

# Lean Bundles and Performance Outcomes in the Pharmaceutical Industry: Benchmarking a Jordanian Company and Operational Excellence International Project

Bashar A. Alkhalidi<sup>1</sup> & Ayman Bahjat Abdallah<sup>2</sup>

<sup>1</sup> School of Pharmacy, The University of Jordan, Amman, Jordan

<sup>2</sup> School of Business, The University of Jordan, Amman, Jordan

Correspondence: Ayman Bahjat Abdallah, School of Business, The University of Jordan, Amman, Jordan, Tel: 962-786-951282. E-mail: a.abdallah@ju.edu.jo

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## Abstract

This study benchmarks the implementation levels and performance outcomes of lean bundles of a Jordanian pharmaceutical manufacturing company with the results of the Operational Excellence (OPEX) model. The OPEX model is an ongoing international research project in the pharmaceutical industry. The results of the OPEX project were obtained, along with permission to use them in the present study. The same question items used in the OPEX project were used to prepare a questionnaire to collect data from the Jordanian pharmaceutical company. Fifteen managers from the Jordanian company with responsibilities related to lean management completed the questionnaire. The results demonstrated that the implementation levels of lean practices and the lean performance outcomes of the Jordanian pharmaceutical company varied in comparison to the OPEX project. The overall assessment showed that the Jordanian company is excellent in the total quality management bundle (at or above the levels of the benchmarked data), good in the human resource bundle (almost at the levels of the benchmarked data), acceptable in the just-in-time bundle (below the levels of the benchmarked data), and weak in the total preventive maintenance bundle (considerably below the levels of the benchmarked data). There are few benchmarking studies in the pharmaceutical industry in the area of lean management. In particular, this area is under-investigated in the developing world. The current study provides insights into the value of benchmarking key lean metrics against leading companies. This approach is expected to support pharmaceutical industry managers in the developing world to evaluate their current lean state, estimate the desired state based on the benchmarking results, and set appropriate strategies to promote lean management and operational excellence in their companies.

**Keywords:** lean management, lean bundles, lean operational performance, benchmarking, pharmaceutical industry, Jordan

## 1. Introduction

The pharmaceutical industry in the developing world faces many challenges, such as the pressures of rising costs coupled with low pricing policies from the authorities, along with strong competition in the markets. All these factors create the need to implement a system that can improve the company's performance and increase profits. In this context, lean management is seen as a key strategic option that can considerably improve the efficiency and effectiveness of pharmaceutical companies' operational processes, thus enhancing their competitiveness in today's globally competitive markets (Abdallah and Matsui, 2007; Phan et al., 2010; Al-Zu'bi et al., 2015; Shokri, 2017).

The pharmaceutical industry in Jordan started in the early 1960s. The industry concentrated on the production of generic drugs (patent-free medicines) and building quality into its products to have the potential for export. The industry was unable to attract foreign partnerships in its early stage due to the small size of the companies and the Jordanian population in comparison with Egypt, Syria, and Morocco (Global Research, 2007).

Today, there are 14 pharmaceutical manufacturing companies in Jordan that are active in the production of pharmaceuticals (JAPM, 2017). The pharmaceutical industry is considered to be a pioneer among the exporting sectors in Jordan; 81% of production capacity is designated for export to more than 60 countries (JAPM, 2017).

Per the Jordan Pharmaceutical Country Profile, published by Jordan's Ministry of Health in collaboration with the World Health Organization (WHO) in 2011, Jordanian pharmaceutical production capabilities are categorized into research and development for discovering new active substances, production of pharmaceutical starting materials (APIs), production of formulations from pharmaceutical starting material, and repackaging of finished dosage forms (WHO, 2011). The report further revealed that in 2008, domestic manufacturers held 33% of the market share according to the produced value.

Although lean management is widely implemented by manufacturing companies (Abu Nimeh et al., 2018; Abdallah et al., 2017; Abdallah and Matsui, 2009), it has been missed by many pharmaceutical companies in developing countries including Jordan (Shehadeh et al., 2016; Awad et al., 2016; Ayoub et al., 2017). Most of the pharmaceutical companies in the Middle East and North Africa (MENA) region focus on compliance with Current Good Manufacturing Practices (cGMP) guidelines while the operational performance of the manufacturing plants is overlooked. These companies mainly use financial performance measures, while operational measures are rarely used. Due to the scarcity of research on lean management and performance in the pharmaceutical industry in developing countries, it was necessary to initiate such research to address these shortcomings.

The driving force behind this study is the need to shed light on the concept of lean management in pharmaceutical companies in developing countries, especially in the MENA region, in order to provide the industry with a new tool to improve operations. These companies usually face problems of underutilization of capacity, low levels of technology, high scrap rates, insufficient product quality, and others (Bello-Pintado and Merino-Díaz-de-Cerio, 2013). In particular, the purpose of this study is to evaluate the levels of lean bundles and lean performance of a Jordanian pharmaceutical company. Next, the collected data is benchmarked with the results of the Operational Excellence (OPEX) model. The OPEX model is an ongoing international research project in the pharmaceutical industry in the area of lean management and operational performance, adopted from St. Gallen University, Switzerland, with permission to use its data and results. Finally, conclusions and recommendations will be derived based on the findings.

