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Digital Transformation and Workforce Readiness in Pharmaceutical Manufacturing: A Competency-Based Framework for Upskilling in Industry 4.0

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ABSTRACT: This study develops a competency-based framework for workforce upskilling in pharmaceutical manufacturing amid Industry 4.0 transformation, addressing the critical gap between current employee capabilities and digital technology requirements. Using a mixed-methods approach, we conducted surveys with 342 pharmaceutical manufacturing employees and semi-structured interviews with 28 HR managers across 15 companies in Asia-Pacific. Competency gap analysis and structural equation modeling identified critical digital competencies and effective upskilling strategies. Results reveal five core digital competency clusters essential for Industry 4.0 readiness: data analytics literacy, automation systems management, AI-assisted quality control, cybersecurity awareness, and digital collaboration skills. Organizations with systematic upskilling programs demonstrated 34% higher digiqqtal adoption rates. The framework extends dynamic capability theory by integrating digital transformation with human capital development in highly regulated industries. HR practitioners gain actionable roadmaps for designing targeted training programs, succession planning, and talent acquisition strategies aligned with technological evolution. This study uniquely combines pharmaceutical regulatory requirements with Industry 4.0 competencies, offering the first comprehensive framework specific to pharmaceutical manufacturing contexts.

KEYWORDS: Digital transformation: Industry 4.0: pharmaceutical manufacturing: competency framework: workforce upskilling: human resource management

I. INTRODUCTION

The pharmaceutical manufacturing industry stands at a critical juncture as Industry 4.0 technologies fundamentally reshape production processes, quality control mechanisms, and regulatory compliance systems (Javaid et al., 2022). This fourth industrial revolution, characterized by cyber-physical systems, Internet of Things (IoT), artificial intelligence (AI), and advanced automation, presents both unprecedented opportunities and significant challenges for pharmaceutical companies worldwide. While these technologies promise enhanced efficiency, improved product quality, and accelerated drug development cycles, their successful implementation hinges critically on workforce readiness and human capital development (Tortorella et al., 2021).

The pharmaceutical sector faces unique constraints that differentiate it from other manufacturing industries. Stringent regulatory requirements from agencies such as the FDA, EMA, and WHO mandate rigorous documentation, validation processes, and quality assurance protocols that must be maintained throughout digital transformation initiatives (Markarian, 2023). This regulatory complexity creates additional layers of competency requirements, as employees must not only master new technologies but also understand how to implement them within compliance frameworks. Furthermore, the high-stakes nature of pharmaceutical production—where errors can have serious public health implications—necessitates exceptionally high levels of technical proficiency and judgment (Balasubramanian et al., 2023).

Recent research indicates that up to 65% of pharmaceutical companies report significant skill gaps hindering their digital transformation efforts (Bharadwaj et al., 2021). Traditional training approaches, often focused on incremental improvements to existing processes, prove inadequate for the paradigm shift demanded by Industry 4.0. The shortage of talent with both pharmaceutical domain knowledge and digital competencies has emerged as a critical bottleneck, with human resource departments struggling to develop effective upskilling strategies that address both technical and regulatory dimensions (Ramirez-Duran et al., 2020).

Despite the growing body of literature on Industry 4.0 and digital transformation, existing research reveals three critical gaps. First, most competency frameworks remain industry-agnostic, failing to account for pharmaceutical-specific regulatory and quality requirements (Kumar et al., 2023). Second, limited empirical evidence exists regarding the relationship between specific digital competencies and actual technology adoption outcomes in pharmaceutical settings. Third, practical guidance for HR practitioners on designing and implementing upskilling programs remains fragmented and largely anecdotal (Ghobakhloo et al., 2021).

This study addresses these gaps through the following objectives:

1. To identify and validate critical digital competency clusters required for Industry 4.0 readiness in pharmaceutical manufacturing
2. To assess current competency levels and gaps among pharmaceutical manufacturing employees
3. To examine the relationship between systematic upskilling programs and digital technology adoption rates
4. To develop a comprehensive competency-based framework that integrates pharmaceutical regulatory requirements with Industry 4.0 capabilities
5. To provide actionable recommendations for HR practitioners in pharmaceutical organizations

This research is grounded in dynamic capability theory (Teece et al., 2020), which posits that organizations must continuously sense, seize, and reconfigure their resources to maintain competitive advantage in rapidly changing environments. We extend this theory by examining human capital as the foundational dynamic capability that enables technological transformation in highly regulated industries. The framework integrates three theoretical perspectives: resource-based view emphasizing internal capabilities, knowledge-based view highlighting tacit knowledge and learning, and institutional theory addressing regulatory constraints unique to pharmaceuticals (Warner and Wäger, 2019).

This research makes several important contributions. Theoretically, it advances our understanding of how dynamic capabilities manifest in human capital development within regulated industries. Methodologically, it demonstrates a robust mixed-methods approach for competency identification and validation. Practically, it provides pharmaceutical companies with evidence-based frameworks and tools for workforce development, addressing a critical industry need as digital transformation accelerates globally (Container et al., 2022)..

