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"Emerging Occupational Risks in a Pharmaceutical Company Under Industry 4.0: An Assessment Using TICHNER and HIRAC Tools"

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Abstract: The integration of Industry 4.0 technologies within the pharmaceutical manufacturing sector aligns with broader industrial objectives, aiming to enhance productivity and adaptability while meeting challenging standards for product quality and diversity while maximizing efficiency. However, this shift is not risk-free. This particularly concerns the well-being of workers which is one of the top concerns shared by manufacturers. As the industry navigates this transition, it is imperative to prioritize the safety of personnel. The rapid pace of technological innovation within pharmaceutical manufacturing carries significant implications, introducing new and emerging risks. Consequently, proactive identification and assessment of these potential threats are essential to effectively mitigate their impact and ensure preparedness for forthcoming changes. To address this gap, this study provides an approach for identifying potential sources and significant factors contributing to its increasing risks in implementing Industry 4.0 in manufacturing industries. This set of sources and factors was evaluated in a medium-sized pharmaceutical manufacturing company aided by TICHNER and HIRAC Tools through a mixed-method approach. The combination of these tools facilitates the identification, characterization, and analysis of new and emerging risks associated with Industry 4.0 implementation. The findings of the study showed that Psychosocial Hazards and Work Experience/ Knowledge are the most common potential sources of Psychological Risks, Unemployment, and Need for Qualified Workers. The approach will allow manufacturers to proactively manage the new and emerging challenges brought by Industry 4.0 and safeguard the well-being of the workforce.

Keywords: Industry 4.0, Pharmaceutical, Manufacturing, Occupational Safety and Health, and Risk Assessment.

I. Introduction

The pharmaceutical manufacturing industry stands at the forefront of transformative change as it integrates the principles and technologies of Industry 4.0 into its operations [1]-[2]. Industry 4.0, often referred to as the Fourth Industrial Revolution, represents a paradigm shift marked by the fusion of digital, physical, and biological systems. In the context of pharmaceuticals, this revolution manifests through the seamless convergence of revolutionary technologies, including automation, artificial intelligence (AI), the Internet of Things (IoT), and data analytics [3]-[4]. Traditionally characterized by rigorous regulatory standards, precision, and a focus on product quality, the pharmaceutical sector is leveraging Industry 4.0 to enhance its efficiency, flexibility, and overall competitiveness [1]. However, this industrial revolution also introduces a critical dimension that demands careful consideration — the impact on occupational health [5].

As pharmaceutical facilities increasingly embrace the principles of Industry 4.0, the nature of work within these environments undergoes substantial changes. Automation and digitalization bring forth new opportunities for productivity but concurrently introduce new challenges to the well-being of the workforce [6]. This study seeks to explore and understand the potential occupational health risks stemming from the implementation of Industry 4.0 in pharmaceutical manufacturing.

By examining this intersection, this study aims to provide insights into how the merging of revolutionary technologies with traditional pharmaceutical processes may affect the physical and mental health of employees. The study recognizes the importance of safeguarding the workforce in an era of rapid technological advancement, ensuring that the pursuit of operational excellence aligns with the preservation of employee health and safety. As the pharmaceutical industry embraces Industry 4.0, this investigation becomes essential for fostering a workplace environment that is not only technologically advanced but also inherently protective of its most valuable asset — its people.

Understanding the perception gap between employers and employees regarding Occupational Health Risks is one of the gaps that this study wants to address.

II. Objectives

The objectives of the study are to identify the sources of New Occupational Health Risks, and determine the significant factors contributing to the increasing risk of New Occupational Health Hazards in the integration of Industry 4.0 in a medium-sized Pharmaceutical Manufacturing Company, and recommend safety programs and controls for the mitigation of New and Emerging Occupational Health Risks resulting in the integration of Industry 4.0.

Scope and Limitations

This study is limited to identifying potential occupational health risks associated with the implementation of Industry 4.0 technologies focusing on a pharmaceutical manufacturing company through related literatures and is limited to a medium-sized pharmaceutical manufacturing company utilizing a semi-automated production of sterile parenteral. Risk Analysis pursued in this study will only include the identified and characterized new and emerging occupational health risks after using the TICHNER Tool. A qualitative analysis will be incorporated into the identification and characterization of NERs using the TICHNER Tool while a quantitative analysis will be applied using the HIRAC Tool. The data gathering will utilize a survey instrument to be distributed to

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the manufacturing company. The concepts of the HIRAC tool will be used as the basis for recommending the appropriate controls for the elimination or minimization of risks.

Industry 4.0 in OSH

The study by Zorzenon et al. (2022) showed that Industry 4.0 has positive and negative impacts on Occupational Safety and Health. The study identified that a safer work environment and mitigation of occupational risks are the potential positive impacts of Industry 4.0. However, the negative impacts are increased stress, fatigue, diseases, musculoskeletal problems, and psychosocial risks [7].

Leso et al. (2018) provides a comprehensive overview of the opportunities and problematical aspects of Industry 4.0 concerning workers' safety and health. The study showed that the opportunities given by Industry 4.0 to OSH are better work-home interface, less monotonous work, enhanced HMI for hazardous tasks, safer and healthier work conditions, monitoring of employees' well-being, and Smart PPE [8]. Fig. 1 shows the diagram of Opportunities of Industry 4.0.

They also discussed the potential issues of Industry 4.0. The widespread automation in Industry 4.0 manufacturing jobs will inevitably lead to a reduction in manual work and hard physical tasks as well as to an increase for the entire workforce in complex management, abstraction, and problem-solving demands in the case of unforeseen events. Psychological risks will become more evident than physical ones in the workplace due to mental overload and work density induced by even more flexible and dynamic smart manufacturing activities. Fig. 2 shows the diagram of the issues and concerns deriving from the applications of Industry 4.0 in workplaces.

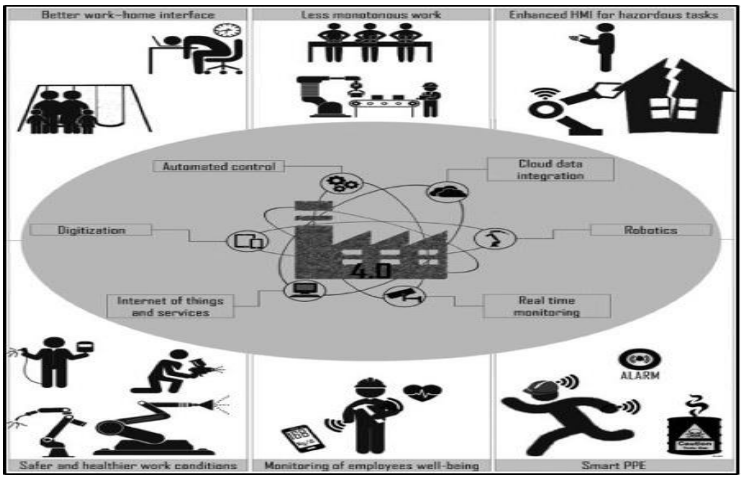

Fig. 1 Opportunities of Industry 4.0

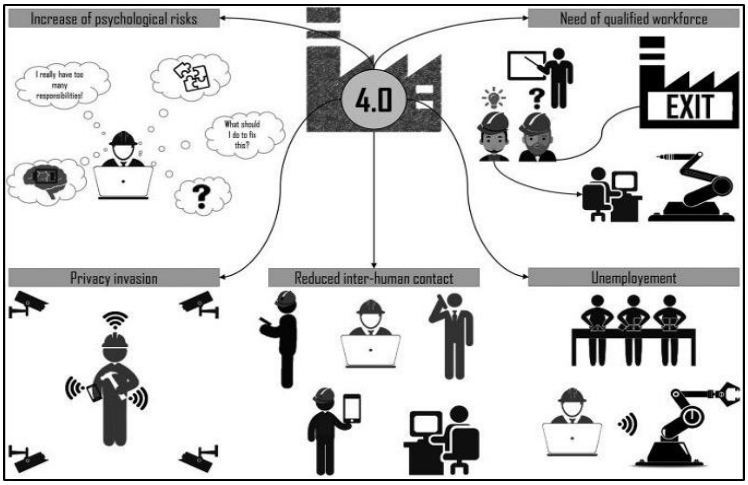

Fig. 2 Issues and Concerns of Industry 4.0 in Workplaces.

