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Risk Assessment, Risk Management, and Risk Communication at Drug Industries PT. Kimia Farma (Persero) Tbk. Plant Bandung

Suherdin[1], Noeroel Widajati[1], Ratna Dian Kurniawati[2], Abdul Rohim Tualeka[1]

[1]Department of Occupational Health and Safety, Faculty of Public Health, Airlangga University, Indonesia,
[2]Bachelor Programme in Public Health, Bhakti Kencana Institute of Health Science Bandung, Indonesia

Abstract

There have been many accidents and occupational diseases caused by weak risk management efforts. Risk management can be carried out by starting with a risk assessment. Risk assessment is an important aspect of occupational health and safety. The pharmaceutical industry has a high risk of occupational health and safety. This study aims to identify the level of occupational health and safety risks and provide control recommendations. This research is descriptively using the Job Safety Analysis (JSA) method. The results of the identification show that from 19 work steps 10 of which include high risk, 8 including moderate risk and 1 low risk. The hazards identified include chemical, physical, ergonomic and fire hazards. High risks include hazards originating from chemicals as raw materials for making drugs. Several control measures have been taken, but to ensure worker health and safety, additional efforts should be made such as noise suppression personal protective equipment, special masks for use in chemical hazards and work accident emergency response procedures. Risk communication at the drug company is going well.

Keywords: *Risk Assessment, Risk Management Risk Communication, Job Safety Analysis, Drugs Industries.*

Introduction

In Indonesia, the number of accidents due to work is still fluctuating, recorded the number of work accidents from 2011-2014 the highest number of accidents occurred in 2013 with 35,917 cases of work accidents (in 2011 there were 9,891 cases; in 2012 there were 21,735 cases, and 2014 occurred 24,910 case). The provinces with the highest number of work accident cases in 2011 were Banten and Central Kalimantan. In 2012, Jambi and Maluku Provinces. In 2013 the provinces of Aceh and North Sulawesi. In 2014 were the provinces of South Sulawesi and Riau[1].

Whereas in the case of Occupational Diseases (PAK) from 2011-2014 the trend has decreased even though in 2012 and 2013 it has increased. In 2011 the number of PAK in Indonesia reached 57,929 cases, in 2012 60,322 cases and in 2013 increased again to 97,144 cases, then in 2014, it began to decline to 40,696 cases. The provinces with the most PAK prevalence in 2011 were Central Java Province, in 2012 North Sumatra, South Sumatra and West Java, 2013 Banten Province, and in 2014 were the Provinces of Bali, East Java, and South Sulawesi. The data shows that efforts to prevent accidents and occupational diseases are still not optimal[1].

Efforts to prevent work-related accidents and diseases can be carried out with a number of approaches, namely, approaches to weaknesses in the human element, such as the selection of employees properly and knowledge building or training. Approach to weaknesses in hardware or production equipment through the design, maintenance of production equipment and planning of the work environment. Approach to all levels of management by conducting equitable distribution of tasks, and determining the implementation of risk assessments[2].

Risk assessment is a systematic effort to identify opportunities for accidents and occupational diseases. Through risk identification efforts we can find out the characteristics of risks from hazards so that it is easier to make security efforts to avoid accidents. One method that can be used to identify risk is the Job Safety Analysis (JSA) method. JSA is a risk identification method by

reviewing and assessing the risk of each stage of the work performed[3].

Job Safety Analysis (JSA) is a process of identifying hazards and risks based on each stage in a work process that has the potential to cause serious harm before an accident occurs. Determine how to control hazards or reduce injury rates and make written documents that can be used for hazard information[4].

Benefits of Using JSA

1. Provide individual training in safety and efficient work procedures.

2. Provide information about hazards in the workplace

3. Hazard information is described based on work stages so that it is more detailed.

4. Provide risk control alternatives based on the results of risk identification in the workplace.

5. Accurate absences, workers compensation becomes cheaper and increases productivity.

The risks identified must be immediately controlled, risk control efforts are known as risk management. Risk management is a systematic effort to determine the best actions in conditions of uncertainty. Risk management is an activity which contains elements: systematic identification, analysis, improvement, monitoring, and communication against risks[5].

