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Exploring Biofarma's Readiness Factors Advancing from Integrated Systems to Predictive Analytics and Real-Time Monitoring

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Abstract:
The global pharmaceutical industry is navigating a complex landscape marked by technological fragmentation, supply chain disruptions, and rising costs, necessitating the adoption of Pharma 4.0 technologies such as predictive analytics, artificial intelligence (AI), and the Internet of Things (IoT). This study examines Biofarma's readiness to transition from Level 3 (*integrated systems*) to Level 4 (*real-time monitoring* and *predictive analytics*) within the Pharma 4.0 maturity framework, while exploring the role of these advanced technologies in enhancing operational efficiency and quality assurance. Using a quantitative approach, structured surveys were administered to 150 employees across various divisions at Biofarma. The collected data were analyzed through Exploratory Factor Analysis (EFA) and Confirmatory Factor Analysis (CFA) to identify latent readiness factors. Results revealed five critical dimensions influencing digital transformation readiness: *Perceived Usefulness* emerged as the dominant factor (explaining 49.09% of variance), followed by *Workforce Digital Competency*, *Technological Infrastructure Readiness*, *Stakeholder Alignment*, and *Ease of Use*. While Biofarma demonstrates strong foundational readiness, particularly in the perceived benefits of digital tools, the findings highlight key gaps in AI/IoT-specific training, real-time data infrastructure, and cross-functional collaboration. The study provides actionable insights for strategic investments to achieve full digital maturity, aligning with global Pharma 4.0 standards. These results contribute to both academic literature and practical implementation frameworks for digital transformation in regulated health technology industries.

Keywords: Pharma 4.0, Digital Transformation, Readiness Assessment, Exploratory Factor Analysis (EFA), Workforce Digital Competency.

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PENDAHULUAN

The pharmaceutical industry is navigating a complex landscape of rapidly growing global demand, driven by COVID-19 vaccines and therapeutics, as well as accelerated product innovations such as cell and gene therapies and mRNA vaccines. These advances in innovation contribute to increased technological fragmentation and evolving supply chains. Broader global challenges—including supply chain disruptions, inflation, and rising labor and material costs—are further constraining profitability. Moreover, increased state interventions and protectionist trade policies may require high-cost regionalization of manufacturing networks. Despite industry resilience through dual sourcing and inventory management, the sector faces sustained pressure to innovate while managing rising costs and geopolitical risks (McKinsey & Company, 2024).

Additionally, the pharmaceutical industry plays a critical role in global healthcare by developing, manufacturing, and distributing products essential for treating and preventing diseases (Tailor P et al., 2024). The following is information from the *Access to Medicine Index*: "The Access to Medicine Index ranks 20 of the world's largest research-based pharmaceutical companies on their efforts to improve access to medicines, vaccines, and diagnostics in low- and middle-income countries. The Foundation also publishes report cards, evaluating the actions these companies are taking to address key access-to-medicine priorities and highlighting areas for improvement" (Access to Medicine Foundation, 2024).

As the industry evolves, it is undergoing profound transformation, propelled by rapid advancements in digital technology. For example, Pfizer and Novartis have successfully implemented and benefited from *Industry 4.0* technologies to increase speed and efficiency in production and research and development processes, demonstrating the critical importance of technology adoption for maintaining competitiveness (Dhiman et al., 2024). These initiatives also illustrate how digital technology can redefine business processes in the pharmaceutical sector.

In this context, Biofarma, as a state-owned enterprise (*SOE*) in Indonesia and a key player in the global vaccine supply chain, is at a crucial juncture. Biofarma was previously the sole vaccine manufacturer capable of fulfilling all Indonesian state demand before the emergence of competitors such as Etana Biotech and Biotis, which have since joined the vaccine industry in Indonesia. Consequently, with increased competition, domestic demand from the state for Biofarma's products has decreased.

Biofarma is currently at Level 3 on its digital transformation journey, characterized by the implementation of integrated systems such as *Enterprise Resource Planning* (ERP), *Laboratory Information Management Systems* (LIMS), *electronic Quality Management Systems* (eQMS), and *electronic Batch Records* (e-BR). These systems enable efficient data processing and cross-department collaboration, supporting daily operational activities (N. Nurlaela Arief et al., 2022). While these systems facilitate operational integration, they do not yet provide real-time monitoring and predictive analytics required to advance to Level 4. Transitioning to real-time monitoring and predictive analytics is not merely a technological upgrade but a strategic necessity to ensure Biofarma's competitiveness, regulatory compliance, and contribution to global health objectives.

