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Development of Digital Competency Framework for Vaccine Manufacturing Industry

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Abstract

Background: Digital transformation in vaccine manufacturing requires advanced technologies and competent personnel capable of operating within highly regulated environments. Existing digital competency frameworks remain broad and insufficiently address critical areas, including data integrity, computerized system validation, electronic quality management processes, operational technology, and regulatory compliance.
Objective: This study developed a Digital Competency Framework and defined proficiency levels for vaccine manufacturing personnel using PT XYZ as a single organizational case study.
Methods: The Design Science Research Methodology and a qualitative descriptive approach were employed. Data were obtained from literature reviews, regulatory and organizational documents, observations, semi-structured interviews with six purposively selected informants, and validation conducted by two domain experts.
Results: The study identified 18 digital competencies organized into five proficiency levels, ranging from digital awareness to digital initiative and transformation. These competencies were categorized into three pillars: data, system governance, and compliance; digital manufacturing and quality systems; and operational technology and advanced digital capabilities. Expert validation confirmed adequate coverage, logical progression, and observable competency descriptions. The framework supports role-based competency mapping, targeted training programs, and workforce planning.
Conclusion: The framework provides a context-sensitive and proficiency-based reference for competency mapping, gap analysis, and workforce development. It contributes to advancing *Pharma 4.0* while maintaining *GxP* compliance. However, the findings are analytically transferable rather than statistically generalizable, reflecting the limitations of a single organizational case study.

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INTRODUCTION

Digital transformation has reshaped how manufacturing industries manage production processes through the adoption of the Internet of Things, automation, data analytics, artificial intelligence, and interconnected systems (Guarda et al., 2021; Lu, 2025). In the pharmaceutical industry, this transformation has evolved through the concept of Pharma 4.0, which integrates people, processes, technology, and information systems while maintaining compliance with quality and regulatory requirements (ISPE., 2023).

Recent sector evidence, however, indicates uneven levels of digital maturity. A 2024

survey involving more than 100 biopharmaceutical executives reported only partial benefits from digitalization in areas such as risk sensing (50%), yield improvement (50%), warehouse efficiency (48%), and cost-effective sourcing (47%), demonstrating that technology investment does not consistently translate into operational value (Deloitte Center for Health Solutions, 2024).

The vaccine manufacturing industry has characteristics that distinguish it from general manufacturing because its products are directly associated with patient safety. All processes, including raw material management, production, laboratory testing, batch release, storage, and distribution, must be documented and traceable. Therefore, the adoption of digital technology is not solely intended to improve efficiency but must also comply with Good Manufacturing Practice (GMP), data integrity requirements, computerized system validation, access security, and electronic record traceability (ISPE, 2022b; WHO., 2024a, 2024b).

The implementation of Pharma 4.0 encourages the adoption of systems such as Enterprise Resource Planning (ERP), Manufacturing Execution Systems (MES), Electronic Batch Records (EBR), Laboratory Information Management Systems (LIMS), and electronic Quality Management Systems (eQMS). At the operational level, sensors, automation systems, process historians, and the Industrial Internet of Things (IIoT) are used to collect and monitor process data in real time. These technologies support deviation detection, production optimization, and predictive maintenance (Phuyal et al., 2020; Webb et al., 2025). However, technology investment does not automatically ensure successful transformation. Human resource readiness and competency remain critical factors in determining whether digital systems can be operated effectively, securely, and in accordance with organizational requirements (Blanka et al., 2022; Steinlechner et al., 2021).

Digital competence in the vaccine manufacturing industry cannot be understood merely as the ability to operate digital applications. Personnel must also understand data context, system risks, GxP requirements, access control, audit trails, electronic signatures, validation processes, system changes, and the relationship between information technology (IT) and operational technology (OT). At an advanced level, individuals must be able to analyze data, evaluate risks, optimize processes, and guide the implementation of digital technologies. These diverse responsibilities create the need for a framework that not only identifies competencies but also defines their respective proficiency levels.

Several frameworks have been developed to map digital competencies. The Skills Framework for the Information Age (SFIA) links professional skills with autonomy, complexity, influence, and responsibility (Foundation., 2024). DigComp provides a general digital competence framework covering information management, communication, digital content creation, safety, and problem solving (Cosgrove & & Cachia, 2025). Meanwhile, Bloom's Digital Taxonomy helps differentiate cognitive capability levels ranging from understanding to creating digital solutions (Akintolu et al., 2022; Churches, 2008). Although these frameworks provide valuable foundations, they remain general and do not directly address the specific requirements of vaccine manufacturing environments.

Previous studies have demonstrated that digital competency gaps continue to exist among laboratory, healthcare, and pharmacy personnel, particularly in data literacy, analytics, and digital technology utilization (Adler et al., 2023; Lee et al., 2023). Expert-based competency frameworks have also been developed for medical education and public health services; however, they have not addressed regulated pharmaceutical production processes (Chen et al., 2025; Yao et al., 2025). In the industrial context, Arief et al. (2022) identified core competencies and the level of Pharma 4.0 implementation in the Indonesian pharmaceutical industry (Arief et al., 2022). Digital maturity models have also been developed for pharmaceutical supply chains and manufacturing organizations (Arief et al., 2022; Benazzouz & Auhmani, 2024; De Carolis et al., 2025). However, these studies have primarily focused on organizational readiness and have not translated individual digital competencies into operational proficiency levels.