The remainder of this paper is structured as follows: section 2 presents the literature review. Section 3 presents research methodology. Section 4 presents results and discussion. Finally, section 5 presents conclusions, recommendations, and research limitations.

## **2. Literature Review**

### *2.1 Lean Management*

The term lean production was first used by Krafcik in 1988, as part of his study of the Toyota Production System (TPS) aimed at the elimination of waste (Krafcik, 1988). The holistic consideration of lean thinking and its principles have been successfully described by Womack et al. (1990) in the book *The Machine that Changed the World*. Later, a second book was published, entitled *Lean Thinking*, by Womack and Jones (1996). In this book, the authors defined the central practices which lead to lean management and provide recommendations for applying these practices in any organization.

The main principles of lean management are the identification of value for the customer, the elimination of waste, and the optimum generation of flow (Melton, 2005; Abdallah and Matsui, 2009; Saleh et al., 2017). Value definition refers to the idea that any 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 (Womack and Jones, 1996). Waste is defined as "any human activity which absorbs resources but creates no value" (Ohno, 1988). Lean management strives to eliminate types of waste that include overproduction, waiting, transport, unnecessary motion, over-processing, defects, excessive inventory, and unused employee creativity (Liker, 2003). The optimum generation of flow refers to the idea that the production flow should be continuous, with no variation. The production line should not be stopped for machine breakdown, delay, or any other problem (Besterfield, 2014). Such lean principles might not be implemented, however, due to time constraints and concerns about the impact of such principles on regulatory compliance (Womack and Jones, 1996).

The literature dealing with lean practices indicates that different authors have different approaches to lean group concepts. For example, Womack et al. (1990) focused on the influence of specific aspects of lean management on manufacturing performance figures. Shah and Ward (2003) postulated four "bundles" of interrelated and internally consistent practices; they proposed just-in-time (JIT), total quality management (TQM), total preventive maintenance (TPM), and human resource management (HRM). Gebauer et al. (2009) concluded that JIT/continuous flow production, preventive maintenance, pull system/kanban, quick changeover techniques, cross-functional workforce, and continuous improvement programs are the most frequently included lean

practices. Azevedo et al. (2012) used the following lean practices in their study: supplier partnership, JIT, pull flow, quality management, and customer relationships. So and Sun (2010) measured lean management in terms of supplier selection, pull production, information technology, process focus, and employee empowerment. Tortorella et al. (2017) empirically validated four bundles of lean practices, namely, elimination of waste and continuous improvement, logistics management, top management commitment, and customer-supplier relationship management. Eriksson (2010) determined the following lean practices: waste reduction, process focus, continuous improvement, customer focus, systems perspective, and cooperative relationships.

This study adopts the approach proposed by Shah and Ward (2003). Accordingly, lean management is measured using four bundles: JIT, TQM, TPM, and HRM. These four bundles were selected to benchmark lean implementation of the Jordanian pharmaceutical company with the ongoing benchmarking project at St. Gallen University, which used this approach to measure lean management in the pharmaceutical industry.

## *2.2 Lean Operational Performance*

Operational performance is defined as “the output or result achieved due to unique operational capabilities” (Tan et al., 2007). It usually refers to measurable outcomes of organizational processes, such as cycle time, inventory turns, and delivery (Neely et al., 1995). In this vein, operational performance is regarded as internal or process performance (Manikas and Terry, 2009). Flynn et al. (2010) pointed out that operational performance is related to internal improvements in a firm’s response to a dynamic environment with regard to its competitors and customers. Lean operational performance refers to performance outcomes achieved as a result of applying lean principles. An organization that is operationally excellent through lean implementation leads its competitors by providing the lowest cost and the highest quality to its customers. It does this by performing the right tasks, at the right time, in the most efficient manner (Abdallah et al., 2009; Sharafat et al., 2016; Al-Sa’di et al., 2017).

Chen (2008) suggested that it is necessary to choose an appropriate range of performance measures, and these measures must be balanced to ensure that one performance or set of performance dimensions is not stressed to the detriment of others. Meanwhile, Gieskes et al. (1999) suggested that performance areas must be operationalized in a way that allows performance to be adequately measured against relevant performance indicators. It is necessary to find a comprehensive tool that can measure the overall lean operational performance of pharmaceutical companies. Benchmarking data are also important, especially with regard to limited published data about developing countries. Upon literature review, this study identified only a limited number of published works on lean practices and associated operational outcomes at pharmaceutical companies in the developing world. Shabaninejad et al. (2014) investigated the development of an integrated performance measurement model for the pharmaceutical industry in the Iranian market. They identified 25 key performance indicators; however, their suggested indicators were not presented as a comprehensive system to measure the overall lean performance of the company.

Friedli et al. (2013) adopted an operational performance model with their research group at the Institute of Technology Management at St. Gallen University. Their model had two distinctive elements: a technical sub-system and a social system. The technical sub-system consisted of the outputs of three lean bundles: TPM, TQM, and JIT. The social system included the outputs of an HRM bundle. Likewise, Bellm (2015) investigated lean operational performance in the pharmaceutical industry in emerging markets. The study used the quantitative data from the ongoing benchmarking project at St. Gallen University.

