ASSESSING COMPETENCY AND SUB-COMPETENCY FOR PHARMACEUTICAL 4.0 – A DELPHI STUDY

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Abstract: This research aims to conduct competency mapping and sub-competencies quantitatively through Delphi method in two rounds to provide comprehensive results. The application of Delphi's approach then refers to several rounds of expert surveys based on existing questionnaires. The first round involved 15 practitioners from the Pharmaceutical Industry. In the first phase, the research explores what competencies are most needed through questionnaires. Furthermore, in phase two, a greater number of participants are obtained through research relations. The second round involves the participation of 71 experts, including practitioners from 19 Pharmaceutical Industries and academics. The results of the study were processed using Exploratory Factor Analysis and produced six factors representing six competencies: learning and innovation skills, research skills, digital skills, bioinformatics, data ethics, and regulatory compliance. In addition, this study produced 44 sub-competencies that representing 6 core competencies. Competencies and sub-competencies achieved can be used as a referral for pharmaceutical practices in the Era of Pharmaceutical 4.0. More research on competencies in the Pharmaceutical Industry is needed to achieve reliable and valid instruments.

Key words: Pharmaceutical 4.0, Competency, Sub-Competencies, Delphi Study

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Introduction

In the Era of Industry 4.0, technology has a significant impact on how people live and work. The pharmaceutical sector is likely to face an "innovator dilemma" when dealing with the Fourth Industrial Revolution (Hemanth Kumar et al., 2020). The pharmaceutical workforce should prepare to adopt technologies, such as the Internet of Things (IoT), Artificial Intelligence (AI), Big Data, Robotic, 3-D printing. It is true to state that in the industry 4.0 era, qualified workforce competence is urgently needed. To survive in Industrial Era 4.0, having sufficient knowledge of technology's changes and speed is essential. Nevertheless, there is no doubt that specific low-skilled jobs will be eliminated (Dirican, 2015). It should be realized that the massive increase in the use of technology aims to facilitate activities and speed up processes in the Industry (Peicheva & Milenkova, 2017). In

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dealing with the Industrial 4.0 era, the development and maintenance of competencies for workers are very important to innovate. New core competencies and technological literacy are indispensable to the key to successful understanding of new concepts of operation and a gradual transition towards smart manufacturing in the Pharmaceutical Industry. Competence is expressed as a skill, knowledge, essential attitude, and value in a person reflected in the ability to think and act consistently (Gregory & Fawkes, 2019; Manley & Valin, 2017).
The purpose of this study is to recognize the core set of competencies and sub-competencies in preparing a qualified workforce. In addition, literature reviews and research seek to highlight the problems of technological development in the Pharmaceutical Industry and competency development. This research seeks to answer the following questions: What competencies are required by the workforce in the face of the Pharmaceutical 4.0 era? What is the possible scope of competency implementation? In particular, the focus of the research was conducted on the workforce in the four core divisions of the Pharmaceutical Industry: Production, Research and Development, Quality Control, and Quality Assurance. To answer the purpose of the research, the researchers previously conducted a literature review on management and competency development in the scope of Pharmaceutical Industry.