Industry 4.0 and the Pharmaceutical Manufacturing in the Philippines

In 2019, a report by Klynveld Peat Marwick Goerdeler (KPMG) stated that the Philippines is the 11th most attractive pharmaceutical market in the Asia-Pacific region and the third-largest pharmaceutical market in ASEAN, after Indonesia and Thailand. The country's pharmaceutical industry is projected to grow by 4.5 percent annually over the next five years, reaching P164 billion in 2018 from P146 billion in 2014, representing the value output or production of the industry, including research-based pharmaceutical and generic companies. This shows that Filipino pharmaceuticals is one of the fastest-growing industries in the country and has grown year to year [9].

The pharmaceutical manufacturing industry benefits significantly from the integration of Industry 4.0 applications for several reasons. However, it also introduces occupational health challenges [10]-[11].

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Potential Occupational Health Risks in Industry 4.0

The following potential occupational health risks were derived from the study of Leso et al. (2017). These risks will be the basis of the study to identify the New and Emerging Occupational Health Risks in the implementation of Industry 4.0 technologies. The study stated that these will be the potential issues to arise once Industry 4.0 is to be applied.

According to the International Labour Organization (ILO, 2011), occupational health risks stem from occupational health hazards [12]. Ergonomic Hazards, Physical Hazards, Chemical Hazards, and Psychosocial Hazards are common occupational health hazards [13]. Thus, this study put to the test whether these hazards could contribute to the increasing risk of New Occupational Risks in the Integration of Industry 4.0.

Additional factors such as demographics [14], work experience/ knowledge [15], and job position [16] were included as Occupational Health Hazards.

Psychological Risks

Psychological risks in the application of Industry 4.0 in pharmaceutical manufacturing can indeed be considered occupational health risks. The implementation of advanced technologies, automation, and digitalization in the workplace can introduce various psychological stressors and challenges for workers, affecting their mental well-being.

For example, the rapid pace of technological change and the need to constantly adapt to new systems and processes can lead to technostress, which is the stress caused by the use of technology [17]. Workers may feel overwhelmed, anxious, or even insecure about their abilities to keep up with evolving technological demands, which can negatively impact their mental health.

Furthermore, job insecurity resulting from automation and the fear of being replaced by machines can also contribute to psychological distress among workers [18]. The uncertainty about the future of work and concerns about job stability can lead to feelings of anxiety, depression, and decreased job satisfaction.

Unemployment

According to the World Health Organization (WHO), unemployment can be considered as an occupational health risk. While it may not be traditionally viewed as a workplace hazard, unemployment has been recognized as a significant factor affecting individuals' health and well being, including their mental and physical health. The stress, financial strain, loss of social support, and other negative consequences associated with unemployment can have profound effects on individuals' health.

The adoption of Industry 4.0 technologies such as artificial intelligence, robotics, and automation can lead to job displacement as tasks previously performed by humans are automated. This phenomenon, known as technological unemployment, can contribute to increased stress, anxiety, and depression among workers who fear losing their jobs or struggle to adapt to new roles. Technological advancements have contributed to widening income inequality and job polarization, which can aggravate occupational health risks [19].

Need of Qualified Workers

From the European Agency for Safety and Health at Work (EU-OSHA 2019), in industries transitioning to Industry 4.0, there is often a demand for workers with specialized skills in areas such as data analytics, automation, and digital technology. This demand may lead to increased pressure on existing workers to upskill or adapt to new technologies, potentially resulting in stress and burnout. Additionally, if there is a shortage of qualified workers, it may lead to understaffing or overworking of existing employees, which can increase the risk of workplace accidents and injuries.

While there may not be direct references specifically linking the need for qualified workers in Industry 4.0 in pharmaceutical manufacturing to occupational health risks, studies on workforce development, labor shortages, and occupational stress in high-tech industries could provide relevant insights.

Privacy Invasion

Privacy invasion in the application of Industry 4.0 in pharmaceutical manufacturing can be considered an occupational health risk, particularly concerning workers' mental well-being and stress levels.

The implementation of Industry 4.0 technologies, such as the Internet of Things (IoT) and data analytics, may involve the monitoring and collection of personal data from workers, including their performance metrics, biometric data, and even their physiological responses.

This invasion of privacy can lead to feelings of mistrust, anxiety, and stress among workers, especially if they perceive their privacy rights to be violated or if they fear repercussions based on the data collected about them. Additionally, concerns about the misuse or unauthorized access to personal data can further intensify stress levels and contribute to a negative work environment [20].

Reduced Inter-human Contact

The digitization of work processes and the rise of remote work arrangements can contribute to social isolation, with remote workers experiencing feelings of loneliness and disconnection from their colleagues [21]. Lack of social support and limited opportunities for interpersonal interaction may further exacerbate feelings of isolation, impacting mental health and job satisfaction.

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The Case Company

The case company is a medium-sized wholly-owned Filipino company that manufactures Sterile Powder for Injection. Its manufacturing facility is designed for Aseptic Processes to ensure sterility of its products. The company is always committed to strictly complying with cGMP and FDA Guidelines to maintain its operations.

The company has been serving people with high-quality pharmaceutical products. As processes evolve and Industry 4.0 concepts are applied, regulations and standards also change. Moreover, because of the company's commitment to complying with changing standards and regulations, the company makes an effort to improve its facilities and processes, especially since the activity designed for its facility is a critical manufacturing activity for pharmaceutical manufacturing.

With the growing demand for drugs and strict compliance with standards, the company has taken a step to move forward and keep up with other companies in the growing revolution of advanced manufacturing where concepts of Industry 4.0 are applied.

The manufacturing and warehouse building processes will apply Automated Controls, Digitization, Internet of Things, and Real-Time Monitoring. The reasons for the company's shift to advanced manufacturing are compliance with standards and regulations, boosting its stand as the leading local pharmaceutical manufacturing company in the Philippines, and improving its efficiency in producing high-quality pharmaceutical products. The company's ongoing project and shift made it a suitable case company for the study. Additionally, the following characteristics are the basis for selecting the case company:

The Facility is designed for Aseptic Processes

Because of the criticality of its processes, embracing Industry 4.0 is essential to improve efficiency, quality, agility, and sustainability while remaining compliant with regulatory requirements and driving innovation in the dynamic healthcare landscape. This checks the criteria that the case company is expected to follow on the transition to Industry 4.0.

Currently Operates in a Semi-Automated System.

The company is currently implementing a semi-automated filling operation of sterile antibiotics in which human intervention in the process is applied, especially in transferring sterilized packaging materials. A process flow of the current operation is shown in Fig. 3. The involvement of workers in the production will ensure that the data gathered is based on their opinions and first-hand experiences in the production.

Ongoing Transition to Fully-Automated System

With the rapid advancement of technology, regulatory bodies also change their standards to adapt to the trend. Furthermore, regulatory compliance is crucial in the pharmaceutical industry, where strict guidelines ensure the safety and efficacy of medications. Companies must adhere to these regulations while implementing advanced automation.

With the changing technology and regulations, the case company has an ongoing plant expansion and plans to incorporate new technologies into its operations. The company is expanding where the operations will be fully automated and human intervention is only at the beginning of the process. Fig. 4 shows the expected process flow diagram of the fully automated Powder Filling Operation.

This checks the criteria that the company needs to have a risk assessment before implementing the new processes that are integrated with new technologies.

