Pharma 4.0: analysis on core competence and digital levelling implementation in pharmaceutical industry in Indonesia

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ABSTRACT

Purpose: This paper aims to explore core competencies and analyze the digital levelling implementation of Pharma 4.0 in Indonesian Pharmaceutical companies.

Method: This study uses a mixed-method Delphi study conducted in the first two rounds. The first and second rounds aimed to determine the core competencies of the Pharmaceutical Industry to face the Pharma 4.0 era. In the first round, FGD was conducted involving 12 participants, and semi-structured interviews were carried out with 10 participants in the second round. Alongside Delphi, this research also employs NVIVO as a tool for content analysis. Furthermore, in the third round, a survey was conducted to determine the levelling of the digital implementation of Pharma 4.0, involving 215 senior management participants representing 34 national pharmaceutical industries.

Result: The study revealed eight core competencies needed by human capital in the pharmaceutical industry to face the Pharma 4.0 era: critical thinking, bioinformatics, entrepreneurial thinking, digital skills, intrapreneurial skills, research skills, regulatory compliance, and data ethics. Regarding digital levelling implementation, this study found five main levels: level 1 (simplification), level 2 (automatization), level 3 (integrated system), level 4 (digital transformation), and level 5 (disease prediction). This study also affirms that most of the pharmaceutical industries in Indonesia are at level 2 (mean = 4.2) and level 1 (mean = 4.0). Several pharmaceutical industries are at level 3 (mean = 3.5), and a few others are at level 4 (mean 3.2) and level 5 (mean = 1.4).

Research implication: This study is the first to analyze the levelling of digital implementation in Pharma 4.0. The results showed that core competencies could be used as a benchmark to develop employee skills. This current study provides the essential data for core competency development and digital levelling implementation for the pharmaceutical industry and government in preparing Pharma 4.0.

1. Introduction

Implementing Industry 4.0 through a transition from conventional manufacturing is challenging, especially for emerging economies (Samaranayake et al., 2018). Manufacturing companies need to recognize the Industry 4.0 vision, as they fail to identify concrete fields of action, programs, and projects (Schumacher et al., 2016). The importance of health information systems affects the quality of care, cost efficiency, and healthcare delivery (Baines et al., 2018). Furthermore, implementing advanced technologies (IT) at the operational level would bring new values and services to customers and the organization itself.

Another change on the horizon for pharmaceutical manufacturing is the “fourth industrial revolution”, or the era of “Pharma 4.0” (Danyysz et al., 2019a). In some ways, the pharmaceutical industry remains in transition to automation despite the exponential growth of technological change. The huge demand for personalized products increases the pharmaceutical industry’s pressure to produce new drugs (Hemanth Kumar et al., 2020a; Van den Heuvel and Stirling, 2017). The discovery of innovative drug products shows that it is necessary to develop product innovations supporting the technology capability to encourage the competitiveness of the pharmaceutical industry (Grzybowska and Lupicka, 2017).

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The pharmaceutical industry is a firm that bases its competitiveness on technological superiority. The Indonesian pharmaceutical industry encounters a significant challenge due to the unprecedented COVID-19 pandemic. Indonesia arguably is a biodiversity superpower due to its diverse natural resources that are valuable for the pharmaceutical industries to increase their product innovation significantly. However, COVID-19 vaccines are still imported from developed countries like Europe and the United States. Not just vaccinations, but most raw materials, such as Active Pharmaceutical Ingredients (API), are also imported from different countries. There are currently 230 pharmaceutical industries, all of which are growing year after year. In realizing national self-reliance on raw materials, the Indonesian pharmaceutical industry needs to use new technologies to increase future competitiveness (Vrchota and Pech, 2019).

There is a gap between the current theoretical knowledge and the practical implementation in the pharma industry 4.0 (Chatterjee, 2020; Hammer, 2018; Hemanth Kumar et al., 2020b; Rahaman et al., 2019). Thus, it is necessary to define the latest core competencies and leveling implementation according to the technology enhancement in the pharma industry. The findings of this study can be used to determine the needs of the workforce and technological development to support practical implementation in the pharmaceutical industry. This is the first study to examine the Pharma 4.0 core competencies and digital leveling implementation in a developing country, particularly Indonesia.

2. Literature review

This paper contributes to the existing core competency knowledge by analyzing digital leveling implementation. To provide context and theoretical underpinning, the literature review covers pharma 4.0, the business process in the pharmaceutical industry, and core competency theory. Pharma 4.0 has not been discussed in detail in previous literature. This research fills the gap in the core competency of Pharma 4.0 and improves digital leveling implementation in the pharma industry.

2.1. Pharma 4.0

The use of technology in the pharmaceutical industry is rapidly increasing and has become the dominant factor in production, supply chain, research, and marketing. Pharma 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 (Berdigaliyev and Aljofan, 2020; Zhang and Mao, 2017). Pharma 4.0 will cause disruptions in company models, competition patterns, and market structures. Because digitization is a context-based process, it requires unique solutions for businesses, value chains, geographies, and markets (Flynn, 2019; Smith, 2018). Digitization creates a new level of transparency in rapid decision-making and provides timely and line control over operations and quality; it also uses advanced data analytics to increase process durability, and improve quality, productivity, and profit (Chethamrongchaisai and Jermsittiparsert, 2020; Hemanth Kumar et al., 2020a). That issue leads to safer and more efficient pharmaceutical production.

The growing demand for health care is one of the challenges faced by drug manufacturers. Catalyzed by a new range of exciting and disruptive technologies, the Pharmaceutical Industry needs to reorganize its future (Taylor, 2016). By 2036, the Pharmaceutical Industry will likely switch from symptom treatment to complete preventive and healing measures (Van den Heuvel and Stirling, 2017). Three fundamental developments drive this shift: innovative new therapies, technological advances, and health consumerization through increased patient data access (Hock et al., 2021). This change and its speed impact on some historical treatment methods are replaced and differ according to therapeutic areas. Moreover, the COVID-19 pandemic is driving digital transformation throughout the industry and the state.