Literature rewiev

Competency towards Pharmaceutical 4.0

Pharmaceutical 4.0 is a digital operating model of pharmaceutical organizations synonymous with trends, such as Big Data, interconnectivity, collaborative robotics, artificial intelligence (AI), virtual and augmented reality, 3D printing, blockchain and cloud-based architecture distribution, which conceptualize a highly systematic automated process. In the face of the Pharmaceutical 4.0 era, pharmaceutical workers are encouraged to increase new capabilities and capacities (Flynn, 2019; Sousa Pinto et al., 2021). In adapting to rapid change and increasing needs, pharmaceutical workers' standard competencies need to be developed. There are various definitions of competence in dynamic and flexible terms. The competency model was first introduced by Spencer et al. (1994) and is defined as a basic characteristic of an individual relating to the effectiveness of an individual's performance. Competencies in an organization need to be identified to translate business needs into faster learning and performance (Gangani et al., 2008). In general, competencies are distinguished by technical competency, managerial competency and sociocultural competence (Kannan & Garad, 2020; Le Deist & Winterton, 2005; Sliter, 2015). Competence has an important role in the development of skills, understanding, knowledge and personal characteristics of workers to achieve desirable results (Jerman et al., 2020). Previously, the competence of pharmaceutical workers was only focused on technical competencies, such as pharmaceutical preparation manufacturing capabilities, quality assurance preparations and research capabilities (Andayani & Satibi, 2016; Atkinson et al., 2016). Several studies related to competency development in the Industrial 4.0 era have been conducted (Fitsilis et al., 2018; Flores et al., 2020; Grzybowska & Łupicka, 2017; Rampasso et al., 2020). Competencies found including entrepreneurial thinking, conflict solving, decision-making, problem-solving, analytical skills, research skills, digital skills and orientation efficiency (Hanif, Rakhman, Nurkholis, & Pirzada, 2019). Therefore, the research of Flores et al. (2020) and Grzybowska & Łupicka (2017) is discussed as the basis of conceptualization and design of research projects and presents a new competency theoretical contribution in the Pharmaceutical Industry context.

Research Methodology

Delphi's approach alludes to an efficient iterative overview strategy with input given by a board of experts to appraise future improvements. Sheng (1995) stated that Delphi’s study’s primary purpose was to reach consensus. The application of Delphi’s approach refers to several rounds of expert surveys based on questionnaires. After each round, the results are summarised and fed anonymously to the participants to stimulate reflection and trigger modifications. To meet the purpose of this research, data collection was conducted on experts in the field of the Pharmaceutical Industry. The survey was conducted in Indonesia as a developing country that faces challenges in national independence (Arief & Gustomo, 2020). This study uses a two-round process, as illustrated in Figure 1.

In the first round, the research intends to identify the competencies required by workforces in the Pharmaceutical Industry using a qualitative survey. All participants are experts in Human Resources in the Pharmaceutical Industry, with fifteen people with more than ten years of industry experience (Pirzada, 2016). In the survey process, the authors present data related to the results of the literature review that has been validated before: (1) Entrepreneurial Thinking, (2) Critical Thinking, (3) Analytical Skills, (4) Research Skills, (5) Efficiency Orientation, (6) Intelligent Skills, (7) Digital Literate, (8) Bioinformatics, (9) Intrapreneurial Skills, (10) Resource Management Skills (Fitsilis et al., 2018; Grzybowska & Łupicka, 2017; Kannan & Garad, 2020; Sliter, 2015). Through the survey given, respondents were given two main questions as preliminary data for core competencies: 1) Choose the Core Competency which is suitable for pharmaceutical workforce in the Pharmaceutical 4.0 era, 2) Sort Competencies from the most relevant to the least relevant. In addition, each respondent is also allowed to give an opinion or enter if there are competencies that were not available before.

In the second round, the survey was conducted to verify the competencies and sub-competencies obtained from the first round. Unlike the first round, the second round looks for as many respondents as possible to meet statistical assumptions. The selection of representative experts is critical to the strength and validity of the Delphi method (Clayton, 1997). Participants were recruited using a purposive sampling strategy based on place of work (Pharmaceutical Industry / Government /

Academic), length of work (minimum five years) and position (minimum senior staff). Prospective participants are contacted via social media or email about their agreement to participate in the research. Research conducted in Indonesia; all experts are Indonesians (Nik Abdullah, & Said, 2014). There were 110 people contacted, but only 71 participants were willing to become participants (response rate: 64,54%). Participants represent 22 National Pharmaceutical Industries in Indonesia, the Food and Drug Administration, and two of the best Pharmaceutical Universities in Indonesia.
The survey was created with a three-step approach. Within to begin, surveys are made based on progressed sub-competencies gotten first round. In the second step, to improve the list of sub-competencies obtained, researchers conducted a literature review. In total, 56 questions were collected from 8 different competencies. In the third step, each sub-competency obtained is confirmed by the experts. All generated questions will be displayed in Table 1. For approval ratings, a five-point Likert scale (from 1 ['completely disagree'] to 5 ['fully agree']) is employed. Surveys have been systematically tested previously with a mixed sample of four experts (Rowe & Wright, 2001). As a result, some ambiguous items are represented, some items are deleted, and some items are revised. Each expert is also asked to add other possible sub-competencies included in the list of questions. Additional changes are reviewed.