This condition highlights a gap between the requirements of digital transformation and the availability of contextual competency frameworks. Existing general frameworks have not sufficiently differentiated the capabilities required by system users, reviewers, validators, engineers, system owners, and leaders who perform different responsibilities. This limitation may hinder organizations from determining training requirements, identifying competency gaps, and

objectively assessing workforce readiness.

The novelty of this study lies in translating Pharma 4.0 and GxP requirements into an integrated, individual-level competency architecture that combines 18 context-specific competencies with five observable proficiency levels. Unlike general digital taxonomies and organization-level maturity models, the proposed artifact explicitly differentiates the capabilities required by users, reviewers, validators, engineers, system owners, and leaders within regulated vaccine manufacturing environments.

This study aimed to identify the digital competencies required in the vaccine manufacturing industry and develop proficiency levels for each competency. The study employed Design Science Research Methodology with a qualitative descriptive approach through literature review, regulatory and organizational document analysis, observation, semi-structured interviews, and expert validation (Peffers, 2007; Tuunanen et al., 2024). The contribution of this study lies in developing a framework that integrates professional digital competence, cognitive depth, autonomy, and Pharma 4.0 and GxP requirements into a structured proficiency-based model for the vaccine manufacturing industry. PT XYZ served as the sole observational case; consequently, the findings are intended for analytical transfer to comparable regulated settings and should not be interpreted as statistically representative of the entire vaccine manufacturing industry.

Theoretically, this study extends digital competency research by integrating cognitive depth, autonomy, responsibility, and regulatory compliance within a single proficiency-based artifact. This integration clarifies how individual capabilities can be aligned with organizational digital maturity in highly regulated manufacturing environments. Practically, the framework provides vaccine manufacturers with a structured foundation for role-specific competency mapping, gap analysis, training prioritization, succession planning, and workforce readiness assessment while maintaining flexibility across technologies, vendors, and job roles.

METHOD

This study used the Design Science Research Methodology (DSRM) with a qualitative descriptive approach. DSRM was selected because the study aimed to develop an artifact rather than merely describe a research problem. The artifact was a Digital Competency Framework for the vaccine manufacturing industry, consisting of digital competency domains and five proficiency levels. The research followed the six DSRM activities: Problem Identification and Motivation, Definition of the Objectives for a Solution, Design and Development, Demonstration, Evaluation, and Communication (Peffers, 2007; Tuunanen et al., 2024). Data collection was conducted from [insert month and year] to [insert month and year]; the authors should replace this bracketed period with the verified fieldwork dates before publication.

The study was based on the absence of a digital competency framework specifically designed to reflect the requirements of vaccine manufacturing. Existing frameworks, such as SFIA and DigComp, provide broad structures for digital skills and competency levels; however, they do not directly address GxP requirements, data integrity, computerized system validation, change control, digital manufacturing systems, and operational technology (OT) environments.

The research was conducted at PT XYZ, a vaccine manufacturing organization that had implemented digital systems across production, laboratory, quality, information technology, and operational technology processes. The organization served as the empirical context for identifying digital competency requirements. However, the framework was designed using application-, vendor-, and job-title-neutral terminology to support broader applicability. As a regulated vaccine producer, PT XYZ integrated production, quality assurance, quality control laboratories, information technology, and operational technology functions through computerized systems that supported GxP-relevant processes. The organization was anonymized to protect institutional confidentiality, and its use as a single case limits statistical generalization while enabling an in-depth examination of cross-functional digital competency requirements.

Data were collected through literature review, regulatory and organizational document analysis, observation, and semi-structured interviews. The literature review covered Pharma 4.0, digital competency, smart manufacturing, SFIA, DigComp, Bloom's Digital Taxonomy, and competency framework development. Regulatory and industry guidelines were analyzed to

identify requirements related to GxP, data integrity, validation, cybersecurity, risk management, change control, and computerized system lifecycle management (ISPE., 2022; WHO., 2024a, 2024b).

Organizational documents were reviewed to understand procedures related to system utilization, access management, change control, incident management, validation activities, and employee training. Observation was conducted to examine digital system utilization, data flows, system integration, audit trails, system modifications, and interactions between personnel and technology.

Semi-structured interviews involved six informants representing system owners, production, information technology compliance, quality control, human resources, and operational technology functions. The informants were selected using purposive sampling based on their professional experience, routine involvement with digital systems, and participation in system control, change management, or evaluation activities. The adequacy of six informants was determined through information power and functional coverage rather than statistical representativeness. Each participant contributed distinct knowledge from a function directly responsible for system utilization, governance, compliance, workforce development, or technology operations. Collectively, the participants covered the principal competency domains examined in the artifact. The research stages were organized according to the six activities of DSRM. The complete research flow is presented in Figure 1.