2.2. Core competencies

Core competencies were defined as a competitive advantage for companies to place technology investments commercially (Fitsilis et al., 2018a,b; García et al., 2020; Kim, 2019). The core competencies from earlier studies may contribute to the company’s response to changing external and internal contexts, such as technological turbulence (Mulder et al., 2018; Suwannaprom et al., 2020). Core competencies must have the following three qualities: (1) enhance consumer benefits, (2) be competitively distinctive and hard to be duplicated by rivals, and (3) must provide access to a broader market (BERGER, 2016; Marneros et al., 2021). Core competencies are linked with quality, cost, cycle time, logistics, and business productivity. The use of core competencies should apply motivation to the outcomes of changes from goals that all workers may recognize to feel committed (Czet et al., 2017; Di Fabio, 2014).

The pharmaceutical industry is highly regulated, as it produces drugs that directly affect human life. In a competitive global market, customer focus compels organizations to deeply understand the entire value chain (Taylor, 2016). Customer demand frequently exceeds the fulfillment of the company’s services in many circumstances. Workers in the pharmaceutical industry are expected to develop competencies in these six main domains: (1) drug discovery and early development, (2) clinical development and clinical trials, (4) drug regulation, (5) drug safety supervision, (6) communication and management (Silva et al., 2013). The pharmaceutical industry is complex, and to date, the development of the core competencies framework in the context of the Pharma 4.0 era has not been unveiled.

2.3. Digital Leveling Implementation

Globalization and technological progress present significant obstacles for corporate industries, particularly intense competition and volatile demand (Hemanth Kumar et al., 2020a; Hernawati and Nurbayani, 2018; Vrchota and Pech, 2019). Given the obstacles faced by Industry 4.0, evaluating digital deployment is critical. Until recently, most research on digital deployment was conducted in manufacturing companies. The transition to Industry 4.0 is a viable approach that will change operations, manufacturing, and management processes (de Campos Martins et al., 2020; Garay-Rondero et al., 2019). Digital transformation planning requires three stages, (1) “imagine” the company, to imagine the potential of industry 4.0, and (2) to “activate” a stage in which more detailed analyses of the strengths and weaknesses of the company were carried out to build a roadmap, (3) to “act” the stage in which the strategy is changed into concrete projects (Pirola et al., 2020; Vrchota and Pech, 2019). According to prior research findings, supervision provides a systematic framework that facilitates performance benchmarking and enhancement (Putri et al., 2021). Each level has lists that must be fulfilled to achieve that level’s maturity, supporting sub-lists that specify the scope and actions required for that level and activities and tasks required to achieve each level.

3. Methodology

The Delphi technique was chosen to acquire a complete perspective of the pharmaceutical industry’s core capabilities and digital levels. A corporate leader is in charge of defining and developing core capabilities strategically. The participants of Delphi studies consist of expert practitioners, academics, and entrepreneurs (Baines et al., 2018; Gregory and Fawkes, 2019; Probst et al., 2020a). Several characteristics of Delphi studies are anonymity, no face-to-face meetings, and having confirmation with controlled feedback that leads to reflective responses. Before the data collection, boundary conditions, assessment criteria, and evaluation standards are set up. Four criteria are utilized to assess the
research findings: completeness, truthfulness, conciseness, and clarity (García et al., 2020; Putri et al., 2021; Trollor et al., 2017). Each criterion is used to guide the first framework’s development. Each Delphi round includes responding to a question and evaluating the framework using those four criteria; the updated findings are then merged to address panelist remarks.

3.1. Ethical issues

The authors state that the work is written with due consideration of ethical standards. The study was conducted following the ethical principles approved by the Ethics Committee of the University under the file (SBM.PN-6-03-2021). The research complied with all ethical standards and anonymity; there were no requirements to provide confidential information (name, date of birth or place of residence, etc.). The respondents gave their written consent for the conduct of the research and data processing.

Figure 1 presents the three rounds of mixed-method Delphi investigations performed to accomplish the study goals. Participants’ inclusion criteria were workers or business owners in the Pharmaceutical Industry with at least ten years of work experience and a minimum manager position. The overall data collection was conducted from December 2020 to August 2021. The first phase included a Focus Group Discussion (FGD) with 12 participants to provide preliminary information on Pharma 4.0 core competencies and digital leveling implementation. The second phase involved in-depth interviews with ten experts to validate core competencies and produce an assessment of Pharma 4.0 digital leveling implementation. The third phase covered an online survey and was distributed to 282 pharmacists; however, only 215 participants established a baseline for Pharma 4.0 implementation and gathered agreement from the research. The data were analyzed using the mixed-method technique combining qualitative and quantitative analyses to achieve the research objectives. The data analysis is further explained in the data analysis section.

According to the Indonesian Ministry of Health, the pharmaceutical industry is separated into four key sectors: bio-pharmaceuticals, vaccines, natural herbal products, and chemicals (Table 1). This research examined those four sectors to collect a comprehensive picture, with the participants including top-level, executive-level, and middle-level positions. Participants were contacted through affiliated and networks of Indonesian professional pharma associations using tools of WhatsApp or email.

3.2. 1st round: experts focus group discussion

RQ1. What core competencies does the pharmaceutical industry need in the face of the Pharma 4.0 era?

Focus Group Discussion (FGD) was conducted to obtain opinions from each individual. To begin, the research team developed an initial list of 15 core competencies deemed critical for the business. The ranking is based on a review of corporate papers pertaining to each country’s pharmaceutical industry’s strategy. Pharmacy experts are all very skilled in their respective professions. They were tasked with analyzing the aforementioned list, compiling, adding, deleting, and operationally defining each required core competency. Snowball sampling was used. Experts are expected to recommend internal or external peers for the next research phase. The FGD was conducted twice in two days, with six people in each round, making 12 participants (Table 2). The first day
aimed to get a benchmark on the description of competencies required by the pharmaceutical industry. The second day aimed to verify the results of the first day. Participants were also allowed to add other competencies, if any, to be added for review.

3.3. Semi-structured interview

RQ2. How to measure the leveling of digital implementation in national pharmaceutical industries?

To supplement the first round FGD findings, the research performed ten expert semi-structured interviews with representatives from each of the four sectors (Table 3). For validating core competencies mapping, the researchers started by asking and analyzing the competencies best suited for each division. Core competencies were carefully mapped and confirmed with each expert until saturated results were obtained. For the case of leveling implementation, researchers first presented the design obtained through a literature review. The researcher then asked each expert whether the leveling proposed was appropriate. These interviews enabled the researchers to get direct information from various perspectives. The interviews lasted 45–60 min with different participants. All interviews were recorded and transcribed.

