SIMTITS
Interdisciplinary School of Management and Technology
Institut Teknologi Sepuluh Nopember

JURNAL TEKNOBISNIS
2022 Vol. 8(2), 109 - 123

Received 25 Jan 2022; Revised 8 Mar 2022; Accepted 29 Mar 2022 | DOI: 10.12962/j24609463.v8i2.1410

Risk Analysis on Documentation Unit Workload in Pharmaceutical Company using Failure Mode and Effect Analysis (FMEA)

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ABSTRACT

Workload can affect employees in completing their work. Furthermore, mental workload can affect the documentation unit performance since the work is monotonous, does not require much physical movement and tends to be boring. There are 6 operators and 1 supervisor in the documentation unit. Due to its critical job, there are possibly risks that arise as a result of workload impact such as errors and delays in carrying out the documentation. Data from 2019 – 2022 shows there are an average of 8.61% delay documents per year and an average of 5.14% error check per year. In this study the researcher would like to figure out the mental workload condition and analyze the risks possibly occurred. Measurement of mental workload will be using NASA-TLX method. Then analyze the risk using the Failure Mode and Effect Analysis (FMEA) method. The result's shows that the documentation operator have 75.60 score and categorized as moderate workload. The risk analysis is conducted using FMEA and the highest RPN number is 30 for error in checking document which will be the priority to mitigate. It is recommended to review and evaluate the risk after recommended action performed and analyze whether the risk can be eliminated or remains other risk.

KEYWORDS: Workload; Risk Analysis; NASA-TLX; FMEA; RPN.

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1. INTRODUCTION

Documentation is the most important part in the pharmaceutical industry, where documentation is an integral part of product history that is made through a series of production and testing processes. Such important documentation includes batch product processing records, batch product packaging records and product test records, hereinafter referred to as production documents. Production documents must be managed in such a way, checked for correctness and completeness then to be used as a recommendation for product release. Documents are stored in accordance with applicable regulations (Badan Pengawas Obat dan Makanan, 2018). Checking documents is a static job that does not involve much physical activity but has the potential to have a risk to employees or the company. Measurement of workload in the documentation unit has never been carried out so that the current condition of the employee's workload cannot be known with certainty. There are several risks that may occur related to workload conditions. Production facilities owned by the company are used to produce its own production and outsourcing company products. Variations in the number of products can put pressure on employees in the documentation unit. Explained by (Jame Chenarboo et al., 2022) workload is the cost incurred for work performed by humans. The workload is physical and mental where both are always related to one another. Workload consists of a group of elements such as environment, community, motivation, and other factors that affect the ability of employees to perform tasks. Workload analysis is one of the most important components of system design. In accordance with the needs and expectations imposed on individuals when carrying out complex tasks, the impact and interaction of physical and mental activities determines the critical workload level of work and the risks that may arise as a result of the workload.

According to (Nino et al., 2020) in the research on operators working in the sterile production of pharmaceutical companies, it was found that mental workload can affect the physicality of employees. Mental workload is measured using the NASA TLX method which is considered sensitive because through the measurement of mental workload we can obtain work situations that affect the physicality of employees. In accordance with research from (Mohammadian et al., 2022) conducted in the mining area on employees in the control room, it was found that employees working in the mining control room have a high level of mental workload which can affect their work. Meanwhile (Hosseini et al., 2019) in his research on measuring the workload of health workers it was found that work factors can determine the work output produced per unit time.

In accordance with the effect of workload described by the researchers, there are several possibilities that can pose certain risks to the company. Where it is necessary to carry out risk identification, risk calculation and risk control as the actions that can be taken to ensure the workload of the documentation unit is in an acceptable risk condition. Based on quality risk research in the pharmaceutical industry conducted by (Alsaidalani & Elmadhoun, 2022) in the sterile section of the product filling stage and final completion using the Failure Mode and Effect Analysis (FMEA) method, the results obtained that risk

determination and actions need to be taken where the workload is a potential risk that should be investigated further. According to research on the process of reducing and controlling the risk of drug delivery carried out by (Phipps et al., 2011) in hospital drug service units and pharmacies using the FMEA method, the results show that the biggest mistake in drug delivery is fatigue from the pharmaceutical professional staff, so action is needed to mitigate the cause of the error. (Ullah et al., 2022) in a risk analysis study to identify and mitigate rapid response systems in hospitals for emergency department employees found that many activities must be immediately given risk reduction measures so that emergency room patients can be treated quickly. Meanwhile (Subriadi & Najwa, 2020) in the research to assess the consistency of using the FMEA method in identifying risks in the IT area, it was found that the FMEA method can be used with results that can be refined with modified FMEA.