Based on the Pharma 4.0 framework and preliminary interviews conducted in 2024, Biofarma remains at Level 3 in its digital transformation, focusing on internal and external system integration through applications such as ERP, e-BR, LIMS, and eQMS (N. Nurlaela Arief et al., 2022). Although these technologies have already enhanced operational efficiency and compliance, the transition to Level 4 still presents significant challenges.

Digital transformation to Level 4 is imperative for pharmaceutical companies adopting Pharma 4.0 technologies to increase agility, ensure compliance, and achieve sustainability objectives. For instance, Pfizer has integrated AI and IoT to enhance supply chain and production process efficiency, while Novartis leverages predictive analytics to accelerate medicine research and development, providing tangible examples of the benefits of digital transformation in this industry (Dhiman et al., 2024). This transformation also supports

Indonesia's *ASTACITA* agenda by accelerating digital transformation in the pharmaceutical sector, thereby enhancing industrial efficiency and national self-reliance.

A significant gap exists between Biofarma's current Level 3 status and the desired Level 4, which requires sophisticated predictive capabilities. To analyze readiness for this digital transformation, this research employs the Exploratory Factor Analysis (EFA) method. EFA is a statistical tool used to identify and group factors influencing an organization's capability to adopt advanced digital technologies. EFA will help uncover latent variables such as technology readiness, workforce digital skills, and critical stakeholder alignment necessary for advancing to Level 4. The results of EFA will provide a structured framework for evaluating readiness factors and identifying gaps to achieve the desired level of digital maturity.

Pharma 4.0 can significantly improve efficiency in production, quality control, and time-to-market by enabling process automation and advanced analytics utilization. Organizations can enhance *Overall Equipment Effectiveness* (OEE), ensure line balancing, and streamline work order management to achieve operational excellence. The implementation of IoT, AI, and big data analytics in Pharma 4.0 has demonstrated increased operational efficiency and cost reduction across various pharmaceutical sectors (A. Zaman et al., 2024), further underscoring the urgency for Biofarma to address transformation challenges.

The company faces the challenge of accelerating digital transformation to Level 4, in alignment with global requirements for transparency and regulatory compliance (N. Nurlaela Arief et al., 2022). This study aims to evaluate Biofarma's readiness to progress from Level 3 to Level 4 digital maturity, emphasizing the use of real-time monitoring systems, artificial intelligence (AI), Internet of Things (IoT), and predictive analytics to enhance operational efficiency and quality assurance. To ensure a robust and focused analysis, the study employs frameworks such as Exploratory Factor Analysis (EFA) and Pharma 4.0 maturity models, concentrating solely on readiness elements rather than financial modeling or cost-benefit analysis for Level 4 digital maturity implementation.

RESEARCH METHOD

Examining Biofarma's readiness for moving from Level 3 to Level 4 digital maturity this study using a quantitative research tool, to make sure a comprehensive assessment by collecting quantitative data on the digital transformation process. It involves the following key techniques:

Survey-Based Data Collection:

Biofarma employee in a number of divisions, including supply chain, operations, IT, and quality assurance, get structured questions. This guarantees that viewpoints from many functional domains are recorded, offering a comprehensive perspective on organizational readiness (Zaman et al., 2024). The purpose of the survey is to evaluate important readiness variables:

- Technological capabilities (AI, IoT adoption, IT infrastructure)
- Workforce readiness (digital literacy, willingness to adopt new technologies)
- Regulatory alignment (understanding of compliance frameworks such as WHO GMP, PIC/S, and FDA 21 CFR)
- Financial constraints (budget limitations affecting digital investments)
- Change management factors (organizational resistance, stakeholder collaboration)

The survey questions are adapted from validated models, such as The Technology Acceptance Model (TAM) to measure perceived usefulness and ease of use of Pharma 4.0 technologies and Regulatory compliance metrics based on WHO GMP guidelines (IRAQI HOUSSAINI, 2017; Venkatesh & Bala, 2008; Yazdanpanahi et al., 2024).