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II. Literature Review

2.1 Industry 4.0 in Pharmaceutical Manufacturing

Industry 4.0 represents the convergence of digital, physical, and biological technologies, creating smart manufacturing environments where data-driven decision-making and autonomous systems predominate (Tortorella et al., 2022). In pharmaceutical manufacturing, these technologies manifest across multiple domains including continuous manufacturing, real-time quality monitoring, predictive maintenance, digital twins, and AI-driven process optimization (Psarommatis et al., 2022).

Recent implementations demonstrate significant benefits. Continuous manufacturing systems, enabled by advanced process analytics and automation, have reduced production times by up to 40% while improving product consistency (Chatterjee et al., 2021). AI-powered quality control systems utilizing machine vision and deep learning algorithms detect defects with 99.8% accuracy, surpassing traditional manual inspection methods. Predictive maintenance using IoT sensors and machine learning algorithms has decreased equipment downtime by 30-50% across multiple pharmaceutical facilities (Arden et al., 2021).

However, technology adoption rates vary considerably. While large multinational pharmaceutical companies have invested heavily in digital infrastructure, small and medium-sized enterprises often lag due to resource constraints and uncertainty about return on investment (Agrawal et al., 2022). Even among early adopters, full integration remains elusive, with many organizations operating in hybrid modes where legacy systems coexist with new technologies, creating additional complexity for workforce management (Machado et al., 2020).

2.2 Competency Requirements for Digital Transformation

Competency frameworks provide structured approaches for identifying, developing, and assessing employee capabilities. In the context of Industry 4.0, emerging research identifies multiple competency domains spanning technical, analytical, and socio-behavioral dimensions (Margherita and Braccini, 2020).

Technical competencies include programming and software skills, understanding of automation systems, data management capabilities, and cybersecurity awareness. Analytical competencies encompass data analytics, statistical process control, algorithm interpretation, and systems thinking. Socio-behavioral competencies involve digital collaboration, change adaptability, continuous learning orientation, and cross-functional communication (Singh et al., 2023).

Pharmaceutical-specific competencies add another layer of complexity. Employees must understand Good Manufacturing Practice (GMP) regulations, validation protocols, data integrity requirements (ALCOA+ principles), and risk-based quality management systems. The integration of regulatory knowledge with digital competencies creates unique challenges, as traditional pharmaceutical training emphasizes documentation and procedural compliance, while digital environments demand agility, experimentation, and iterative learning (Parenteau et al., 2021; Leso et al., 2021).

Recent studies identify significant competency gaps. A survey of European pharmaceutical manufacturers found that 73% of employees lacked adequate data analytics skills, while 68% demonstrated insufficient understanding of automation technologies (Kumar et al., 2023). More concerning, 81% of supervisory personnel reported difficulty in assessing digital competency levels of their teams, suggesting that evaluation mechanisms themselves require development (Prifti et al., 2020).

2.3 Workforce Upskilling Strategies

Upskilling—the process of teaching current employees new skills to handle changing job requirements—has emerged as a strategic imperative for pharmaceutical companies (Bharadwaj et al., 2021). Traditional training approaches, typically involving classroom instruction and standard operating procedure (SOP) reviews, prove insufficient for complex digital competencies requiring hands-on practice and contextual application.

Effective upskilling strategies incorporate multiple elements. Blended learning approaches combining online modules, simulation environments, and on-the-job training demonstrate higher retention rates and practical application compared to single-method approaches (Tortorella et al., 2021). Microlearning—delivering content in small, focused segments—aligns well with pharmaceutical manufacturing environments where extended time away from production lines proves challenging. Peer learning and communities of practice facilitate knowledge sharing and problem-solving, particularly valuable for tacit knowledge transfer (Hecklau et al., 2020).

Several pharmaceutical companies have pioneered innovative approaches. Roche established "digital academies" providing role-specific learning paths spanning 6-18 months with certification requirements. Novartis implemented "digital champions" programs identifying and training employees who then serve as change agents within their departments. Pfizer developed augmented reality (AR) training modules allowing employees to practice equipment operation and troubleshooting in safe virtual environments (Arden et al., 2021).

However, systematic evaluation of upskilling program effectiveness remains limited. Most companies track completion rates and satisfaction scores but rarely measure actual competency improvement or correlation with business outcomes (Agrawal et al., 2022). This evaluation gap makes it difficult to optimize investments and refine approaches (Kohnova et al., 2020).

2.4 Research Gaps

The literature review reveals several critical gaps that this study addresses:

1. Industry-specific frameworks: Existing competency frameworks remain generic, lacking integration of pharmaceutical regulatory requirements with Industry 4.0 capabilities
2. Empirical validation: Limited quantitative research validates which specific competencies most strongly correlate with successful digital transformation outcomes
3. Implementation guidance: Practical frameworks guiding HR practitioners through competency assessment, gap analysis, and program design remain underdeveloped
4. Contextual factors: Insufficient understanding of how organizational characteristics (size, digital maturity, geographic location) moderate competency requirements and upskilling effectiveness
5. Longitudinal perspectives: Cross-sectional studies dominate, providing snapshots rather than understanding how competency needs and development evolve over time

This study contributes by developing and validating a pharmaceutical-specific competency framework through rigorous mixed-methods research, examining relationships between competencies and adoption outcomes, and providing actionable implementation guidance for practitioners

III. RESEARCH METHOD

3.1 Research Design

This study employs a sequential explanatory mixed-methods design, combining quantitative and qualitative approaches to achieve comprehensive understanding (Creswell and Creswell, 2023). The research proceeded in three phases: (1) exploratory qualitative research identifying preliminary competency dimensions, (2) quantitative survey research measuring competency levels and validating the framework, and (3) follow-up qualitative research providing deeper insights into implementation challenges and best practices.

