Design Business Process Management Model for Pharmaceutical with Good Manufacture Practice and Good Distribution Practice in Indonesia

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Abstract: This study aims to present the business processes management of the pharmaceutical industry combined with supply chain management processes Good Drug Distribution (GDP) and Good Manufacturing Practice (GMP). Thereby can complete business process management (BPM) by government regulations, giving a good picture of business processes within the company or pharmaceutical industry by GDP and GMP. This research was conducted with a qualitative approach, which was carried out by reviewing the literature of several literary articles related to the subject of this research and conducted a discussion forum with the pharmaceutical industry in Indonesia. Business process management model with a combination of GMP and GDP approaches to improve efficiency and effectiveness by creating automation, speed, and process accuracy in change management. With this BPM model, the BPM can improve business processes and supply chain management processes in the pharmaceutical industry, and the BPM can provide efficiency and effectiveness in the industrial drug distribution process. New BPM can reduce the problems in the pharmaceutical industry in the circulation of medicines and the availability of medicines in the market.

1 INTRODUCTION

The development of information technology in the current era provides a change in competitiveness that is so terrible. The effect of this change has an impact on companies today, so companies try to always improve their competitiveness by changing all orientations from functional to process (Buttigieg et al., 2016) (Smolnik et al., 2011) (Ramos-Merino et al., 2019)(Rentes et al., 2019) (Venkatraman and Venkatraman, 2019). This change leads to the concept of business process management (BPM) by directing company changes in the systematic identification, modelling, and process improvement of company performance. In improving this process, a process of planning and implementation must lead to improvement and is carried out by combining knowledge in analyzing the strengths and weaknesses of the company and its resources to suit the company (Couckuyt and Van Looy, 2019) (Fernando et al., 2018) (Kitsios and Kamariotou, 2019) (Tsakalidis et al., 2019).

BPM has a scope and objectives related to changes and improvements that stem from the analysis of problems that occur in companies that hurt the effectiveness and efficiency of the process that is being implemented (Bitkowska et al., 2018) (Malinova and Mendling, 2018) (Niehaves et al., 2014) . The main process in supporting the company's development process that is increasing in the process, building a knowledge base that leads to all aspects of BPM implementation (Brocke, 2018) (John, 2008). BPM has been widely used in various companies with various fields, specifically in the pharmaceutical industry. The pharmaceutical industry is an industry that provides drugs on the market. From the focus group discussion process, there are some problems in the industry that are most crucial in the manufacturing stage is not being able to do good planning in fulfilling the supply of drugs from the ingredients of making the drug formula to packing material (Hamilton, 2013) (Marcketti, 2005) (Puri and Ranjan, 2012). This process is triggered by the uncertain supply of drug ingredients and the unavailability of drugs at distributors or influenced by ignorance of the number of drugs on the market (Puri and Ranjan, 2012). Also, problems arise in the distribution process that has problems with many distributions that do not comply with the provisions that lead to the circulation of illegal drugs in the market. With this problem, the pharmaceutical industry needs BPM for managing business processes that

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are carried out following its supply chain (material providers, manufacturing industries, distributors, retailers, consumers) so that they can be more effective and efficient in the process. BPM can be combined with GMP and GDP by government regulations.

This study aims to present or describe the management of business processes of the pharmaceutical industry combined with supply chain management processes, GMP, and GDP methods. Thereby can complete business process management by government regulations, giving a good picture of business processes within the company or pharmaceutical industry by good drug distribution and good manufacturing practice. The development of BPM in this article was developed an update to reach the final stage starting from the supply of raw materials, the manufacturing process to the good distribution process for consumers. This gets certainty from the outstanding and quality drugs.

2 THEORY FOUNDATION

2.1 Supply Chain Management in the Pharmaceutical Industry

The supply chain management (SCM) process in the pharmaceutical industry is an activity carried out from the process of raw materials being managed into drugs to the distribution process to users and guaranteeing or ensuring that drugs can be well received, quality and in accordance with needs(Shao and Ji, 2006) (Law, 2016) (Rovers and Mages, 2017). In this SCM, the pharmaceutical supply chain complexity results from the involvement of many large, highly diverse independent organizations (Dachyar and Novita, 2016) (Van der Aalst, 2013). The main stakeholders in this supply chain include government agencies, hospitals, clinics, drug manufacturers, drug distributors, pharmaceutical chains, retailers (Indonesia, 2009). The same supply chain is responsible for the distribution of existing drugs such as prescription drugs, over-thecounter drugs, generic drugs, hard drugs and drugs with narcotics that have different operational objectives (Grüne et al., 2014) (Nwabueze, 2012).