From a number of journals that have been studied related to workload analysis using the NASA-TLX method, an overview can be obtained of how to measure the mental workload of employees working in the documentation unit so that from these conditions a risk assessment can be carried out using the FMEA risk assessment method to determine what risks are possible. occur and the control measures required.

The expected result of this research is to obtain an overview of the mental workload of the documentation unit in the company to control the risks that may arise as a result of this workload and determined the correct action taken to mitigate the risk, so the risk can be accepted.

2. LITERATURE REVIEW

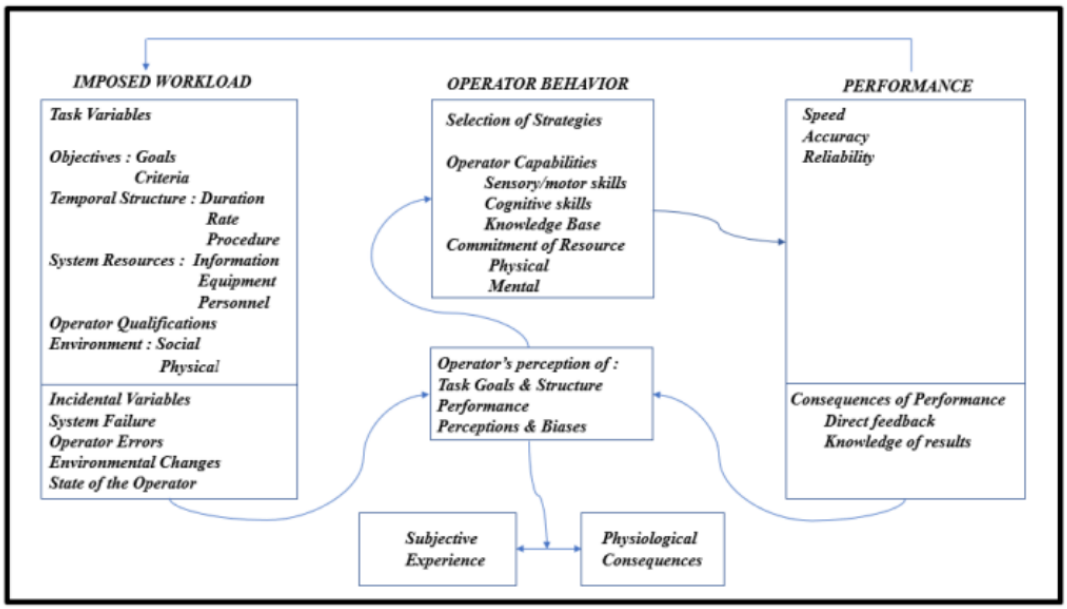
According to (Menteri Tenaga Kerja dan Transmigrasi Republik Indonesia, 2010) workload is a number of work targets or target results that must be achieved in a certain time unit. Workload will greatly affect the employee quality and productivity in completing their work. According to (Tropschuh et al., 2022) excessive physical and mental workload can cause decreased performance and increase employee sick days. According to (Jame Chenarboo et al., 2022) workload evaluation is the most important component that must be designed and analyzed. Workload calculation using the appropriate method is one of the tools to determine the current workload conditions in the documentation unit of the company.

Several studies related to the workload calculation tools have been carried out, where one of the mental workload calculation methods that can be used is the NASA-TLX quantitative method. The NASA-TLX method was first developed by (Hart & Staveland, 1988), where workload is influenced by several factors and interrelationships as shown in Figure 1.