As the objective of this study is to benchmark lean bundles and lean operational performance of one Jordanian pharmaceutical company with the ongoing benchmarking project at St. Gallen University, lean operational performance indicators were adopted from the model proposed by St. Gallen University and its benchmark data. These lean operational performance indicators included items related to JIT performance, TQM performance, TPM performance, and HRM performance.

## **3. Research Methodology**

### *3.1 Benchmarking Model Selection*

The OPEX model was selected as a benchmarking model for this study. The model was adopted from an international research project in the pharmaceutical industry in the area of lean management and operational performance. The project was begun in 2004 at the Institute of Technology Management at the University of St. Gallen, Switzerland, and the Transfer Center for Technology Management at the University of St. Gallen, Switzerland (Friedli et al., 2013). The project provides participating firms the opportunity to position their plants against a broad range of pharmaceutical plants, to identify possibilities for improving lean operational performance (Gütter, 2014). Since 2008, pharmaceutical firms have been permitted to enter the continuous

benchmarking process at any time. The OPEX database includes more than 280 pharmaceutical plants from small and medium-sized companies (Bellm, 2015).

The OPEX benchmarking model includes lean enablers and outcomes. Enablers include lean bundles of JIT, TQM, TPM, and HRM. The outcomes reflect lean operational performance indicators related to JIT performance, TQM performance, TPM performance, and HRM performance (Gütter, 2014; Bellm, 2015).

Quantitative benchmarking data from OPEX was collected from Bellm (2015) and Friedli et al. (2013).

### 3.2 Measures

The survey items were adopted from the OPEX research project. In particular, the items were adopted from Bellm (2015) and Friedli et al. (2013). In the OPEX project, each lean bundle consists of several widely cited practices in the literature. Each practice was measured using several question items. The number of items to measure each practice ranged from 3 to 10. The JIT bundle included the practices of setup time reduction, pull production, layout optimization, and planning adherence. The TQM bundle included the practices of process management, cross-functional product development, customer integration, and supplier quality management. The TPM bundle included the practices of preventive maintenance, technology assessment and usage, and housekeeping. The HRM bundle included direction setting, management commitment and company culture, employee involvement and continuous improvement, and functional integration and qualification.

Respondents were asked to indicate the degree to which the provided statements apply to their plants, using a Likert scale of 1–5 where 1 indicated not at all and 5 indicated completely.

Lean operational performance was measured using key operational performance indicators adopted from the OPEX project. The indicators are related to JIT performance, TQM performance, TPM performance, and HRM performance. Table I summarizes lean operational performance indicators of each lean bundle and their respective definitions, as adopted from Bellm (2015), and the measurement unit of each indicator.

Table 1. Performance indicators of lean bundles

| Lean bundle | Performance indicator     | Definition  | Unit                                 |
|-------------|---------------------------|---|--------------------------------------|
| JIT         | Cycle time                | “Cycle time (from weighing to packaging). E.g. 30% of all products have a cycle time of 15-30 days. 70 % of all products have a cycle time of more than 30 days”.   | < 15 days<br>15-30 days<br>> 30 days |
|             | Service level (delivery)  | “Perfect order fulfillment (percentage of orders shipped in time from your site (+/- days of the agreed shipment day) and in the right quantity (+/- 3% of the agreed quantity) and right quality) to your customer”. | %                                    |
|             | Finished goods turns      | “Annual cost of goods sold divided by the average finished goods inventory”.  | Number                               |
|             | Raw material turns        | “Annual cost of raw materials purchased divided by the average raw material inventory”.   | Number                               |
| TQM         | Scrap rate                | “Average difference between 100% and real achieved output in packaging operations”.   | %                                    |
|             | Complaint rate (supplier) | “Number of complaints as a percentage of all deliveries received (from your supplier)”.   | %                                    |
|             | Rejected batches          | “Number of rejected batches as a percentage of all batches produced”.   | %                                    |
|             | Complaint rate (customer) | “Number of justified complaints as a percentage of all customer orders delivered”.  | %                                    |
| HRM         | Training                  | “Number of training days per employee (all kinds of training off and on the job”.   | days                                 |
|             | Unskilled employees       | Number of unskilled employees as a percentage of all employees  | %                                    |
|             | Absenteeism               | Average number of absented days per employee per year   | days                                 |
|             | Fluctuation               | “Employees leaving per year your site due to terminations, expired  | %                                    |

|     |                                 |  |   |
|-----|---------------------------------|--|---|
|     |                                 | work contracts, retirements etc. as a percentage of all employees.”  |   |
| TPM | Dedicated equipment             | “The percentage of your equipment that is dedicated to one product”.   | % |
|     | Setup and cleaning              | “The time spend for setup and cleaning as a percentage of the scheduled time”.   | % |
|     | Unplanned maintenance           | “Proportion of unplanned maintenance work as a percentage of the overall time spend for maintenance works”.  | % |
|     | Overall equipment effectiveness | “OEE= (OEE) availability x (OEE) performance x (OEE) quality<br>(OEE) availability = (Scheduled time – Downtime) / Scheduled time<br>(OEE) Performance = (Amount produced x Lead cycle time) / Available time<br>(OEE) Quality = (Inputs – Defects) / Inputs”. | % |

### 3.3 Data Collection

The data were collected from one Jordanian pharmaceutical company and were verified by site visits and observations at the manufacturing site. A questionnaire was prepared with constructs reflecting lean bundles and lean operational performance. The same question items used in the OPEX model were adopted for this study. The questionnaire was completed by fifteen managers, principal persons, and supervisors from various departments. In addition, interviews were conducted with the respondents to ensure that all the question items were understood and carefully answered. Respondents were encouraged to refer to the company’s enterprise resource planning (ERP) system and various company units to ensure the accuracy of their responses whenever it was appropriate. The average response of the fifteen respondents was calculated for each question item and used later for benchmarking purposes.