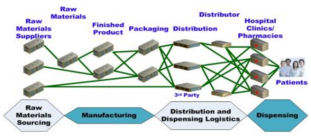

Figure 1: Supply Chain Management (Tipton, 2015)

2.2 Business Process Management

Business process management is a model approach to improve efficiency and effectiveness by building an automation process, speed, and precision in the management of a change. This business process management analyses existing performance processes then makes changes by designing new processes by optimizing existing or available processes using various facilities and methodologies (John, 2008) (Ramos-Merino et al., 2019). BPM is a dynamic system, so you can always change what is needed continuously according to the situation and conditions (John, 2008). BPM examines each increase in the company's performance to achieve business processes that are managed with a maximum or optimum. The most important part of BPM is the process because of how it can understand, manage and develop an organization to provide products or services of greater or greater value to partners or customers (Brocke, 2018)(Malinova and Mendling, 2018). BPM can be supported by technology to accelerate the processes carried out in it. Also, many parties discuss GMP from a technological or multi-person point of view (John, 2008).

In many companies today, many are implementing BPM with the main reason for the company to become more competitive in today's fierce commercial competition and its future (Niehaves et al., 2014) (Van der Aalst, 2013). This competitive is because the company has the challenge of being able to survive or be superior in business competition. Improvements can be made by providing added value, increasing productivity, reducing costs, and improving the company's business processes. These are some of the benefits of BPM that will help a company navigate business competition, namely: Improve business capacity, reduce costs and increase profits, increase efficiency, improve visibilit(John, 2008) (Koster, 2009).

BPM main components Each Business Process Management (BPM) solution has four main components (Smolnik et al., 2011) (Van der Aalst, 2013):

2.2.1 Modelling

Users can define and design the structure of each business process graphically.

2.3 Integration

In BPM, each element can be related in carrying out the process so that collaboration or exchange of information occurs to complete the goal.

2.3.1 Supervision

Users can monitor and control the performance of the ongoing business processes and the performance of each staff involved in the business process.

2.3.2 Optimization

Users can analyze and monitor a business process and also take measures to improve their efficiency.

An excellent way to do this is to describe the process view of the organization and the list of processes from beginning to end, giving a more detailed view of the process and the list of processes from beginning to end of the organization.

In the design process, can group the processes that occur, the grouping can be done on three levels:

1. Strategic processes: this level represents a strategic process, which must ensure that the underlying process meets and continues to meet the specified objectives.
2. Core processes: this level represents the principal or main business activities of the organization
3. Support processes: this level describes noncentral processes, which support the central operations of the organization

2.4 BPM IN SCM PHARMACY

The pharmaceutical industry has continued to develop due to globalization, consolidation, and regulatory compliance. Manufacturing needs to combine more efficient and quality-focused processes. The pharmaceutical supply chain must be scalable and agile enough to adapt to changing scenarios and partners worldwide. Research and development (R&D) are under pressure to reduce costs and cycle times (Koster, 2009) (Nwabueze, 2012) . When managed care organizations limit medication forms and promote generic drugs, pharmaceutical companies develop strategies to compete with drugs. Staying competitive in this developing environment has never been more challenging. Sales and marketing must overcome regulatory demands by reassessing how they manage more and more channels and partners (Hein et al., 2015). Amid this background, efficient management of business processes is essential for sustainability and growth. The standard BPM solution allows organizations to dynamically manage workflows and electronic form processing with a steady BPM.

2.5 Good Distribution Practice in Indonesia

This guide is used as a reference to carry out the process of distribution of medicines by interested parties (pharmaceutical industry, pharmaceutical industry, and community services (pharmacies, hospitals, public health centres) at the hands of consumers. HK 03.1 .34.11.12.7542 of 2012 (BPOM RI, 2012) includes:

2.5.1 Quality Management

The quality system developed must be fully documented, and its effectiveness monitored. Within the system, there must be a change control system that includes the principles of quality risk management.

2.5.2 The Organization, Management, and Personnel

The correct implementation and management of a quality management system and the correct distribution of the medications and/or ingredients of the medications depend very much on the personnel who carry them out.

2.5.3 Buildings and Equipment

Buildings and equipment to guarantee the protection and distribution of drugs and/or drug ingredients. Buildings must be designed and adapted to ensure that good storage conditions can be maintained, have adequate security and sufficient capacity to allow safe storage and handling of drugs, and the storage area is equipped with adequate lighting to allow that all activities are carried out accurately and safely.

2.5.4 Operational

All actions taken by the distribution facilities must ensure that the identity of the drugs and/or the ingredients of the drugs is not lost and that the specifications listed on the packaging manage their distribution.

2.5.5 Self-inspection

Self-inspection should be carried out to monitor the implementation and compliance with CDOB compliance and to follow up on the necessary corrective measures.

2.5.6 Complaints of Drugs and/or Drug Ingredients That Are Returned, Allegedly False, and Withdrawn

All complaints and other information about potentially damaged medications should be collected, reviewed, and investigated by written procedures. The responsible personnel must approve medications to be resold by their authority.

2.5.7 Transportation

The transport process must apply appropriate transport methods. The medicine must be transported with storage conditions according to the information on the package. Appropriate methods of transport should be used, including transport by land, sea, air or a combination of the above.

2.5.8 Facilities based on Contract

All contract activities must be in writing between the contract grantor and the contract recipient, and each activity must comply with CDOB requirements.

2.5.9 Documentation

Good documentation is an essential part of the quality management system. Written documentation must be clear to avoid errors in verbal communication and to facilitate follow-up, including batch history, instructions, and procedures.

