pharmaceutical industry in the utilization of these quality indicators. However, there was a statistically significant difference in only one quality indicator, namely: rejected batches. There was also significant difference between pharmaceutical and the food

industry in the opinion of respondents of how well quality indicators will help direct operations in the right direction.

The aim of this study was to investigate and compare quality KPIs in the pharmaceutical and food industries. This target was achieved. Further studies about quality KPIs are required because of small sample size. Future studies should involve data obtained from big pharmaceutical multinational companies. However, this survey presented important information about less-published quality indicators, which helps pharmaceutical companies on the way towards lean practices and continuous improvement.

Ethical Standards The experiments comply with the current laws of the country in which they were performed.

Conflict of Interest The authors declare that they have no conflict of interest.

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