This design was selected for several reasons. The complexity of pharmaceutical Industry 4.0 competencies requires rich qualitative description that quantitative methods alone cannot capture. Conversely, generalizability and statistical validation of competency relationships necessitate large-sample quantitative approaches. The sequential design allows qualitative findings to inform survey instrument development, while quantitative results guide targeted follow-up interviews.

3.2 Sampling and Data Collection

3.2.1 Qualitative Phase

The initial qualitative phase involved semi-structured interviews with 28 HR managers and 15 manufacturing directors across 15 pharmaceutical companies in the Asia-Pacific region (Singapore, Malaysia, Indonesia, Thailand, and India). Companies were purposively selected to ensure variation in size (small, medium, and large), digital maturity level (early adopters, moderate implementers, and beginners), and product focus (generic drugs, branded pharmaceuticals, and biologics).

Interview protocols explored current digital transformation initiatives, perceived competency gaps, existing training programs, implementation challenges, and success factors. Interviews lasted 60-90 minutes, were conducted via video conference, recorded with permission, and transcribed verbatim. Thematic analysis using NVivo software identified recurring patterns and preliminary competency categories.

3.2.2 Quantitative Phase

Based on qualitative findings, we developed a comprehensive survey instrument measuring five competency clusters across 32 specific competency items. The survey was administered to 342 pharmaceutical manufacturing employees across the same 15 organizations, plus 8 additional companies, ensuring representation across functional roles (production operators, quality assurance specialists, maintenance technicians, process engineers, and supervisors).

Sampling employed stratified random selection within each organization, with strata based on job function and experience level. Response rate reached 78%, considered excellent for organizational research. Respondents averaged 8.3 years of pharmaceutical experience, with 62% in technical roles and 38% in supervisory or specialist positions.

The survey measured competency levels using 7-point Likert scales (1=no proficiency, 7=expert level), assessed training participation and effectiveness, gathered demographic and organizational information, and measured digital technology adoption indicators within respondents' work areas.

3.2.3 Follow-up Qualitative Phase

After quantitative analysis, we conducted 18 follow-up interviews with survey participants representing high-performing and low-performing organizations based on digital adoption scores. These interviews explored implementation practices, barriers to competency development, organizational support systems, and contextual factors influencing upskilling success.

3.2.4 Measurement and Variables

Digital Competency Clusters

Based on literature review and initial interviews, we identified five core competency clusters:

a) Data Analytics Literacy: Ability to interpret data visualizations, understand basic statistical concepts, use analytics software, identify patterns and anomalies, and make data-driven decisions (7 items, $\alpha=0.89$).
b) Automation Systems Management: Knowledge of programmable logic controllers (PLCs), human-machine interfaces (HMIs), troubleshooting automated equipment, understanding control loops, and optimizing automated processes (6 items, $\alpha=0.91$).
c) AI-Assisted Quality Control: Understanding machine learning basics, interpreting AI system outputs, validating AI recommendations, identifying system limitations, and integrating AI insights with human judgment (5 items, $\alpha=0.87$).
d) Cybersecurity Awareness: Recognizing security threats, following data protection protocols, understanding access controls, implementing secure practices, and responding to security incidents (7 items, $\alpha=0.85$).
e) Digital Collaboration Skills: Using digital communication platforms, participating in virtual teams, managing digital documentation, coordinating across time zones, and leveraging collaborative technologies (7 items, $\alpha=0.88$).

Digital Adoption Rate

Organizational digital adoption was measured through a composite index including percentage of processes using advanced automation, implementation of real-time quality monitoring systems, utilization of predictive analytics, deployment of digital documentation systems, and integration level of manufacturing execution systems (MES). Scores were standardized and combined into a single adoption index ($\alpha=0.84$).

Control Variables

Analysis controlled for organizational size (number of employees), digital maturity level (assessed through independent expert rating), geographic location, employee experience level, job function, and prior digital training exposure.

3.3 Data Analysis

3.3.1 Qualitative Analysis

Qualitative data underwent thematic analysis following Braun and Clarke's six-phase approach: familiarization, initial coding, theme identification, theme review, theme definition, and report production. Two researchers independently coded transcripts, achieving inter-rater reliability of 0.87 (Cohen's kappa). NVivo 14 software facilitated coding organization and pattern identification.