The company selected for the survey is a local manufacturer and distributor of a broad range of pharmaceutical products. The manufacturing site has three main production plants, one for general products and the other two for cephalosporin and penicillin. The major production line at the company is solids, which represent 65.46% of the product portfolio, followed by semisolids at 26.54%, liquids at 6.16%, and sterile vials at 1.83%.

The company has a large production staff of more than 400 full-time employees working in eight-hour day shifts. The company has many export markets in the Middle East and some European countries. The company is referred to as Jordanian Pharmaceutical Company (JPC) throughout the paper.

### 3.4 Treatment of Data

As the results of the OPEX benchmark data are reported in percentages, the data collected from the JPC was also converted to percentages. For lean constructs, the implementation level was calculated as a percentage of each practice by taking the average value of the set from the 5-point Likert scale, dividing it by 5, and multiplying by 100. Most performance indicators were reported in percentages. In order to convert the remaining performance values into a percentage, each value was divided by its corresponding complete value in %; for example, to convert absenteeism (in days) into a percentage, the value was divided by 365 days and multiplied by 100 to generate a percentage.

The OPEX benchmark data regarding the implementation levels of the practices of lean bundles were split into four categories for comparison purposes with JPC: top 10 refers to the top ten companies from the advanced sample; advanced refers to companies in Europe, USA, Canada, and Japan; offshore refers to multinational companies operating in emerging markets; and domestic refers to local companies from developing countries.

With regard to lean operational performance indicators, an average value for the entire OPEX data set was calculated and labeled average industry, which was compared to JPC results.

## 4. Results and Discussion

### 4.1 Benchmarking JPC’s Implementation Levels of Lean Practices with OPEX Data

Table 2 shows the comparison of the implementation levels of lean practices between JPC and other sites. JPC implementation levels varied among practices. Practices at JPC were higher than the top-10 sample in preventive maintenance, customer integration, and pull production; in supplier quality management, employee involvement, and functional integration, JPC was at the level of the advanced sites. JPC was lower than the benchmark data in the implementation of technology assessment, housekeeping, process management, cross-functional development, setup time reduction, layout optimization, and management commitment.

Table 2. Implementation levels of lean practices

| Lean practices                                | JPC | Top-10 | Advanced | Offshore | Domestic |
|---|-----|--------|----------|----------|----------|
| <b>JIT</b>                                    |     |        |          |          |          |
| Setup time reduction                          | 58% | 69%    | 63%      | 60%      | 66%      |
| Pull production                               | 68% | 62%    | 49%      | 47%      | 51%      |
| Layout optimization                           | 58% | 73%    | 64%      | 63%      | 66%      |
| Planning adherence                            | 87% | 76%    | 71%      | 71%      | 71%      |
| <b>TQM</b>                                    |     |        |          |          |          |
| Process management                            | 66% | 73%    | 72%      | 72%      | 73%      |
| Cross-functional product development          | 64% | 76%    | 68%      | 73%      | 63%      |
| Customer integration                          | 75% | 75%    | 73%      | 73%      | 73%      |
| Supplier quality management                   | 71% | 75%    | 69%      | 69%      | 68%      |
| <b>TPM</b>                                    |     |        |          |          |          |
| Preventive maintenance                        | 81% | 79%    | 75%      | 75%      | 75%      |
| Technology assessment and usage               | 50% | 64%    | 60%      | 60%      | 61%      |
| Housekeeping                                  | 80% | 87%    | 83%      | 84%      | 82%      |
| <b>HRM</b>                                    |     |        |          |          |          |
| Direction setting                             | 77% | 88%    | 80%      | 83%      | 77%      |
| Management commitment & company culture       | 65% | 76%    | 73%      | 74%      | 72%      |
| Employee involvement & continuous improvement | 67% | 71%    | 67%      | 70%      | 64%      |
| Functional integration & qualification        | 68% | 71%    | 66%      | 64%      | 67%      |

\*Source of Table with major data except JPC data were obtained from St. Gallen University with Permission.

#### 4.2 Benchmarking JPC's JIT Performance with Industry Average

The results in Figure 1 show that cycle time at JPC from weighting to packaging is 22.5 days, which is similar to the industry average of 22.7 days. This indicates well-optimized processes with the supply chain. However, JPC's performance in the aspects related to working capital was not as expected. In raw materials turns, JPC was only 2.4 while the OPEX average was about 8. In addition, the finished goods turns value at JPC was 3.9 turns per year compared to an average of about 16 for the industry.

JPC's performance at the service level (order fulfillment on time) was 97%, which was higher than the OPEX average value of 95%. This high service performance can be attributed to JPC's effective use of pull production; JPC's value was 68%, as shown in Table 2, which was higher than all the other sites. Interviews with managers at JPC revealed that the company adopts both a pull system and a push system simultaneously. They use the push system for the local market, while the pull system is used for the export markets. The company's policy in the local market is to maintain a sufficient stock of products; production for export is upon request from customers. However, the usage of both pull and push systems simultaneously seems to have an effect on raw materials and finished goods turns. In addition, JPC showed the worst result regarding set-up time reduction, as shown in Table II; this might also have had an effect on raw materials and finished goods turns.