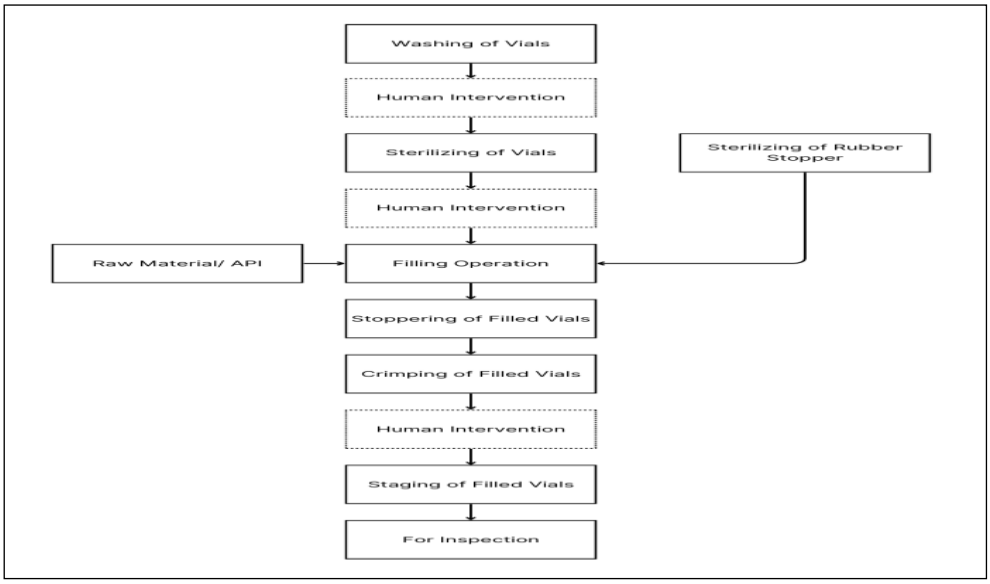

Fig. 3 Semi-Automated Sterile Filling Operation

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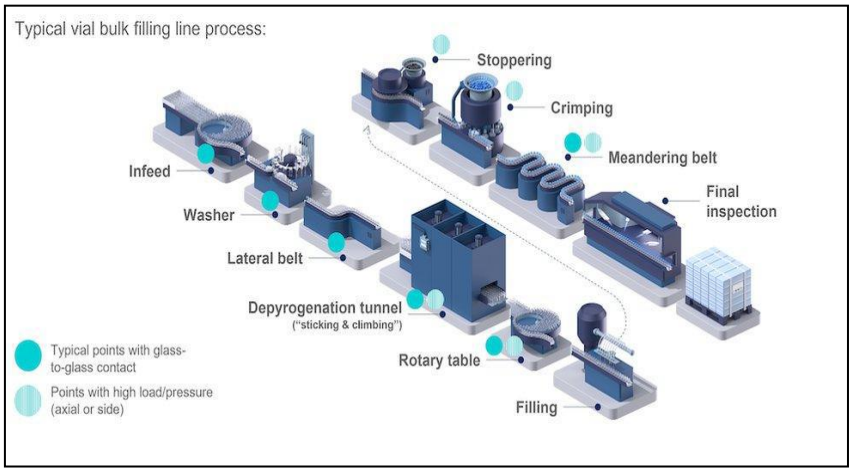

Fig. 4 Expected Flow Process Diagram

Personnel across the manufacturing system are potential sources of contamination. Lack of appropriate training with aseptic practices, unauthorized access into controlled areas, and personal cleanliness are a few of the areas in which personnel can compromise sterile production. Thus, the Quality Risk Assessment is the usual risk assessment done in the Pharmaceutical Manufacturing Industry. Likewise, this research wants to assess the Safety and Health of the employees during production, especially in the advanced automated processes that are now rampant in any Manufacturing Industry.

Tichner Tool

In the research study conducted by Brocal et al. (2018), they developed a technique aimed at identifying and characterizing new and emerging risks that are generated in the automated manufacturing process besides the traditional occupational risks. It is based on the theoretical framework proposed by Brocal et al. (2017), with special consideration given to their definitions and risk models. TICHNER can be considered part of the risk assessment process described by standard ISO/IEC 31010:2009. This process consists of the stages of identification, analysis, and evaluation of the risk. How this process is applied depends on the context of the risk management process and on the methods and techniques used to conduct the risk assessment. The application context of TICHNER will be configured by a manufacturing process. TICHNER can be applied at any stage of the lifecycle of a manufacturing process. It may also be used in conjunction with other risk identification techniques [22]-[28].

In the analysis conducted by Fernandez et al. (2015), risk can be considered NER if the conditions developed are satisfied by that identified risk [29]. The following are the conditions developed:

The risk is “NEW” if:

C1:	The risk did not previously exist and is caused by new processes, new technologies, new types of workplaces, or social or organizational change.
C2:	A long-standing issue is newly considered as a risk due to a change in social or public perceptions.
C3:	New scientific knowledge allows a long-standing issue to be identified as a risk.

The risk is “INCREASING” if

C4:	The number of hazards leading to the risk is growing.
C5:	The exposure to the hazard leading to the risk is increasing (exposure level and/or the number of people exposed.
C6:	The effect of the hazard on workers' health is getting worse (seriousness of health effects and/or the number of people affected).

Because NER is defined as "any occupational risk that is both new and increasing," it follows that for a given configuration, NER must be satisfied at least one of the conditions that determine a new risk (coded C1 to C3) and another at least of the conditions relating to when a risk is increasing (coded C4 to C6). References [27] and [29] concluded that Industry 4.0 brings numerous advantages. However, this paradigm also carries emerging risks and challenges related to organizational and human performance. These emerging risks include both industrial risks and occupational risks. Arguably, the human factor is the main link between industrial emerging risks and occupational emerging risks in the Industry 4.0 context. They also recommended a need for case applications to articulate clearly the potential of approaches developed by the authors.

HIRAC Tool

Hazard Identification, Risk Assessment, and Controls (HIRAC) is a structured process for identifying hazards and specifying actions to mitigate these hazards for a work activity or task with controls. The risk assessment process provides a method for assessing the

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likelihood of health, safety, and environmental impacts of potential operating risk events. It enables a common approach to the prioritization and management of risk [22], [30]-[33].

The qualitative risk assessment is the most widely used technique and is mostly a group effort involving experts with various competencies and experience in factors. Sometimes, companies or individuals have to reply to the information that qualitative may not give, so it is better to go with an alternate method. While a quantitative technique is largely used in the engineering and fabrication phases [34]-[36].

The following tables and figures were based on the. Guidelines for hazard identification, risk assessment and risk control (HIRARC) of the Department of Occupational Safety and Health Malaysia, 2008. The following tables and figures are also widely used in the Risk Assessment of Occupational Safety and Health in the Philippines.

Table 1 Likelihood Table

Likelihood	Example	Rating
Possible	The most likely result of the hazard/event being realized	5
Most Likely	Has a good chance of occurring and is not unusual	4
Conceivable	Might occur at some time in future	3
Remote	Has not been known to occur after many years	2
Inconceivable	Is practically impossible and has never occurred	1

Table 2 Severity Table

Severity	Example	Rating
Catastrophic	Numerous fatalities, irrecoverable property damage and productivity	5
Fatal	Approximately one single fatality major property damage if the hazard is realized	4
Serious	Non-fatal injury, permanent disability	3
Minor	Disabling but not permanent injury	2
Negligible	Minor abrasions, bruises, cuts, first aid type injury	1