3.4. 3rd round: survey

RQ3. To what extent is the level of digital implementation in the national pharmaceutical industry in Indonesia?

After obtaining the results of the first and second stages, the questionnaire, consisting of five levels of digital implementation in the national pharmaceutical industry, was designed. To address the research objective, a broader population was used on the Delphi method. Furthermore, the authors contacted prospective participants by WhatsApp and email and obtained 282 participants who agreed to participate in the research. Only 215 participants completed the questionnaire in two months, from June to July 2021 (response rate of 60.2%). The sample included 120 managers, 80 head departments, and 15 directors representing 34 national pharmaceutical industries. The measurement used a 5-point Likert scale (1 = disagree; 5 = strongly agree). The survey is presented in the Indonesian language following the results obtained in the qualitative survey (Table 6). The data were analyzed using descriptive statistics and mapped to see the shortcomings and the extent to which digital implementation has been carried out in Indonesia.

3.5. Data analysis

3.5.1. Qualitative data analysis

In this research, qualitative data analysis revealed the core competencies in contemporary pharma industries. The data were analyzed following the thematic analytical guidelines presented by Kiger and Varpio (2020). Thematic analysis is a method used to identify, analyze, and interpret patterns of meaning in qualitative terms. The thematic analysis emphasizes the main role of researchers in formulating themes from the data obtained. The approach used for thematic analysis is a deductive approach where previous researchers have several main themes based on a literature review. Several rounds were made to capture the emerging themes. All FGD and semi-structured interviews were transcribed verbatim into Microsoft Word. Information obtained from FGDs and semi-structured interview were examined and classified into several common themes using NVivo software (Miles and Huberman, 1984; Nag et al., 2007).

NVivo is one of the most prevalent techniques in categorizing and scrutinizing textual data from interviews to advocate proper coding and pattern detection (Leech and Onwuegbuzie, 2011; Nowell et al., 2017). NVivo software is suitable for extracting pertinent themes, developing categories, and visualizing data in different formats (Sotiriadou et al., 2014; Nowell et al., 2017).

The steps of data analysis followed the recommendation of Kiger and Varpio (2020): (a) organize the data and become familiar with data, (b) put codes to the transcript of the interviews (c) think about the proper theme for several codes, (d) reevaluate the theme, and last, (e) create a definition of the theme with the researcher interpretation. Employing NVivo streamlined the data organization process by recognizing the word frequencies and brainstorming trends and patterns throughout the text. This research coding the text passages with equivalent phrases to formerly coded content. There is a lot of repetition of words and sentences with the same core subject. NVivo software is a valuable instrument for coding and categorizing a high volume of texts (Hilal and Alabri, 2013; Paulus et al., 2017). NVivo could systematically extract the themes throughout the data and provide visualization data in various formats such as word clouds, maps, and graphs. A meaningful theme is ensured by understanding the coder and the proportionate data validation process (Claps et al., 2015). Data validation could be conducted through triangulation, looking at data saturation, and research boundaries (Yin, 2013). In this research, triangulation was carried out by confirming the incomplete concept in the interview session after the FGD.

3.5.2. Quantitative data analysis

Quantitative data analysis aims to determine the digital implementation leveling of the national pharmaceutical industry. The data was collected by administering the online questionnaire to the senior-level pharmacists. The online survey was created on the google form. The quantitative data were then analyzed using SPSS 20. Descriptive statistics analysis and Pearson correlation test were conducted. Descriptive statistics, including the maximum and minimum values, and mean, shows the digital leveling of the pharmaceutical industries. Based on the digital implementation in the industry, there are five levels of categorization that will be elaborated more in the following sections, with level one being the lowest and five being the highest. Pearson correlation examined the significance of the study.

3.6. Validity and reliability

The researchers contend that validity and reliability are critical to the quality of original research and strongly emphasize the data collection.
and analysis procedure (Franco and Alfonso-Lizarazo, 2017; Probst et al., 2020b). The prospect of reproducing the same results in subsequent research is reliability. The interpretation of the outcomes of a given phenomenon is referred to as validity. The development of correct interview and FGD methodologies, recording, and transcription to achieve inter-code reliability are all part of the qualitative method’s reliability. In qualitative research, validity is determined through triangulation, member examination, and the use of researcher bias in responding to questions and validating data. The Pearson Bivariate approach is used to assess the validity of the quantitative method. The result is genuine if the r count is greater than r table 5%. The Cronbach’s alpha value ranges from 0.79 to 0.90, indicating that the calculated factors have a range of dependability ratings from good to outstanding (Al-Haqan et al., 2021).

4. Results

4.1. Core competency mapping

A total of 22 pharma top management and experts participated in focus group discussions and Semi-structured Interviews, and 215 participated in the survey, as shown in Table 1. FGDs answers revealed that existing competencies need to be improved with new knowledge and developed in a broader and more complex way. One of the leading companies was the government affiliation, which focused on the vaccine market. The participants were quite supportive in the FGD and interviews since they also urgently formulated the core competence in the Pharma industry, especially after the pandemic. The extent of the resemblances among FGD’s members and interviewee responses and the level of Pharma industry implementation were presented in annual reports of the affiliated companies supported the results.

Furthermore, companies’ annual reports and public website contents are being used to support the triangulation process. The research boundaries are also made to limit the broad range of data. This research examined the frequency of themes using NVivo to investigate the precision of the analysis and improve confirmability. Although the participant is from different companies with different job positions, they emerge with a joint proposition.

Data were analyzed using Thematic Analysis (Table 4). In the thematic analysis stage, first the researchers sorted the interview results (in column “The excerpt”) according to the appropriate code. Each code describes the skills relevant and needed in facing the Pharma 4.0 era (in column “Code”). After the code was created, pattern identification was conducted, and themes were identified (in column “Theme”). The analysis was carried out by interpreting the interview results to identify the themes of skills needed by the pharmaceutical industry in facing the Pharma 4.0 era. The determination of the theme and the interview results were processed by the research team and expert representatives (Table 4). Furthermore, the results were re-verified when conducted FGD and small interviews, to determine whether the skill needed for Pharma 4.0 is already appropriate to be translated into leveling, and which level is apt for the Indonesian situation and proceeding to the questionnaire.