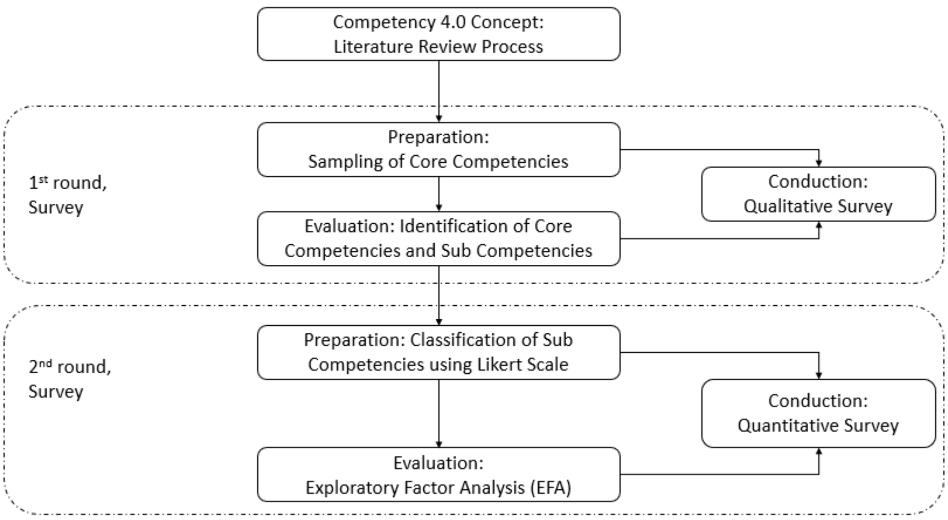

Figure 1: Delphi Research Process

Table 1. Competency and Sub-Competency Lists

Competency	**Sub-Competency**
Intrapreneurial Skills (IS)	Able to see, utilize and adopt opportunities that exist within the corporate environment (IS1)
	Able to create new things and ideas for the company (IS2)
	Able to use knowledge effectively in their work (IS3)
	Able to build networks with others to collaborate and negotiate (IS4)
	Have an active role in national and international organizations such as IAI, GPFI, ISPE, WHO, DCVMN, OIC, and GAVI (IS5)
	Able to see innovation and collaboration opportunities in line with global challenges (IS6)
Entrepreneurial Thinking (ET)	Able to create viable business concepts (ET1)
	Able to see market opportunities and gaps to innovate (ET2)
	Able to work independently (ET3)
	Able to create value and creativity (ET4)
	Able to collaborate with many external and internal subsystems (ET5)
	Able to find the best source, time, and best approach to turning ideas into reality (ET6)
	Able to learn from mistakes and failures (have resilience) (ET7)
Critical Thinking (CT)	Able to interpret and explain the meaning of any information obtained (CT1)
	Able to identify, analyze arguments, and generate ideas (CT2)
	Able to identify problems, determine goals, and find solutions (CT3)
	Able to question the evidence of each argument, seek alternative solutions, and draw conclusions (CT4)
	Able to identify claims and assess arguments (CT5)
	Able to make arguments and communicate information (CT6)
	Able to perform reflections, examinations, and self-corrections (CT7)
Digital Skills (DS)	Able to create critical judgment and use digital tools for a variety of purpose in work (DS1)
	Able to understand and use information and communication technology (ICT) applications to get the job done (DS2)
	Understand digital culture and able to work in a digital environment (DS3)
	Able to use technology to generate new ideas (DS4)
	Have the knowledge and digital skills to communicate and collaborate (DS5)
	Able to use information and communication technology (ICT) applications to understand the process and solve problems in work (DS6)
	Able to use business intelligence, big data, and bioinformatics technology in business decision making (DS7)
Bioinformatics (BI)	Able to perform data mining, storage, integration, manipulation, and data sharing (BI1)
	Understand computational programming in the context of drug discovery (BI2)