Measurement of mental workload using NASA-TLX according to (Hart & Staveland, 1988) is a multidimensional procedure involving 6 (six) scales, as follows:

1. Mental Demand (MD)
2. Physical Demand (PD)

3. Temporal Demand (TD
4. Performance (P)
5. Effort (E)
6. Frustration Level (FL)



Source: (Hart & Staveland, 1988)

FIGURE 1. Conceptual framework linking performance and workload

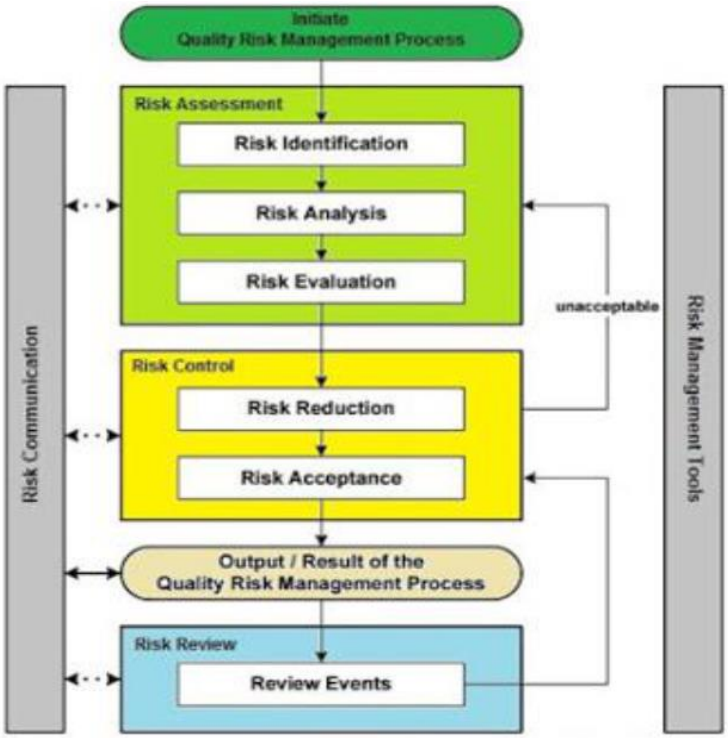
This workload measurement involves 2 (two) evaluation procedures, namely weighting and rating. Each employee surveyed will give an assessment on the 6 (six) scales above which are made in pairs, which will be given a weight which is more dominant in completing their work. Furthermore, a rating is given to each scale that reflects the magnitude of the factor in completing the work. Employees provide ratings for each factor based on perceived work experience. Measurement of mental workload is obtained by multiplying each weight by the rating filled by the employee. The result of the multiplication is then divided by 15 (fifteen).

Workload analysis needs to be done on different days to see the effect of differences in workload on certain days as was done by (Nino et al., 2020) who found that there were differences in workload calculated using NASA-TLX for officers working in sterile units of pharmaceutical companies, where during busy days results in high workloads, especially for certain task sections. According to research conducted by (Braarud, 2021) workload analysis using NASA-TLX must consider the conditions of the 6 (six) scales that have been set. Make a comparative analysis of the workload felt by each surveyed officer based on his perceived work experience. A more detailed explanation is needed to obtain objective measurement results. From this study, there were differences in results between working officers based on the focus of the existing work. Where the NASA-TLX measurement method can be used to perform complex job analysis.

Failure Mode and Effect Analysis Mode (FMEA) is a way that can be used to carry out risk analysis to identify possible failures that can occur and to solve known errors,

analyze the causes and effects of failures and eliminate or reduce risk effects through risk reduction actions. or risk elimination. After identifying and listing all possible failures, calculate the risks from the various factors that may arise for the next steps to reduce the risk until the risks are acceptable (Guiñón et al., 2020).

The FMEA risk analysis method according to research conducted by (Ouyang et al., 2021) plays an important role in the industrial world. In addition to identifying the failure model and the resulting risks, it is considered more appropriate and efficient for several risk analysis cases. Generally, the use of the FMEA method begins with determining the level of risk obtained from the multiplication of probability, severity and detectability, hereinafter referred to as RPN. Where for the assessment of P, S and D given a value range of 1-5 or 1-10.