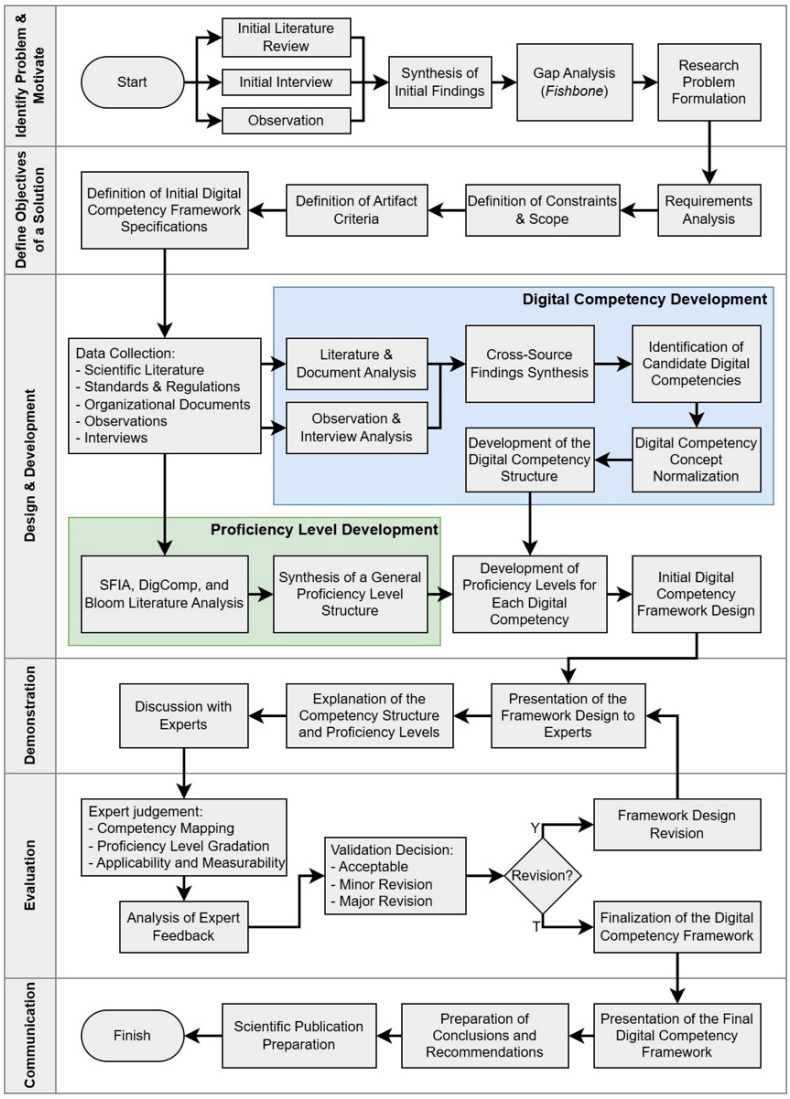

Figure 1. Research Stages

The first stage was Identify Problem and Motivate. Preliminary studies, observations, and interviews were conducted to identify gaps between digital transformation initiatives and workforce competency readiness. The findings were categorized into five aspects: people, processes, technology, governance and regulation, and framework and standardization.

The second stage was Define Objectives of a Solution. At this stage, the required characteristics of the framework were defined. The framework had to be relevant to vaccine manufacturing processes, aligned with GxP requirements, establish clear competency boundaries, demonstrate proficiency level gradation, and serve as a basis for competency assessment.

The third stage was Design and Development. The artifact was developed through two main processes: identifying digital competencies and defining proficiency levels. Candidate competencies were derived from literature, regulations, organizational documents, observations, and interviews. Each candidate competency was documented along with its source to maintain traceability.

The candidate competencies were normalized by consolidating similar terms, reviewing overlapping concepts, and converting application-specific terms into broader competency terms. This process produced a competency structure that was independent of specific technologies, applications, or vendors.

The proficiency levels were developed by integrating SFIA, DigComp, Bloom's Digital Taxonomy, and the internal competency model. SFIA was used to describe autonomy, complexity, responsibility, and influence (Foundation., 2024). DigComp was used to represent digital capability development, ranging from basic digital tasks to advanced problem-solving capabilities (Cosgrove & & Cachia, 2025). Bloom's Digital Taxonomy was used to differentiate cognitive capabilities, progressing from understanding and applying knowledge to analyzing, evaluating, and creating solutions (Akintolu et al., 2022; Churches, 2008). The synthesis resulted in five proficiency levels, which were subsequently applied to each competency.

The fourth stage was Demonstration. The initial framework was presented to experts by explaining its objectives, structure, definitions, proficiency levels, and examples of its application in competency mapping and assessment. The fifth stage was Evaluation. Expert judgment was used to assess competency relevance, proficiency level gradation, applicability, and measurability. The final stage was Communication, in which the framework and research findings were communicated through the thesis and scientific publications.