3.3.2 Quantitative Analysis

Quantitative analysis employed multiple techniques using SPSS 28 and AMOS 26 software:

1. Exploratory Factor Analysis (EFA): Confirmed the five-factor competency structure using principal axis factoring with oblique rotation. Kaiser-Meyer-Olkin measure (0.92) and Bartlett's test ($p<0.001$) indicated sampling adequacy.
2. Confirmatory Factor Analysis (CFA): Validated the measurement model with acceptable fit indices ($\chi^2/df=2.34$, CFI=0.94, TLI=0.93, RMSEA=0.06, SRMR=0.05).
3. Structural Equation Modeling (SEM): Examined relationships between competency clusters, upskilling program characteristics, and digital adoption outcomes while controlling for confounding variables.
4. Cluster Analysis: Identified distinct organizational profiles based on competency levels and adoption patterns using hierarchical clustering with Ward's method and k-means validation.
5. Regression Analysis: Assessed predictive relationships between specific competencies and adoption outcomes, testing moderation effects of organizational characteristics.

3.4 Validity and Reliability

Multiple strategies ensured research quality. Content validity was established through expert review panels including five HR directors and three academic researchers specializing in pharmaceutical management. Construct validity was demonstrated through CFA with all factor loadings exceeding 0.70. Convergent validity was confirmed through average variance extracted (AVE) values above 0.50 for all constructs. Discriminant validity was established through Fornell-Larcker criterion and heterotrait-monotrait (HTMT) ratios below 0.85.

Reliability was assessed through Cronbach's alpha coefficients (all >0.85), composite reliability scores (all >0.88), and test-retest reliability with a subsample of 42 respondents after three weeks ($r=0.89$, $p<0.001$).

Qualitative rigor was ensured through member checking (sharing findings with 12 interview participants for verification), triangulation across multiple data sources, rich thick description, and reflexivity statements documenting researcher assumptions and potential biases.

3.5 Ethical Considerations

The research received approval from the institutional ethics review board. All participants provided informed consent, with explicit assurance of confidentiality and anonymity. Company names were coded, individual responses were aggregated, and no identifying information appears in reports. Participants could withdraw at any time without consequences. Data were stored securely with encrypted access limited to the research team.

IV. RESULTS AND DISCUSSION

4.1 Resultz

4.1.1 Descriptive Statistics

4.1.1.1 Sample Characteristics

The final sample comprised 342 pharmaceutical manufacturing employees across 23 organizations. Table 1 presents demographic characteristics. The sample showed balanced representation across experience levels, job functions, and organizational types, enhancing generalizability of findings.

Table 1: Sample Demographic Characteristics

Characteristic	Category	N	Percentage
Experience	<3 years	89	26.0%
	3-7 years	118	34.5%
	8-15 years	95	27.8%
	>15 years	40	11.7%
Job Function	Production Operator	127	37.1%
	Quality Assurance	86	25.1%
	Maintenance Technician	54	15.8%
	Process Engineer	48	14.0%
	Supervisor/Manager	27	7.9%
Organization Size	Small (<250)	98	28.7%
	Medium (250-1000)	134	39.2%

	Large (>1000)	110	32.2%
Digital Maturity	Early Adopter	92	26.9%
	Moderate Implementer	168	49.1%
	Beginner	82	24.0%

4.1.1.2 Competency Levels

Mean scores across the five competency clusters revealed significant variation (Table 2). Digital Collaboration Skills showed the highest proficiency (M=4.82, SD=1.23), likely reflecting increased remote work and digital communication during recent years. Conversely, AI-Assisted Quality Control demonstrated the lowest proficiency (M=2.91, SD=1.45), indicating this emerging area requires substantial development.

Table 2: Descriptive Statistics for Competency Clusters

Competency Cluster	Mean	SD	Min	Max	Skewness	Kurtosis
Data Analytics Literacy	3.67	1.38	1.00	7.00	0.21	-0.68
Automation Systems Management	3.94	1.52	1.00	7.00	0.09	-0.89
AI-Assisted Quality Control	2.91	1.45	1.00	6.86	0.48	-0.52
Cybersecurity Awareness	4.12	1.31	1.14	7.00	-0.14	-0.61
Digital Collaboration Skills	4.82	1.23	1.57	7.00	-0.38	-0.44

Competency gaps—defined as the difference between required proficiency (determined by job-specific requirements) and current proficiency—averaged 1.89 points on the 7-point scale. AI-Assisted Quality Control showed the largest gap (M=2.47), followed by Data Analytics Literacy (M=2.13) and Automation Systems Management (M=1.94).

4.1.1.3 Confirmatory Factor Analysis

CFA confirmed the five-factor competency structure with excellent model fit: $\chi^2(454)=1062.18$, $p<0.001$; $\chi^2/df=2.34$; CFI=0.94; TLI=0.93; RMSEA=0.06 (90% CI: 0.056-0.067); SRMR=0.05. All standardized factor loadings exceeded 0.70, ranging from 0.73 to 0.92, indicating strong relationships between observed items and latent constructs.

Discriminant validity was confirmed through Fornell-Larcker criterion, with the square root of AVE for each construct exceeding correlations with other constructs. HTMT ratios ranged from 0.52 to 0.79, all below the conservative threshold of 0.85, further supporting discriminant validity.

4.1.1.4 Competency-Adoption Relationships

Structural equation modeling examined relationships between competency clusters and digital adoption rates while controlling for organizational and individual characteristics. The hypothesized model demonstrated good fit: $\chi^2(612)=1389.27$, $p<0.001$; $\chi^2/df=2.27$; CFI=0.93; TLI=0.92; RMSEA=0.061; SRMR=0.058.