	Able to apply methodologies to design, implement, and maintain systems in scientific environments (BI3)
	Able to understand virtual screening in molecular tethering, virtual pharmacology, and molecular dynamics (BI4)
	Able to understand molecular biology, cellular biology, genomics, and genetics (BI5)
	Able to master the application of statistics and modeling methods in the context of biology (BI6)
Data Ethics (DE)	Responsible for every result and report for innovation and research (DE1)
	Able to override personal, family, and group interests in collecting, managing, or using data (DE2)
	Able to use and process data legally, fairly, and equally (DE3)
	Able to build morale frameworks, such as principles, rules, theories and ethical guidelines (DE4)
	Able to use skills and behaviors according to the expected norms (DE5)
	Able to distinguish and evaluate ethical and unethical behavior (DE6)
	Able to adhere to the morality of the law (DE7)
Regulatory Compliance (RC)	Understand the fast-growing regulations in the Pharmaceutical Industry (RC1)
	Aware of the latest regulatory developments (RC2)
	Able to adopt regulations in innovating (RC3)
	Able to innovate amid narrow regulatory scope (RC4)
	Participate in producing incremental and radical innovations (RC5)
	Able to anticipate uncertain policies and their future implementation (RC6)
	Comply with the growing regulations in the pharmaceutical industry (RC7)
Research Skills (RS)	Able to conduct the assessment process and understand the pattern of disease (RS1)
	Able to identify molecules/compounds that will be the basis of product development (RS2)
	Able to develop methods from upstream to downstream processes for product development (RS3)
	Able to apply knowledge of the utilization of genetic engineering for product innovation (RS4)
	Able to utilize big data, artificial intelligence, and machine learning to accelerate research activities (RS5)
	Able to apply safety, quality, and efficacy criteria in the process of developing new products (RS6)
	Able to produce accurate and relevant data related to product development (RS7)
	Able to conduct product research following trends and regulation (RS8)
	Able to prepare the commercialization aspect of the product (RS9)

Results

During the first round, experts sort some core competencies from the most important, i.e., Intrapreneurial Skills, Critical Thinking, Digital Literate, Research Skills, Entrepreneurial Thinking and Bioinformatics. As a result of the qualitative survey, "what competencies are not included in the lists" experts provide input on competencies, such as Data Ethics and Regulatory Compliance. The first round produces a list of eight core competencies. Sub-competencies are obtained in qualitative results and reprocessed by the research team with literature review until finally obtained 56 sub-competencies. 56 sub-competencies that were obtained in the first round, retested in round two quantitatively with more participants involved.

During the second round, Exploratory Factor Analysis (EFA) is conducted through a structured setting. The use of the EFA method aims to find patterns and relationships between several variables. The use of samples with N=50 can be specified as the minimum amount (de Winter et al., 2009). Hauben et al. (2017) provide EFA tools and evaluate factorability through various aspects of reliability and factor structure. Here, robust EFA is analyzed using IBM SPSSS 25.0. Based on the 71 responses received, no data were discarded due to incomplete data.

Before conducting exploratory activities for analysis, the authors calculated the Barlett of Sphericity test ($\chi 2 = 5389.465$; $P = 0.000$) and Kaiser-Meyer-Olkin size adequacy of sampling 0.690 (limit> 0.50). The determinant value is 0.001, indicating that the analytics factor solution can be met (cutoff > 0.0001) (Spoorthy et al., 2021). The Barlett Sphericity test was conducted to confirm the relevance of the analysis factors evaluated by examining the correlation matrix of the collected data (Mor et al., 2020). Anti-Image-Correlation results have a value of <0.5 on all items so that data processing can continue. Findings show that the samples of the study meet the requirements for different generations and reliable factors.