Source: (European Medicine Agency, 2015)

FIGURE 2. Flow of risk analysis

According to Figure 2, the workload risk study in the documentation unit is carried out from identify the effect of workload on the likelihood of risk occurring, the severity of the risk consequences, the detection of known risks and the control measures that can be taken.

3. METHODS

Figure 2 below shows the flowchart of this study:

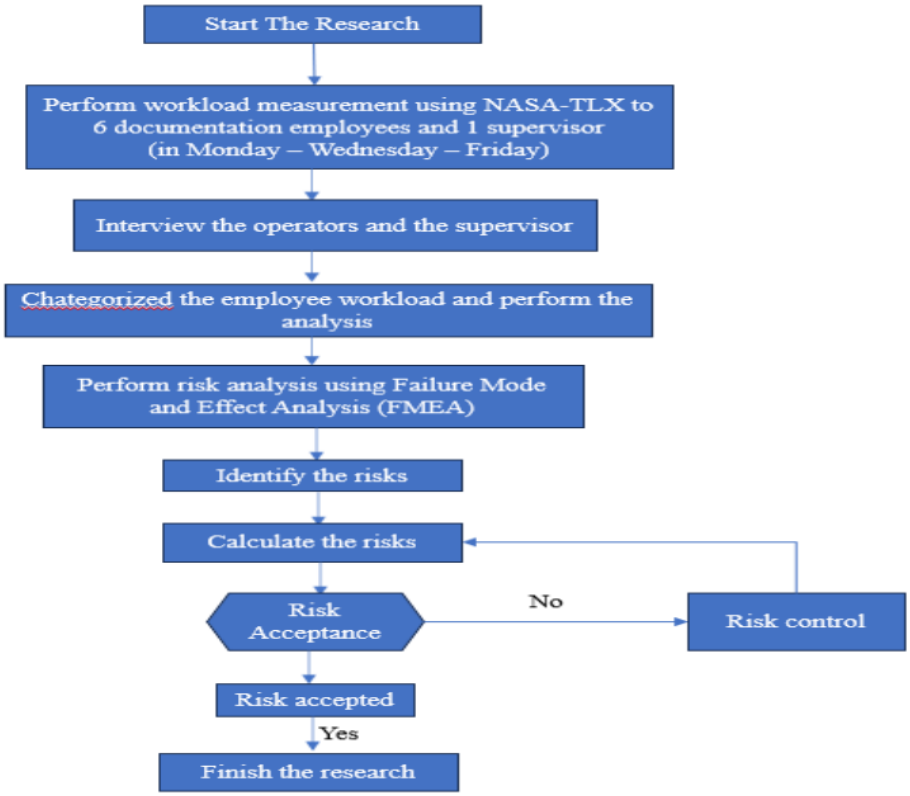


FIGURE 2. Research flowchart

The research performed by following steps:

- 6 operators and 1 supervisor filles the NASA-TLX workload questioner
- The questioner filled in 3 (three) different day : Monday – Wednesday - Friday
- Calculate the result for 6 operators and 1 supervisor
- Categorized the documentation unit workload, the category divided into :
  1. Score < 50 Low workload
  2. Score 50 – 80 moderate workloads
  3. Score > 80 high workload
- Perform risk analysis according to the workload condition using FMEA method
- Identify the risk using fishbone and root cause analysis (5 why's)
- Calculate the risk (Risk Priority Number)

  RPN = S x O x D
- Categorized the risk,

TABLE 1. Risk Category

RPN	Risk category	Risk interpretation
1 - 10	Low	Risk can be accepted
12 – 32	Moderate	Risk can be accepted but mitigation action needed
36 - 125	High	Risk can't accepted

Source: (Alsaidalani & Elmadhoun, 2022)

- Conclusion of risk

1. Accepted
2. Non accepted – need suitable action to decrease the risk

- Perform risk control action
- Evaluate the action
- Communicate the risks to relevant unit

4. RESULTS

In total 6 operators' documentation and 1 supervisor who filled the NASA-TLX workload questionnaire, below is the result. The questionnaire is filled in Monday – Wednesday – Friday,