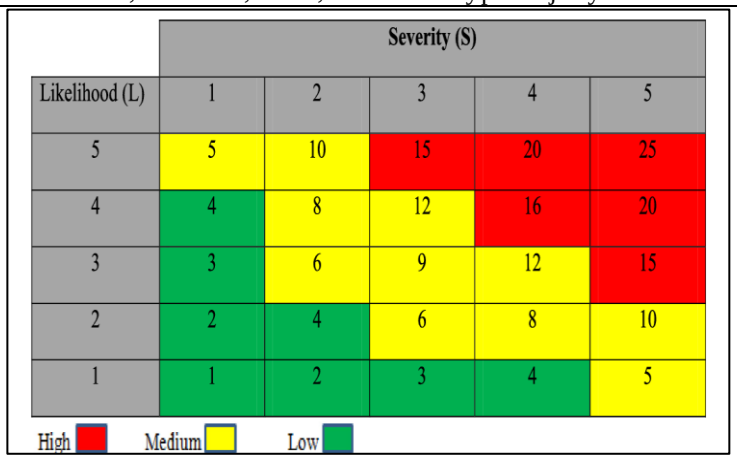

Fig. 5 Risk Rating Matrix

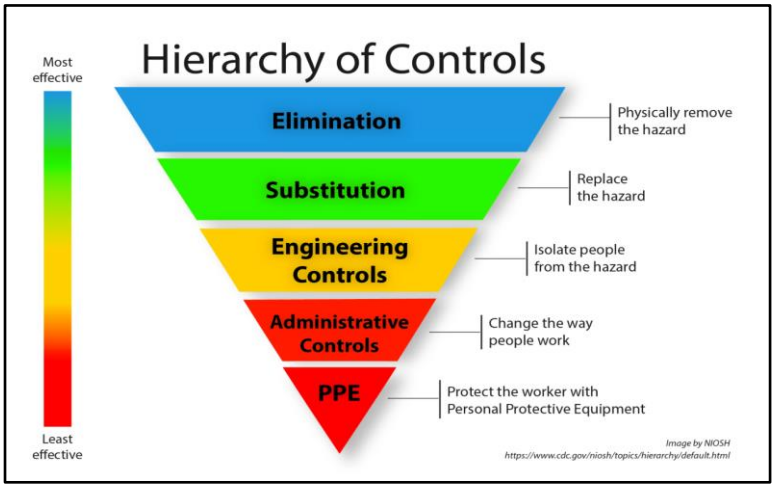

Fig. 6 Hierarchy of Controls

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Theoretical framework

References [7] and [8] concluded that Automated Production Operation in Industry 4.0 would result to an Improved Workplace Safety where occupational safety risks are minimized. However, the application of this process also results in New Occupational Health Risks – Psychological Risk, Unemployment, Invasion of Privacy, Need for Qualified Workers, and Reduced Inter-human Contact. From references [13]-[16], some factors have the potential to affect the increasing risks, and these risks will eventually become New and Emerging Occupational Health Risks.

These risks need to be systemically identified and characterized to have a proper assessment and control of the risks.

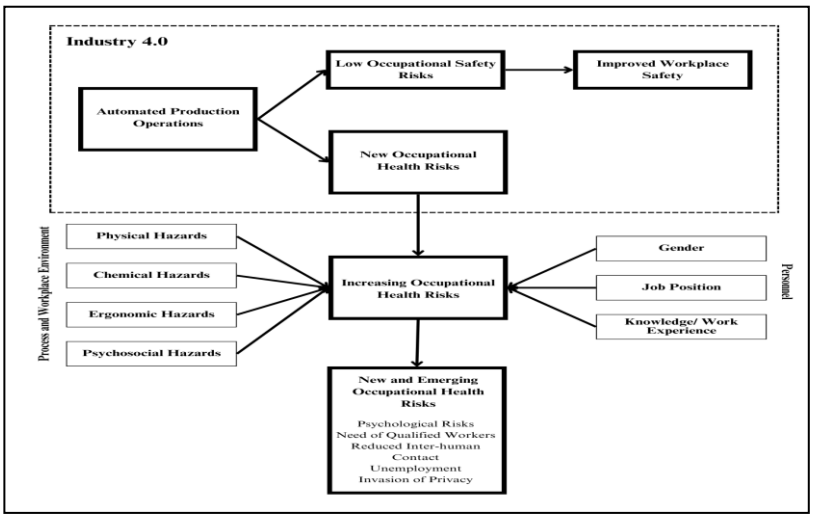

Fig. 7 Theoretical Framework

Conceptual framework

This study's conceptual framework is to systematically identify and characterize the New and Emerging Occupational Health Risks in the application of Industry 4.0 concepts in the pharmaceutical manufacturing processes using the TICHNER Tool formulated by Brocal et al. (2018) and to assess and control these risks using the HIRAC Tool. In the application of the recommended control, controlled hazards and a safe and healthy workplace will be hypothetically attained.

In the identification and characterization phase using the TICHNER Tool, Traditional Risks, New Risks, Increasing Risks, and New and Emerging Risks will be recognized. However, this study will only characterize the potential occupational health risks from the study of Leso et al. (2018). All of which will be considered New Risks. Following the result of the data analysis using the Statistical Tools, these new risk can be characterized as both new and increasing risks.

New and Emerging Risks will be assessed in this study as stated in the scope and limitations. Recommended controls for the mitigation of these NERs will follow the Hierarchy of Control.

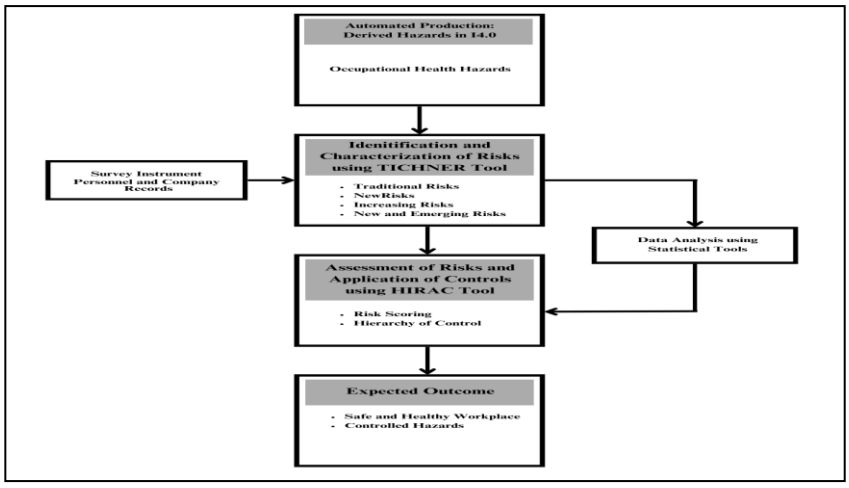

Fig. 8 Conceptual Framework

III. Methodology

A. Research Design

The data gathering will utilize a survey instrument to determine the increasing risks and the factors that contribute to these risks. Scoring of the weighted average will be used to identify the sources of the risks. On the other hand, the Chi-Square Test for

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Independence will be used to identify the significant relationships between the sources and demographics of the New and Emerging Occupational Health Risks. This research will make use of the qualitative approach for the identification and characterization of risks and the quantitative method for the assessment of risks. Two (2) tools will be used for Risk Identification and Characterization, and Risk Assessment and Control. The first tool is the Technique to Identify and Characterize New and Emerging Risks (TICHNER) Tool. This will systematically identify and characterize the risks associated with an automated production process. After NERs have been identified, the second tool which is the Hazard Identification, Risk Assessment, and Control (HIRAC) Tool, will be used to assess them. Recommendations for risk control will be made after the risk assessment. Risk scoring will be applied to correlate and summarize the overall risks identified in the survey. The order of the suggested safety controls and practices will follow the Hierarchy of Controls.

Published Reports and Studies

Published reports and studies on potential Occupational Health Risks brought by Industry 4.0 will be reviewed and will be the basis for the preparation of the survey questionnaires.

Survey

Google Forms will be used as the survey hosting platform due to its ability to remain anonymous, highly customizable layout, and proven data collection reliability. If needed, survey questionnaires will be distributed within the organization. This survey will be used to gather the data needed for the study. The survey will contain questions intended to be answered by the respondents. The answers of the respondents will be the basis for the assessment, analysis, and discussion of results. The survey will be divided into four (4) Sections. The first section will focus on demographics, the second section will focus on dichotomous questions, and the third section is a 5-point Likert-type Rating Scale. These will be used to identify and assess the hazards and risks from the perspective of the respondents. The fourth section will be an open-ended question requiring their insight on issues related to the study.

Statistical Analysis

To help with the quantitative analysis of the data gathered from the survey, Statistical Package for the Social Sciences (SPSS) will be used to organize and analyze the data. Scoring will be used to identify whether potential factors are sources of New and Emerging Occupational Health Risks. A passing score of seventy percent (70%) will be assigned. The Chi-Square Test of Independence determines whether there is an association between categorical variables. It will be used in this study to test whether the potential sources and demographics are related or independent of New and Emerging Occupational Health Risks. Cramer's V will be used to measure how strongly the sources and demographics are associated with New and Emerging Occupational Health Risks.