Table 3: Standardized Path Coefficients - Competencies to Digital Adoption

Path	β	SE	t-value	p	R²
Data Analytics Literacy → Adoption	0.28	0.06	4.67	<0.001	
Automation Systems → Adoption	0.31	0.05	6.20	<0.001	
AI-Quality Control → Adoption	0.19	0.05	3.80	<0.001	
Cybersecurity Awareness → Adoption	0.15	0.05	3.00	0.003	
Digital Collaboration → Adoption	0.22	0.06	3.67	<0.001	
Overall Model R²					0.64

Results indicate that all five competency clusters significantly predict digital adoption rates, collectively explaining 64% of variance. Automation Systems Management showed the strongest relationship ($\beta=0.31$, $p<0.001$), suggesting hands-on technical capabilities most directly enable technology implementation. Data Analytics Literacy demonstrated the second strongest effect ($\beta=0.28$, $p<0.001$), highlighting the importance of data-driven decision-making in digital environments.

Control variables revealed important contextual effects. Organization size positively predicted adoption ($\beta=0.18$, $p<0.001$), with larger companies showing higher implementation rates. Digital maturity level strongly predicted adoption ($\beta=0.41$, $p<0.001$), confirming that accumulated experience accelerates further implementation. Employee experience showed a curvilinear relationship, with mid-career professionals (8-15 years) demonstrating highest competency levels.

4.1.1.5 Upskilling Program Effectiveness

Organizations were classified into three groups based on upskilling program characteristics: (1) systematic programs with formal competency assessment, structured learning paths, and regular evaluation (n=8 organizations, 127 employees); (2) ad-hoc programs with sporadic training without formal structure (n=10 organizations, 143 employees); and (3) minimal programs with limited training offerings (n=5 organizations, 72 employees).

ANOVA revealed significant differences in digital adoption rates across groups: $F(2,339)=47.83$, $p<0.001$, $\eta^2=0.22$. Organizations with systematic programs showed 34% higher adoption rates (M=6.78, SD=1.12) compared to ad-hoc programs (M=5.06, SD=1.45), and 52% higher than minimal programs (M=4.45, SD=1.38). Post-hoc Tukey HSD tests confirmed all pairwise differences were significant ($p<0.001$).

Further analysis examined specific program characteristics associated with effectiveness. Regression models controlling for organizational characteristics identified five critical success factors (Table 4):

Table 4: Upskilling Program Characteristics Predicting Competency Development

Program Characteristic	β	SE	t	p	ΔR²
Formal Competency Assessment	0.34	0.08	4.25	<0.001	0.12
Personalized Learning Paths	0.29	0.07	4.14	<0.001	0.08
Hands-on Practice Opportunities	0.38	0.06	6.33	<0.001	0.14
Regular Progress Evaluation	0.26	0.07	3.71	<0.001	0.07
Manager Support and Coaching	0.31	0.08	3.88	<0.001	0.09

Hands-on practice opportunities emerged as the strongest predictor ($\beta=0.38$, $p<0.001$), emphasizing the importance of experiential learning for technical competencies. Formal competency assessment ($\beta=0.34$, $p<0.001$) and personalized learning paths ($\beta=0.29$, $p<0.001$) also showed substantial effects, suggesting that structured, individualized approaches outperform one-size-fits-all training.

4.1.1.6. Organizational Profiles

Cluster analysis identified four distinct organizational profiles based on competency levels and adoption patterns:

Profile 1: "Digital Leaders" (23% of organizations, n=5) - High competency across all clusters (M>5.5) and highest adoption rates (M=7.12). These organizations implemented systematic upskilling programs 3-5 years ago, integrated digital transformation into strategic planning, and maintained dedicated HR resources for competency development. Examples included multinational pharmaceutical companies with robust innovation cultures.

Profile 2: "Selective Adopters" (31% of organizations, n=7) - Moderate overall competency (M=4.2-4.8) with strength in traditional areas (automation, cybersecurity) but weakness in emerging domains (AI, advanced analytics). Adoption rates moderate (M=5.34). These organizations focused digital investments on core manufacturing processes while lagging in advanced technologies. Primarily medium-sized companies with steady growth trajectories.

Profile 3: "Struggling Implementers" (28% of organizations, n=6) - Low to moderate competency (M=3.1-3.9) with significant gaps across all clusters. Despite attempting digital initiatives, adoption rates remained low (M=4.18). Challenges included limited financial resources, high turnover, and lack of digital leadership. Mostly smaller companies in competitive generic drug markets.

Profile 4: "Early-Stage Explorers" (18% of organizations, n=5) - Very low competency (M<3.0) with minimal digital adoption (M=3.45). These organizations were just beginning digital transformation journeys, often prompted by regulatory pressure or market requirements. Characterized by traditional cultures and limited exposure to Industry 4.0 concepts.

Qualitative interviews revealed critical differentiators between high and low-performing profiles. Digital Leaders emphasized top management commitment, long-term investment perspectives, and integration of digital competencies into performance management systems. They established "digital champions" networks, provided regular learning opportunities, and celebrated digital innovation successes. Conversely, Struggling Implementers and Early-Stage Explorers faced unclear digital strategies, short-term budget constraints, and cultural resistance to change.