Exploratory Factor Analysis (EFA)

EFA is used to identify and group latent variables influencing Biofarma's ability to transition to Level 4. This method is essential for structuring multi-dimensional factors such as technological capability, financial investment, and regulatory compliance into measurable components (Saadah & Hendarman, 2022). To extract important readiness dimensions, EFA applies Principal Component Analysis (PCA) (Dhiman et al., 2024). Previous research supports the validity of EFA-based readiness evaluations for this study by showing their success in Pharma 4.0 deployments globally (Zulqarnain et al., 2022). EFA Implementation steps:

A. Use Principal Component Analysis (PCA) to extract key components explaining the variance in responses (Zaman et al., 2024).
B. Ensure the factors align with theoretical constructs in Pharma 4.0 readiness models (N. Nurlaela Arief et al., 2022)
C. Perform Confirmatory Factor Analysis (CFA) to validate factor structures against existing Pharma 4.0 frameworks (Zulqarnain et al., 2022) including the SEM (structural Equation Model) to validate the CFA.

According to the latest data, total employees of Biofarma has a population of 1,835 people, this will be adjusted proportionate using stratified sampling approach to choose the amount of survey sample. Recognizing that digital transformation activities affect all functional areas of the firm, not just certain departments, the sampling approach disseminated participants proportionally throughout the workforce. The targeted respondent is 150 people. This sample size yields an approximate margin of error of 7-8%, which is deemed appropriate for organizational research (Creswell & Creswell, 2018).

Structured questionnaires are created to examine important aspects including worker skills, stakeholder alignment, and technology readiness to evaluate Biofarma's readiness for digital transformation. In order to ensure validity and reliability in assessing the elements driving Biofarma's transition to Level 4 Pharma 4.0, these questions were modified from validated constructs in the literature (Saadah and Hendarman, 2022). The main instrument for obtaining quantitative information from internal stakeholders is the questionnaire, which enables statistical assessment of digital maturity components and exploratory factor analysis (EFA). The questionnaire includes core constructs that capture Biofarma's digital transformation readiness:

- Technological Readiness (TR): Evaluates whether Biofarma's existing digital infrastructure can support advanced Pharma 4.0 technologies
- Workforce Digital Competency (WC): Assesses employees ability to adapt and utilize digital tools effectively.
- Perceived Ease of Use (PE): Measures how user-friendly digital transformation initiatives are for Biofarma employees.
- Perceived Usefulness (PU): Evaluates whether employees believe that AI, IoT, and predictive analytics improve efficiency.
- Stakeholder Alignment (SA): Assesses how well departments collaborate to integrate digital technologies

Questionaries administration would be as follow, The questionnaire is structured with Likert-scale responses to quantify perceptions and readiness levels will be sent electronically to a diverse group

of stakeholders, including management, IT personnel, operations teams, and regulatory compliance staff within Biofarma. The collected responses will be statistically analyzed using Exploratory Factor Analysis (EFA) to identify key readiness factors.

RESULTS AND DISCUSSION

The analysis reveals the underlying readiness dimensions by means of data suitability assessment, factor extraction, and preliminary interpretation of component structures.

Extracting key components explaining the variance in responses using Principal Component Analysis (PCA) (Zaman et al., 2024). Here are PCA loadings results:

	PC1	PC2	PC3	PC4	PC5	PC6	PC7	PC8	PC9	PC10	PC11	PC12	PC13	PC14	PC15	PC16	PC17	PC18	PC19
TR1	-0,164	-0,394	0,127	0,230	0,138	0,039	0,168	0,120	0,137	-0,262	0,222	-0,027	0,040	0,470	-0,179	-0,243	0,181	-0,268	-0,280
TR2	-0,187	-0,179	0,359	0,155	-0,253	-0,091	-0,222	-0,029	-0,017	0,234	0,131	-0,319	-0,103	-0,366	0,114	-0,122	0,427	-0,027	0,107
TR3	-0,167	-0,305	0,182	0,225	-0,105	0,239	0,478	-0,164	-0,185	0,116	-0,142	0,185	-0,060	0,123	-0,070	0,093	0,069	0,402	0,296
TR4	-0,191	0,150	0,261	0,311	0,242	0,288	-0,071	0,011	0,039	-0,009	-0,207	-0,362	-0,057	-0,098	-0,190	-0,112	-0,523	0,119	-0,045
TR5	-0,192	0,087	0,108	0,243	-0,436	-0,137	-0,079	0,054	-0,406	-0,164	-0,197	0,168	0,158	-0,046	-0,017	-0,160	-0,283	-0,406	0,079
WC1	-0,167	0,239	0,165	0,260	0,176	0,291	-0,409	-0,086	-0,047	0,064	0,474	0,302	0,231	0,149	0,085	0,235	0,093	-0,039	0,142
WC2	-0,156	-0,377	-0,018	-0,135	0,313	-0,196	0,022	-0,232	-0,020	0,362	0,202	0,299	-0,155	-0,257	-0,175	-0,004	-0,358	-0,253	-0,012
WC3	-0,194	0,209	-0,010	0,017	0,361	-0,408	-0,007	0,071	-0,344	0,047	-0,124	0,091	0,072	0,174	-0,010	-0,151	0,160	0,267	0,065
WC4	-0,209	-0,084	-0,182	0,186	0,306	-0,283	-0,284	-0,002	-0,210	-0,074	-0,168	-0,113	-0,277	0,034	0,028	0,116	0,119	0,048	-0,088
WC5	-0,192	0,016	-0,133	0,019	0,037	0,170	0,149	0,789	-0,082	0,183	-0,035	0,139	-0,058	-0,207	-0,142	0,212	0,127	-0,070	0,001
PE1	-0,186	-0,278	-0,179	0,099	0,222	0,124	-0,008	-0,085	0,200	-0,323	-0,350	0,101	0,293	-0,257	0,411	0,249	0,055	-0,157	0,143
PE2	-0,192	0,003	-0,295	-0,291	0,022	0,381	-0,106	-0,192	-0,277	-0,162	-0,017	-0,243	0,106	-0,070	-0,461	0,020	0,186	-0,123	-0,064
PE3	-0,200	-0,128	-0,237	-0,266	-0,008	0,284	-0,140	0,094	-0,099	0,356	-0,073	-0,086	0,032	0,272	0,343	-0,464	-0,051	-0,064	0,231
PE4	-0,203	-0,106	0,146	-0,270	-0,159	-0,199	-0,277	0,187	0,298	-0,175	-0,074	-0,049	-0,163	0,347	-0,203	0,273	-0,169	0,025	0,456
PE5	-0,213	-0,280	0,058	-0,090	-0,143	-0,010	-0,293	0,098	0,136	-0,082	-0,064	0,053	0,093	-0,059	0,141	-0,136	-0,085	0,396	-0,440
PU1	-0,211	0,161	0,286	-0,293	0,083	0,051	0,013	-0,034	0,301	0,151	-0,148	0,185	0,145	-0,088	-0,124	-0,120	0,062	-0,046	-0,017
PU2	-0,214	0,179	0,274	-0,291	0,025	-0,061	0,094	-0,097	-0,044	-0,155	-0,139	0,218	0,229	-0,091	-0,120	-0,086	0,166	0,109	-0,133
PU3	-0,228	-0,085	0,107	-0,181	-0,136	-0,230	0,222	-0,020	-0,172	0,035	0,145	-0,227	0,172	0,019	0,083	0,282	-0,038	-0,196	-0,122
PU4	-0,223	0,138	0,116	-0,225	0,015	0,124	0,163	-0,212	-0,182	-0,037	0,041	-0,182	-0,275	0,197	0,351	0,280	-0,051	-0,047	-0,091
PU5	-0,205	0,289	0,117	-0,032	0,201	0,018	0,285	0,149	0,193	-0,186	0,158	-0,103	-0,284	-0,151	0,241	-0,176	0,010	-0,167	0,016
SA1	-0,226	-0,053	-0,231	-0,052	-0,119	-0,035	0,060	0,067	-0,053	-0,217	0,491	-0,096	0,091	-0,235	-0,028	0,024	-0,218	0,391	0,065
SA2	-0,218	0,147	-0,304	0,107	-0,103	-0,149	0,132	-0,148	0,177	-0,225	0,152	0,117	-0,053	-0,078	-0,023	-0,355	0,029	0,017	0,290
SA3	-0,213	0,115	-0,157	0,084	-0,278	0,155	-0,112	-0,167	0,092	-0,012	-0,120	0,348	-0,556	-0,007	-0,069	0,064	0,119	-0,019	-0,247
SA4	-0,210	0,123	-0,223	0,231	-0,031	-0,145	0,087	-0,189	0,338	0,304	-0,126	-0,282	0,173	0,031	-0,230	0,114	0,169	-0,054	0,076
SA5	-0,217	0,189	-0,220	0,139	-0,193	-0,092	0,110	0,014	0,161	0,302	0,007	0,024	0,224	0,217	0,135	0,132	-0,177	0,044	-0,326