TABLE 2. Weighted Workload result

No	Risk category	Weighted Workload				Mean Overall
		Monday	Wednesday	Friday	Mean	
1	A	82.00	79.67	82.00	81.22	
2	B	61.67	69.00	60.33	63.67	
3	C	75.33	79.33	67.67	74.11	
4	D	93.33	91.33	94.00	92.89	75.60
5	E	73.33	72.67	73.33	73.11	
6	F	82.00	72.00	77.33	77.11	
7	Supervisor	67.33	65.00	69.00	67.11	

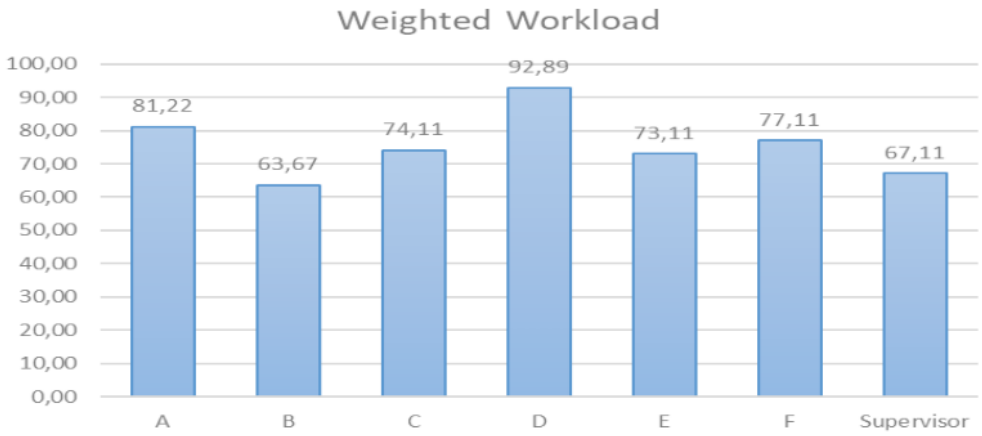


FIGURE 4. Weighted Workload

Workload measurement is carried out on Monday, Wednesday and Friday considering the rhythm and volume of work on that day. According to (Nino et al., 2020) it is likely that the workload will be different every day. Therefore, research on workload is carried out on Monday, Wednesday, and Friday because Monday is the start of the week where work is usually high due to completing the remaining work at the end of last week, while Wednesday is the middle of the week where some of the work has already been done on Tuesday and Friday is the end of the week. where there is mostly demand for the product to be ready for distribution as early as next week.

Overall, the workload described in the documentation unit as described in table is included in the Moderate category(Hart, 2006). The workload conditions experienced by documentation operators also vary between operators. Some feel a high mental workload, and some feel a low mental workload. But in general documentation operators feel that the mental workload they feel is in the moderate category.

The lowest mental workload is experienced by operator B with an average workload of 63.67 which is categorized as low workload. While the highest mental workload is experienced by operator D with an average workload of 94 which is categorized as high workload.

TABLE 3. Rating Composition

No	Rating/Day		Weighted Workload							Mean Overall
			A	B	C	D	E	F	G	
1	MD	Monday	255	300	240	500	255	360	240	286
		Wednesday	400	320	80	80	240	400	225	
		Friday	255	300	160	500	255	320	320	
2	PD	Monday	240	0	0	40	20	0	0	37
		Wednesday	85	0	0	60	20	0	0	
		Friday	300	0	0	0	20	0	0	
3	TD	Monday	70	225	320	360	300	240	325	254
		Wednesday	0	375	360	270	320	270	240	
		Friday	80	225	280	270	300	240	260	
4	P	Monday	240	225	140	200	150	450	240	228
		Wednesday	240	110	240	100	300	270	240	
		Friday	255	225	180	180	150	400	260	
5	E	Monday	425	75	350	300	375	120	85	240
		Wednesday	320	80	350	360	210	120	160	
		Friday	340	75	350	360	375	140	75	
6	FL	Monday	0	100	80	0	0	60	120	88
		Wednesday	150	150	160	500	0	20	110	
		Friday	0	80	45	100	0	60	120	