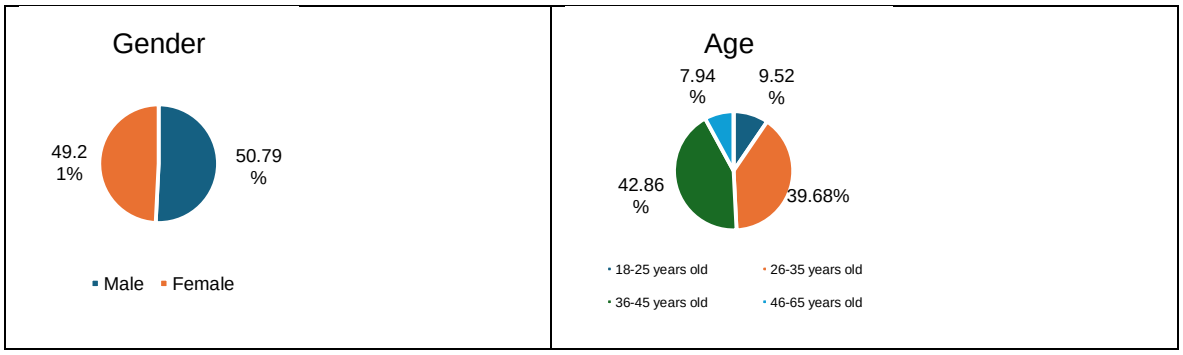
Data Collection

The data collection process involves deploying a survey instrument outlined to assess and address occupational health risks stemming from the integration of Industry 4.0 technologies within production operations in the pharmaceutical manufacturing sector. This survey is designed to gather insights from operators and production personnel directly engaged in the manufacturing processes. It encompasses a spectrum of questions created to explore the specific occupational health hazards introduced by Industry 4.0, focusing on factors such as work experience and knowledge, Ergonomic, Psychosocial, Physical, and Chemical.

The survey instrument aims to extract firsthand experiences and perceptions related to the physical, mental, and ergonomic health risks attributed to the adoption of these technologies. Furthermore, it aims to identify challenges posed by rapid technological changes, employee adaptability, and the overall impact on occupational well-being within the production sphere. By taking employee perspectives and concerns, this survey strives to provide a holistic view of occupational health, enabling targeted interventions and proactive measures to mitigate risks while promoting a safer and healthier work environment within pharmaceutical production operations.

Specifically, the survey will target the participation of a pharmaceutical manufacturing company operating in a semi-automated production of sterile parenteral. Including this pharmaceutical company will ensure an understanding of the challenges and opportunities inherent in integrating advanced technologies within the industry, thereby enriching the survey's findings and insights.

Demographic Profile



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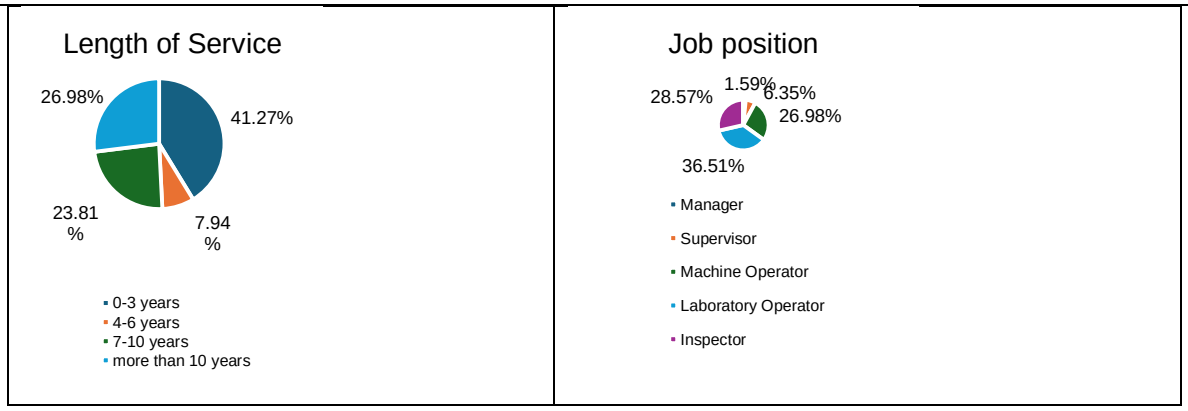

Based on the profile of the respondents, the following are observed:

There is an insignificant difference in the number of male and female workers employed in the production area of the case company. There are thirty-two (32) male and thirty-one (31) female workers employed.

Ages between 26-35 years old and 36-45 years old are the dominant age group of the respondents. 25 respondents were from the age group of 26-35 years old while 27 respondents were from the 36-45 years old age group. From the 2020 statistics conducted by the Philippine Statistics Authority (PSA), the 25-34-year-old age group made up the biggest share of the employed at 27.3 percent, followed by the 35-44-year-old group at 23.4 percent. The employment rate was also higher among men compared to women.

The highest number of respondents were employees working 0-3 years in the company. However, the combination of respondents working in the company for 4 years and beyond had a total of 37. This shows that the respondents' profiles have sufficient experience in production operations, thus making their answers and opinions dependable.

The highest number of respondents were the laboratory operators followed by the machine operators and inspectors. These job positions are highly immersed and involved in production operations. This shows that respondents have first-hand experience with the risks during the operations and will have a greater impact in the application of Industry 4.0 in the processes

IV. Data Analysis and Procedure

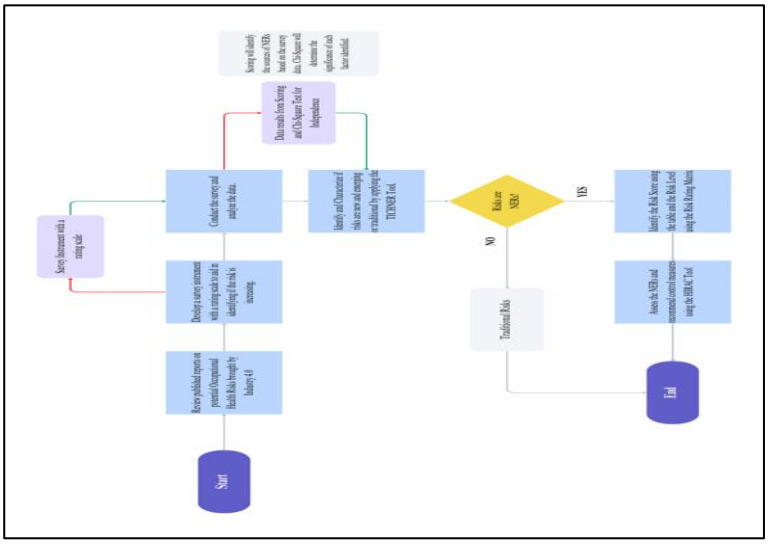

Fig. 9 Proposed Mixed-method Approach

V. Findings and Results

A. Test for reliability

Reliability is a basis of comprehensive research methodology, ensuring that the measurements and instruments used consistently yield accurate and consistent results. In research, reliability refers to the extent to which a particular measure or instrument produces

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stable and consistent results over time, across different conditions, and among different observers or raters. A reliable test or measure instils confidence in the validity and credibility of research findings, enabling researchers to draw meaningful conclusions and make informed decisions based on their data. The purpose of testing the reliability of data is to ensure that the information used for research, analysis, or decision-making is dependable, consistent, and free from significant errors or biases.

In this study, the researcher tested the reliability of the data gathered before proceeding to the analysis. Cronbach's alpha was used to test the reliability of the data gathered. The measurement of Cronbach's alpha is used to evaluate internal consistency, which is the degree of how closely related a group of items are as a whole.

Cronbach's Alpha	Reliability Level
More than 0.90	Excellent
0.80-0.89	Good
0.70-0.79	Acceptable
0.6-0.69	Questionable
0.5-0.59	Poor
Less than 0.59	Unacceptable

The data was run on SPSS to test the reliability. The Cronbach's alpha determined was 0.825 for the 63 valid cases. This means that the level of reliability of the instrument is good and reliable.