Figure 2 shows the most frequent keyword was data, industry, skills, digital, technology, pharmacy, management, ability, and development. Meanwhile, Table 4 indicates the most frequent nodes, themes, and usage frequency. The most frequent nodes depicted the importance of the topic, confirmed in the Thematic Analysis that shows the theme of decision making, which includes nodes cognitive, critical skills, data analytics, and problem-solving are the most coded along with the transcription.

The results from thematic analysis using NVivo show seven themes regarding core competencies the pharmaceutical industry needs in the face of the Pharma 4.0 era, including a) intrapreneurial skills, b) entrepreneurial thinking, c) critical thinking, d) digital skills, e) bioinformatics, f) regulatory compliance, and g) data ethics. Figure 3 presents the hierarchy chart and points out that the current issue related to Pharma 4.0 in Indonesia is mostly about Data Analytics under the theme of Critical Thinking.

New competencies will focus more on managerial skills, and more vital digital skills for integrating the skills and areas of expertise will be provided. The analysis results are presented in Tables 5 and 6 to answer the research questions in the 1st Round and 2nd Round.

The core competencies mentioned by the pharmacist were management competencies and some technical skills, including a variety of knowledge, such as entrepreneurial skills, intrapreneurial skills, critical thinking, data ethics, research skills, bioinformatics, digital skills, and regulatory compliance. Among those competencies, bioinformatics and regulatory intelligence differentiate pharmaceutical sectors from others. Experts believe that the knowledge of the pharmaceutical industry in the 4.0 era, i.e., regulatory compliance, research skills, data ethics, and bioinformatics, will be the key for developing drugs in uncertain circumstances. Bioinformatics and regulatory intelligence are expected to fasten the research & development and production process and ensure product quality. In addition, digital skills are crucial for the Industrial 4.0 era and the future. It is reflected that there will be improved machine operation and software and hardware maintenance in future jobs requiring more advanced programming and technical skills.

4.2. Levelling of digital implementation Pharma 4.0 measurement tools

This research develops previous research by Kupfer (2019) that fairly primitive generations of digital technology currently dominate the examined companies. However, significant steps toward digitalization are expected in the future. Nonetheless, the most organizations are still-prepared to achieve expected future advancements. Large firms in high- and medium-technology industries appear to be better equipped to introduce digital technologies than their smaller counterparts in lower-technology industries (Kupfer, 2019). Based on the semi-structured interview with the expert, researchers tried to create the proper measurement methods with more detail and specialized in the Pharmaceutical Industry. Before determining the level, researchers and experts design the measurement method and prepare the categorization of each level in Pharma 4.0 functions and contexts. The measurement tools will be presented in Table 7. This study also provides an overview and meaning at each level, as follows:

- Level 1: Implementing functions to simplify bureaucratic processes with complex and rigid pharmaceutical industry systems. A practical example at this level is managing a digital standard operating procedure (SOP) system or e-paper based.
- Level 2: The implementation of the automation function using digital technology, automatic machines in biopharm & life science, and 3D printing in the production process. An example of this level is visual inspection automation or semi-automation in the pharmaceutical industry.
- Level 3: The implementation of the integration function, the internal data management process of the company has been integrated comprehensively with the internal and external functions. AI and Big data based on IT platforms design clinical supply chains and integrate internal & external support systems. For example, ordering products through marketing is integrated with production, Production Planning & Inventory Control (PPIC)-warehouse, and other functions, such as implementing Enterprise Resource Planning (ERP) tools, Laboratory Information Management System (LIMS), and other tools.
- Level 4: The application of the digital transformation function. At this stage, it has implemented digital transformation with technology that has artificial intelligence, big data, and the Internet of Things to support core functions. For example, monitoring the track & trace system of vaccine product distribution concerning international standards from upstream to downstream. Another practice is the company’s ability to identify potential predictors of future diseases, such as the results of lifestyle, genetic factors, or heredity.
| Definition                                                                 | Theme                          | Code       | The excerpt                                                                                                                                                                                                 | Words Count |
|---------------------------------------------------------------------------|-------------------------------|------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| Ability to work together to optimize potential and achieve common goals   | Intrapreneurial skills        | Collaboration | Collaboration in functions not only internal but external, e.g., vaccine distribution involves various ministries, institutions, companies, and related agencies. The narrative starts with an ecosystem-based business. | 2           |
| Stakeholder Management                                                   |                               |            | Since the type of industry is predicted as oligopoly and most use market focus and customer focus as a growth strategy, we need a combination with talent because knowledge accumulation is necessary to produce new products. Competency characteristics will be related to business strategy. Pharma needs to emphasize managing the stakeholders, responsibility answering, going the extra mile, and persistence. | 2           |
| Partnership                                                               |                               |            | A partnership strategy is very important because the industry cannot develop itself. People in the Pharmaceutical Industry not only have technical skills (mastery of operations, etc.), but soft skills such as negotiation, etc., are also required. | 2           |
| Ability to have creative thinking, create innovation, and implement it   | Entrepreneurial thinking      | Entrepreneurship | We need to have core competencies in accordance with the company purpose: character, cognitive ability, critical skills, behavior, innovation, and soft skills.                                                                 | 4           |
| Innovation                                                               |                               |            | We are already part follows the innovative factory program and the R&D. However, because we need to follow the complicated regulations, development becomes hampered because everything must work following SOPs. | 5           |
| Dynamics                                                                 |                               |            | Millennials play a role urgent in facing change because millennials can study fast and adapt; they also have more soft skills to self-development.                                                                 | 2           |
| Adaptive                                                                 |                               |            | HR 4.0 is very disruptive. The HR team must prepare team members as well as possible if there is opportunity and potential. Industry 4.0 is related to big data: velocity, volume, & variety. At this time, recruitment can be conducted online. Very data-driven and used primarily in the recruitment process. Match behavior and profile personnel very much depend on big data. | 3           |
| Responsive                                                               |                               |            | For pharmacy, the most dominant variable is time to market and lower cost. Especially when we are prepared for vaccines and diagnostic tools, we cannot depend on continuing imports (because flight delays, lockdown, etc. are very troublesome). If referring to the 4.0 industry, we need to speed up the time of the product to the market. Existing processes need to have a shortcut to speed up the system. | 3           |
| Learning Ability                                                         |                               |            | The development could be conducted by the employee by themselves, such as through LinkedIn and or with one-on-one coaching, in which we actually have a culture of learning. We expect some programs can align with the performance, so the learning process can be performed effectively. | 3           |
| Ability to analyze the problems, share insight for decision-making, and respond fast to recent changes or challenges | Critical Thinking             | Cognitive | We need to find the extent to which robotics, IoT, and other technology roles in the operation process, which of course, require different competencies. Competence should be linked to business strategy, for instance, new products, new markets, and product diversification. We need talent, leadership drive, and focus on customer focus. | 6           |
| Critical Skills                                                          |                               |            | We need competence from Core Industry Pharmacy: Production, QC, QA, and R&D, ensuring that the product is made appropriately on schedule (efficient) and effective. Thus, in the implementation in industry, all systems must be integrated to facilitate monitoring anytime and anywhere; one of them is vaccine covid; smartphone distribution can already monitor distribution. | 6           |
| Data Analytics                                                           |                               |            | The use of big data is very urgent for looking at those who only have registered in the recruitment process. For example, our company already uses a talent pool integrated with the government personnel department to set specifications in the recruitment process. Until the moment, HR people should not originate from a pharmacy background. However, one must understand pharmacy. HR is rotated to understand the whole process in pharmacy. | 8           |
| Problem Solving                                                          |                               |            | When a pandemic occurs, we no longer just collaborate with other industries. We collaborate with Research Institutions and Agencies and global partners to produce vaccines. Research ability is still low compared to the ability of production, though we need it the most. | 6           |