4.1.1.7. Competency Development Trajectories

Analysis of organizations at different digital maturity stages revealed typical competency development sequences. Initial digitalization efforts typically focused on Cybersecurity Awareness and Digital Collaboration Skills—foundational competencies with relatively low implementation barriers. As organizations gained experience, emphasis shifted to Automation Systems Management and Data Analytics Literacy, requiring more substantial technical capabilities. AI-Assisted Quality Control emerged as an advanced competency developed only after foundational capabilities were established.

This sequential pattern suggests staged upskilling approaches may prove more effective than attempting simultaneous development across all competency areas. Organizations that attempted to "skip stages" by implementing AI systems without adequate data analytics foundations experienced higher failure rates and employee frustration.

4.1.1.8 Moderation Effects

Hierarchical regression analyses tested whether organizational characteristics moderated relationships between competencies and adoption. Three significant interactions emerged:

1. Organization size × Data Analytics Literacy ($\beta=0.17$, $p=0.008$): The positive relationship between analytics capabilities and adoption strengthened in larger organizations, likely reflecting greater data infrastructure and analytical tool availability.
2. Digital maturity × AI-Quality Control ($\beta=0.23$, $p=0.002$): More digitally mature organizations derived greater adoption benefits from AI competencies, suggesting that foundational digital infrastructure amplifies AI effectiveness.
3. Geographic location × Digital Collaboration ($\beta=-0.14$, $p=0.021$): Organizations in countries with more developed digital infrastructure (Singapore) showed weaker relationships between collaboration skills and adoption compared to those in developing digital economies (Indonesia, Thailand), possibly because advanced infrastructure compensates for lower individual skills.

These moderation effects underscore the importance of context-sensitive upskilling strategies that account for organizational characteristics rather than applying uniform approaches.

4.1.2 Qualitative Insights

Follow-up interviews provided rich insights into competency development challenges and success factors. Three major themes emerged:

Theme 1: Integration of Regulatory and Digital Knowledge – Respondents consistently emphasized difficulty in bridging traditional pharmaceutical compliance mindsets with digital innovation requirements. As one quality manager stated: “We’ve trained people for years to follow procedures exactly as written, document everything in ink, and avoid deviations. Now we’re asking them to experiment with AI systems, make data-driven adjustments, and trust digital workflows. It’s a fundamental culture shift, not just skills training.”

Successful organizations addressed this challenge through “dual-competency” training approaches that explicitly connected regulatory requirements with digital tools. For example, teaching data integrity principles (ALCOA+) alongside database management skills helped employees understand how digital systems support rather than threaten compliance.

Theme 2: Learning Curve Heterogeneity – Significant variation in learning speeds and styles created challenges for group-based training programs. Younger employees with digital native backgrounds often progressed rapidly through technical content but lacked pharmaceutical domain knowledge. Experienced employees possessed deep process understanding but struggled with digital concepts. One training manager explained: “We ended up creating three parallel tracks—fast, moderate, and supported pace—for the same content. It tripled our development effort but dramatically improved outcomes.”

Theme 3: Organizational Support Systems – Competency development success depended heavily on supporting infrastructure beyond formal training. Factors included protected time for learning (rather than expecting employees to train during off-hours), availability of mentors or coaches for troubleshooting, recognition systems acknowledging skill development, and career pathways incorporating digital competencies. Organizations lacking these support systems experienced high training completion rates but low practical application.

Several organizations implemented innovative practices worth highlighting. One company established “digital sandboxes”—safe environments where employees could experiment with new technologies without affecting production systems or regulatory compliance. Another created “reverse mentoring” programs pairing digitally skilled younger employees with experienced pharmaceutical professionals, facilitating bidirectional knowledge transfer. A third organization implemented "micro-credentials"—digital badges earned for completing competency modules—that employees could display on internal profiles and external professional networks, providing intrinsic and extrinsic motivation.

4.2 DISCUSSION

4.2.1 Theoretical Contributions

This study makes several significant theoretical contributions to digital transformation and human resource management literature. First, it extends dynamic capability theory by demonstrating how human capital serves as a foundational dynamic capability in regulated industries. While previous research emphasized technological and financial resources, our findings highlight that workforce competencies enable sensing, seizing, and reconfiguring capabilities necessary for digital transformation success (Teece et al., 2020; Warner and Wäger, 2019). The strong relationship between competency clusters and adoption rates (R^2=0.64) empirically validates human capital as a critical mechanism through which organizations achieve digital agility.

Second, we advance competency theory by developing and validating a multidimensional framework specifically tailored to pharmaceutical manufacturing contexts. Existing frameworks either remain industry-agnostic (Margherita and Braccini, 2020) or focus narrowly on technical skills without considering regulatory constraints (Singh et al., 2023). Our framework integrates five distinct yet interrelated competency clusters that collectively address both technological capabilities and regulatory requirements unique to pharmaceuticals. The strong psychometric properties (all α>0.85, good CFA fit) provide confidence in the framework's validity and utility.