B. Potential Sources

The potential sources or Occupational Health Hazards gathered from the review of the literature were Work Experience/ Knowledge, Ergonomic Hazards, Psychosocial Hazards, Physical Hazards, and Chemical Hazards. These sources were put under investigation to know whether these potential sources will exist or not in the current and future production setup. The questions were categorized in each potential source and were given correct answers. Respondents must have a 70% score for each potential source to conclude that it is a hazard. Table 3 shows the result of whether a hazard is a source or not a source.

Table 3 Summary of Potential Sources

Potential Sources	Source		Not a Source		Total	
	f	%	f	%	f	%
Work Experience/ Knowledge	44	69.84	19	30.16	63	100.00
Ergonomic Hazards	42	66.67	21	33.33	63	100.00
Psychosocial Hazards	46	73.02	17	26.98	63	100.00
Physical Hazards	36	57.14	27	42.86	63	100.00
Chemical Hazards	13	20.63	50	79.37	63	100.00

C. Significant factors

The Chi-Square Test for Independence was used to test whether the potential sources and demographics are significantly related to Occupational Health Risks. The decision rule for the evaluation is "there is no significant relationship if the p-value is less than or equal to alpha (0.05)". Cramer's V was used to identify the strength of the relationships. Table 4 shows the summary of the significant factors that resulted from the test.

Table 4 Summary of Significant Factors

Variables Tested		Chi Square p-value	Interpretation	Cramer's V	Interpretation
Psych	Work Experience/ Knowledge	0.025	Significant relationship	0.421	very strong relationship
	Psychosocial Hazards	0.003	Significant relationship	0.500	very strong relationship
U	Work Experience/ Knowledge	0.047	Significant relationship	0.338	very strong relationship
Need for	Work Experience/ Knowledge	0.004	Significant relationship	0.464	very strong relationship
	Psychosocial Hazards	0.013	Significant relationship	0.414	very strong relationship

D. Risk Assessment

The TICHNER Tool was used to characterize and present the new and emerging occupational health risk. Characterization of NERs involves a qualitative method that assesses indicators that contribute to the increasing risks. The factors discussed below are the components of Industry 4.0. Work Experience/ Knowledge and Psychological Hazards were only considered in the characterization of NERs because they are the only factors that have significant relationships with the identified risks. The following tables show the summary of the results of the components that help characterize these new and emerging risks. Characterization of the NER is directly linked to the source of risk. This restriction may limit the analysis of other risk components.

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Industry 4.0

There is proof that the case company will undergo the transition to Industry 4.0, so Industry 4.0 as a source of risk is new.

		Result
Indicator	:	Application of Industry 4.0 Concepts in the manufacturing.
Ordered Pair	:	(SR, C1)
Risk Type	:	New Risk

Automated Control

Fully Automated Control is one of the components of Industry 4.0. This will be assessed because the case company will apply and integrate new automated manufacturing controls.

		Result
Indicator	:	Application of Fully Automated Processes in the Production of Sterile Powder for Injections
Ordered Pair	:	(SR, C1)
Risk Type	:	New Risk

Psychological risks

Previous studies found that introducing industrial robots causes workers' perceived job insecurity, which can lead to increased mortality and physical or psychological distress [37].

According to Statista, the Philippines is experiencing a surge in the adoption of robotics, particularly in industrial manufacturing. Over the past years, the industrial robotics market has expanded annually, averaging 10%. According to a market study conducted by 6Wresearch, this is due to the adoption of Industry 4.0 principles, rising labor costs, and the need for more precision in manufacturing.

		Result
Indicator	:	Increase in the introduction of Industrial Robots
Ordered Pair	:	(SR, C4)
Risk Type	:	Increasing Risk

Unemployment

Smart factories are becoming current issues where machine robots perform almost impeccable manufacturing, and the human factor is minimized in production. Due to the increase in the number of smart factories in the forthcoming period, it is thought that unskilled laborers will be unemployed.

Medium-sized companies are more likely to adopt Smart Manufacturing technologies [38]. According to the International Trade Administration report, advanced manufacturing in the Philippines continues to evolve along an upward trajectory, driven by government support, a skilled workforce, and strategic advantages. While challenges exist, ongoing investments in infrastructure and a commitment to Industry 4.0 position the Philippines as a promising destination for advanced manufacturing.

		Result
Indicator	:	Growing investments and effort for Smart Manufacturing in the Philippines
Ordered Pair	:	(SR, C4)
Risk Type	:	Increasing Risk

Need for Qualified Workers

Workers' perceived job insecurity increases as they become more anxious about the speed of technological development and automation. Job insecurity is well-known as the cause of workers' poor mental health [39]. The literature also establishes an association between workers' concern over their jobs being replaced by smart machines and job dissatisfaction.

Workers with lower levels of education and who perform routine tasks face the most significant risks of their jobs being automated. Previous studies estimate that anywhere from 9% to 47% of jobs could be automated.

		Result
Indicator	:	Decrease of employment of unskilled workers
Ordered Pair	:	(CO, C6)
Risk Type	:	Increasing Risk

Invasion of Privacy and Reduced Inter-human Contact

		Result
Indicator	:	Application of Industry 4.0 technologies
Ordered Pair	:	(SR, C1)
Risk Type	:	New Risk

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Based on the survey data, Invasion of Privacy and Reduced Inter-human Contact are new to the respondents. However, no significant factors were identified during the analysis. Given this study's limitations, the sources will be assessed to determine whether they contribute to the increasing risk. Since no significant factors were identified, Invasion of Privacy and Reduced Inter-human Contact will be considered New Risks only.

Table 9 Summary of Tichner Results

Source of Risk	Indicators	Ordered Pair	Risk Type
Industry 4.0	Application of Industry 4.0 Concepts in the manufacturing.	(SR, C1)	New Risk
Automated Control (Fully)	Application of Fully Automated Processes in the Production of Sterile Powder for Injections	(SR, C1)	New Risk
Psychological Risk	Increase in the introduction of Industrial Robots	(SR, C1), (SR, C4)	New and Emerging Risk
Unemployment	Growing investments and effort for Smart Manufacturing in the Philippines	(SR, C1), (SR, C4)	New and Emerging Risk
Need for Qualified Workers	Decrease of employment of unskilled workers	(SR, C1), (CO, C6)	New and Emerging Risk
Invasion of Privacy	Application of Industry 4.0 technologies	(SR, C1)	New Risk
Reduced Inter-human Contact	Application of Industry 4.0 technologies	(SR, C1)	New Risk

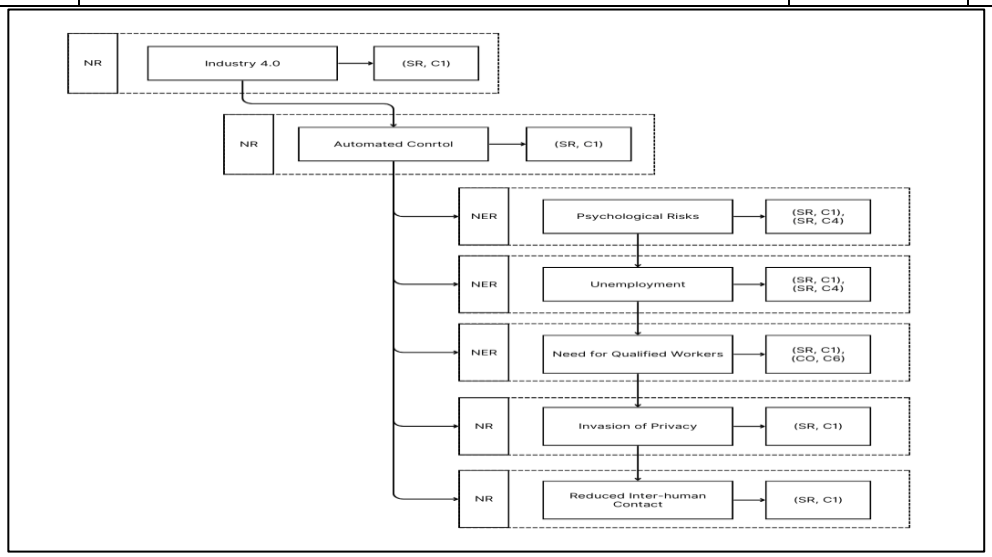

Fig. 9 TICHNER

E. HIRAC Tool

The primary aim of HIRAC is to identify potential risks, evaluate their severity and likelihood, and implement appropriate measures to minimize or eliminate these risks. The initial step in HIRAC involves identifying hazards. However, in this study, TICHNER was employed first for the identification and characterization of risk. HIRAC is then employed to thoroughly analyze the risk through hazard identification. Following hazard identification, the Risk Assessment stage follows. During this step, the severity and likelihood of each identified hazard are assessed to determine the level of risk it presents. Risks are categorized as high, medium, or low, allowing organizations to prioritize and address the most critical issues first.