(continued on next page)
Level 5: The application of digital functions with capabilities for disease prediction. At this stage, the industry has implemented Pharma 4.0 practices to support AI, Big Data, and IoT with unstructured data. Level 5 is the highest in the application of pharma 4.0. For example, with the knowledge of disease prediction, the industry can prevent the disease.

4.3. Levelling of digital implementation Pharma 4.0 quantitative result

Quantitative data analysis is carried out based on the development results of measurement tools in Table 8. In developing countries, digital adoption patterns will vary depending on the company's profile. To date, digitization is considered a new process that has not been consolidated. Quantitative data are analyzed using descriptive statistics in Tables 8, 9, 10, 11, and 12, covering maximum, minimum, and mean values. The mean of each level will be averaged and mapped to determine the leveling of digital implementation in the national pharmaceutical industry.

5. Discussion

5.1. Pharma 4.0 digital competency

This study revealed seven main competencies: intrapreneurial skills, entrepreneurial thinking, research skills, critical thinking, regulatory compliance, bioinformatics, digital skills, and data ethics (see Table 4, Table 5, and Table 6). The implications of digitization on skills are a much-debated topic, given the complex nature of the changes involved. The digital age has brought many changes to professions and jobs (Prečko, 2017). An individual may have various competencies unmatching the qualifications, so it is crucial to have a competency benchmark (Abel, 2008; Mitchelmore and Rowley, 2010;
Pharmaceutical companies must be capable of adapting to rapid change, prepared to deal with digitalization, and keeping up with the times.

Innovative, well-balanced cognitive ability and character, a high capacity for learning, not only values but also a sense of purpose.

An open mind to technology and digitalization, data utilization, and contribution to Indonesia.

HR contributes to business objectives by adapting to technology and changing times by striking a balance between cognitive ability and character, learning opportunities, and self-development.

Responsible, striving for the best result, persistent, managing stakeholders, processing data, collaborating, balancing cognitive ability and behavior, and purposeful.

Discussion on culture, adapting to the rapid changes, less hierarchical structure, digital savvy, collaborative, innovative, processing of pharmaceutical data.

Professionals in the pharmaceutical industry must possess cross-disciplinary skills, specifically mastery of technology and data processing. It is critical to react quickly to the transformation.

Intrapreneurship skills, entrepreneurship skills, data analytics, cognitive ability, soft skills, purpose, digital mindset, analytical thinking, persistence.

Intrapreneurship, innovative, adaptive, dynamics.

Digital mindset, technology savvy, data analytics, purposeful.

Tele-pharmacy, cognitive ability, soft skills, entrepreneurial skills, learning, and self-development.

Intrapreneurship skills, entrepreneurship skills, data analytics, cognitive ability, soft skills, purpose, digital mindset, analytical thinking, persistence.

Innovative, agile, intrapreneurship, bioinformatics.

Technological savvy, bioinformatics, precision medicine.

Biotechnology, research skills, technology adoption.

Tele-pharmacy, data science, data analytics, agility.

Digital mindset, responsive, innovative, adaptive, dynamics.

Learning agility, innovation, regulatory compliance.

Table 5. Qualitative data coding.