In data processing, the study iterated three times until adequate results were obtained. Exploration factor analysis with 56 items results in eleven factors with eigenvalue >1. In the first iteration, eight items (IS2, IS4, IS5, IS6, ET1, ET2, ET3, ET5) appear on the >1 factor. Therefore, the eight items were moved, and further analysis was carried out. The second iteration obtained the results of eight factors, ET4, DE1, DE2, BI6, moved because it has a loading factor value of <0.5. Furthermore, in the last iteration, adequate results were obtained with a total of six factors (Table 3). The communalities state the proportion of variants of the 44 items extracted six factors. All items have a similar value ≥ of 0.5, then significant (Table 3). The internal reliability of such statements is observed through Cronbach Alpha, which ranges from 0.90 to 0.95 (Table 3) and is therefore acceptable (Bagozzi & Yi, 1988).

The first factor had an Eigen score of 22.270, followed by a second factor of 3.578, the third factor of 2.749, the fourth factor of 2.302, the fifth factor of 1.458 and the sixth factor of 1.262. They are extracted after rotation of varimax by Kaiser standardization. These six factors account for 80.641% variance. However, the inflection in the scree plot suggests the presence of only five factors (Figure 2). The first factor was named "Learning and Innovation Skills" and explained 17.758% variance. The second factor was named "Research Skills" and explained 15.187% variance. The third factor was named "Digital Skills" and explained 12.531% variance. The fourth factor was named "Bioinformatics" and explained 11.227% variance. The fifth factor was named "Data Ethics" and explained 11,095% variance. The sixth factor was named "Regulatory Compliance" and explained 10.041% variance.

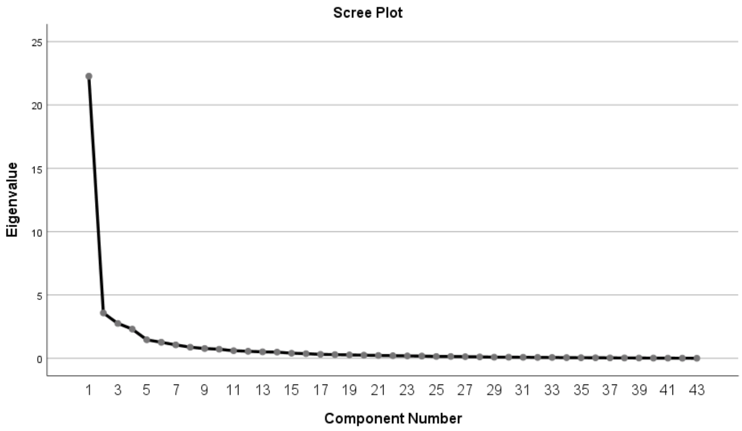

Figure 2: Scree Plot of EFA

Table 2. Exploratory Factor Analysis Results

Factor no.	Sub-Item	Communality	Factors						Measurement on five-point Likert scale	
			F1	F2	F3	F4	F5	F6	Mean	Std. Dev
1	IS1	0.674	0.54						4.37	0.78
	IS3	0.809	0.79						4.41	0.67
	ET6	0.739	0.65						3.93	0.95
	ET7	0.572	0.60						4.46	0.61
	CT1	0.816	0.73						4.10	0.81
	CT2	0.805	0.81						4.14	0.77
	CT3	0.796	0.80						4.31	0.69
	CT4	0.812	0.84						4.11	0.82
	CT5	0.779	0.69						4.01	0.89
	CT6	0.852	0.63						4.17	0.77
	CT7	0.750	0.64						4.24	0.77
	Overall Factor Score								**4.20**	**0.78**