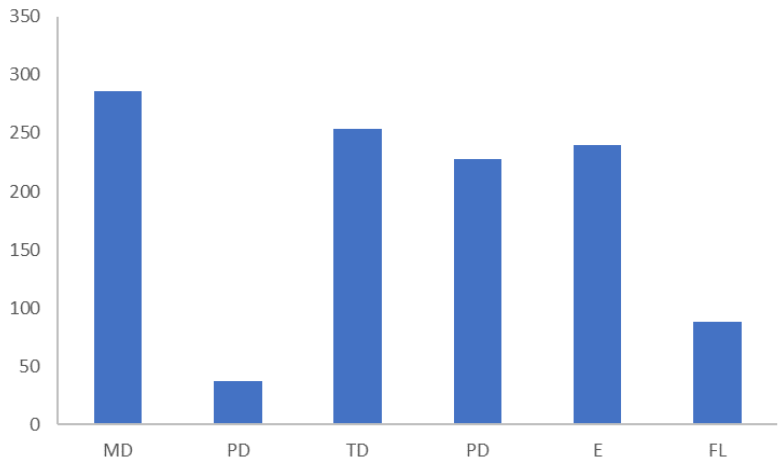


FIGURE 5. Rating Composition

According to tab. 3 and fig. 5 explain that mental demand become the higher rating that documentation operator feel when completion their work then temporal demand in the second place followed by effort. Documentation operators feel the mental load when finish the work they are afraid and worry they cannot finish the work on time with good quality work, while temporal demand felt by the operator because there is not much time to complete the work especially when there is urgent required document and a lot of documents arrived at the same time. Effort gives some other feel for the documentation operator since they have to finish the work based on the target, the time and the quality of their work.

After the mental workload for documentation unit defined then the researcher performs the risk identification by carried out interviewing to key members of the project team and based on their competencies and risk identification is achieved through brainstorming meetings with all interested parties (Sarvari et al., 2019) The list of possible risk than analyze by pareto diagram below is the result

TABLE 4. Possibility Risks

No.	Risks may occur	Case/year	Percentage	Cumulative percentage
1	Uncomplete document because broken scanner	12	0,68%	0,68%
2	Received a complaint because uncomplete document	2	0,11%	0,79%
3	Received a complaint because miss check	10	0,56%	1,35%
4	Received a complaint because miscalculation	3	0,17%	1,52%
5	Work completion is too slow	4	0,23%	1,75%
6	Uncomplete document because work completion too fast	2	0,11%	1,86%
7	Unconfidence	0	0,00%	1,86%
8	Hurts hand by staples	23	1,30%	3,16%
9	Hurts hand by paper	27	1,52%	4,68%
10	Hurts hand by staples fill	24	1,35%	6,03%
11	Document mix up	0	0,00%	6,03%
12	Substandard document check result	0	0,00%	6,03%
13	Headaches	52	2,93%	8,96%
14	Unfocused	0	0,00%	8,96%
15	Fed up	0	0,00%	8,96%
16	Worries	0	0,00%	8,96%
17	Mistakes when there is urgent demand	0	0,00%	8,96%
18	Received a complaint from outsourcing company	13	0,73%	9,70%
19	Uncomplete archieved	12	0,68%	10,37%
20	Delay check	792	44,64%	55,02%
21	Unfocused when finished urgent check	0	0,00%	55,02%
22	Received a complaint from other division	2	0,11%	55,13%
23	Delay released	792	44,64%	99,77%
24	Low productivity	4	0,23%	100,00%
25	Missed production document	0	0,00%	100,00%

No.	Risks may occur	Case/year	Percentage	Cumulative percentage
26	Sick	0	0,00%	100,00%
27	Reduce vision	0	0.00%	100,00%

