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Quality management benchmarking: FDA compliance in pharmaceutical industry

Roland Jochem and Katja Landgraf
Institute for Industrial Science and Process Management, University Kassel, Kassel, Germany

Abstract

Purpose – By analyzing and comparing industry and business best practice, processes can be optimized and become more successful mainly because efficiency and competitiveness increase. This paper aims to focus on some examples.

Design/methodology/approach – Case studies are used to show knowledge exchange in the pharmaceutical industry. Best practice solutions were identified in two companies using a benchmarking method and five-stage model.

Findings – Despite large administrations, there is much potential regarding business process organization. This project makes it possible for participants to fully understand their business processes. The benchmarking method gives an opportunity to critically analyze value chains (a string of companies or players working together to satisfy market demands for a special product).

Practical implications – Knowledge exchange is interesting for companies that like to be global players. Benchmarking supports information exchange and improves competitive ability between different enterprises. Findings suggest that the five-stage model improves efficiency and effectiveness. Furthermore, the model increases the chances for reaching targets. The method gives security to partners that did not have benchmarking experience.

Originality/value – The study identifies new quality management procedures. Process management and especially benchmarking is shown to support pharmaceutical industry improvements.

Keywords Benchmarking, Quality management, Process management, Pharmaceuticals industry, Germany

Paper type Case study

Introduction

Companies must continuously search and exploit potential to improve their competitiveness (Mertins *et al.*, 2004). Benchmarking means orienting a company in the best market position, aiming to be the best of the best in the business field. To meet this goal the objectives are to:

- analyze the organization's strengths and weaknesses;
- compare the company's position with its competitors';
- define success factors; and
- implement performance improvements (Schuster and Mang, 2001).

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After analyzing the organization's and market competitor's positions, new and promising enterprise strategies can be developed (Mertins and Kohl, 2004). To make profits a company is constantly forced by today's buyers' market to supply competitive products and services. This only succeeds if a company acts effectively and orientates its processes according to value streams or value chains. Otherwise, company results decrease and investment benefits are not realized.

To be a global active company means not only overcoming cultural or logistic barriers but also integrating company and product requirements. The pharmaceutical industry ranks world-wide among businesses with the largest regulation and information density. Millions of documents and strict guidelines must be followed, which are issued by regulatory authorities; for example in the US by the Food and Drug Administration (FDA). The FDA's mission includes ensuring that human and veterinary drugs are safe and effective. The security and effectiveness of devices intended for human use must be ensured. In order to sell food and medications in the USA, production plants must correspond with FDA regulations (Benson, 2005; FDA Center for Drug Evaluation and Research, 2003). Enterprises wanting to enter the US market not complying with FDA requirements can learn from other US companies by benchmarking – the search for solutions based on industry best methods and procedures used by leading and top performing companies (Camp, 1994). Benchmarking helps goal-oriented staff to use new ideas, methods, procedures and processes. The method answers questions about strategic adjustment by companies outside the company's organization or exterior to its business. The benchmarking project helps staff understand business procedures, strengthens competitive ability and supports continuous improvement processes. This enables staff to offer superior services with a competitive advantage to the customer's benefit (Figure 1). For that reason, benchmarking is an interesting business process management method.

Our project's goal was knowledge exchange between two pharmaceutical companies concerning FDA compliance and quality management. The two companies learned from the experiences and the competences of each other. In this case, the competence of one company was the accomplishment of the FDA compliance and the strength of the other company was executing quality management. Learning efficiently and effectively from each other means that structured proceedings are necessary. The benchmarking procedure orients itself within the five-stage model (Figure 2), which is a structured and process-oriented approach. For goal-oriented procedures, it is necessary to specify benchmarking