2	RS1	0.787		0.74					3.75	1.25
	RS2	0.861		0.84					3.85	1.13
	RS3	0.810		0.87					3.70	1.05
	RS5	0.801		0.72					4.07	0.99
	RS6	0.884		0.76					3.75	1.12
	RS7	0.823		0.73					4.01	1.17
	RS8	0.716		0.76					3.70	0.92
	RS9	0.694		0.66					3.83	1.17
	Overall Factor Score								**3.83**	**1.1**
3	DS1	0.864			0.62				3.82	1.00
	DS2	0.754			0.70				3.94	0.98
	DS3	0.828			0.72				4.14	0.93
	DS4	0.870			0.80				4.07	0.85
	DS5	0.867			0.64				4.13	0.84
	DS7	0.881			0.61				4.04	0.87
	DS8	0.890			0.65				3.59	1.02
	Overall Factor Score								**3.96**	**0.93**
4	BI1	0.786				0.67			3.61	1.10
	BI2	0.835				0.80			3.17	1.15
	BI3	0.816				0.57			3.55	1.20
	BI4	0.908				0.75			3.11	1.21
	BI5	0.877				0.72			3.30	1.24
	Overall Factor Score								**3.35**	**1.18**
5	DE3	0.825					0.67		4.18	0.93
	DE4	0.761					0.76		4.35	0.85
	DE5	0.791					0.77		4.37	0.78
	DE6	0.822					0.78		4.44	0.67
	DE7	0.780					0.81		4.37	0.74
	Overall Factor Score								**4.34**	**0.80**
6	RC1	0.826						0.65	4.15	1.04
	RC2	0.867						0.71	4.13	0.93
	RC3	0.815						0.74	4.21	0.84
	RC4	0.808						0.64	4.11	0.92
	RC5	0.803						0.52	3.83	1.11
	RC6	0.887						0.54	3.93	0.95
	RC7	0.733						0.59	4.34	0.81
	Overall Factor Score								**4.1**	**0.94**
Reliability (Cronbach Alpha value) of identified factors			0.94	0.93	0.94	0.94	0.90	0.95		

Discussion

The results presented in this study provide results that six factors represent six main competencies: “Learning and Innovation Skills”, “Research Skills”, “Digital

Skills", "Bioinformatics", "Data Ethics", and "Regulatory Compliance". In the 4.0 era, digital skills and regulatory compliance still seem to be a competency gap for workers. A total of 43 sub-competencies were found in the study, representing six core competencies (Figure 3). Through EFA results, some intrapreneurial skills (IS), entrepreneurial thinking (ET) and critical thinking (CT) form new factors. Based on the competence of the 21st Century, to form learning and innovation skills, critical thinking, problem-solving, communication and collaboration are needed (Nguyen et al., 2020). These three skills intersect (in terms of IS, ET, and CT) and are declared as new skills, namely "Learning and Innovation Skills".

Learning and Innovation Skills	Research Skills	Digital Skills
• See, utilize, and adopt opportunities • Use knowledge effectively in work • Generating ideas and turn into reality • Learn from mistakes and failures • Identify problems, determine goals, and find solution • Make arguments and communicate information	• Understand the pattern of disease • Product research following trends and regulation • Identify molecules/compounds that will be the basis of product development • Developing methods and ideas for product development • Genetic engineering for product innovation • Utilize bid data, artificial intelligence, and machine learning • Preparing commercialization aspect	• Using digital tools for a variety of purpose in work • Use information and communication technology (ICT) for work • Understand digital culture • Able to work in a digital environment • Use technology to generate new ideas, communicate, and collaborate
Bioinformatics	**Data Ethics**	**Regulatory Compliance**
• Perform data mining, storage, integration, manipulation, and data sharing • Understand computational programming in the context of drug discovery • Apply methodologies to design, implement, and maintain systems in scientific environments • Understand virtual screening in molecular tethering, virtual pharmacology, and molecular dynamics	• Use and process data legally, fairly, and equally • Build morale frameworks such as principles, rules, theories, and ethical guidelines • Use skills and behaviours according to the expected norms • Distinguish and evaluate ethical and unethical behaviour • Adhere to the morality of the law	• Understand the fast-growing regulations in the Pharmaceutical Industry • Aware of the latest regulatory developments • Adopt regulations in innovating • Innovate amid narrow regulatory scope • Producing incremental and radical innovation • Anticipate uncertain policies and their future implementation • Comply with the growing regulations in the pharmaceutical industry

Figure 3: Core and Sub-Competencies of the workforce in Pharmaceutical 4.0

Learning and innovation skills are indispensable in the Pharmaceutical Industry, especially in making new drugs or new vaccines. The challenge in development lies in highly regulated processes, limited innovation and import dependence (Van den Heuvel & Stirling, 2017). The cornerstone of competitive advantage in the Pharmaceutical Industry lies in successful innovation. Openness to learning is indispensable for cooperating with robots and technology. Following the sub-competencies found, workers in the Pharmaceutical Industry should be able to see new opportunities, utilize science, collaborate, learn from the past and have critical thinking.