#### 4.3 Benchmarking JPC's TQM Performance with Industry Average

The results from JPC indicate high internal performance with regard to rejected batches; it was 0 at JPC, while it was about 1% for the OPEX industry average. The scrap rate at JPC of 3.5% was a bit higher than the OPEX average of 2.5%. Zero rejected batches at JPC can be attributed to the well-implemented cGMP requirements. JPC uses well-known cGMP systems, such as annual product quality review and trend analysis, to monitor all quality-related issues. Site visits at JPC revealed that the use of measurement methods, such as statistical process control, are poorly implemented. This may explain the high scrap rate compared to the OPEX average. This is supported by the extent to which the TQM practice of process management is implemented; process management includes the documentation, measurement, and improvement of processes. It was 7% lower at JPC compared to the top 10 sites, as shown in Table 2.

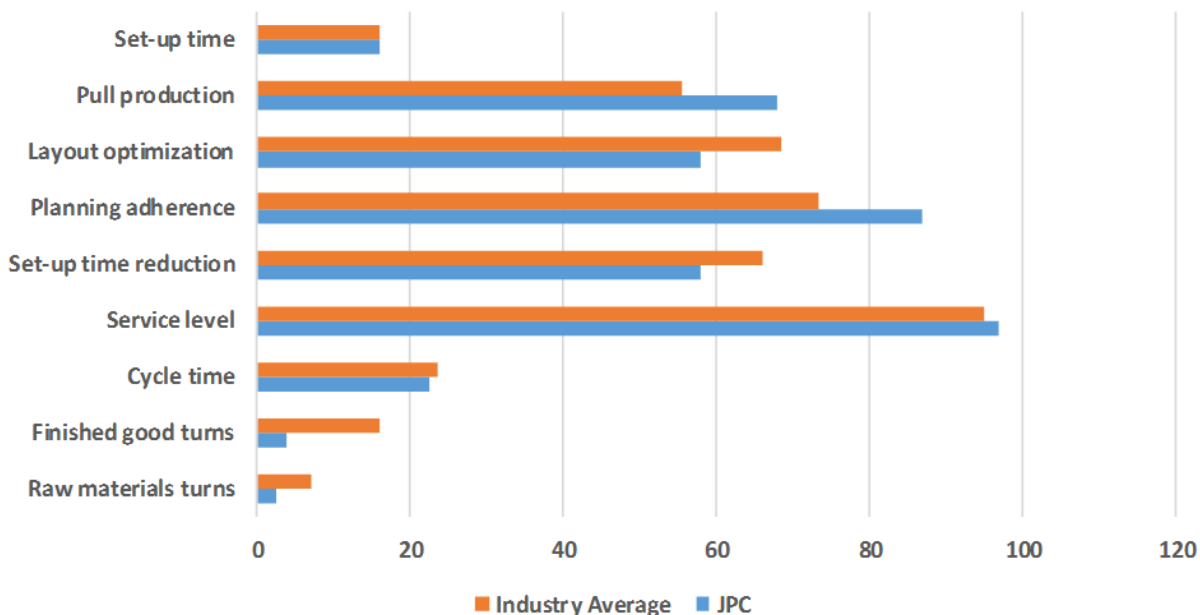


Figure 1. JIT implementation and performance at JPC compared to industry average

As for the indicators of external TQM performance, JPC showed similar high performance as the OPEX average, with regard to customer complaints (< 1%). In addition, supplier complaints were only slightly higher at JPC, with 4%, as compared to the OPEX average. The high external TQM performance results at JPC can be attributed to the extensive implementation of the TQM practices of supplier quality management and customer integration; the JPC levels of implementation are very close to top-10 companies, as shown in Table 2. Interviews with supply chain managers at JPC revealed that the company has 180 active suppliers (35% from India, 25% from Europe, 15% from the Middle East, 7% from China, and 18% from the rest of the world). The company applies a vendor qualification system, according to cGMP requirements. For example, to approve a supplier of active pharmaceutical ingredients (API), they require a GMP certificate for the manufacturer site and a drug master file (DMF) for the API; in addition, they perform the audit at the site.