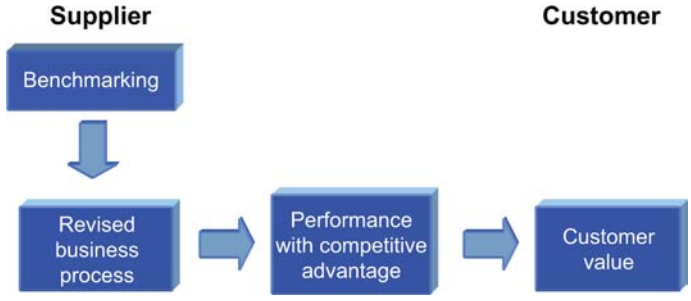

Figure 1.
Benchmarking strategy

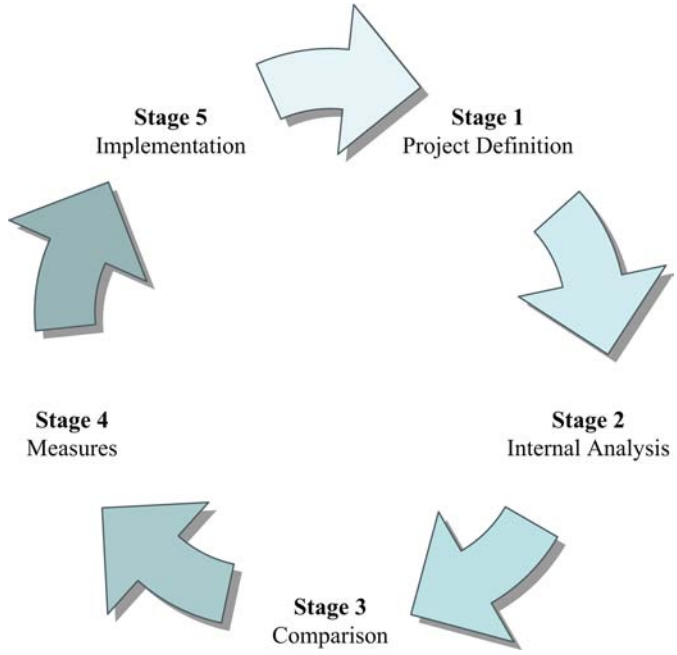

Figure 2.
Five stage model

methods and requirements. With this short but effective model, it is possible to modify the five main processes depending on language and the project's intentions. The modified model supports benchmarking method understanding and compliance. Using the structured procedure, milestones can be defined and processes controlled (Mertins and Kohl, 2004).

Procedure

A temporal project overview is represented in the project plan (Figure 3) – the individual project phases.

To define project results and specify strategic targets, it is necessary to involve all participants in a target-setting workshop (Mertins *et al.*, 2004). This is why projects start with a workshop on organizational issues and objectives (project definition). Leading the team to a common understanding about targets and assessment criteria for project success are important parts of the workshop. During stage 1, the workshop is part of the benchmarking goals, which informs the processes' exact scope. These targets were used for project control and deciding success at the end of the project (Mertins *et al.*, 2004). Briefly, common processes include:

- change management;
- change control;
- re-qualification (new accreditation); and
- maintenance.