The data were analyzed using thematic analysis and content analysis. Interview data were analyzed to identify digital processes, risks, capability requirements, and competency gaps. Literature, regulatory documents, and organizational records were analyzed to identify requirements, activities, responsibilities, and control mechanisms that could be translated into digital competencies.

Findings from different data sources were compared through triangulation. Competency selection was based on relevance to quality, risk management, regulatory compliance, and process continuity rather than merely the frequency of occurrence. Competencies with strong regulatory foundations were retained even when they were not frequently mentioned by informants. Operational needs identified from work practices were incorporated when supported by literature and aligned with Pharma 4.0 principles.

Expert validation involved two experts selected through purposive sampling. The experts had at least five years of experience in the pharmaceutical industry, information technology governance, risk management, information security, GxP compliance, or data integrity. Validation covered three aspects: competency mapping, the five proficiency levels, and framework applicability and measurability. Two validators were considered appropriate for the formative expert judgment stage because they provided complementary perspectives—technology governance and security on one side, and GxP compliance and data integrity on the other. Their roles were to evaluate and refine the artifact rather than to generate statistically generalizable consensus estimates.

The first aspect assessed competency completeness, relevance, terminology consistency, and potential overlap among competencies. The second aspect assessed proficiency level gradation based on complexity, independence, responsibility, and influence. The third aspect evaluated whether the framework could be practically applied and objectively observed during

competency assessment. Expert feedback was classified as appropriate, requiring minor revision, or requiring major revision. The artifact was revised iteratively until the framework was considered sufficiently adequate and applicable.

RESULTS AND DISCUSSION

This study produced a Digital Competency Framework for the vaccine manufacturing industry. The framework consisted of 18 digital competencies and five proficiency levels. It was developed from regulations, industry guidelines, scientific literature, organizational documents, observation, and interviews with six informants. The initial framework was validated by two experts representing technology governance, GxP compliance, and data integrity.

Identification of Digital Competencies

The identification process generated concepts related to digital systems, work activities, controls, data risks, and responsibilities. These concepts were normalized by combining similar terms, separating concepts with different purposes, and converting application-based terms into broader competency terms. This process ensured that the framework was not dependent on specific applications, vendors, or job titles. The normalization process produced 18 final digital competencies, as presented in Table 1.

Table 1
Final Digital Competencies

Code	Digital Competency
C1	GxP Data Integrity (ALCOA+)
C2	System and Data Risk Management
C3	Computerized System Validation
C4	System Change and Release Management
C5	Digital Supplier Management
C6	System Access and Security
C7	Audit Trail and Electronic Signature
C8	Electronic Data Backup, Restore, and Archiving
C9	System Data Integration and Migration
C10	Periodic System Review
C11	Digital Deviation, Incident, and CAPA Management
C12	Manufacturing Execution System (MES) and Electronic Batch Record (EBR)
C13	Electronic Quality Management System (eQMS)
C14	Statistical Analytics and Quality Risk Management
C15	Process Analytical Technology (PAT) and Real-Time Monitoring
C16	Industrial Internet of Things and Equipment Monitoring
C17	Advanced Analytics and Predictive Maintenance
C18	Digital Technology for Optimization and Traceability

The competencies can be grouped into three areas. The first area focused on data, system governance, and compliance, such as data integrity, risk management, validation, access security, audit trail, backup, system review, and digital incident management. The second area focused on digital manufacturing and quality systems, such as manufacturing execution system, electronic batch record, electronic quality management system, analytics, quality risk management, process analytical technology, and real-time monitoring. The third area focused on operational technology and advanced digital capabilities, such as Industrial Internet of Things, equipment monitoring, predictive maintenance, optimization, and traceability.

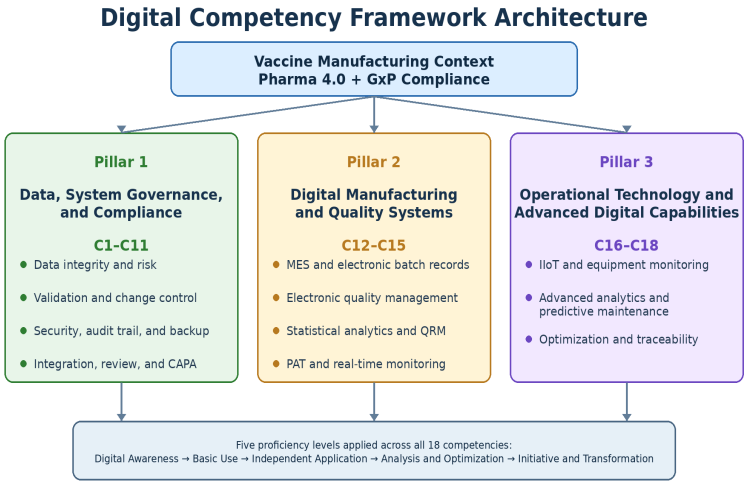

Figure 2. Architecture of the Digital Competency Framework

The result shows that digital competence in vaccine manufacturing is not limited to operating software. It also includes maintaining data integrity, controlling system risk, supporting validation status, ensuring traceability, and using technology for process improvement.