Research skills are the spearhead of the skills required by workers in the pharmaceutical industry. Through high research capabilities, it is expected that research and innovation productivity continues to increase. Innovation is needed to produce innovative medicines that can save millions of lives and improve people's quality of life. The use of AI, Big Data, IoT, Robots, and Machine Learning (ML) is expected to help the drug discovery process in a predictive and preventive manner. Through adequate research skills, it is expected that every individual in the industry understands the patterns of disease and benefits existing materials.

Digital skills are indispensable to face the era characterized by cyber-physical systems (CPS) as well as machine-to-machine (M2M) communication through the Internet of Things (IoT) (Buda et al., 2015; Peicheva & Milenkova, 2017). Digital skills are the ability to follow digital developments, understand, and use them effectively (Juwita et al., 2020). The implementation of the manufacture of drugs or medicinal materials must be accompanied by supporting technology ranging from processing raw materials, packaging materials to obtaining finish goods. To avoid obstacles from the development of information technology, the skills of each worker need to be improved. Digital skills will be needed in the Pharmaceutical 4.0 revolution due to the improvement of machine operations in the drug manufacturing process, requiring programming and technical skills (Arniati, Puspita; Amin, Pirzada, 2019). The results show that every worker needs to understand the digital culture and work in a digital environment.

Bioinformatics is becoming an intrinsic part of research in the pharmaceutical context, but the last decade has seen continued deficiencies in essential expertise (Attwood et al., 2019; Maloney et al., 2010; Mulder et al., 2018). Bioinformatics is one of the supporting sciences in the pharmacy that combines computer science, mathematics and statistics. To date, many drug and vaccine candidates have failed due to the patient's unintended effects. In addition, bioinformatics helps reduce the time and investment required in trials of various pharmaceutical products: synthetic vitamins, vaccines, antibiotics, synthetic hormones, enzymes, and other biological products.

Data Ethics is one of the critical skills in pharmaceutical practice. In the last ten years, pharmaceutical ethics have not been taken seriously. Only a few research has been done on the ethical dilemma faced by the pharmaceutical workforce (Da Glória Prado et al., 2017; Delpasand et al., 2018). The Pharmaceutical Industry has massive data on information from patients. Digital health systems can access relevant information from other reliable and high-quality departments. In the Era of Industry 4.0, the use of Big Data has several risks that include data security and data privacy (Hemanth Kumar et al., 2020). The use of data becomes more integrated, implementing algorithms to summarize the data clustering and analyze it in a shorter time. The more data you have, the more likely it is to be sold and misused by irresponsible parties. Concerning sub-competencies, individuals must be able to take responsibility, process data legally, comply with minimum morality, distinguish and evaluate ethical behavior.

Regulatory Compliance is the ability to follow developments and understand the regulations that are developing in the Pharmaceutical Industry. Until now, the national Pharmaceutical Industry is difficult to develop because it is shackled by regulation (Bates et al., 2016). In the Era of Pharmaceutical 4.0, the use of AI is expected to help companies in obtaining regulation updates. Every worker must understand the evolving regulations in order to innovate in accordance with the narrow authority.