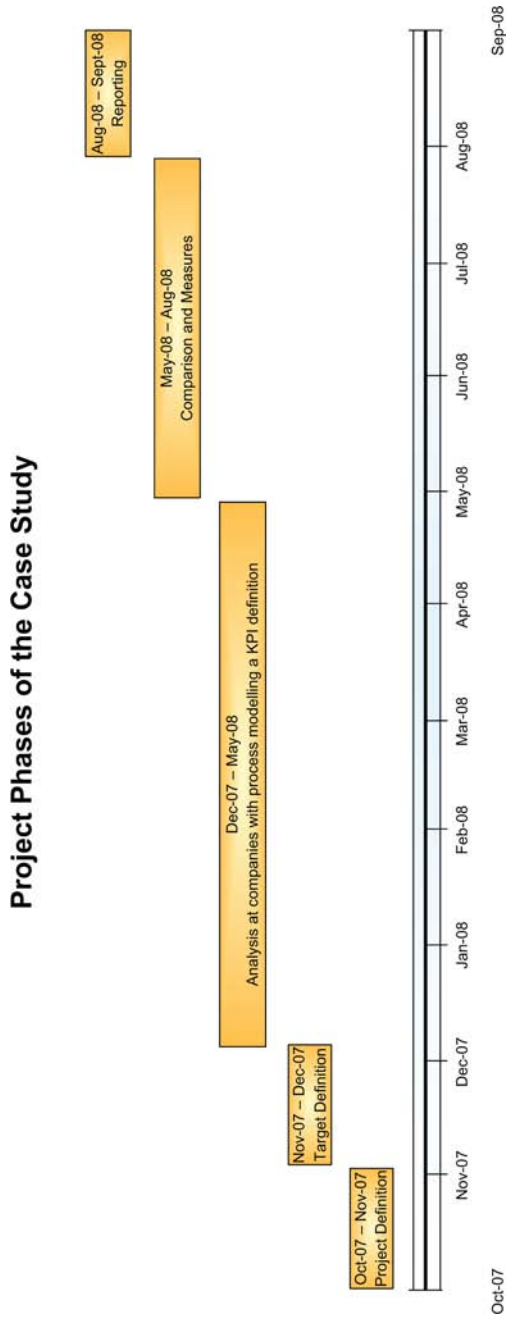

Figure 3.
Project plan

With benchmarking partners, we identified these project goals:

- Identifying key performance indicators (KPI), making sure processes are measurable and comparable.
- Analyzing and optimizing standard operation procedures (SOP).
- Exchanging experiences regarding FDA compliance.

Basic process-oriented benchmarking is about visualizing partner business processes for resolving problems (Steven and Werding, 2001). Well directed business process identification and documentation is a basic benchmarking condition. The process model works as a reference for benchmarking partner company analysis (Mertins and Jochem, 2000). For comparing in a benchmarking project, we need at least two companies described by their processes in the same manner, if not then you will compare apples and berries. In this case you cannot achieve project target desired results.

And so the focus of stage 3 (internal analysis) is defining and modeling business processes for the comparison, which were taken up with the help of company managers and their SOPs. These analyses are supported by software, which determines exactly where and which data are recorded, processed and passed on. Process modeling is based on benchmarking project targets (Binner, 2005). One process model example is provided in Figure 4. The horizontal bars represent process parts, while representing the business process temporal and operational sequence. Individual process activities are represented by a rectangle. Process inputs (information, services, products etc.) as well as outputs (data, information, products, etc.) are embodied as a process step in arrow form. Sub processes are illustrated by shading. Process decisions are represented by hexagons. Other key performance indicators in the process are embodied in dark gray and explicitly as text.

This makes operational sequences transparent. The processing concepts were presented to benchmarking partners and two processes were selected: re-qualification and maintenance. In tandem with interviewing and process modeling, a questionnaire was constructed so that two companies in stage 3 could be compared, key performance indicators were generated and key indicators defined and aligned to fixed goals along with their success factors (Nagel, 2007). Collecting and evaluating key indicators in all participating companies took place. By comparing KPIs, company potential can be identified. Additionally, exchanging FDA experiences occurred. The benchmarking partners audited themselves to underline their potential. After this comparison phase and results analyzed appropriate measures were generated (stage 4) and implemented (stage 5).

KPI description

Company 1

Change management. This process comprises procedures for handling deviations. Good manufacturing practice (GMP) differences arise whenever fixed process, their expiration, a specification or a standard is observed. If deviations occur then registration will be affected and reported to the quality management team, who evaluate and examine all deviations. After this evaluation in which safety, quality, identity, purity and potency are examined, strategies are implemented to prevent discrepancies re-occurring. Subsequently, GMP conformity starts. At the end of the process, product blocking is cancelled and all procedures are written in a final report.