Figure 1. PCA loadings results

Explained variance per component results:

Principal Component	Explained Variance Ratio	Cumulative Variance
PC1	49,1%	49,1%
PC2	7,9%	57,0%
PC3	4,8%	61,8%
PC4	4,1%	65,9%
PC5	4,0%	69,9%
PC6	3,2%	73,1%
PC7	2,8%	75,9%
PC8	2,4%	78,3%
PC9	2,2%	80,5%
PC10	2,2%	82,7%
PC11	2,0%	84,7%
PC12	1,9%	86,6%
PC13	1,8%	88,3%
PC14	1,6%	90,0%
PC15	1,6%	91,5%
PC16	1,5%	93,0%
PC17	1,4%	94,4%
PC18	1,3%	95,7%
PC19	1,2%	96,9%
PC20	1,1%	98,0%
PC21	1,0%	98,9%
PC22	0,8%	99,7%
PC23	0,8%	100,5%
PC24	0,7%	101,2%
PC25	0,6%	101,8%

Figure 2. Explained Variance per Component Results

The table above presents the variance explained by each principal component (PC1 through PC25) from the survey data, extracted using Principal Component Analysis (PCA). PC1 explains approximately 49.09% of the total variance, making it the most significant component, at PC5, around 69.90% of the variance is explained, which is typically considered sufficient for summarizing the structure of the data. PC6 to PC10 add smaller portions of variance (~3.2% to 2.2% each), potentially capturing more subtle

patterns. PC11 to PC25 contribute very little individually (less than 2% each), often considered noise or less interpretable variations unless strongly justified.

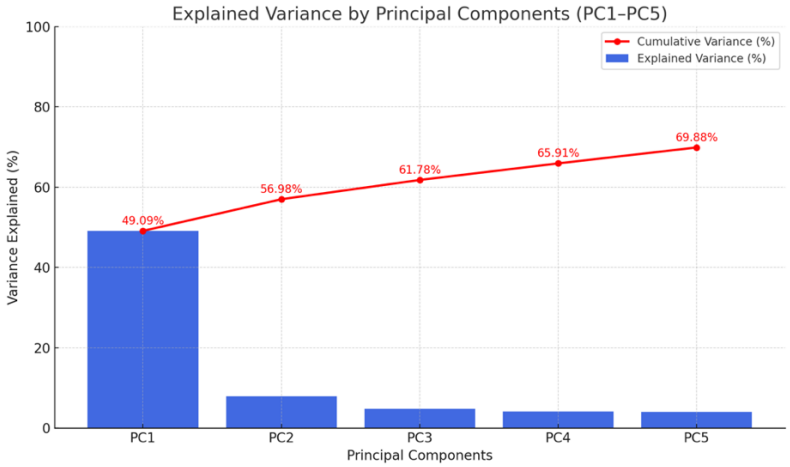

Figure 3. Explained Variance by Principal Component (PC1 – PC5)

This chart only represents the percentage of variance explained by component PC1 to PC5. This chart illustrates that **PC1 alone accounts for 49.09%,** and **by PC5,** we reach **approximately 69.9%** of the total variance explained, thus these five components capture most of the important patterns in the data.

Table 1. PCA Analysis

Component	High Loadings	Interpretation	Implication
PC1 – Perceived Usefulness & Operational Impact	PU1, PU2, PU3, PU4, PU5	Reflects employee belief in the usefulness of digital transformation for operational excellence and compliance.	High scores suggest strong belief in AI, IoT, and analytics for enhancing operations and compliance.
PC2 – Workforce Digital Competency	WC1, WC2, WC3, WC4, WC5	Captures employee confidence and support in digital skills and training.	Employees feel well-prepared digitally and supported by training programs.
PC3 – Technological Infrastructure Readiness	TR1, TR2, TR3	Measures confidence in company's digital infrastructure readiness for Pharma 4.0.	Confidence in ERP, data systems, and AI capabilities for digital transformation.
PC4 – Stakeholder Alignment	SA1, SA2, SA3	Indicates the level of inter-departmental collaboration and leadership support for digital initiatives.	Effective collaboration and alignment among teams and leaders in digital transformation.
PC5 – Ease of Use of Digital Systems	PE1, PE2, PE3	Assesses user-friendliness and accessibility of digital tools.	Low resistance to adoption due to ease of system use.