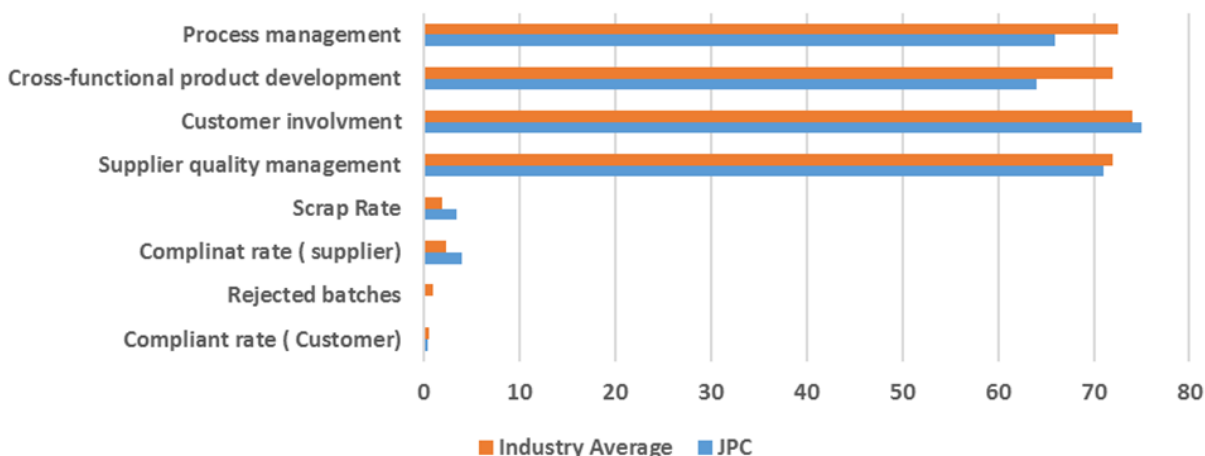


Figure 2. TQM implementation and performance at JPC compared to industry average

4.4 Benchmarking JPC’s HRM Performance with Industry Average

The performance indicators of the lean HRM bundle are shown in Figure 3. Absenteeism and fluctuation are used as measures of employee satisfaction (Bellm, 2015). Absenteeism, at 2.1%, was lower at JPC than the industry average value of 3.3%. In fact, the low absenteeism rate at JPC might be traced to strict roles in the pharmaceutical industry in Jordan, where absenteeism may lead to loss of employment. Fluctuation, however, was higher at JPC, at 13%, compared to the industry average of 7.5%. Fluctuation seems to have a greater

negative effect on the company, since knowledge can be lost when workers leave the company. In the Middle East region, there is a tendency for experienced workers to go work in the Gulf countries, where the salaries are much higher for the same position compared to Jordan. The generic pharmaceutical industry in that region is developing quickly, which is very attractive to Jordanian workers. Another reason for high fluctuation at JPC could be the lack of empowerment and qualification programs. Transferring authority from supervisors to line staff is not a common practice on the shop floor, as was observed from the site visits. Employees have limited authority to act on the problems they face during production, where a wrong decision could cost an employee his job. In fact, the degree of cross-trained employees was not high at JPC. It seems that the management at the company was not previously aware of the importance of job rotation and qualification programs; a newly implemented policy at the company is aimed at improving this weak point by providing more training and rotation.

Staff qualification, represented by the portion of unskilled employees as a percentage of the total number of employees, was similar to the OPEX industry average. However, the number of training days at JPC was 2.4 days, compared to the industry average of almost 17 days. This could be attributed to company culture at JPC. Site visits revealed that executive management believes there is no place for individual involvement in any changes that are not within the regulations, so they consider following rules and regulations more important than giving suggestions or employee involvement in improvement. They feel that giving the employees freedom to implement change would negatively affect compliance with regulations. It is therefore obvious that the direction of development, orders, decisions, and new projects flow from top management to employees without feedback from shop floor employees.

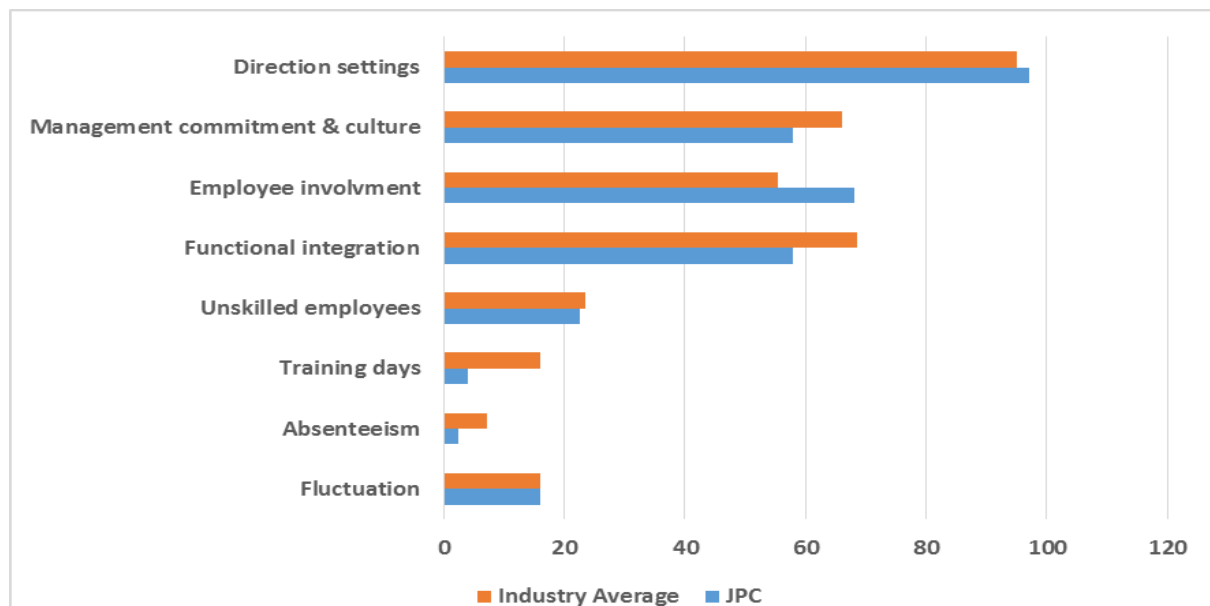


Figure 3. HRM implementation and performance at JPC compared to industry average

#### 4.5 Benchmarking JPC's TPM Performance with Industry Average

The backbone of a manufacturing site is its production lines, which are dependent on machines. Thus, the main concern is to keep the machines running at full capacity during production time. Machine failure, lower production capacity, and low product quality are issues that have been addressed in depth in the literature as the results of poor production maintenance (Ahuja and Khamba, 2008; Abdallah, 2013).