| Respondent | Quotation | Code |
|------------|-----------|------|
| Q1         | Capable of adapting to rapid change, prepared to deal with digitalization, and keeping up with the times. | Agility, change management, digital mindset |
| Q2         | Innovative, well-balanced cognitive ability and character, a high capacity for learning, not only values but also a sense of purpose | Innovative, leadership, business acumen, learning capability, entrepreneurship, respect, persistence, critical skills, purposeful, Intrapreneurial skills, entrepreneurial skills, analytical skills, |
| Q3         | An open mind to technology and digitalization, data utilization, and contribution to Indonesia | Digital mindset, technology savvy, data analytics, purposeful |
| Q4         | HR contributes to business objectives by adapting to technology and changing times by striking a balance between cognitive ability and character, learning opportunities, and self-development | Tele-pharmacy, cognitive ability, soft skills, entrepreneurial skills, learning, and self-development |
| Q5         | Responsible, striving for the best result, persistent, managing stakeholders, processing data, collaborating, balancing cognitive ability and behavior, and purposeful. | Intrapreneurship skills, entrepreneurship skills, data analytics, cognitive ability, soft skills, purpose, digital mindset, analytical thinking, persistence |
| Q6         | Discussion on culture, adapting to the rapid changes, less hierarchical structure, digital savvy, collaborative, innovative, processing of pharmaceutical data. | Innovative, agile, intrapreneurship, bioinformatics. |
| Q7         | Professionals in the pharmaceutical industry must possess cross-disciplinary skills, specifically mastery of technology and data processing. It is critical to react quickly to the transformation. | Technological savvy, bioinformatics, precision medicine |
| Q8         | Interdisciplinary between genomic and biotechnology, responsive to rapid transformation, acceleration for product research and development based on technology and data utilization. | Biotechnology, research skills, technology adoption |
| Q9         | Individuals working in the pharmaceutical industry must also be familiar with data science and analytics. Pharmacy has shifted its focus to tele-pharmaceuticals in response to the current trend. The rapid pace of change requires a high degree of adaptability. | Tele-pharmacy, data science, data analytics, agility. |
| Q10        | Every employee needs to have a basic understanding of design thinking, even though there is no need to be an expert in digital technology. Maintaining the digital culture/mindset of employees is necessary to keep updated with the latest digital technology. With rapid technological advancements/changes, employees (including digital natives) are sometimes resistant to adopting new technologies, as in employees who belong to groups other than millennials. | Digital mindset, responsive, innovative, adaptive, dynamics |
| Q11        | Pharmaceutical companies must be able to optimize technology in order to increase access and tracking. However, human resources must possess regulatory compliance expertise. Human resources must be adaptable and innovative. | Learning agility, innovation, regulatory compliance |

Table 6. Competency description and definition from FGD and semi-structured interview.

| Theme                      | Code                       | Definition                                                                 |
|----------------------------|----------------------------|---------------------------------------------------------------------------|
| Intrapreneurial skills     | Collaboration, stakeholder management, partnership | Ability to work together to optimize potential and achieve common goals |
| Entrepreneurial thinking   | Entrepreneurship, innovation, dynamics, adaptive, responsive, learning ability | Ability to have creative thinking, create innovation, and implement it |
| Critical Thinking          | Cognitive, critical skills, data analytics, problem-solving | Ability to respond fast to recent changes or challenges Ability to analyze the problems and share insight for decision-making |
| Digital skills             | Digital mindset, digital literacy, technology savvy | Ability to continuously update with the contemporary digital technology, understand it, and use it effectively |
| Bioinformatics             | Biotech, tele-pharmacy, precision medicine | Ability to process the information for pharmaceutical industry development |
| Regulatory compliance      | Regulatory intelligence | Ability to constantly update, understand, and comply with national and international regulations |
| Data ethics                | Data ethics, data security | Ability to protect data and follow the data ethic of the public health information |

Figure 2. Word cloud of NVivo.

Previous research did not address the competencies associated with the digital age, especially in the Pharma 4.0 era (Anderson et al., 2010; Liboni et al., 2019). Based on the literature review and confirming competencies through the Delphi method, the findings indicate that digital skills are the most prioritized skill. The capabilities involve a basic ability to process information and communication technology (ICT) (Jarab et al., 2021; Wuri Handayani et al., 2018). ICT is at
the core of rapid change in the economy and is the foundation for innovation. In the Industrial 4.0 era, today’s workplace requires highly skilled workers faced with increasingly complex and interactive tasks (Danzysz et al., 2019b; Eger and Mahlich, 2014; Sony and Naik, 2019). In addition to increasing digital capabilities, employees must also prepare their managerial and technical capabilities (Asbari et al., 2020; Kumar et al., 2020; Pazireh et al., 2019).

Apart from digital capabilities, entrepreneurial thinking is required to achieve the aim of Pharma 4.0. Entrepreneurial thinking is required not only by employers but also by employees (Bissola et al., 2017; Leitch and Volery, 2017; Mohamad et al., 2019). Entrepreneurial thinking is critical in the pharmaceutical sector because it enables individuals to develop products and services collaboratively and rapidly in response to technological advancements and market conditions (Peschl et al., 2021). Besides, intrapreneurial thinking is necessary to comprehend the internal and external environment. Intrapreneurial is a term that refers to the technique of empowering employees within a business or organization by analyzing employee ideas and converting them into new profit or commercial opportunities for the business (van Wetten et al., 2020). These skills must be developed through critical thinking to identify an issue, unearth pertinent facts and evidence, simplify information, and apply reasoned logic. Critical thinking abilities have been traditionally seen as critical for aspiring pharmacists. It is paramount for various reasons, including the ability to use available resources strategically, be output-oriented, and be able to examine problems from multiple perspectives, and integrate them systematically (Ennis, 2018).

This research led to the development of new talent, namely regulatory compliance. The pharmaceutical sector faces numerous obstacles as it expands. Regulatory issues hinder the pharmaceutical industry (Jambulingam and Kathuria, 2020). Pharmaceutical items are highly regulated, and personnel must understand them for the sector to thrive and innovate (Blind, 2012). Regulatory compliance refers to the ability to keep abreast of and comprehend changes in the pharmaceutical industry’s legislation and regulations. Additionally, this research demonstrates that data ethics is one of the most critical abilities in today’s pharmaceutical industry (Delpasand et al., 2018). It is a subject of ethics examining data practices—the collecting, creation, analysis, and dissemination of structured and unstructured data—that may negatively impact persons and society. Ethical data usage is critical for innovation, scientific and medical advancement, patient safety, and healthcare improvement, benefiting individual patients and society. Finally, the study’s findings have substantial consequences for the concept of necessary competency profiles. Employees in the pharmaceutical business have a high level of technical skills. This research provides technical expertise and new perspectives on intelligent industrial systems.

5.2. Leveling of Digital Pharma Implementation

This research is the first to explain and improve the application of digital pharmaceuticals. As a benchmark, this research determined that the median value for digital implementation is 3.5, and the value below needs to be improved to enhance the implementation of digital leveling phama. The analysis of leveling implementation reveals that most national pharmaceutical industries are at level 2 (automatization) (mean = 4.2) and level 3 (integrated system) (mean = 3.5). Most pharmaceutical industries automatically transfer to the fully integrated stage between one process and another at level 3 (see Figure 4). Participants expect that the pharmaceutical industry in Indonesia can develop digital implementation at least at level 4 (digital transformation) in the next five years. Other countries are preparing both technology and human resources to reach level 5 (disease prediction) (Hemanth Kumar et al., 2020a; Rahaman et al., 2019; Sousa Pinto et al., 2021).

