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Complying pre-qualification world health organization (PQ-WHO) audit finding by job scheduling

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Abstract. The PQ-WHO Certification (Pra Qualification) is a standard covers requirements of product quality, processes, systems, safety, and health services in pharmaceutical industries related to HIV disease, reproductive disorders and acute diarrhea of children. The PQ-WHO released by the World Health Organization. A Pharmaceutical company that meet the WHO PQ requirements deserves to apply for getting approval, certification and recognition in the production of drugs. This paper described how to overcame the gap between the ideal conditions according to PQ-WHO requirements and the actual implementation. Action plan carried out to met PQ-WHO requirements by the scheduling of job method. The results of research in a pharmaceutical industry in Bekasi showed that the improvement to met PQ-WHO requirements fulfillment mostly effective done by method of Shortest Process Time (SPT) compared to other method. It resulted the shortest average time of work completion, highest utilization rate, and lowest delay. Mean flow time about 70.09 days (90 days available), average delay about 14.57 days, and tardy jobs by 7 times, and utilization about 11.96%. This result is best compared to other methods.

1. Introduction

Increasing competitiveness in the world force organizations take the policy for improving quality standard in global stage. The pharmacy industry is trying to improve competitiveness by meeting the market needs and standards that international authorities require, such as WHO prequalification standard (PQ-WHO). World Health Organization will certify the organization who meet it's requirements could boosting competitive advantage of organization of pharmacy industry. A Company with certified PQ-WHO will get approval for producing medicine and medical stuff from WHO Program. Getting PQ-WH certification means opportunity of pharmacy industry to supply and produce all product from WHO Program to whole the world (WHO, 2010).

PQ-WHO is a WHO Prequalification standard for medicines and health services issued by WHO to assess the quality, safety and efficacy of drug products in WHO Program. Initially, PQ-WHO focused on drugs of HIV/AIDS treatments, tuberculosis and malaria. In 2006, the drug product list was expanded including medicines for reproductive health. Then in 2008 expanded again included acute diarrhea for children. At the end of 2012, PQ-WHO issued a list of WHO Prequalification drug products containing 316 drugs for priority diseases.

The PQ-WHO certification process is applied by a pharmaceutical industry to WHO through the submission of an audit request and inspection invitation, then sending dossier. If the audit request

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agreed, WHO Representatives make assessment for verifying products, process, system and safety related to the PQ-WHO standard.
Companies must submit data and information on registered pharmaceutical products, equipped with the required information according to file submission instructions that available on the WHO website. Relevant documentation such as contracts, quality documents, and records of key production operations should indicate that the company fully control overall the manufacturing process and ensuring all proposed product meet standard of prequalification of PQ-WHO requirements.
This paper purpose to describe the method of job scheduling for overcoming non-compliance that have not met the PQ-WHO requirements (non-conformity) from the WHO audit finding in one of the Pharmaceutical Industries in Bekasi. Also providing how to choose the strategy making improvements to implement the recommendations of the audit results, so that is done effectively and efficiently through the selection of work scheduling method.
The fulfillment of PQ-WHO requirements as an indicator of the pharmaceutical industry in global competitiveness verified by audit. The corrective actions carried out for every nonconformity from audit findings by a work mapping mechanism in the form of job scheduling based on the time aspect of the required work completion as the time limit given by WHO assessors.