Source Contribution to the Competencies

Each competency was traced to three source groups: regulations or industry guidelines, scientific literature, and interviews. This traceability ensured that the competencies were supported by normative, scientific, and empirical foundations. The mapping of regulatory and guideline sources is presented in Table 2.

Table 2
Regulatory/Guideline Sources for Each Competency

Regulatory/ Guideline	C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13	C14	C15	C16	C17	C18
(ISPE, 2023b)	✓											✓						
(ISPE, 2022a)		✓	✓	✓	✓				✓	✓		✓						
(WHO, 2024a)	✓					✓	✓				✓		✓					
(WHO, 2024b)	✓		✓			✓		✓		✓	✓	✓	✓					
(European Commission, 2011; Pallavi Gorukanti et al., 2025)			✓	✓	✓	✓	✓		✓	✓								
(FDA, 2011; Zhang et al., 2026)	✓					✓	✓	✓										
(FDA, 2011; Zhang et al., 2026)															✓			
(Duarte et al., 2025; FDA, 2004)															✓			
(Bekele, 2026; FDA, 2006)											✓							
(FDA, 2013; Huynh-Ba, 2022)														✓				
(FDA, 2026)			✓										✓					
(GSK, 2024)																		✓
(Huynh-Ba, 2022; ICH, 2008)				✓	✓						✓		✓					

Regulatory/ Guideline	C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13	C14	C15	C16	C17	C18
(Bhavna et al., 2022; ICH, 2009)														✓	✓			
(ICH, 2022)															✓			
(ICH, 2023)		✓												✓				
(Engineering, 2022; ISPE, 2017a)												✓		✓				
(Engineering, 2022; ISPE, 2017b)	✓																	
(ISPE, 2023a)																✓		
(McDowall & Burgess, 2025; MHRA, 2018)	✓						✓	✓										
(NIST, 2024)		✓				✓												
(McDowall & Burgess, 2025; PIC/S, 2021)	✓					✓	✓	✓		✓								
(Tuunanen et al., 2024; WHO, 2021)	✓	✓					✓	✓	✓	✓								

Regulations and guidelines mainly supported competencies related to GxP, data integrity, validation, access control, audit trail, electronic records, change control, backup, and system review. Advanced technology competencies were not always direct regulatory requirements, but their application still needs to follow quality, security, validation, and intended-use principles. The mapping of scientific literature is presented in Table 3.

Table 3
Scientific Literature Sources for Each Competencies

Scientific Literature	C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13	C14	C15	C16	C17	C18
(Phuyal, Bista, & Bista, 2020; Webb et al., 2025)	✓																	✓
(Chen et al., 2025)																		✓
(Arief et al., 2022)		✓		✓	✓				✓									
(Abd Wahab et al., 2024)																	✓	
(Abdulhussain et al., 2026)																	✓	✓
(Arden et al., 2021; Suriyaamporn et al., 2026)	✓															✓		✓
(Arunagiri et al., 2024)											✓							
(Bianchini et al., 2024)												✓						
(Carvalho et al., 2024)																	✓	
(Charoo et al., 2023)	✓						✓	✓		✓								
(Chopra et al., 2012; Li et al., 2026)														✓				
(de Carvalho Junior & Bandiera-Paiva, 2018; Manchadi et al., 2026)						✓												
(Denk, 2023)																		✓

Scientific Literature	C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13	C14	C15	C16	C17	C18
(Gokulakrishnan & Venkataraman, 2025)							✓	✓		✓								
(Harrison, 2022)																		✓
(Hole et al., 2021; Kodumuru, Sarkar, Parepally, & & Chandarana, 2025)			✓	✓	✓				✓				✓					
(Hu et al., 2023)																		✓
(Jiang et al., 2024)																		✓
(Kavasidis et al., 2023)																	✓	
(Chopda et al., 2022; Kim et al., 2021)															✓			
(Kodumuru, Sarkar, Parepally, & Chandarana, 2025)		✓				✓										✓		
(Kumari et al., 2025)																✓		
(Maharjan et al., 2025)																		✓
(Mallioris et al., 2024)																	✓	
(Ganesan et al., 2023; Marsh & Eyers, 2016)												✓						
(Raja et al., 2024)			✓															
(Dakhole et al., 2026; Rattan, 2018)	✓																	
(Rezaeizadeh et al., 2026)																	✓	
(Wu et al., 2025)											✓		✓					

Scientific literature contributed strongly to competencies related to digital manufacturing, analytics, Industrial Internet of Things, real-time monitoring, predictive maintenance, integration, and traceability. Literature also supported future-oriented competencies. The interview source mapping is presented in Table 4.