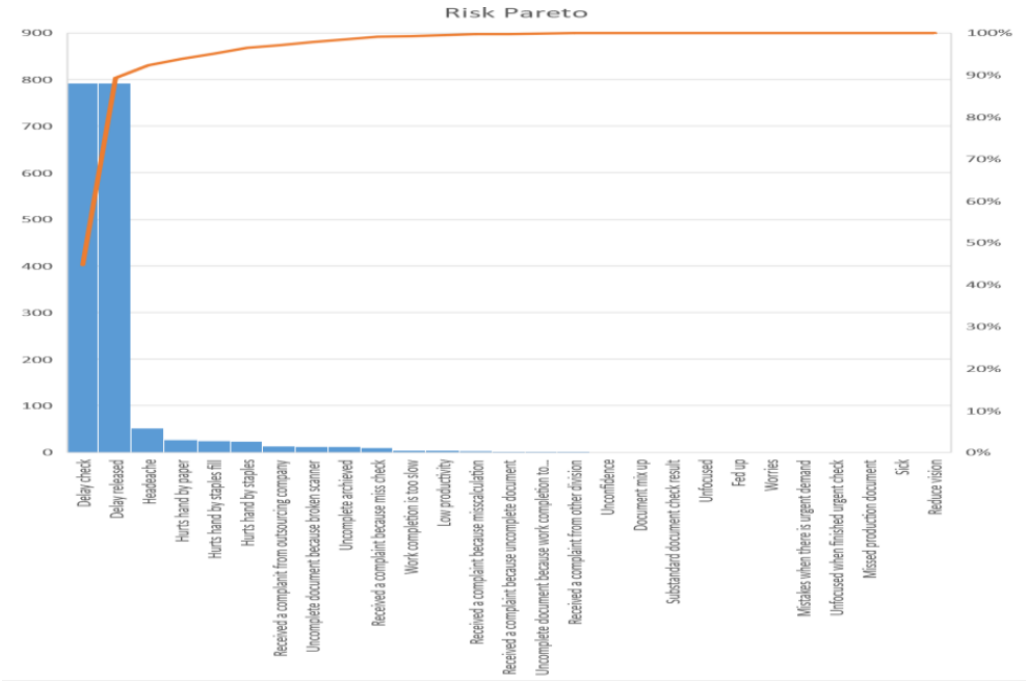


FIGURE 6. Pareto of possible risks

According to research conducted by (Yucenur et al., 2020) in research on the risk approach in the quality control section of the pharmaceutical industry, it is known that the initial step taken to identify risks is to look for possible risks using the fishbone diagram method, after that the possible risks collected and seen the number of occurrences based on existing historical data. It can also be seen from the pareto diagram which risks are most likely.

TABLE 5. Risk Identification

Risk No.	Identification Possible Risk	Identification Possible Causes Risk	Identification Risk Impact
R - 2301	Check error	Fed up Not confident Worries and afraid Unfocused In a hurry Urgent request	Complaint delay product released
R-2302	Miscalculation	Fed up Not confident Worries and afraid Unfocused In a hurry	Complaint delay product released

Risk No.	Identification Possible Risk	Identification Possible Causes Risk	Identification Risk Impact
		Urgent request	
R-2303	Uncomplete document	Fed up Not confident Worries and afraid Unfocused In a hurry Urgent request	Complaint delay product released
R-2304	Delay released	Work completion too slow, because: - Operator performance variation - Operator competency variation	Decreased company competitiveness
R-2305	Low productivity		
R-2306 R-2307	Headache sick	Down often fatique	Increased employee absent
R-2308	Reduce vision	Eye fatique	Employee with glasses
R-2309	Hand hurts	hit by staples hit by paper	Increased employee absent
R-2310	Uncomplete document archieve	inadequate tools	Document archieve can't be used

The level of risk is determined by the consequence of the risk, the likelihood of the risk occurring and the ability to detect the risk. It is something that must be done to determine the level of risk of each risk that has been identified. The level of risk is expressed by the Risk Priority Number (RPN). A risk score can help assess risk and focus on the causes of the risk. This can serve as a decision-making criterion for the next required action. RPN can be calculated by multiplying the consequence of failure (S - severity), probability of failure event (O - event) and probability of failure detection (D - detection). Based on the results of the RPN assessment it is necessary to decide when and what steps will be taken to reduce the RPN. Every identified risk can occur, it is necessary to take the necessary actions to prevent future risks (Kardos et al., 2021).

Risk assessment is required to determine the value of the RPN (Risk Priority Number) for each predetermined risk. Where the RPN value will be categorized into Low, Medium, and High values. Determine the actions needed to reduce risks that are Medium – High.