2. Theoretical basis

In accordance with the Decree of the Minister of Health of the Republic of Indonesia No.43 / Menkes / SK / II / 1988 on Good Manufacturing Practice (CPOB = Cara Pembuatan Obat yang Baik), the CPOB Guidelines aim to ensure the drug is made consistently as well as the ISO 9000 quality system (Badan POM, 2012). CPOB covers all aspects of production and quality control. The quality of the drug depends on the material, packaging, production process, quality control, building, equipment used, personnel involved and all resources. Therefore, the Quality Assurance of a drug should be made in a carefully controlled and monitored condition.
CPOB is in line with PQ-WHO requirements. CPOB recognized as the PQ-WHO audit item and becoming the reference of the PQ-WHO audit. Prior to the submission of the PQ-WHO Certification, the pharmaceutical company should conduct a gap analysis to determine the current factual conditions to the fulfillment of PQ-WHO requirements through the CPOB standard. By doing a gap analysis, The company can identify what the company need to bridge the gap (Prakasa, 2014). The first step of the gap analysis is to develop a checklist that serves to identify gaps between standards and actual conditions.
Literally "gap" identifies a disparity between one thing and another. The elements of the gap analysis process consist of humans, tools, environments, measurements, methods, and materials (Muchsam 2011).
The gap between the PQ-WHO requirements and the factual condition of both the Gap analysis and the PQ-WHO audit results contains a list of nonconformities that corrective action should be taken. Overcoming gap shall consider some of aspects such as the length of time, priorities, degree of distress, cost, difficulties, and many other aspects. This paper focused on the time aspect because WHO provides a short time limit (in case less than 90 days) for the pharmaceutical industry to take action for fulfillment PQ-WHO requirements. Work scheduling is an appropriate method of completing tasks related to time aspect with Involving work, resources, and limited time in this PQ-WHO address. Scheduling is the allocation of resources to implement a set of tasks by time (Baker and Timetsch, 2009).
In previous research, generally work scheduling applied to production activities, project, job shop, and other industry types. Mostly nothing is implemented in action plan for improvement to meet a standard or system audit findings. Indah Puspitasari and colleagues (2016) conducted research on the implementation of job scheduling in the Job Shop model industry showed that job scheduling was able to present various choices of strategies and priorities that can be used by the users and can provide information about the length of time each post activity and possible delays , so it can be selected which one is the most efficient and effective.

The other research mentioned that work scheduling is able to detect priority and work optimization to reduce the delay in production process in company (Goriwondodan and William, 2012). This is exactly what is described in research by Azila-Nadiah et al. (2012) who apply job scheduling to the Job Shop model industry by selecting a work arrangement based on priority. The preparation of work activities based on priority aspects can be effective in the field of production or other similar operations (Bennydiktus, 2017).
The application of job scheduling to the corrective action plan in overcoming the gap between the PQ-WHO requirements and the factual conditions is a breakthrough. This is because the tight deadline given by WHO Assessor requires the company to complete PQ-WHO requirements in the short span of time (usually 90 days). The time aspect becomes the main consideration. The best work scheduling method is chosen to determine each corrective action based on the time required, the time limit available and the estimate of how long it can be completed.

3. Methods

The method used in this research is as follows:

1. Collecting data on WHO audit results and Gap Analysis from one pharmaceutical industry in Bekasi.
2. Compile a list of audit findings and scores
3. Mapping the list of audit findings and corrective action based on the time required and priorities
4. Perform data processing in the form of graph, histogram, pareto, and percentage of scores for getting problem real picture.
5. Do discussion, interview and observation in various forms with the management involved in the PQ-WHO team
6. Compiling sequences of improvement plan overcoming nonconformity of PQ-WHO audit findings based on priorities, time and degree of difficulty
7. Monitoring and evaluation of results
8. Making decision to choose the best method
9. Conclusion

4. Result and discussion

The data obtained is the result of WHO PQ audit. The WHO PQ audit in a pharmaceutical companies is based on CPOB and PQ-WHO requirements consisting 6 dimensions and 26 sub-dimensions of requirements. Based on the results of audits was conducted in every department in one pharmaceutical factory in Bekasi, the results of sufit score calculated as below:

Table 1. Score of audit result in departments/work unit

No	PQ WHO Requirements	Score Total	Target Score	Qt Item	Average (%)
1	QA	9425	10000	100	94.25
2	QS	300	300	3	100
3	PGA	400	400	4	100
4	HRD	1350	1500	15	90
5	Production	10475	1100	110	95.23
6	RND	900	900	9	100
7	Logistic	9225	9300	93	99.2
8	Quality Control	10850	11000	110	98.63
	Total	47125	48600	486 .00	97.47

Based on the audit results, the total score of each department could be concluded was good because it has an average of more than 85. If reviewed detail based on the dimensions of the items audited, there were items with score has not met the requirements of less than 85 such as Quality Assurance (QA), HRD, Production, Logistic, and Quality Control (QC). It happened by score have not met the requirements. Here are the score which below 75.