Conclusion

This research is a preliminary study related to the development of competencies and sub-competencies of Pharmaceutical 4.0. Pharmaceutical Industry is a company based on technological excellence as competitiveness. Technology is not the most significant barrier to adopting the Pharmaceutical 4.0 era, but workforce readiness is the biggest challenge. Until now, there have not been many publications related to the topic of competence in the Pharmaceutical 4.0 era. To study this case, the authors of the present study chose the Pharmaceutical Industry case in Indonesia, which is achieving national independence in both medicinal raw materials and drug production. The findings of the study have important implications for creating the concept of competency profiles that workers need. Workers in the Pharmaceutical Industry have a high level of technical knowledge. Not only technical capabilities, but we also provide new insights into smart factory systems. Workers are an element that must be considered to implement the relevant aspects of Pharmaceutical 4.0. Experts emphasize that digital capabilities are critical and needed in transformation. Not only digital capabilities, in competition activities in the market, companies need to develop personal managerial such as intrapreneurial skills, entrepreneurial skills, also learning and innovation skills. Conceptual competency models can be used by practitioners to be developed and applied in the Pharmaceutical Industry. The sub-competency information obtained can be used to provide an overview of each of the proposed core competencies. Competency knowledge is needed to adapt to changes in manufacturing and research processes. For researchers, this study paves the way for competency Pharmaceutical 4.0 research, including the extent to which competencies can be mapped and applied to organizational functions. Competency-related approach is a core component in order to prepare the workforce towards Pharmaceutical 4.0. In addition to the information offered, this study has limitations in terms of methodology. Delphi's study provides an intelligent guess of the competencies needed; nevertheless, the study results cannot guarantee following future changes in terms of competencies and sub-competencies. In addition, the third limitation is on the number of research participants and the context of the research. Research is only conducted in Indonesia with a limited number of experts. More research can be done with more samples for model enhancement to improve quality and accuracy.

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OCENA KOMPETENCJI I PODKOMPETENCJI DLA FARMACEUTYKI 4.0 – BADANIE DELPHI

Streszczenie: Niniejsze badanie ma na celu ilościowe mapowanie kompetencji i podkompetencji metodą Delphi w dwóch rundach w celu uzyskania kompleksowych wyników. Zastosowanie podejścia Delphi odnosi się następnie do kilku rund ankiet eksperckich opartych na istniejących kwestionariuszach. W pierwszej rundzie wzięło udział 15 praktyków z branży farmaceutycznej. W pierwszej fazie badanie za pomocą kwestionariuszy sprawdza, jakie kompetencje są najbardziej potrzebne. Ponadto w fazie drugiej większą liczbę uczestników uzyskuje się poprzez relacje badawcze. W drugiej turze udział bierze 71 ekspertów, w tym praktycy z 19 Branży Farmaceutycznej oraz pracownicy naukowi. Wyniki badania zostały przetworzone za pomocą eksploracyjnej analizy czynnikowej i wygenerowały sześć czynników reprezentujących sześć kompetencji: umiejętności uczenia się i innowacji, umiejętności badawcze, umiejętności cyfrowe, bioinformatykę, etykę danych i zgodność z przepisami. Ponadto w badaniu uzyskano 44 podkompetencje, które reprezentują 6 kluczowych kompetencji. Uzyskane kompetencje i podkompetencje mogą być wykorzystane jako skierowanie do praktyk farmaceutycznych w Erze Farmaceutyki 4.0. Potrzebne są dalsze badania nad kompetencjami w przemyśle farmaceutycznym, aby uzyskać niezawodne i ważne instrumenty.

Słowa kluczowe: Farmaceutyka 4.0, Kompetencje, Podkompetencje, Badanie Delphi

评估制药 4.0 的能力和子能力 德尔福研究

摘要:本研究旨在通过德尔菲法分两轮对胜任力映射和子胜任力进行定量分析, 以提供综合结果。德尔福方法的应用然后是指基于现有问卷的多轮专家调查。第一轮涉及来自制药行业的15名从业者。在第一阶段, 研究通过问卷调查最需要哪些能力。此外, 在第二阶段, 通过研究关系获得了更多的参与者。第二轮有71位专家参加, 包括来自19个制药行业的从业者和学术界人士。研究结果使用探索性因素分析进行处理, 并产生代表六项能力的六个因素:学习和创新技能、研究技能、数字技能、生物信息学、数据伦理和法规遵从性。此外, 这项研究产生了44个子能力, 代表了6个核心能力。获得的能力和子能力可作为制药4.0时代制药实践的参考。需要对制药行业的能力进行更多研究, 以实现可靠和有效的仪器。

关键词:制药4.0, 胜任力, 子胜任力, 德尔福研究