Table 4
Interview Sources for Each Competency

Informants	C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13	C14	C15	C16	C17	C18
IF-01 (System Owner)		✓		✓		✓			✓	✓	✓							
IF-02 (Production)	✓		✓		✓	✓	✓	✓			✓	✓			✓	✓		✓
IF-03 (IT Compliance)	✓	✓	✓	✓		✓	✓	✓		✓	✓		✓					
IF-04 (Quality Control)	✓					✓	✓	✓	✓	✓				✓				
IF-05 (Human Resource)				✓	✓	✓							✓					
IF-06 (Operational Technology)		✓			✓	✓		✓	✓			✓	✓	✓	✓	✓	✓	✓

Development of Proficiency Levels

The second component of the framework was the proficiency level structure. The synthesis of SFIA, DigComp, Bloom's Digital Taxonomy, and the internal competency model produced five proficiency levels. These levels were not designed as job grades, but as indicators of competency depth. The general definition of each level is shown in Table 5.

Table 5
Definition of Five Digital Competency Proficiency Level

Level	Level Name	General Definition	Competency Level Adaptation			
			SFIA	DigComp	Bloom	PT XYZ
1	**Digital Awareness**	Individuals recognize the basic functions of technology, understand key terms and the general purpose of digital competencies, and are able to follow instructions for simple tasks.	1	1	1	1
2	**Basic Use**	Individuals are able to use digital systems, applications, or procedures for routine tasks with limited guidance and begin to demonstrate compliance with usage rules.	2	1	2	2
3	**Independent Application**	Individuals are able to apply digital competencies in their work, solve common problems, and adjust the use of technology according to task requirements.	3	2	3, 4	3
4	**Digital Analysis and Optimiza-tion**	Individuals are able to analyze more complex digital data or situations, evaluate options, propose improvements, and optimize the use of technology in work processes or across functions.	4, 5	3	4, 5	4
5	**Digital Initiative and Transfor-mation**	Individuals are able to lead, design, or initiate the use of digital technology for broader change, produce new solutions, and drive transformation and strategic decision-making based on digital capabilities.	6, 7	4	6	5

The five levels represent progression from basic awareness to digital transformation leadership. Level 1 describes awareness and the ability to follow simple instructions. Level 2 describes routine use of digital systems. Level 3 describes independent application. Level 4 describes analytical and optimization capability. Level 5 describes the ability to lead, design, or initiate broader digital transformation.

The five-level structure was applied to all 18 competencies, producing 90 combinations of competencies and proficiency levels. An example of level mapping for GxP Data Integrity is shown in Table 6.

Table 6
Proficiency Level Mapping for GxP Data Integrity (ALCOA+)

Level	Proficiency Description	Mastery Indicator
Level 1	**Understands** that GxP data are important, sensitive, and must be recorded correctly according to basic rules.	Knows that data must not be changed arbitrarily; recognizes basic terms such as ALCOA+, audit trail, and data integrity; follows basic instructions for data input and storage.
Level 2	Able to **perform basic** data management procedures according to SOPs in routine work.	Enters data in a timely manner; uses personal user accounts; follows data recording and storage rules; understands the importance of contemporaneous, attributable, and accurate principles in daily work activities.
Level 3	Able to **independently apply** data integrity principles in work processes under their responsibility.	Maintains data completeness and consistency; recognizes potential data integrity violations; reviews data generated in their own work area; escalates anomalies, missing records, or recording discrepancies.

Level	Proficiency Description	Mastery Indicator
Level 4	Able to **analyze** data integrity risks, evaluate control weaknesses, and propose improvements to processes or systems.	Assesses data integrity risk points in a workflow; reviews process compliance with ALCOA+; provides recommendations for SOP, control, or training improvements; guides other users in applying data integrity principles.
Level 5	Able to **lead** the strengthening of data governance and data integrity at the functional or organizational level.	Establishes the direction for data integrity control across systems or processes; leads data governance improvement initiatives; ensures audit readiness and regulatory compliance; integrates data integrity principles into policies, process design, and strategic decisions.

The same logic was applied to other competencies. For example, Computerized System Validation moved from basic understanding to validation strategy, while Manufacturing Execution System and Electronic Batch Record moved from routine use to digital manufacturing leadership.

Expert Validation Results

The framework was evaluated by two experts. EV-01 had experience in information security, governance, risk, and information technology compliance. EV-02 had experience in Good Manufacturing Practice compliance, data integrity, and data integrity risk assessment. The validation covered competency mapping, proficiency levels, applicability, and measurability.
The validation result for competency mapping is presented in Table 7.

Table 7
Validation Summary of Competency Mapping

Aspect	EV-01	EV-02	Decision
Competency completeness	Already represents industry needs	Generally covers all required needs	Number of competencies was retained
Competencies to be added	None	None	No competency was added
Competencies to be merged	None	None	No competency was merged
Competencies to be removed	None	No competency needed to be removed, but some competencies were considered non-mandatory	All competencies were retained
Electronic Data Backup and Archiving	The word “Restore” should be added to the title	No specific comment	Revised to Electronic Data Backup, Restore, and Archiving
MES and EBR	The abbreviations should be expanded	The abbreviations should be expanded to make them easier to understand	Competency name was clarified
PAT	The abbreviation should be expanded	The abbreviation should be explained using clearer wording	Competency name was clarified
Advanced technology competencies	Still relevant	Depended on company maturity and readiness	Retained as contextual and future-oriented competencies

Both experts assessed that the 18 competencies had covered the required areas. No competency was added, merged, or removed. The revisions were minor and focused on terminology. The competency related to backup and archiving was revised by adding the restore element. The abbreviations MES, EBR, and PAT were expanded. Advanced technology competencies were retained as contextual and future-oriented. The validation result for proficiency levels is presented in Table 8.