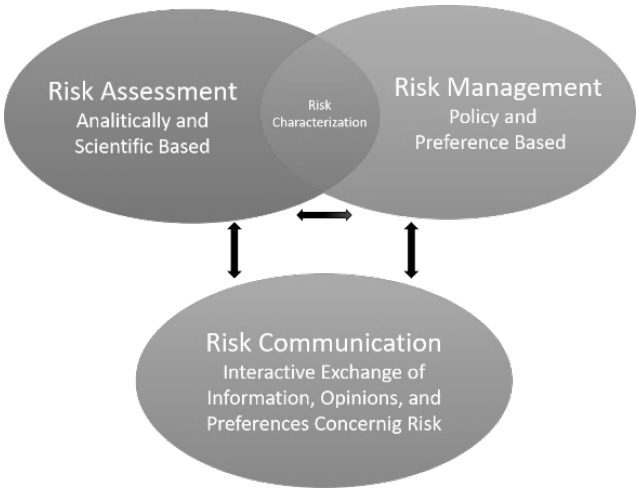

Figure 1. Correlation between Risk Assessment,

Risk Management and Risk Communication[5]

Based on figure 1, occupational health and safety risks need to be communicated. Risk communication is the exchange of information between interested parties about the circumstances, magnitude, and importance of risk control. risk communication itself is included in the risk analysis process[5].

PT. Kimia Farma (Persero) Tbk. Plant Bandung, is one of the State-Owned Enterprises (BUMN) engaged in the production of drugs or pharmaceuticals. In an effort to guarantee the supply of drugs on the market, this company provides 3 parts of the production. Particularly for production I, producing solid drug preparations in the form of tablets and caplets.

Based on the visits made to the production section I, there are some potential hazards that can lead to accidents and occupational diseases. During the production process, workers make physical contact either through inhalation or dermal with chemicals as raw material for making drugs. The chemical ingredients for the manufacture of drugs, namely ethyl alcohol, dextrose anhydrous, amylum maydis, and microcrystalline cells have the potential to cause health problems such as irritation, respiratory disorders, and nervous system disorders.

The purpose of this study is to conduct occupational health and safety risk assessments in the Production Section I of PT. Kimia Farma (Persero) Tbk. Plant Bandung using the Job Safety Analysis (JSA) method.

Material and Method

This study used a descriptive observational research design[6]. The danger is a potential hazard, risk refers to actual danger[7]. Risks can be identified through direct observation at the production site[8].

The study was conducted in the Production Section I of PT. Kimia Farma (Persero) Tbk. Plant Bandung. The risk assessment method uses the JSA with the following risk assessment steps:

1. Select the place to be analyzed

2. Describe the stage of work

3. Identify the various hazards and risks that exist in each step of the job, and identify various possibilities that have the potential to become accidents;

4. Risk assessment (likelihood and severity)

5. Categorize risk (risk assessment matrix)

6. Provide control recommendations

Risk Management is carried out by selecting control options that are in accordance with the characteristics of the risk. Evaluation of available controls, so that it can provide additional control recommendations[5]. Data on risk communication is obtained by direct observation at PT. Kimia Farma (Persero) Tbk. Planting Bandung. Risk communication can generally be observed through the media, company management meetings with workers and local stakeholders.

Table 1. likelihood

Value	Description	Information
A	Almost Certainly Happens	Can occur at any time under normal conditions, such as traffic accidents.
B	Often occur	Occurs several times in a certain period of time, such as a train accident.
C	Can occur	Risk can occur but not often, falling from a height at the construction site.
D	Sometimes	Sometimes it happens, for example, the leakage of nuclear installations or other machines.
E	Rarely	Can occur under certain conditions, such as people being struck by lightning.

Source: [3]

Table 2. Severity

Value	Description	Detailed Example
1	Not significant	Losses do not cause harm or injury to humans
2	Small	A minor injury, a small loss, and no serious impact
3	Moderate	Severe injuries, do not cause disability, moderate financial losses.
4	Great	Causes severe injury and permanent disability, heavy financial losses.
5	Disaster	Can stop the company's activities forever.