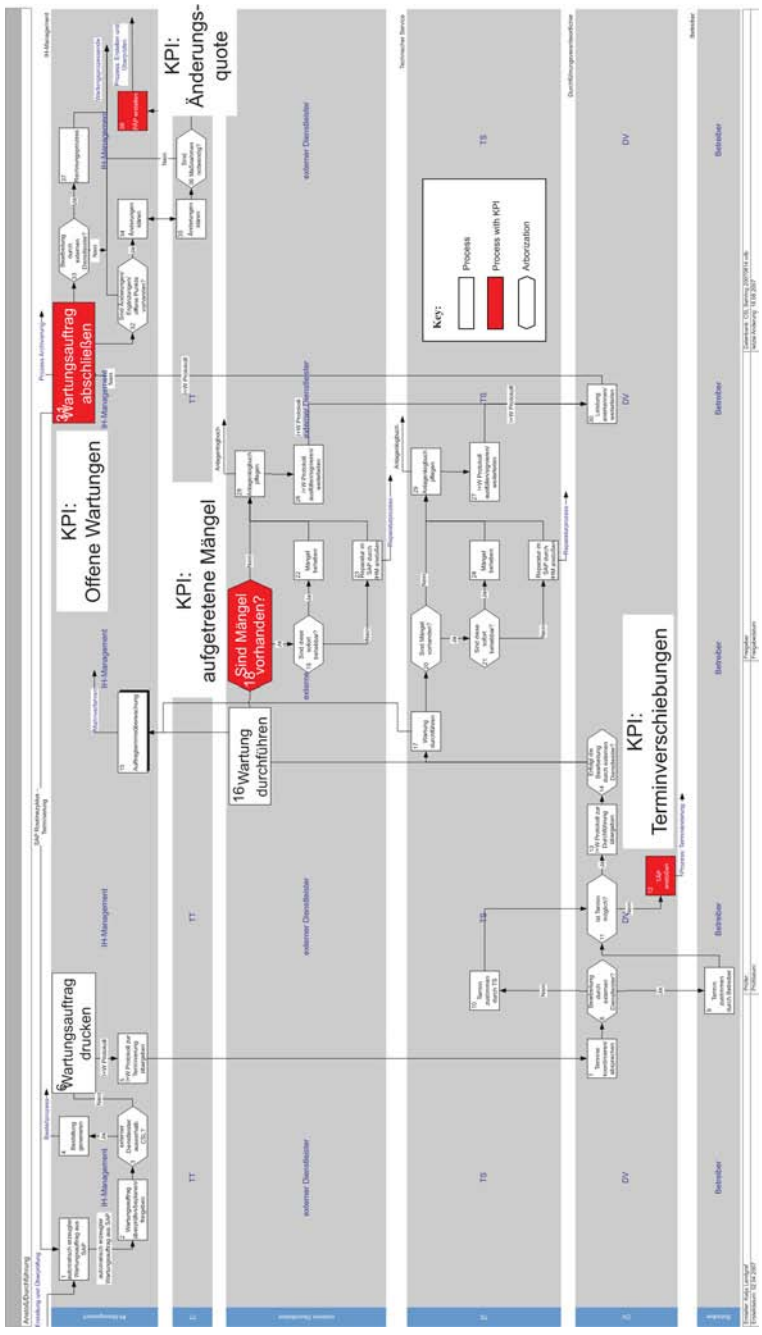

Figure 4.
Benchmarking processes

Change control. This process describes procedures for guaranteeing changes are GMP accomplished. The applicant has to plan, examine and evaluate change at the beginning of the process. Further procedures are dependent on the change's scale and the changes taking place in different categories. For example, one category includes technical and document changes, which influence status. At the beginning of these change categorizations, modifications must be documented and examined by an appropriate quality manager, regulatory affairs and quality assurance teams. Only modifications that are examined are allowed to change. Subsequently, all changes are documented in the IT system.

Re-qualification. By means of a periodic re-qualification, a plant's sterilization, virus depletion, etc., status remains critical. Re-qualification intervals depend on plant type and are divided into four processes:

(1) Re-qualification planning.

(2) Equipment control.

(3) Plant re-qualification, which is system dependent.

(4) Final evaluation.

The re-qualification process starts with an order produced automatically by the IT system, which sets out all re-qualification requirements. Before the re-qualification process is executed, documents are checked to see if they are up-to-date. In the equipment control phase, measuring devices are examined for serviceability. Based on defined measuring points, actual values are documented and evaluated during the plant re-qualification phase. If re-qualification is not successful then arrangements are introduced that include one of three KPI tests. The KPI target is 100 percent, thereby enforcing a zero-error strategy. The KPI should support quality improvement and FDA compliance. After validation, re-qualification is approved by appropriate quality management department staff and re-qualification results are documented in the IT-system, thereby closing the process. During re-qualification, two KPIs are measured. The re-qualification documents not approved by quality management department staff at the first stage are related to all documents, which is part of the zero-error and FDA compliance strategy, thereby increasing process quality. If any re-qualification dates are exceeded then they form part of the whole re-qualification process.