This PCA analysis demonstrates that Perceived Usefulness is the most important hidden factor influencing Biofarma's digital transformation readiness. It accounts for nearly half of the variance in survey responses, indicating that employees' confidence in the utility of AI, IoT, and predictive analytics—particularly in terms of improving efficiency, compliance, and supply chain transparency—is a major motivator for their willingness to embrace pharma 4.0 technologies. We contrast the PCA-

derived elements with the core competencies and digital readiness themes specified in the Pharma 4.0 Digital Transformation Leveling study by N. Nurlaela Arief et al. (2022) to guarantee that the Principal Component Analysis (PCA) factors extracted from the survey fit the theoretical constructs.

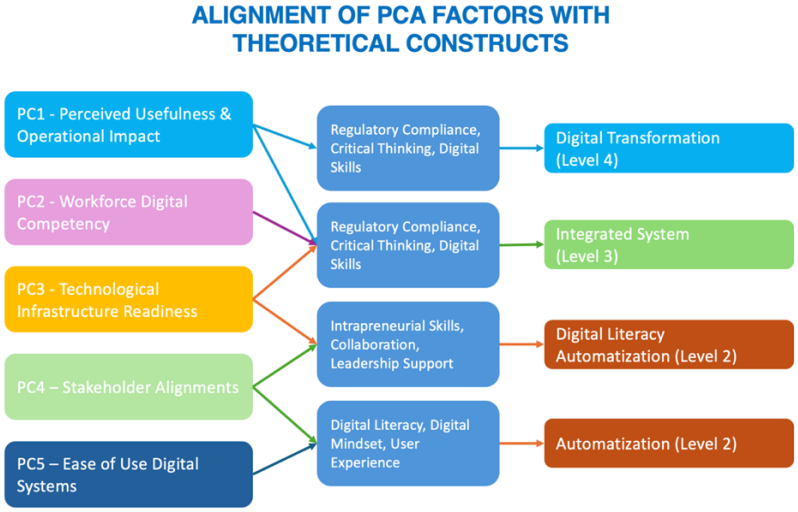

Figure 4. Alignment of PCA Factors With Theoretical Construct

These are the evidences (Arief et al., 2022):

- Core competencies: include digital skills, regulatory compliance, bioinformatics, critical thinking, and data ethics.
- Digital leveling: the journey from simplification in Level 1 until desease prediction in Level 5
- Survey Structure: The five PCA components is perfectly mirror the survey characteristics required to assess readiness and competency for Pharma 4.0.

The results of PCA are very consistent to the theoretical constructions of Pharma 4.0 model. This verifies the survey instrument's structure and confirms that the selected elements, such as Perceived Usefulness and Digital Competency, are important and supported by current literature.

A Confirmatory Factor Analysis (CFA) was performed to confirm the factor structure of the survey instrument and guarantee alignment with defined constructs in Pharma 4.0 and Quality 4.0 frameworks, therefore validating factor structures against current Pharma 4.0 frameworks. Statistical verification by CFA shows that the identified latent variables—such as Perceived Usefulness, Workforce Competency, and Technological Readiness—are in line with theoretical expectations derived from earlier models (Zulqarnain et al., 2022; N. Nurlaela Arief et al., 2022). This stage is essential to support the construct validity of the measurement tool by confirming that observed variables correctly reflect the underlying readiness dimensions vital to digital transformation in the pharmaceutical sector. The resulting factor loadings and model fit support the robustness and applicability of the survey design to assess Biofarma's readiness for transitioning to Pharma 4.0 maturity. The following alignment was discovered using Digital Levelling (N. Nurlaela Arief et al., 2022) and the 11 Dimensions of Quality 4.0 (Zulqarnain et al., 2022):

Table 2. PCA Factor Alignment to Pharma 4.0 Construct

PCA Factor (Survey Result)	Corresponding Pharma 4.0 Construct
Perceived Usefulness & Operational Impact	Compliance, Analytics, Data, Management Systems