Table 5 Hirac Table

Hazard	Risk	L	S	RR	Control
Unfamiliarity of Industry 4.0 concepts	Mental Fatigue	5	4	20	Proper and comprehensive aining on the application of Industry 4.0 concepts before implementation of new processes Establish a Refresher Training frequently
Too much information to understand and cope on new processes	Mental Fatigue	5	4	20	Establish a Training Program and Schedule on the application of Industry 4.0 concepts
Changes in job roles and responsibilities	High stress and anxiety	5	4	20	Cross-training on employees to be familiarize with different and new

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	levels of new roles and responsibilities				processes while integrating a fully automated system.
	Higher rate of unemployment of unskilled workers	5	4	20	Offer up skilling training for regular employees especially for machine operators and inspectors that are closely involved in the production. Cross-training on employees to be familiarize with different and new processes while integrating a fully automated system
No adequate training regarding the potential health risk associated with industry 4.	High stress and anxiety levels	5	4	20	Offer up skilling training for regular employees especially for machine operators and inspectors that are closely involved in the production. Cross-training on employees to be familiarize with different and new processes while integrating a fully automated system.
Job displacement due to integration of Industry 4.0	High stress and anxiety levels	5	3	15	Cross-training on employees to be familiarize with different and new processes while integrating a fully automated system.
	Higher rate of unemployment of unskilled worker	5	4	20	Establish a Training Program and Schedule on the application of Industry 4.0 concepts
In demand of new skill needed for Industry 4.0	Lower employment rates of unskilled workers	5	4	20	Establish a Training Program and Schedule on the application of Industry 4.0 concepts

The severity and likelihood of the Risks were based on answers of the respondents from the survey. To determine the Risk Rating, the likelihood for each was assigned a rating of 5, possible, assuming that the new and emerging risks will be the result of the potential hazards. This ensures that the recommended controls are just yet for application. Rating the severity is from the weighted mean computed from the survey.

From the Hierarchy of Controls, Elimination and Substitution controls concentrate on the primary source of the hazard and find ways to eliminate it or apply less hazardous processes to minimize the risk. Hence, in this study, both controls cannot be applied because the main source of the risk in this study would be the application of Industry 4.0 concepts to manufacturing processes. Next in the hierarchy would be the Engineering Controls. This control is more focused on controlling the process to minimize the risk, thus, Engineering Controls were not recommended in this study because the study aims to focus on the health and wellness of the employees when Industry 4.0 concepts are applied. Lastly, the application of Personal Protective Equipment (PPE) was not recommended because one result of the application of Industry 4.0 is the elimination of humans in the process.

From the controls recommended by the researcher, administrative controls are highly suggested. The involvement of the Management, Human Resource, and Occupational Safety and Health Committee is highly needed to lower the risks of new and emerging occupational health risks identified in the study. Comprehensive training and retraining practices for the machine operators, laboratory operators, and inspectors are very much recommended to control the Psychological Risk, Risk of Unemployment, and Risk of Need for Qualified Workers.

Since elimination and substitution were not applicable controls for the New and Emerging Occupational Health Risks in the integration of Industry 4.0, mitigation of these risks will not be immediate. Risks should be reassessed and controls should be monitored to ensure that they are effective. In this study, the researcher has provided initial steps on the mitigation of these New and Emerging Occupational Health Risks.

VI. Conclusion

In conclusion, this study presents a set of potential sources of new and emerging risks in the integration of industry 4.0 concepts in a medium-sized pharmaceutical manufacturing company. The potential sources of new and emerging risks are Physical hazards, Psychosocial hazards, Ergonomic Hazards, and Insufficient Work experience/ Lack of Knowledge. This study shows that the common and significant factors contributing to the increasing risk are Insufficient Work Experience/ Lack of Knowledge and

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Psychosocial hazards. The identification, characterization, and analysis of these new and emerging risks were performed through the use of the TICHNER and HIRAC Tools. The combination of these tools is very efficient in identifying, characterizing, and analyzing comprehensively the potential risks in the application of Industry 4.0 concepts, especially in the fully automated manufacturing process.

The New and Emerging Occupational Health Risks identified and characterized by the researcher involve mostly psychological aspects. With this, controls recommended by the researcher are administrative controls, which mean, management, human resources, and the OSH Committee must change how people work. Therefore, they should plan and focus on the training and retraining of machine operators, laboratory operators, and analysts.

Nzioka and Njuguna (2017) provided empirical evidence supporting the notion that effective training programs can positively influence employees' attitudes toward their jobs and enhance their overall satisfaction and willingness to work. The study also highlighted the importance of continuous learning opportunities and professional development as key factors in maintaining a motivated and satisfied workforce [40]. Thus, the application of the recommended administrative controls would lessen workers' job anxiety and improve their willingness to work because management made an effort not to substitute them with robots.

Another study conducted by Wilson et al. (2017) provides a comprehensive overview of how training and reskilling initiatives can help mitigate employee anxiety about automation and ensure a more secure and motivated workforce. The study finds that workers are increasingly anxious about the potential of automation to replace their jobs [41]. To address this anxiety, the authors recommend comprehensive training and reskilling programs that equip employees with new skills relevant to the evolving technological landscape. By investing in continuous learning and development, companies can help their employees transition to new roles and reduce fears about job displacement.

This study shows that the need for a risk assessment when applying new processes is very relevant to planning appropriate controls for the forthcoming changes in the manufacturing processes.

The results of this study confirm the results of the literature review conducted by Leso et al. (2018), which found that Psychological risks will become more evident than physical ones in the workplace due to mental overload and work density induced by even more flexible and dynamic smart manufacturing activities. Furthermore, the study validated that the negative impacts of Industry 4.0 on the pharmaceutical manufacturing industry gathered from different studies can be a potential source of NERs and significant factors in increasing the risks.

Recommendation

The study encountered difficulties in gathering data using an online survey. Thus, the study only limited the potential new and emerging risks and their potential sources. The researcher recommends interviewing the respondents to uncover other new potential risks.

The researcher also used a literature review to identify, characterize, and analyze new and emerging risks to confirm their existence. The researcher recommends using company records and documents as indicators in characterizing new and emerging risks and rating their severity and likelihood.

Administrative Control is the most appropriate control found by the researcher to control the risk. Hence, mitigation of the risk will not be immediate. The researcher recommends having a determined frequency of risk assessment to monitor if the recommended controls are effective. The researcher also recommends exploring controls that are process-driven to minimize occupational health risks

The researcher also recommends the use of the proposed mixed-method approach in different industries integrating Industry 4.0 to identify, characterize, and analyze not only the Occupational Health Risks but also the Occupational Safety Risks.