Maintenance. This process describes periodic maintenance, which starts with entering a maintenance order in the IT system. After that, maintenance dates between engineering and production staff are coordinated. The order is signed by participating departmental staff and maintenance orders are updated in the IT system, which triggers the maintenance process. Faults are repaired immediately as far as possible. When maintenance is finished, documents are updated and the process completed. If changes and unresolved issues remain after maintenance is concluded then and an updating schedule is generated. At this point KPIs monitor the situation. The aim is to decrease process costs and improve productivity and quality. Benchmarking underlines how many maintenance procedures are delayed. All open maintenance issues are monitored by one KPI in which adherence to delivery dates is expected. Other KPIs are measured including repairs and maintenance expenses, maintenance frequency, fault reports and failure rates caused by maintenance processes. The KPI aims to decrease costs and increase productivity.

Company 2

Change management. Change management represents the general procedure for collecting and documenting performance deviations. If a deviation is present then a report is generated and inserted into the database. Immediate correction measures as well as the statement concerning the cause are initiated. Immediate mitigation strategies have to be agreed, which contain procedures for correcting errors. Subsequently, documentation is released by the appropriate department staff, which explains the cause and corrective steps. Deviations are verified and checked for recurring problems. All deviations are summarized in a report.

Change control. Change control ensures that materials, equipment, processes and the end product are controlled. Product quality, therefore, is guaranteed. Initially, the person responsible for production submits an application to the change control coordinator, who documents the information in a database. Subsequently, changes are evaluated. After the change is made, it is evaluated and logged in a change control and a final report.

Re-qualification. Re-qualification concerns processes for products already marketed. Critical pharmaceutical product producing processes are examined. Re-qualification is based on manufacturing date, test results and production records. Product quality, therefore, is controlled. Initially, plant staff file a re-qualification application with the quality management team, which are logged in the IT system and re-qualification activities defined. The order is sent to the appropriate department. Afterwards, processes are evaluated. The re-qualification process is specified and set in train. Once completed, re-qualification outcomes are evaluated. Two outcomes are possible: not approved; re-qualification; and re-qualification date exceeded. Sequentially, quality management department staff compile a re-qualification report, which finishes the re-qualification process.

Maintenance. The process describes how technical plants are maintained. Maintenance begins with deciding which measures are used. Maintenance must strictly comply with the maintenance schedule if re-qualification is to be achieved. If repairs are needed then specific processes are implemented. At this point the number of changes following maintenance confirmation is measured as a change ratio. Furthermore, once finished all open maintenance; repairs and maintenance expenses; maintenance frequencies; faults; and failure quotes are related to the company's KPI. After maintenance, monitoring and documentation take place. These processes improve the company's efficiency and effectiveness.

Results

Best practices are documented and evaluated by benchmarking. Knowledge exchange between pharmaceutical companies concerning FDA compliance and quality management is supported by key performance indicators and mutual auditing. Company potential is catalogued and by identifying and realizing improvements, companies improve their processes and became top performers which are based on the results of the benchmarking project and respectively knowledge exchange by staff in the two companies. By exchanging experiences, company 2's FDA requirement endeavors will find entering the US-market easier, while company 1 confirmed its quality assurance processes. All findings were communicated in a final presentation to benchmarking partners.

The five-stage model supports an efficient and effective learning process in two different companies. During the workshops, better understanding and new business

processes emerged. The model's structured approach was helped by a transparent step-by-step process analysis. Furthermore, key indicators, placed directly in business processes to make them measurable, helped the companies achieve a zero-error strategy. Consequently, productivity and quality increased. With this information, performance deficiencies were identified; new resolutions were defined and implemented. In short, the benchmarking project benefits were higher than its costs for both companies.

Benchmarking participants expect their relationships to continue and increase their potential. Benchmarking makes organizational learning possible; new findings help to boost economic success. Benchmarking projects are an important step in the continuous improvement process. Benchmarking's goal-oriented approach highlights new ideas, methods, procedures and processes, which increase company competitiveness.

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Corresponding author

Roland Jochem can be contacted at: jochem@ifa.uni-kassel.de