Workforce Digital Competency	Competency, Digital Skills, Culture
Technological Infrastructure Readiness	Connectivity, App Development, Scalability, Web-based Applications
Stakeholder Alignment	Collaboration, Leadership, Internal-External Coordination
Ease of Use of Digital Systems	Culture, User-Friendliness, ERP System Design

Discussion

Using organized survey responses, the goal is to find and assess important latent factors affecting Biofarma's Pharma 4.0 preparation. Since every latent construct generated using PCA and validated via CFA closely corresponds with major ideas from existing Pharma 4.0 and Quality 4.0 frameworks, this mapping confirms the theoretical validity of the found components. For example:

- As N. Nurlaela Arief et al. (2022) explain, the Operational Excellence and Regulatory Compliance pillars of Pharma 4.0 directly connect to Perceived Usefulness and Operational Impact. This component includes respondents' perceptions that AI, IoT, and predictive analytics improve process efficiency, transparency, and compliance—all important aims of digital transformation in regulated businesses.
- Workforce Digital Competency corresponds to the People & Organization domain in the Pharma 4.0 Readiness Index. It demonstrates employees' readiness to adapt and use new technologies, which Zulqarnain et al. (2022) consider to be a fundamental criterion for digital maturity.
- Technological Infrastructure Readiness corresponds to the Digital Infrastructure pillar of the Quality 4.0 framework. This factor assesses readiness in terms of system integration, data platforms, and AI/IoT capabilities required for real-time operations.
- Stakeholder Alignment shows the importance of cross-functional collaboration and top-down digital leadership, both of which are highlighted in Pharma 4.0 literature as essential enablers of organizational transformation.
- Ease of Use of Digital Systems is related to the User Experience and Technology Acceptance constructs, which are commonly mentioned in both TAM (Technology Acceptance Model) theories and Pharma 4.0 implementation recommendations.

Thus, the CFA findings confirm that the survey constructs are not only statistically valid, but also anchored in the larger theoretical and operational models controlling digital transformation in pharmaceutical firms. This improves both the construct validity and the model's practical usefulness in measuring Biofarma's readiness to transition to Pharma 4.0 maturity.

From all of the analysis here are the key findings:

1. Perceived Usefulness is the Dominant Readiness Factor Driver
   PCA results revealed that employees' belief in the operational benefits of digital tools (AI, IoT, analytics) strongly influences readiness for digital transformation. This dimension showed the highest variance explained.
2. Workforce Digital Competency and Infrastructure Readiness are Foundational Enablers

Survey and interview results confirm that workforce skills and system capabilities significantly affect readiness. Although general digital literacy is strong, gaps in AI/IoT-specific training and real-time data infrastructure still exist.

3. Ease of Use and Stakeholder Alignment Influence Adoption
   Ease of use and cross-departmental support were identified as moderate influencers of readiness. Improving system intuitiveness and collaborative engagement are key strategic levers.

The analysis confirms that Biofarma is strategically positioned to transition toward Pharma 4.0, with clear strengths in perceived usefulness, stakeholder engagement, and regulatory integration. However, achieving full digital maturity will require enhanced focus on infrastructure scalability, intuitive system design, and specialized digital upskilling. These findings form the evidence base for strategic recommendations in the final chapter and serve as a foundation for further research into implementation pathways.

CONCLUSION

This study evaluated Biofarma's readiness to advance from Level 3 to Level 4 in the Pharma 4.0 maturity framework, identifying five key factors—Ease of Use, Stakeholder Alignment, Technological Infrastructure Readiness, Workforce Digital Competency, and Perceived Usefulness—through Exploratory and Confirmatory Factor Analysis. Perceived Usefulness emerged as the most influential factor, highlighting strong employee belief in the benefits of technologies like AI, IoT, and predictive analytics for operational efficiency and compliance, while workforce competency and infrastructure were also foundational but limited by gaps in AI/IoT training and real-time data integration. The study's alignment with established frameworks validates its practical relevance for Biofarma's strategic planning, emphasizing the need for targeted upskilling, infrastructure upgrades, and enhanced cross-functional collaboration to achieve Level 4 digital maturity and global competitiveness. For future research, it is recommended to conduct longitudinal studies that track the impact of specific digital interventions and training programs over time, as well as to explore the integration of emerging technologies such as blockchain for further strengthening transparency and regulatory compliance in pharmaceutical operations.

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