Third, the identification of organizational profiles through cluster analysis contributes to contingency theory by demonstrating that competency requirements and development approaches vary systematically based on digital maturity stages. The finding that organizations following sequential competency development (foundational skills before advanced capabilities) achieve better outcomes than those attempting simultaneous development across all areas suggests path-dependent learning processes. This aligns with capability lifecycle theories emphasizing staged capability evolution (Kumar et al., 2023; Ghobakhloo et al., 2021).

Fourth, our findings regarding upskilling program effectiveness contribute to training and development literature. The 34% adoption rate difference between systematic and ad-hoc programs quantifies the return on structured competency development investments. Moreover, the identification of five critical program characteristics (formal assessment, personalized paths, hands-on practice, regular evaluation, manager support) provides evidence-based guidance extending beyond anecdotal best practices common in practitioner literature (Hecklau et al., 2020; Prifti et al., 2020).

Finally, the moderation effects identified in this study advance understanding of contextual factors influencing competency-performance relationships. The finding that organization size, digital maturity, and geographic location moderate competency effects suggests that universal "best practices" may prove suboptimal without contextual adaptation. This reinforces calls for contingent approaches to human capital development (Tortorella et al., 2022; Kohnova et al., 2020).

4.2.2 Practical Implications

Our findings offer actionable guidance for pharmaceutical HR practitioners, manufacturing leaders, and policy makers.

For HR Practitioners

1. Implement Comprehensive Competency Assessment: Organizations should conduct systematic assessments identifying current competency levels, gaps, and development needs across all five competency clusters. Assessment should be role-specific, recognizing that production operators, quality specialists, and engineers require different competency profiles. The validated framework provided in this study offers a ready-to-use tool for such assessments.
2. Design Staged Upskilling Programs: Rather than attempting simultaneous development across all competencies, prioritize foundational capabilities (Cybersecurity Awareness, Digital Collaboration) before advancing to technical competencies (Automation Systems Management, Data Analytics Literacy) and finally emerging capabilities (AI-Assisted Quality Control). This staged approach respects learning capacity limitations and builds confidence progressively.
3. Emphasize Hands-On Practice: Given that experiential learning showed the strongest association with competency development (β=0.38), training programs should allocate substantial time to practical exercises, simulations, and real-world application opportunities. Digital sandboxes allowing safe experimentation without production impact offer valuable learning environments.
4. Personalize Learning Paths: The heterogeneity in learning speeds and prior knowledge documented in our qualitative findings suggests one-size-fits-all training proves ineffective. Invest in competency-based learning management systems enabling individualized pacing, adaptive content, and role-specific modules.
5. Integrate Regulatory and Digital Training: Explicitly connect digital competencies with pharmaceutical compliance requirements to bridge the culture gap between traditional documentation-focused approaches and digital innovation mindsets. Training modules should demonstrate how digital tools enhance rather than threaten regulatory compliance.

6. Establish Support Infrastructure: Training alone proves insufficient. Organizations must provide protected learning time, accessible mentors, troubleshooting support, and recognition systems acknowledging competency development. Consider implementing digital champions networks and reverse mentoring programs to facilitate peer learning.

4.2.3 For Manufacturing Leaders

1. Align Digital Strategy with Workforce Development: Digital transformation initiatives should include explicit workforce readiness components from inception. Technology investment decisions should consider not only technical capabilities but also competency requirements and development timelines.
2. Champion Learning Culture: Top management commitment emerged as a critical differentiator between high and low-performing organizations. Leaders should visibly support learning initiatives, celebrate competency development successes, and integrate digital capabilities into performance evaluation and career advancement criteria.
3. Allocate Adequate Resources: The 34% adoption rate improvement associated with systematic upskilling programs justifies substantial investment in competency development. Budget allocations for digital transformation should include dedicated workforce development components, typically representing 15-20% of total transformation investments based on successful organizations in our sample.
4. Balance Short-term and Long-term Perspectives: While production pressures create urgency for immediate implementation, sustainable digital transformation requires patient, long-term workforce development. Organizations must resist the temptation to "skip stages" through external hiring alone, as institutional knowledge and regulatory understanding prove difficult to replicate.

4.2.4 For Policy Makers and Industry Associations

1. Develop Industry-Wide Competency Standards: Pharmaceutical industry associations should establish standardized digital competency frameworks and certification programs, facilitating workforce mobility and providing clear development targets for organizations and individuals.
2. Support SME Competency Development: Small and medium enterprises face disproportionate challenges in workforce development due to limited resources. Industry associations and government agencies should provide subsidized training programs, shared learning platforms, and collaborative learning opportunities enabling SMEs to access high-quality upskilling resources.
3. Update Educational Curricula: Pharmacy, chemical engineering, and related educational programs should integrate Industry 4.0 competencies into curricula, producing graduates better prepared for modern pharmaceutical manufacturing environments. University-industry partnerships can ensure relevance and practical applicability.

4.2.5 Limitations

Several limitations warrant acknowledgment. First, the cross-sectional design limits causal inference. While SEM techniques address some directional ambiguity, longitudinal research tracking organizations over time would strengthen causal claims about competency development effects on adoption outcomes.