Figure 4 shows the benchmarking results of TPM implementation practices and TPM performance at JPC compared with the industry average. The overall equipment effectiveness (OEE) level at JPC was 36%, which is less than the industry average of 51%. In addition, unplanned maintenance work at JPC represented 70% of its overall maintenance time. The percentage seems to be very high compared to 33% for the OPEX benchmark data. JPC visits and interviews with managers revealed that the company suffered from a lack of real preventive maintenance programs. This issue is currently undergoing improvement; the implementation level at JPC, at 81%, is higher than the top-10 sites (Table 2). Engineering management is serious about implementation of preventive maintenance programs and has already started training programs for production and maintenance staff, in



addition to the performance of full maintenance programs for the machines. They are also working on autonomous maintenance by empowering shop floor employees and machine operators. The new policy at the company is to shift from reactive to proactive maintenance. JPC is still lagging in the issues of utilization of equipment and minimizing downtime. The issue of OEE was still new to the company when they implemented a new program to measure it for all machines.

Dedicated equipment at JPC is only about 1%, while it represents about 36% of the OPEX benchmark data. The dedication of equipment to certain products reduces the need for changeovers and lowers the need for full cleaning validation between different batches after line clearance. This is evident from the TPM performance indicator of set up and cleaning, which represents 25% of schedule time at JPC as compared to the OPEX average of 15%. JPC's low percentage of dedicated equipment is explained by its large product portfolio, which comprises more than 200 formulations in 1554 different stock keeping units (SKUs). The level of dedicated equipment is closely linked to the type of pharmaceutical industry; in Jordan, it is mainly a generic industry.

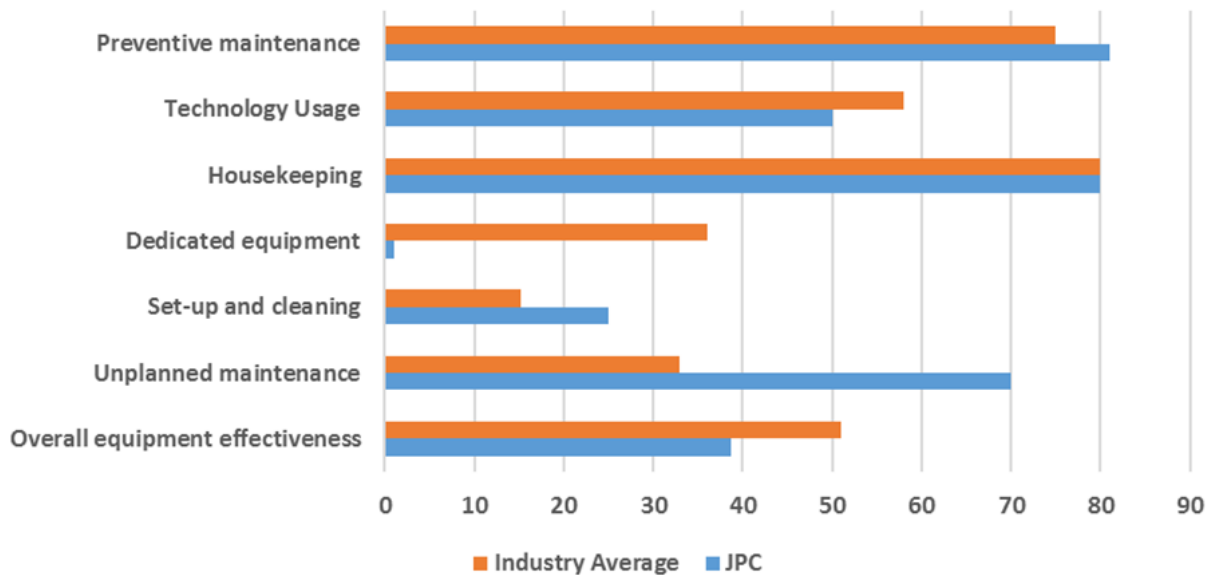


Figure 4. TPM implementation and performance at JPC compared to industry average

## 5. Conclusion, Recommendations, and Limitations

### 5.1 Conclusion

In this study, the extent to which lean practices have been implemented at one Jordanian pharmaceutical company were benchmarked with the results of the international research project in the pharmaceutical industry (OPEX). The adopted operational excellence (OPEX) benchmarking model provides a comprehensive methodology to evaluate the overall lean levels and performance of pharmaceutical manufacturing companies. The proposed model can assist pharmaceutical companies in emerging markets to evaluate their performance and develop appropriate implementation procedures for improving and enhancing operational effectiveness and efficiency. The model includes four lean bundles: JIT, TQM, TPM, and HRM. Each bundle was benchmarked in terms of the implementation levels of its main practices and the performance of the lean bundle.