Table 8 shows that the development of bureaucratic simplification is still required (mean = 3.1). The pharmaceutical industry is closely related to complex bureaucracy and often changes over time. With this, the pharmaceutical industry can prepare digital technology in anticipation of complex bureaucracy. Simplifying testing and production (mean = 3.4) is also sometimes still monitored complicated in the pharmaceutical industry. The sheer number of tests in the production process sometimes makes the production process slow. The development of digitalization, automation, and online testing in the control process is an opportunity for the pharmaceutical industry. Digitization and automation will have a significant impact with a clear planning process. New advances in equipment connectivity enable direct transcription of thousands of data points without manual or review data input (Danzysz et al., 2019a; Minero and Augeri, 2018).

Quantitative research results show that the highest level of the Indonesian pharmaceutical industry is at level 2 and is heading for
To improve the achievement of level 3, the pharmaceutical industry needs to enhance the performance of the integrated quality management system (mean = 3.2), integrated continuous manufacturing (mean = 3.3), and process and regulatory integration (mean = 3.1). The pharmaceutical industry is determined by specific regulations, compliance, and application to ensure quality, safety, and efficiency of finished products. Quality management is necessary to provide customers with excellent product quality to maintain human health and quality of life (Rantanen and Khinast, 2015). The quality control process must be carried out in the manufacturing process from the beginning, during, and end of the product. Moreover, the supply and demand for drug needs increased drastically during the pandemic era (Ajaz et al., 2021). Sustainable processes are needed in the pharmaceutical industry to produce better quality products, improve yield, and lower costs and time.

As for levels 4 and 5 (Tables 11 and 12), Figure 5 shows that the Indonesian pharmaceutical industry needs to improvise many aspects, including digital transformation and disease prediction. AI and Big Data have not been done evenly in every international pharmaceutical industry (Cave, 2020). At this time, the quick and precise discovery of the drug is indispensable. AI and Big Data can help the pharmaceutical

### Table 7. Measurement tools for digital levelling in pharmaceutical industry.

| Digital Levelling | Description                                                                 | Var | 1   | 2   | 3   | 4   | 5   |
|-------------------|-----------------------------------------------------------------------------|-----|-----|-----|-----|-----|-----|
| **Level 1 – Simplification** |                                                                 |     |     |     |     |     |     |
| SOP Simplification |                                                                 | L1.1| 0   | 0   | 0   | 0   | 0   |
| Testing and Production Process Simplification |                                                                 | L1.2| 0   | 0   | 0   | 0   | 0   |
| Bureaucracy Simplification |                                                                 | L1.3| 0   | 0   | 0   | 0   | 0   |
| Bio Process (R&D, Production, QA, QC, and Packaging) simplification |                                                                 | L1.4| 0   | 0   | 0   | 0   | 0   |
| Supply Chain Simplification |                                                                 | L1.5| 0   | 0   | 0   | 0   | 0   |
| **Level 2 – Automatization** |                                                                 |     |     |     |     |     |     |
| Self-Operated Production Process |                                                                 | L2.1| 0   | 0   | 0   | 0   | 0   |
| Process, Environment, and Utility Control Automation |                                                                 | L2.2| 0   | 0   | 0   | 0   | 0   |
| Automation Testing and Production |                                                                 | L2.3| 0   | 0   | 0   | 0   | 0   |
| Automation in Regulatory Control |                                                                 | L2.4| 0   | 0   | 0   | 0   | 0   |
| Automation in Detecting Process Failures (CMA, CPP, and CQA) |                                                                 | L2.5| 0   | 0   | 0   | 0   | 0   |
| Automation in the Reporting Process |                                                                 | L2.6| 0   | 0   | 0   | 0   | 0   |
| Automation in Product Research and Development |                                                                 | L2.7| 0   | 0   | 0   | 0   | 0   |
| **Level 3 – Integrated System** |                                                                 |     |     |     |     |     |     |
| Integrated Quality Management System |                                                                 | L3.1| 0   | 0   | 0   | 0   | 0   |
| Supply Chain Track and Trace System |                                                                 | L3.2| 0   | 0   | 0   | 0   | 0   |
| Integrated Continuous Manufacturing |                                                                 | L3.3| 0   | 0   | 0   | 0   | 0   |
| Integrated Performance Measurement |                                                                 | L3.4| 0   | 0   | 0   | 0   | 0   |
| Process and Regulatory Integration |                                                                 | L3.5| 0   | 0   | 0   | 0   | 0   |
| **Level 4 – Digital Transformation** |                                                                 |     |     |     |     |     |     |
| Big Data and Genomics in Drug Discovery |                                                                 | L4.1| 0   | 0   | 0   | 0   | 0   |
| Digitization of Clinical Trial Process such as Virtual Trials |                                                                 | L4.2| 0   | 0   | 0   | 0   | 0   |
| Use of Connected Devices and Robots in Manufacturing |                                                                 | L4.3| 0   | 0   | 0   | 0   | 0   |
| Real-Time Regulatory Updates |                                                                 | L4.4| 0   | 0   | 0   | 0   | 0   |
| Digital Marketing |                                                                 | L4.5| 0   | 0   | 0   | 0   | 0   |
| AI and Big Data in the Decision-Making Process |                                                                 | L4.6| 0   | 0   | 0   | 0   | 0   |
| Digital Supply Chain and E-Procurement |                                                                 | L4.7| 0   | 0   | 0   | 0   | 0   |
| **Level 5 – Disease Prediction** |                                                                 |     |     |     |     |     |     |
| Prediction of New Disease Discovery that has the potential to become an epidemic or pandemic |                                                                 | L5.1| 0   | 0   | 0   | 0   | 0   |
| New Drug Discovery Predictions |                                                                 | L5.2| 0   | 0   | 0   | 0   | 0   |
| Predicted Upcoming Regulatory Developments |                                                                 | L5.3| 0   | 0   | 0   | 0   | 0   |
| **Expected Level** |                                                                 |     |     |     |     |     |     |
| Expected Level for Indonesia Pharmaceutical Industry in Next five years |                                                                 | EL  | 0   | 0   | 0   | 0   | 0   |