Second, the sample focuses on Asia-Pacific pharmaceutical manufacturers, potentially limiting generalizability to other regions. Western pharmaceutical markets may exhibit different patterns due to varying regulatory environments, labor markets, and digital infrastructure maturity. However, Asia-Pacific represents the fastest-growing pharmaceutical manufacturing region, making findings particularly relevant for emerging markets.

Third, self-reported competency measures introduce potential bias. While anonymity and aggregation mitigate social desirability concerns, objective competency assessments through skills tests would provide stronger validity. Practical constraints prevented large-scale objective testing, but future research should incorporate direct competency measurement.

Fourth, the study focuses on manufacturing contexts within pharmaceutical organizations, excluding R&D, clinical development, and commercial functions. Digital competency requirements likely differ across these functional areas, suggesting need for parallel research in non-manufacturing contexts.

Fifth, the three-year time frame of organizational upskilling programs examined in this study represents relatively early-stage implementation. Longer-term tracking would reveal sustainability, competency retention, and evolution of requirements as technologies mature.

Finally, while the study identifies critical competency clusters, it does not deeply examine learning processes, pedagogical approaches, or psychological factors influencing competency acquisition. Future research should investigate cognitive and motivational mechanisms underlying effective upskilling.

4.2.6 Future Research Directions

Building on this study's foundations, several research directions warrant attention:

1. Longitudinal Studies: Track organizations over 5-10 years to understand competency evolution, sustainability of upskilling programs, and changing requirements as technologies mature and new innovations emerge.

2. Comparative Regional Research: Replicate this study in North American, European, and other pharmaceutical markets to identify universal versus context-specific competency requirements and development approaches.
3. Functional Area Expansion: Extend the framework to R&D, clinical development, regulatory affairs, and commercial functions, developing comprehensive organizational competency architectures spanning entire pharmaceutical value chains.
4. Learning Process Research: Conduct detailed cognitive studies examining how individuals acquire digital competencies, identifying optimal pedagogical approaches, sequencing strategies, and individual difference factors influencing learning effectiveness.
5. Technology-Specific Deep Dives: While this study examined broad competency clusters, future research should investigate specific technology competency requirements (e.g., machine vision systems, digital twins, blockchain for supply chain) in greater depth.
6. Return on Investment Analysis: Develop methodologies for calculating financial returns on upskilling investments, enabling more sophisticated business case development and resource allocation optimization.
7. Competency Retention and Transfer: Examine factors influencing competency retention over time, transfer to novel contexts, and obsolescence as technologies evolve, informing continuous learning strategies.
8. Cultural and Leadership Factors: Investigate organizational culture, leadership styles, and change management practices that facilitate or inhibit competency development and digital transformation success.

CONCLUSIONS

This study addresses a critical challenge facing pharmaceutical manufacturers worldwide: developing workforce capabilities necessary for successful Industry 4.0 transformation. Through rigorous mixed-methods research involving 342 employees across 23 pharmaceutical organizations, we developed and validated a comprehensive competency-based framework integrating five essential clusters: Data Analytics Literacy, Automation Systems Management, AI-Assisted Quality Control, Cybersecurity Awareness, and Digital Collaboration Skills.

Our findings demonstrate that these competency clusters significantly predict digital technology adoption rates, collectively explaining 64% of variance. Organizations with systematic upskilling programs incorporating formal assessment, personalized learning paths, hands-on practice, regular evaluation, and manager support achieve 34% higher adoption rates compared to those with ad-hoc approaches. These results quantify the substantial return on structured workforce development investments and provide evidence-based guidance for HR practitioners.

The identification of four distinct organizational profiles—Digital Leaders, Selective Adopters, Struggling Implementers, and Early-Stage Explorers—reveals that competency requirements and development strategies vary based on digital maturity stages. Successful organizations follow sequential development patterns, establishing foundational competencies before advancing to sophisticated capabilities, respecting learning capacity limitations and building confidence progressively.

Qualitative insights highlight critical implementation challenges, particularly the integration of traditional pharmaceutical compliance mindsets with digital innovation requirements, heterogeneity in learning speeds across workforce segments, and the importance of organizational support systems beyond formal training. Innovative practices such as digital sandboxes, reverse mentoring programs, and micro-credentials demonstrate creative approaches to addressing these challenges.

Theoretically, this research extends dynamic capability theory by demonstrating human capital as a foundational mechanism for organizational agility in regulated industries, advances competency theory through development of a validated pharmaceutical-specific framework, and contributes to contingency theory by revealing contextual factors moderating competency-performance relationships.

As pharmaceutical manufacturing continues its digital transformation journey, workforce readiness will increasingly differentiate successful organizations from those struggling to adapt. This study provides both conceptual frameworks and practical tools enabling organizations to systematically develop the human capabilities necessary for thriving in Industry 4.0 environments. By investing in comprehensive, structured, and sustained competency development, pharmaceutical manufacturers can unlock the full potential of digital technologies while maintaining the rigorous quality and compliance standards essential to their critical public health mission.

The path forward requires commitment, patience, and substantial investment in human capital—but the rewards, measured in enhanced operational efficiency, improved product quality, and sustained competitive advantage, justify these investments. Organizations that recognize workforce competency as the foundation of digital transformation will position themselves for long-term success in an increasingly technology-driven pharmaceutical landscape

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