The criteria shown in Table 3 were adopted in order to assess the implementation and performance levels at JPC compared to the benchmarked data.

The proposed criteria combine the implementation and performance levels of each lean bundle in order to make an overall assessment and rating of each bundle relative to the benchmarking data. The overall assessments are based on the results of JPC regarding the practices and performance indicators of each bundle compared with the benchmarking data reported in the previous sections. In addition, site visits to JPC by the authors and interviews with managers were taken into consideration to avoid misleading conclusions.

Table 3. Proposed criteria for rating JPC’s results compared with the benchmarked data

| Category of rating | Definition   |
|--------------------|--|
| Excellent          | The implementation and performance levels of the lean bundle at JPC are at or above the levels of the benchmarked data.        |
| Good               | The implementation and performance levels of the lean bundle at JPC are almost at the levels of the benchmarked data.          |
| Acceptable         | The implementation and performance levels of the lean bundle at JPC are below the levels of the benchmarked data.              |
| Weak               | The implementation and performance levels of the lean bundle at JPC are considerably below the levels of the benchmarked data. |

A careful assessment reveals a rating for JPC that is close to excellent for the TQM bundle. The implementation of TQM practices at JPC was excellent with regard to customer integration and supplier quality management. Process management and cross-functional product development showed levels ranging between good and acceptable. Likewise, the TQM performance was excellent, especially given the 0% of rejected batches and customer complaint rate. In addition, good performance results were shown with regard to scrap rate and supplier complaint rate.

The overall assessment of the HRM bundle reveals a rating close to good. The implementation level of the HRM practice of functional integration was excellent. Employee involvement showed a good implementation level. The practices of direction setting and management commitment showed acceptable implementation levels. HRM performance indicators showed excellent ratings regarding three indicators: unskilled employees, absenteeism, and fluctuation. However, JPC showed a weak rating regarding training days.

The overall rating of the JIT bundle is close to acceptable. The implementation levels of the JIT practices of pull production and planning adherence at JPC were excellent. However, the two other practices, setup time reduction and layout optimization, showed acceptable implementation levels. As for JIT performance, JPC showed excellent performance concerning delivery service level and good performance concerning cycle time. Nevertheless, JPC showed weak performance with regard to finished goods turns and raw materials turns.

Regarding the TPM bundle, the overall assessment of JPC tended to be weak. Although the implementation level of TPM practice of preventive maintenance was excellent, the levels of technology assessment and housekeeping were weak and acceptable, respectively. TPM performance showed an excellent rating regarding setup and cleaning. However, performance indicators of dedicated equipment, unplanned maintenance, and OEE showed weak ratings at JPC. Figure 5 summarizes the overall rating of each lean bundle.



Figure 5. Overall rating of implementation levels and performance of lean bundles at JPC

### 5.2 Recommendations

With regard to TQM, it is recommended that JPC management maintain customer complaints at a low level while keeping rejected batches to zero. In addition, improvement plans are needed to reduce supplier complaints and scrap rates. With regard to JIT, it is recommended that JPC continue working on reducing cycle and setup times. In addition, considerable improvements are needed to improve performance metrics on raw material and finished product turns. With regard to HRM, JPC management should make an effort to diffuse the strategic direction company-wide, to positively influence the organizational culture and reflect management’s commitment to lean philosophy. Training represents one major weakness at JPC; it should be given priority, as it promotes cross-functional teams and provides the basis for real improvements. Likewise, emphasis should be

given to reducing fluctuation and increasing employee involvement. With regard to TPM, there is plenty of room for improvement by enhancing preventive maintenance programs while initiating OEE monitoring, reducing unplanned maintenance, improving housekeeping, and increasing the qualification of the maintenance staff through training.

### 5.3 Managerial Implications

The pharmaceutical industry, like other industries, faces challenges associated with severe global competition and pressure to improve quality while reducing cost. This situation is even more evident in developing countries, where many companies struggle to sustain their market shares and improve the efficiency and effectiveness of their operations. While lean management has grown in popularity in the pharmaceutical industry in developed countries, it is still a new concept in developing countries. Managers must consider lean management as an effective competitive strategy for achieving operational excellence. Benchmarking the levels and performance outcomes of lean bundles with leading international companies enables companies in the developing world to assess their success and determine areas that should be targeted for improvement. The current benchmarking study of the pharmaceutical manufacturing company in Jordan provides insights regarding the usefulness of comparing key lean metrics against leading companies. This new approach to the pharmaceutical industry in developing countries can support senior management in adopting appropriate strategic plans to promote lean management and operational excellence in their companies. In addition, the data presented in this study represent essential information in this field that can be utilized by companies to implement a lean program and steer themselves toward operational excellence, regardless of the region in which the manufacturing site is located.

### 5.4 Limitations

This study was applied to only a single pharmaceutical company in Jordan. This was due to the familiarity of this company with lean management; in addition, other companies declined to participate. Future studies are needed in developing countries with an appropriate sample size of pharmaceutical companies to obtain more generalizable results regarding lean management and enable investigation of causal relationships. Finally, only fifteen responses were received from JPC. This small number is inappropriate for performing validity and reliability analysis of the constructs. Future studies with an appropriate sample size will avoid this limitation.

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