Table 8
Validation Summary of Proficiency Levels

Aspect	EV-01	EV-02	Decision
Ease of understanding Levels 1–5	Easy to understand	Fairly easy to understand	Structure was retained
Gradation of difficulty and complexity	Appropriate	Appropriate	No structural change
Gradation of independence and responsibility	Logical	Logical	No structural change
Realism of Level 5	Generally achievable	Generally achievable	Level 5 was retained
Level terminology	No change was needed	Explanatory keywords were needed	Level names were retained and keywords were added
Additional behavioral examples	Not required	Not required	Descriptions were retained
Changes in gradation for each competency	None	No change	All gradations were retained

Both experts considered the five levels understandable and logical. The levels showed an increase in complexity, independence, responsibility, and influence. Level 5 was considered realistic for leaders or senior experts, but not as a mandatory target for all workers. Therefore, the level structure was retained and strengthened with clearer keywords. The validation result for applicability and measurability is presented in Table 9.

Table 9
Validation Summary of Framework Applicability and Measurability

Aspect	EV-01	EV-02	Conclusion
Implementation across companies	Can be implemented	Depends on the company's digital readiness	Can be applied with adjustments to organizational maturity
Observability	Observable	Sufficiently describable and observable	Meets the principle of observability
Measurability	Generally can be measured objectively	Generally can be measured	Can be used as a basis for assessment
Neutrality toward job positions and technology	Already neutral	Already neutral	Can be applied across functions and organizations
Competencies that are difficult to assess	None	Generally none	No substantive barriers were found

The experts assessed that the framework could be applied in other vaccine manufacturing organizations because it was not dependent on specific job titles, applications, or vendors. However, competency selection and target levels need to be adjusted to digital maturity, technology use, role responsibilities, and process risks. The competency descriptions were considered observable through behavior, documents, analysis results, demonstrations, or other work evidence. Where EV-01 and EV-02 differed, the research team compared each recommendation against regulatory requirements, source traceability, empirical interview evidence, and the artifact's intended scope. Agreement led to direct terminology refinement, whereas divergent views, particularly regarding advanced technologies, were resolved by retaining the competency while classifying it as contextual and future-oriented rather than universally mandatory.

Final Digital Competency Framework

Expert feedback was analyzed by considering its consistency with regulations, literature, interviews, and the study objectives. The comparison between the framework before and after

validation is shown in Table 10.

Table 10
Comparison of the Framework Before and After Validation

Component	Before Validation	After Validation
Number of competencies	18 competencies	Remained 18 competencies
Number of proficiency levels	5 levels	Remained 5 levels
K8	Electronic Data Backup and Archiving	Electronic Data Backup, Restore, and Archiving
K12	MES and EBR	Manufacturing Execution System and Electronic Batch Record (MES and EBR)
K15	PAT and Real-Time Monitoring	Process Analytical Technology and Real-Time Monitoring
Level keywords	Not specifically stated	Differentiating keywords were added for each level
Status of advanced technology competencies	Not yet explained	Explained as contextual and future-oriented competencies
Framework implementation	Presented as a general framework	Adjusted according to roles and organizational digital maturity
Level 5	Highest level in the framework	Clarified as not a mandatory target for all workers

The final framework retained 18 digital competencies and five proficiency levels. The main changes included terminology refinement, expansion of technical abbreviations, addition of level keywords, and clarification of advanced technology competencies. The final framework consisted of three layers: the list of competencies, the general five-level structure, and level descriptions for each competency. It can be used for competency mapping, target level definition, gap identification, and workforce development planning. Its implementation should still be adjusted to job roles, process risks, technology use, and organizational digital maturity

Discussion

Interpretation of the Findings

The results indicate that digital competence in vaccine manufacturing is not limited to the ability to operate software or digital tools. In a regulated manufacturing environment, personnel also need to understand data integrity, GxP requirements, computerized system validation, access control, audit trail, system risk, traceability, and lifecycle control. Therefore, digital transformation in vaccine manufacturing must balance technology adoption with compliance and risk management.

The 18 competencies reflect two main needs. The first is the need to keep digital systems and data reliable, controlled, and compliant. This is shown in competencies such as GxP Data Integrity, Computerized System Validation, Audit Trail and Electronic Signature, Periodic System Review, and Digital Deviation, Incident, and CAPA Management. The second is the need to support process improvement through digital manufacturing, analytics, Industrial Internet of Things, real-time monitoring, and predictive maintenance.