Source: [3]

Table 3. Risk Level Matrix

Likeli-hood	Severity				
	Not significant	Small	Moderate	Great	Disaster
A	High	High	Extreme	Extreme	Extreme
B	Moderate	Moderate	High	Extreme	Extreme
C	Low	Moderate	High	Extreme	Extreme
D	Low	Low	Moderate	High	Extreme
E	Low	Low	Moderate	High	High

Information:

Risk level	Information
Extreme Risk	Activities may not be carried out or continued. If it is not possible to reduce risk because resources are limited, then activities may not continue.
High Risk	Activities may not be carried out until the risk has been reduced.
Moderate Risk	The action is needed to reduce risk, but the costs needed must be carefully calculated and limited.
Low Risk	The risk is acceptable, additional controls are not needed. But monitoring must still be carried out.

Source: [3]

Findings

a. **Risk Assessment**

There are 9 stages of work then clarified into 19 job descriptions. The first stage is the weighing of raw materials carried out at the weighing center. The weighing process has 3 job descriptions, opening drums containing medicinal raw materials, weighing drug-making materials and manual lifting process. The risks identified are, workers inhale the raw materials of drugs that can cause shortness of breath. Workers sitting too long can cause Lob Back Pain (LBP), lifting the manual can cause LBP and Thoracic Outlet Syndrome (TOS). All work descriptions at this stage are included in the high risk.

The second working stage is a wet granulation process, in this stage described into 4 job descriptions. Climb the ladder of the granulation machine, insert the solvent of water or organic alcohol into the machine, hold the granulation results into a plastic barrel and there are operators as supervisors. The risks identified include, workers can experience injury, dizziness, shortness of breath and eye irritation. Two job descriptions are included in the high-risk level and the other 2 are moderate risk levels.

The third working stage is the drying process, there are 2 job descriptions in the drying process. Enter the raw material into the dryer with the average temperature of the 70^0C machine and the manual lift process. The risk identified at this stage is that workers can become dehydrated due to exposure to a hot work climate, and workers can experience fatigue, LBP, TOC due to the position of non-ergonomic apes. The level of risk in this stage is included in the low and moderate levels.

The fourth working stage is sieving, there is one job description in this process. Workers enter mixtures that have previously been dried into the sieving machine. The risk identified in this process is LBP due to work position when overseeing the sieving process for too long sitting and not ergonomic. The level of risk in this job description is included in the level of moderate risk. The fifth working stage is dry granulation, in this stage, there are 3 job descriptions. Workers put the mixture into a dry granulation machine, pour additives in powder or liquid form and bring the results of dry granulation to the drug printing section. The risks identified are workers can experience LBP, shortness of breath nervous system disorders, fatigue, and TOS. Two work descriptions are included in the level of moderate risk and 1 other is high-risk level.

The sixth working stage is drug printing, in this stage, there are two job descriptions. First Enter the ready-made material into the printing press. The risks identified are the risk of shortness of breath and nervous system disorders due to workers being too close to the reach of the dust collector. The level of risk in this job description includes high risk. Both operators process to monitor printing machines. The identified risks are workers experiencing varicose veins and fires from electrical installations. The level of risk includes high risk.

The seventh working stage is in coating the drug, there is one job description at this stage. Workers put drugs into the coating machine. The risks identified are workers at risk of experiencing varicose veins due to too long standing when watching the machine. Included in the median risk level.

The eighth stage is the primary packaging. There are 2 job descriptions at this stage. First, the workers send the drug into the engine, the identified risks are that workers can experience hearing loss due to noise produced by the primary packaging machine. Second, workers control the packaging results. The risks identified are that workers can experience LPB as a result of too often sitting in a non-ergonomic position. This risk is included in the level of moderate risk.

The ninth working stage is secondary packaging. There is one job description where the worker enters the drug into the box. The risk identified is that workers can experience varicose veins due to too long standing when packing. The level of risk in this job description is included in the high-risk level.

b. **Risk Management**

Based on the risk assessment above, it shows that of the 9 work stages and 19 job descriptions, 10 descriptions or 52.6% are at high risk for Occupational Safety and Health. The weighing and printing stage is a part of which all work descriptions are high risk. The remaining 8 descriptions or 42.1% are medium risks and 1 description or 5.3% low risk of Safety and Occupational Safety.

Referring to the results of the risk assessment that there are several job descriptions that have a high risk, the activities may not be carried out until the risk has been reduced or controlled. The purpose of risk control is to avoid workers from the worst consequences that can cause loss of work time and worker productivity.