Figure 2: Good Distribution Practice

Business processes carried out among them are:

1. Receipt of orders
   This activity is to receive goods by carrying out activities such as a collection of order letters, write of order letters, correction of customer orders.
2. Procurement of Goods
   The process of procurement of goods carried out, such as recapitulation of demand, determine the procurement policy, procurement of goods, release of supplies, order goods to the main external actors.
3. Manufacture invoice
   This process will be carried out by verifying the order letter, the approval of the transaction, the printing of the invoice, the calculation of VAT, the claim process, and the customer discount.
4. Delivery of goods
   Some of the processes carried out include the delivery orders (DO) for customers, the preparation of products, the shipment of products.

2.6 Good Manufacturing Practice

Good Manufacturing Practices in Figure 3 are : a model used in the pharmaceutical industry at each stage of processing from raw material control, formula manufacturing validation, equipment validation, manufacturing process validation, test method validation , audit and review functions, material testing, testing of finished products, material control, handling of raw materials, storage, packaging processes, environmental monitoring, approval of manufacturing instructions, approval of the use of materials, including the use of water, exhaustive documentation to create system quality (Van der Aalst, 2013). Good Manufacturing practice consists of:

1. Trained Personal
2. Quality System with Traceable Documentation and Records
3. Approved Materials (including Water)
4. Approved Manufacturing instructions
5. Controlled Materials Handling, Storage, Segregation, Packaging's, and Labelling
6. Materials, intermediates and finished products testing
7. Internal Audits and reviews
8. Validated test methods
9. Validated manufacturing processes
10. Validated Equipment's
11. Approved Manufacturing Facilities

Figure 3: Good Manufacturing Practice (Van der Aalst, 2013)

3 METHOD

This research was conducted with a qualitative approach, which was carried out by reviewing the literature of several literary articles related to the subject of this research and conducted a discussion forum with the pharmaceutical industry in Indonesia. The following research models can be seen in figure 4.

Figure 4: Research Model

The process carried out in Figure 4 is maps out the processes that exist in GMP and GDP against the levels that exist in the business process management (BPM).

4 RESULTS AND DISCUSSION

This study analyzes the design of the BPM model needed by companies or the pharmaceutical industry, especially in Indonesia. According to John Jeston and Johan Nelis(John, 2008) in the design of BPM, it is necessary to consider the process architecture, which is how to provide a process level description of the business process that is occurring. In the process of analyzing the BPM model by mapping out existing processes according to the three BPM process levels, the BPM process can be seen in Figure 5.

Level BPM	Sub Level BPM dan SCM pharmaceutical	GMP	GDP	Additional by reference
Strategic process	Governance Processes	1. Quality System 2. Audit Compliance (internal Audits and review) 3. Traceable Document and Record 4. Controlled environment	1. Self-inspection 2. Legal Compliance	-
	Management Processes	-	Corporate & Operational	1. Risk Management 2. Budget Management 3. Performance Management 4. Change Management
Core Process	Raw Materials Sourcing	1. Approved raw Material 2. Material, Intermediates and Finished products testing	-	-
	Manufacturing	1. Approve Manufacturing instruction 2. Validated Manufacturing Processes 3. Validated test methods 4. Validated Equipment 5. Approve Manufacturing Facilities	-	-
	Warehouse	1. Storage 2. Segregation	-	-
	Distributing & dispensing Logistic And Dispensing	-	Facilities based on contract	1. Receive order 2. Manufacture invoice 3. Delivery of Goods
Supporting process		1. Quality Management 2. Trained Personal 3. Building Management	1. Quality Management 2. Building and equipment Management 3. Transportation Management 4. Documentation	1. Human Resource Management 2. Information Technology Management 3. Financial Management 4. Procurement Management 5. Knowledge Management

Figure 5: BPM Process Mapping GMP and GDP in Supply Chain Management Pharmaceutical.

From the mapping process that is then carried out by modelling the BPM design of the pharmaceutical industry with combined GMP and GDP so that it can be seen in Figure 6.

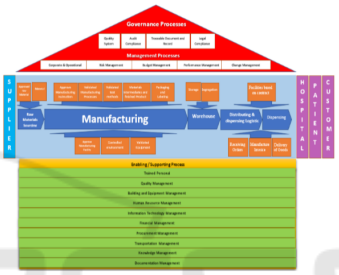

Figure 6: Business Process Management in the pharmaceutical industry with Combination GMP and GDP

5 CONCLUSION AND FUTURE RESEARCH

This study designed a business process management model with a combination of GMP and GDP approaches to improve efficiency and effectiveness by creating automation, speed, and process accuracy in change management. This business process management analyses existing performance processes then makes changes when designing new processes by optimizing existing or available processes using various facilities and methodologies. With this BPM model, can improve business processes and supply chain management processes in the pharmaceutical industry, and can provide efficiency and effectiveness in the industrial drug distribution process. With this, it can reduce the problems in the pharmaceutical industry in the circulation of medicines and the availability of medicines in the market.

In the next stage, it is expected that it can validate BPM for several existing industries, as well as be able to measure the level of all the components of the BPM model for the pharmaceutical industry.

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