The five proficiency levels show that digital competence develops gradually. Individuals may begin with basic awareness and routine use, then progress to independent application, analysis, optimization, and digital transformation leadership. These levels should not be treated as fixed job grades. A person may have a higher level in competencies related to their main responsibility but only a basic level in other competencies. Therefore, the framework is more suitable for role-based competency mapping.

Comparison with Previous Studies

The findings are consistent with studies that identified digital competency gaps in healthcare, laboratory, and pharmacy contexts (Adler et al., 2023; Lee et al., 2023; Shiferaw et al., 2020). However, those studies mainly focused on competency needs or perceptions. This study

extends them by developing structured competencies and proficiency levels for vaccine manufacturing.

The frameworks developed for medical students and public health services also used expert-based approaches (Chen et al., 2025; Yao et al., 2025). However, their context differs from regulated pharmaceutical production. Competencies such as computerized system validation, electronic batch record, audit trail, process analytical technology, periodic system review, and GxP data integrity were not the focus of those studies.

This study also complements research on Pharma 4.0 and digital maturity. Previous studies examined core competencies, digital levels, and maturity models at the organizational level (Arief et al., 2022; Benazzouz & Auhmani, 2024; De Carolis et al., 2025). In contrast, this study focused on individual competencies needed to support digital transformation in operational and governance activities.

The results are related to studies on digital employee competencies and career-level competency frameworks (Muzulon et al., 2025; Sergi et al., 2022; Steinlechner, Schumacher, Fuchs, Reichsthaler, & Schlund, 2021). However, this framework does not directly connect proficiency levels to career stages. A role-based approach was selected because competency needs in vaccine manufacturing depend on system use, process risk, responsibility, and organizational maturity.

Compared with studies on smart pharmaceutical manufacturing, artificial intelligence, digitalization, and Pharma 4.0 implementation (Arden et al., 2021; Hole et al., 2021; Kodumuru, Sarkar, Parepally, & Chandarana, 2025), this study provides a more human resource-oriented contribution. Those studies emphasized technology adoption, while this study translated digital transformation needs into competencies for mapping, assessment, and workforce development.

The findings do not fully converge with earlier competency taxonomies. Arief et al. (2022), for example, identified eight broad Pharma 4.0 competencies (such as critical thinking, research skills, regulatory compliance, and data ethics) whereas the present study generated 18 operational and governance competencies. Likewise, career-level and organizational maturity models link competence to career progression or enterprise readiness (Muzulon et al., 2025; Steinlechner et al., 2021), while this study found role-based targets more appropriate. These differences are attributable to the narrower GxP-regulated unit of analysis and caution against treating any single taxonomy as universally applicable.

Implications and Limitations

The framework can be used to define target competencies, identify competency gaps, and design more specific training programs. It may help organizations distinguish the needs of users, reviewers, validators, system owners, engineers, and leaders. However, the framework cannot yet be used directly as a certification instrument because it does not define scoring weights, minimum evidence, or passing criteria.

This study was conducted in one vaccine manufacturing organization and involved six informants and two experts. Therefore, the findings may not represent all vaccine manufacturing contexts. Future research should develop evidence-based assessment rubrics, test inter-assessor consistency, and validate the framework across more roles and organizations.

Field implementation should be tested through a staged pilot: first, map selected job roles to target proficiency levels; second, assess personnel using behavioral evidence, work products, demonstrations, and document review; third, calculate inter-assessor agreement and compare identified gaps with training outcomes; and fourth, reassess competency performance after a defined intervention period. This procedure would test usability, reliability, sensitivity to change, and organizational feasibility beyond expert validation.

Further research should convert the descriptive framework into a quantitative assessment instrument with scoring weights, minimum evidence standards, and passing criteria; conduct cross-organizational construct and criterion validity testing; and examine its transferability to non-vaccine pharmaceutical manufacturing, including small and medium-sized firms with different levels of digital maturity.

CONCLUSION

This study developed a Digital Competency Framework for the vaccine manufacturing industry consisting of 18 digital competencies and five proficiency levels, ranging from Digital Awareness to Digital Initiative and Transformation. The framework covered key areas such as GxP compliance, data integrity, computerized system validation, system security, digital manufacturing, analytics, IT–OT integration, and advanced digital technologies. Expert validation showed that the competencies were adequate, the proficiency levels were logically structured, and the descriptions could be used as a basis for competency assessment. The revisions after validation were minor and did not change the main structure of the framework. The implementation of this framework should be adjusted to job roles, process risks, technology use, and organizational digital maturity. Future research should develop evidence-based assessment rubrics and test the framework across more roles and vaccine manufacturing organizations. Subsequent studies should develop and psychometrically evaluate a quantitative assessment instrument, test cross-organizational validity and inter-assessor reliability, and examine applicability in non-vaccine pharmaceutical manufacturing. These steps are necessary to move the framework from expert-validated design to evidence-based field implementation.

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AUTHOR CONTRIBUTION STATEMENT

All authors collaboratively contributed to the completion of this research, reviewed and approved the final version of the manuscript, and take responsibility for the integrity, accuracy, and accountability of all aspects of the work.

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