### Table 8. Digital levelling- level 1 result.

| Variable | L1.1 | L1.2 | L1.3 | L1.4 | L1.5 | Overall Mean |
|----------|------|------|------|------|------|--------------|
| Max      | 4    | 5    | 3    | 5    | 5    | 4.3          |
| Min      | 2    | 1    | 1    | 3    | 3    | 3.1          |
| Mean     | 4.3  | 3.4  | 3.1  | 4.6  | 4.5  | 4.2          |
| Pearson Correlation | 0.79** | 0.76** | 0.82** | 0.83** | 0.69** |             |
| Sig      | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |              |

### Table 9. Digital levelling- level 2 result.

| Variable | L2.1 | L2.2 | L2.3 | L2.4 | L2.5 | L2.6 | L2.7 | Overall Mean |
|----------|------|------|------|------|------|------|------|--------------|
| Max      | 5    | 5    | 5    | 5    | 5    | 5    | 5    | 5.0          |
| Min      | 2    | 3    | 4    | 3    | 4    | 3    | 4    | 3.4          |
| Mean     | 4.2  | 4.4  | 4.5  | 4.1  | 4.6  | 4.3  | 3.9  | 4.2          |
| Pearson Correlation | 0.73** | 0.71** | 0.83** | 0.84** | 0.79** | 0.79** | 0.79** |             |
| Sig      | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |              |

### Table 10. Digital levelling- level 3 result.

| Variable | L3.1 | L3.2 | L3.3 | L3.4 | L3.5 | Overall Mean |
|----------|------|------|------|------|------|--------------|
| Max      | 4    | 5    | 4    | 4    | 4    | 4.0          |
| Min      | 2    | 3    | 2    | 2    | 1    | 2.5          |
| Mean     | 3.2  | 4.2  | 3.3  | 3.6  | 3.1  | 3.5          |
| Pearson Correlation | 0.69** | 0.72** | 0.81** | 0.83** | 0.76** |             |
| Sig      | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |              |
industry discover new compounds and develop potential drugs (Gregório and Cavaco, 2020; See et al., 2019). Currently, some countries deal with the mutations of new viruses, as there are predictions, but their accuracy remains unknown. Some new diseases must be predicted, so the industry must be anticipatory. It agrees with the previous findings, where developing countries attract attention by showing the potential for digitalization measures for the manufacturing industry (Kupfer, 2019). First, to be effective requires more complex capability requirements that will result in the rigorous learning efforts process. Second, digitalization implementation can be obtained in the short and long run. It also can mean structural change at firm, competitive and sectoral levels. Third, the investment cost for the implementation is continuous technical progress. The only guaranteed requirement is that the introduction of digital technology in firms requires efforts and capabilities at a level of effectiveness to adopt the intended solution. Fourth, the investment in digital technology in developing countries is limited. Hence, the labor force for firms needs to catch up with the notion of digital technology.

Digitalization technology is strongly related to the Pharma 4.0 practice. In the current years, it has been proved that the practice can improve access to medicines for pharmaceutical companies, ensure safety, and protect the well-being of society (Prikshat et al., 2019). Furthermore, the Pharma 4.0 practice is cascading within its value chain, including healthcare providers, pharmacies store, and distributors. The circumstances require a company to enhance its technologies, service, and labor capability to keep up with the current competition of Pharma 4.0. As mentioned above, implementing Pharma 4.0 activities has constraints for developing countries, especially Indonesian pharmaceutical companies. Exploiting new technologies in Pharma 4.0 will facilitate sustainable value creation, obtaining Indonesian pharmaceutical companies competitive advantages in the global market.

6. Conclusion

Overall, this study recommends that, first, digital skills are prominent and highly influential, implemented by smart manufacturing in the pharmaceutical industry. Other supporting skills, including intrapreneurial skills, entrepreneurial thinking, research skills, critical thinking, regulatory compliance, bioinformatics, and data ethics, are also mapped to fit the company’s business strategy. Second, the Assessment of digital implementation aims to identify potential risks, opportunities, and challenges associated with digitization. Additionally, digital implementation assessment enables the pharmaceutical industry to address issues. Third, Indonesia’s pharmaceutical industry is primarily at level 2 (automatization) and is progressing toward level 3 (integrated system). It is predicted to reach level 4 (digital transformation) in the next five years, incorporating digital transformation using artificial intelligence (AI), big data, and the Internet of Things (IoT). The pharmaceutical industry in Indonesia and other developing countries need to be well-prepared to achieve the projected future progress. It should be considered that the path to Pharma 4.0 has been made possible due to rapid digital changes. The adoption of digital technology can transform business models towards more efficient product quality, shorter waiting times, and increased flexibility, especially in terms of resource usage. The core of Pharma 4.0 itself is incorporating and integrating different but firm, competitive and sectoral levels. Third, the investment cost for the implementation is continuous technical progress. The only guaranteed requirement is that the introduction of digital technology in firms requires efforts and capabilities at a level of effectiveness to adopt the intended solution. Fourth, the investment in digital technology in developing countries is limited. Hence, the labor force for firms needs to catch up with the notion of digital technology.

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complementary digital technologies into concurrent systems. In summary, the research has produced outputs that have value and contributed to core competency development and digital leveling implementation for the pharmaceutical industry and government in Indonesia and other developing countries.

7. Limitation and future research

The findings are robust and important. However, there are some limitations to be acknowledged. The sample size was relatively small due to the time constraint in conducting the study, and the respondents were limited from the top level or senior management in Pharma. The framework of digital leveling may require additional studies on digital HR competency practices in pharma companies. Future studies on Mapping industrial readiness in the application of Pharma 4.0 can be carried out with a larger sample population.

Declarations

Author contribution statement

N. Nurlaela Arief, Doctor; Aghnia Nadhira Aliya Putri, SSi. Apt.: Conceived and designed the experiments; Performed the experiments; Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data; Wrote the paper.

Aurik Gustomo, Professor; Mas Rahman Roestan, Doctor; Muthya Islamiaty, SSi: Conceived and designed the experiments; Performed the experiments; Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data.

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Data availability statement

Data will be made available on request.

Declaration of interests statement

The authors declare no conflict of interest.

Additional information

No additional information is available for this paper.

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