Tabel 2. List of score ≤ 75 with item standard

No	No. Standard/ Department	Critical (M,m,c)	Score (0-100)	Ideal score
1	2.1 Quality Assurance	Major	75	100
	2.5 Quality Assurance	Major	75	100
	2.7 Quality Assurance	Major	75	100
	2.10 Quality Assurance	Major	75	100
	2.10 Quality Assurance	Major	75	100
	7.5 Quality Assurance	Major	0	100
	7.5 Quality Assurance	Major	50	100
	7.5 Quality Assurance	Minor	0	100
2	7.6 HRD	Minor	0	100
	7.6 HRD	Minor	50	100
3	2.9 Prod.	Major	75	100
	2.9 Prod.	Major	50	100
	6.2 Prod.	Major	75	100
	6.2 Prod.	Major	75	100
	6.2 Prod.	Major	0	100
4	4.1 Logistic	Major	50	100
	4.1 Logistic	Major	75	100
5	7.3 Quality Control (QC)	Major	75	100
	7.3 Quality Control (QC)	Critical	0	100
	7.3 Quality Control (QC)	Major	75	100
	7.3 Quality Control (QC)	Critical	0	100

Table 3 shows low score as audit result necessary to take actions immediately according to WHO Auditor request at latest in 90 days completed overall, then the company decided to create a team for handling any causal that has not met the requirements. Companies have to do the right scheduling method. Here is the data of work scheduling of action plan for PQ-WHO audit findings and Process Time needed per item audit.From the composition of the work scheduling above, then prepared a simulation with several methods to select the best method.

Initially, the company composed work assignments based on priority recommendations as instructed by top management and agreed by all departments of work units. This case caused by limited time available and tightened deadline from WHO Auditor. Before decision made, a Manager gave an idea for trying some method . FCFS method was considered fair because this principle prioritizes orders that come first to do, but this method is not necessarily effective for the company. The FCFS method only addresses the deadline for completion of the order, without looking directly at the process. Based on Table 8, the comparison of scheduling method to solve the gap that occurred in the PQ-WHO audit result, the SPT resulted in the shortest average time of completion of the work, the highest utilization rate, the average number of jobs in the lowest system, and the average the lowest delay.

5. Conclusions and suggestions

After the effectiveness of each scheduling method calculated, the comparison of the effectiveness of each of the four methods were analyzed. The following is a comparison of the effectiveness of the scheduling calculation of all methods:

Table 3. The Comparison of all methods

	Method	Mean Flow Time	Average Tardiness	Tardy Job	Utility (%)	Job Qty.
Early Metode	FCFS	82.62	17.81	9	10.02	9.98
Metode	SPT	70.09	14.57	7	11.96	8.36
Proposed	EDD	82.28	18.39	9	10.19	9.82
	LPT	114.28	35.95	14	7.33	13.64

The results above showed that the method of Shortest Processing Time (SPT) is superior in the four criteria of effectiveness. This could be a proposal for the company to use SPT's job scheduling method to manage the settlement of gaps occured for resolving inconsistencies in the PQ-WHO audit results.

The comparative analysis of scheduling method used job sequencing technique, The SPT method resulted in the lowest average time of completion of work, the highest utilization value, the average number of jobs in the lowest system, and the lowest average delay. With the mean flow time value of 70.09, the average delay of 14.57, the number of tardy jobs of 7, the utilization value of 11.96% and the number of jobs in the system of 8.36. So The SPT Method is the best compared to others.

The recommendations for company is to needs to determine the most effective and efficient scheduling method. Other methods should be developed to enrich any alternatives. The limited method in this paper is due to the limited time and deadline for completing the improvement of the PQ-WHO audit results at one of the pharmaceutical companies in Bekasi. The consideration focused the time aspect to answer the choice for avoiding delay of PQ-WHO Certification. Companies should explore other methods to integrate priority, time, cost, and other aspects in sequencing of improvement activities to minimize delays and achieve time targets in PQ-WHO Certification

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