Some stages of the production run the risk of causing health problems. Identified ergonomic risks such as errors in manual handling, excessive physical loads, and posture incompatibility with work stations, risk causing muscle disorders[9].

Research conducted by Wahyu, P.D and Tualeka, A.R., 2013 in one of the welding industries in East Java, Indonesia explained that there were still residual risks despite risk control. So that the residual risk assessment needs to be done so that it can further determine additional risk control recommendations[10].

PT. Kimia Farma (Persero) Tbk. Plant Bandung has carried out several efforts to control identified risks. The effort is a combination of technical control, administrative and use of personal protective equipment. controls that have been carried out between, providing masks, making Standard Operating Procedures, providing chairs for workers, working rooms equipped with refrigeration equipment, providing lightweight fire extinguishers, and efforts to maintain workers' fitness with gymnastics every morning.

Such control is still not enough to reduce some of the identified risks. Some controls must also be carried out, such as conducting safety talk, safety inspections, stretching work intervals, giving awards and reprimands, providing accident and fire emergency response procedures, exchanging with colleagues who are already tired and weak and providing earplugs.

c. **Risk Communication**

PT. Kimia Farma (Persero) Tbk. Plant Bandung applies OHSAS 18001: 2007 as work safety and health management system. One form of implementation of the system is communication, participation, and consultation[11]

Risk communication is the exchange of information about the magnitude of health risks in the work environment[5]. The forms of application of risk communication carried out in the company include, meetings between the entire corporate structure include workers in communicating occupational health and safety policies. Risk communication media are installed such as posters and banners. In addition to these efforts, PT. Kimia Farma (Persero) Tbk. Plant Bandung routinely holds meetings with workers on the National Occupational Health and Safety commemoration. This meeting was held so that there was an exchange of information between workers and managing the company.

Conclusion

Based on the results of the study it can be concluded that of the 9 work stages and 19 job descriptions, 10 descriptions are at high risk for Occupational Safety and Health. 8 description is the moderate risk, and 1 description low risk. Risk management has been carried out, but additional control is needed so that the risk of illness and occupational accidents can be reduced. The process of risk communication works well, risk communication involves management and workers. Communication media have been installed, and information exchange with routine workers is carried out.

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Ethical Clearance: The study was approved by the institutional Ethical Board of The Bhakti Kencana Institute of Health Science.

All subjects were fully informed about the procedures and objectives of this study each subject prior to the study signed an informed consent form.

References

1. Infodatin. Occupational Health Situation. Jakarta: RI Ministry of Health; 2015.
2. Halimah. Factors Affecting Employee Safe Behavior at PT. SIM Tambuhan Plant II in 2009. Syarif Hidayatullah State Islamic University; 2009.
3. Ramli S. OHSAS 18001 Occupational Health and Safety Management System. Jakarta: Dian Rakyat; 2010.
4. Sitepu HK, Tambunan MM. Identification of Hazard Levels in Higher Education Laboratories (Case Studies) Laboratories in the Department of Industrial Engineering, University of Sumatra. RAPI Nas XIII. 2014; 47–52.
5. Tualeka AR. Risk Assessment, Risk Management, & Risk Communication in the Work Environment. Surabaya: Graha Ilmu Mulia; 2015.
6. Sugiyono. Quantitative and Qualitative Research Methods. Alfabeta, editor. Bandung; 2015.
7. Sucipto CD. Occupational Health and Safety. Yogyakarta: Gosyen Publishing; 2014.
8. Prasetyani T, Djunaidi Z. Risk Assessment of Occupational Health and Safety of Offshore Pipe Coatings. KnE Life Sci [Internet]. 2018;4:332. Available from: https://knepublishing.com/index.php/Kne-Life/article/view/2565.
9. Rizkiani DO, Modjo R. Health Risk Assessment of Workers at the Mining Company PT. HIJ Site in South Kalimantan: An Overview. KnE Life Sci [Internet]. 2018;4:616. Available from: https://knepublishing.com/index.php/Kne-Life/article/view/2591.
10. Wahyu, P.D; Tualeka AR. Risk Assessment and Risk Control in the Welding Industry. Int J Occup Saf. 2013; III.
11. Matatula J. Occupational Health and Safety Management Systems-Requirements [Internet]. 2007. p. 19. Available from: http://mhconsulting-indonesia.com/file-download/Klausul-OHSAS-18001.pdf.