References

1. Kumar, S. H., Talasila, D., Gowrav, M. P., & Gangadharappa, H. V. (2020). Adaptations of Pharma 4.0 from Industry 4.0. Drug Invention Today, 14(3).
2. Reinhardt, I. C., Oliveira, J. C., & Ring, D. T. (2020). Current perspectives on the development of industry 4.0 in the pharmaceutical sector. Journal of Industrial Information Integration, 18, 100131.
3. Popkova, E. G., Ragulina, Y. V., & Bogoviz, A. V. (2019). Fundamental differences of transition to industry 4.0 from previous industrial revolutions. In Industry 4.0: Industrial Revolution of the 21st Century (pp. 21-29). Springer, Cham.
4. Thomas, P., & Nicholas, D. (2018). The Fourth Industrial Revolution: Shaping New Era. Journal of International Affairs, 72(1), 17-22.
5. Min, J., Kim, Y., Lee, S., Jang, T. W., Kim, I., & Song, J. (2019). The fourth industrial revolution and its impact on occupational health and safety, worker's compensation and labor conditions. Safety and health at work, 10(4), 400-408.
6. Arden, N. S., Fisher, A. C., Tyner, K., Lawrence, X. Y., Lee, S. L., & Kopcha, M. (2021). Industry 4.0 for pharmaceutical manufacturing: Preparing for the smart factories of the future. International Journal of Pharmaceutics, 602, 120554.
7. Zorzenon, R., Lizarelli, F. L., & Daniel, B. D. A. (2022). What is the potential impact of industry 4.0 on health and safety at work? Safety Science, 153, 105802.
8. Leso, V., Fontana, L., & Iavicoli, I. (2018). The occupational health and safety dimension of Industry 4.0. La Medicina del lavoro, 109(5), 327.
9. https://kpmg.com/ph/en/home/insights/2019/02/philippines-pharma-all-set-for-continuous-growth.html (Accessed: Decem b er 20, 2023 12:17 am)

ISSN 2278-2540 | DOI: 10.51583/IJLTEMAS | Volume XIII, Issue VI, June 2024

10. Magnavita, N., & Chirico, F. (2020). New and emerging risk factors in occupational health. Applied Sciences, 10(24), 8906.
11. Arana-Landín, G., Laskurain-Iturbe, I., Iturrate, M., & Landeta-Manzano, B. (2023). Assessing the influence of industry 4.0 technologies on occupational health and safety. Heliyon, 9(3).
12. International Labour Organization (ILO). (2011). Safety and health at work: A vision for sustainable prevention. Geneva: ILO.
13. Benson, C., Dimopoulos, C., Argyropoulos, C. D., Mikellidou, C. V., & Boustras, G. (2021). Assessing the common occupational health hazards and their health risks among oil and gas workers. Safety science, 140, 105284.
14. Marmot, M., & Wilkinson, R. (Eds.). (2005). Social Determinants of Health. Oxford University Press.
15. Griffin, M. A., & Neal, A. (2000). "Perceptions of Safety at Work: A Framework for Linking Safety Climate to Safety Performance, Knowledge, and Motivation." Journal of Occupational Health Psychology, 5(3), 347-358.
16. National Institute for Occupational Safety and Health (NIOSH). (1999). "Stress at Work." NIOSH Publication No. 99-101.
17. Tarafdar, M., et al. (2015). Examining the impact of technostress on productivity: A longitudinal study. IEEE Transactions on Engineering Management, 62(3), 366-376.
18. Ferrie, J. E., et al. (2016). Job insecurity and health: A meta-analytical review of prospective studies. BMJ Open, 6(2), e010085.
19. Brynjolfsson, E., & McAfee, A. (2014). The second machine age: Work, progress, and prosperity in a time of brilliant technologies. WW Norton & Company.
20. Eurofound. (2020). Working conditions in the European Union: Manufacturing. Luxembourg: Publications Office of the European Union.
21. Golden, T. D., & Eddleston, K. A. (2020). Is there a price telecommuters pay? Examining the relationship between telecommuting and objective career success. Journal of vocational behavior, 116, 103348.
22. Flaspöler, E., Reinert, D., Brun E., 2005. Expert Forecast on Emerging Physical Risks Related to Occupational Safety and Health. EU-OSHA (European Agency for Safety and Health at Work), Luxembourg.
23. Brun, E., Beeck, R.O.,Van Herpe, S., Isotalo, L., Laamanen, I., Blotière, O., Mur, J.M., Orthen, B., Wagne, R.E., Flaspöler E., Reinert, D., et al., 2007a. Expert Forecast on Emerging Biological Risks Related to Occupational Safety and Health. EU-OSHA (European Agency for Safety and Health at Work), Luxembourg.
24. Brun, E., Milczarek, M., Roskams, N., Op De Beeck, R., Pahkin, K., Berthet, M., Morvan, E., Kuhn, K., Kaluz, S., Hupke, M. et al., 2007b. Expert Forecast on Emerging Psychosocial Risks Related to Occupational Safety and Health. Office for Official Publications of the European Communities, Luxembourg.
25. Brun, E., Op de Beeck, R., Van Herpe, S., Isotalo, L., Laamanen, I., Blotiere, C., Mur, J.M., Orthen, B.,Wagner, E., Flaspöler, E. et al., 2009. Expert Forecast on Emerging Chemical Risks Related to Occupational Safety and Health. EU-OSHA (European Agency for Safety and Health at Work), Luxembourg.
26. Brocal, F., Sebastia´n, M.A., Gonza´lez, C., 2017. Theoretical framework for the new and emerging occupational risk modeling and its monitoring through technology lifecycle of industrial processes. Safety Science 99, 178e186
27. Brocal, F., Gonza´lez, C., Sebastia´n, M.A., 2018. Technique to identify and characterize new and emerging risks: a new tool for application in manufacturing processes. Submitted to Journal Safety Science, 109, 2018, 144e156
28. Brocal, F., Sebastián, M. A., & González, C. (2019). Advanced manufacturing processes and technologies. In Management of Emerging Public Health Issues and Risks (pp. 31-64). Academic Press.
29. Fernández, F. B., & Pérez, M. Á. S. (2015). Analysis and modeling of new and emerging occupational risks in the context of advanced manufacturing processes. Procedia Engineering, 100, 1150-1159.
30. Faisal, K., Rathnayaka, S., Ahmed, S., 2015. Methods and models in process safety and risk management: past, present and future. Process Saf. Environ. Prot. 98, 116–147.
31. Raafat, H. M. N. (1989). Risk assessment and machinery safety. Journal of Occupational Accidents, 11, 37-50.
32. Suhardi, B., Estianto, A. A. V., & Laksono, P. W. (2016, October). Analysis of potential work accidents using hazard identification, risk assessment and risk control (HIRARC) method. In 2016 2nd International Conference of Industrial, Mechanical, Electrical, and Chemical Engineering (ICIMECE) (pp. 196-200). IEEE.
33. Shaleh, M. K., & Leman, A. M. (2016). Systematic approach for hazard identification, risk assessment and risk control (HIRARC) in workplace according to DOSH guidelines. In International Graduate Conference on Engineering, Science and Humanities.
34. Altenbach, T. J. (1995). A comparison of risk assessment techniques from qualitative to quantitative.
35. Embrey, D. (2004). Qualitative and quantitative evaluation of human error in risk assessment. Human factors for engineers, 2, 151.
36. Coleman, M. E., & Marks, H. M. (1999). Qualitative and quantitative risk assessment. Food Control, 10(4-5), 289-297.
37. Baek, S. U., Yoon, J. H., & Won, J. U. (2022). Association between Workers' Anxiety over Technological Automation and Sleep Disturbance: Results from a Nationally Representative Survey. International journal of environmental research and public health, 19(16), 10051.
38. Barroga, K. D., Wabina, V. E. R., & Sales, A. C. (2021). Level of Awareness of Smart Manufacturing Technologies and its Nexus to Adoption among Micro, Small, and Medium Enterprises in the Philippines. Philippine Journal of Science, 150.
39. Erebak, S., & Turgut, T. (2021). Anxiety about the speed of technological development: Effects on job insecurity, time estimation, and automation level preference. The Journal of High Technology Management Research, 32(2), 100419.
40. Nzioka, J., & Njuguna, R. K. (2017). The impact of training on employee job satisfaction and work motivation in hotels in Kenya. Strategic Journal of Business & Change Management, 4(2), 209-227.
41. Wilson, H. J., Daugherty, P. R., & Morini-Bianzino, N. (2017). "Preparing for the Future of Work: Addressing the Impact of Automation on Workforce Anxiety." Harvard Business Review