TABLE 6. Risk Calculation

Risk No.	Severity (S)	Occurance (O)	Detectablity (D)	RPN	Risk Category	Risk Control
R-2301	2	3	3	18	Medium	Yes
R-2302	2	2	3	12	Medium	Yes
R-2303	2	2	3	12	Medium	Yes
R-2304	5	2	3	30	Medium	Yes
R-2305	2	2	3	12	Medium	Yes
R-2306	2	2	2	8	Low	No
R-2307	1	1	2	2	Low	No
R-2308	1	2	2	4	Low	No

Risk No.	Severity (S)	Occurance (O)	Detectablity (D)	RPN	Risk Category	Risk Control
R-2309	3	3	2	18	Medium	Yes
R-2310	3	2	3	18	Medium	Yes

According to (Alsaidalani & Elmadhoun, 2022) moderate category risk is an acceptable risk but lower the risk with the necessary actions. Meanwhile, for risks with a low category, the risk is acceptable. Based on table 4.4.1, there are 7 risks in the medium category and 3 risks in the low category. For risks in the moderate category, it is necessary to reduce the risk so that the risk can be reduced as much as possible.

According to (Stamatis, 2003) every risk analysis using FMEA must be accompanied by recommendations for the necessary actions. The required action can be in the form of specific action or further study. The recommended actions to be taken in the FMEA system are to reduce severity (S), opportunity (P) and detection (D), or all of these parts. In general, the principle of FMEA is to reduce system deficiencies so as to reduce failures. Below is mitigation action will be taken to decrease the risks.

TABLE 7. Risk Control

Risk No.	Mitigation	PIC	Evaluate The Action Taken
R-2304	Create JKN product list Socialized the list to the employee Create timeline for job completion Weekly meeting with related division (PPIC, Marketing, production, QC) Create Batch Record Right at the First Time System Socialized Batch Record Right at the First Time system to related division Monthly evaluation of the achievement	Documentation Supervisor	December 2023 December 2023 December 2023 December 2023 December 2023 December 2023 December 2023
R-2301	Interview the employee to gain the cause of fed up Job rolling Employee competency evaluation Retraining Make a list of production document part that often tend to be wrong Re verify the document check result	Documentation Supervisor	December 2023 December 2023 December 2023 December 2023 December 2023 December 2023
R-2309	Evaluate the possibility of use hand cover to prevent hurts Use hand cover Evaluate how to use the correct staples Implement the correct staples usage Safety talk	Documentation Supervisor	December 2023 December 2023 December 2023 December 2023 December 2023
R-2310	Purchase new scanner Re check the scanned document before archiving	Documentation Supervisor	December 2023 December 2023
R-2302	Evaluate the employee competencies Retraining Make a list of production document part that often tend to be miscalculation Re verify the document calculation result	Documentation Supervisor	December 2023 December 2023 December 2023 December 2023

Risk No.	Mitigation	PIC	Evaluate The Action Taken
R-2303	Periodically check the achievement of work completion Create Batch Record Right at The First Time (BRFT) system Socialized the Batch Record Right at The First Time (BRFT) system Coordination meeting with related division	Documentation Supervisor	December 2023 December 2023 December 2023

5. CONCLUSIONS

The mental workload of the documentation unit using NASA-TLX obtained by the operator is 75.60 in the moderate category. There are 10 possible risks identified using fishbone diagrams and root cause analysis with 7 moderate risk categories and 3 low risk categories. Risks in the moderate category are reduced with mitigation action, while risks in the low category are used as opportunities for continuous improvement.

Several actions have been determined to reduce risk, such as determining a timeline for completing inspection of production documents for products included in the JKN list, evaluating operator competence, evaluating how to use staples safely, purchasing backup scanners with the same specifications as the main scanner, etc

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How to cite this article:

Shufianti, H., & Sudiarno, A. (2022). Risk Analysis on Documentation Unit Workload in Pharmaceutical Company using Failure Mode and Effect Analysis (FMEA). *Jurnal Teknobisnis*, 8(2): 109 - 123. DOI: 10.12962/j24609463.v8i2.1410