APPLICATION OF STRATEGIC SKILL MANAGEMENT in Pharma 4.0™

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The complex transformation toward Pharma 4.0™ requires comprehensive skill management. This case study builds on a previously presented framework and follows the fictional company NewCo as it tackles the challenge of developing a future-ready workforce during a plant expansion project. Guided by the framework, NewCo first establishes skill management governance and a cross-functional team. It then identifies and maps current and future skill requirements. A subsequent gap analysis reveals key insights. Leveraging the framework, NewCo systematically addresses critical knowledge gaps using modern virtual reality (VR) and augmented reality (AR) learning methods, which are discussed in detail. Following the project's success, NewCo decides to embed strategic skill management into the broader organizational context.

The concept of Pharma 4.0™ is regarded as an imperative to lasting organizational success in times characterized by volatility, uncertainty, complexity, and ambiguity (VUCA) [1, 2]. This holistic transformation toward digital and artificial intelligence (AI) fundamentally changes the industry. Pharmaceutical organizations face a unique challenge: They must balance rapid technological advancement with skill development of the workforce while continuously ensuring regulatory compliance.

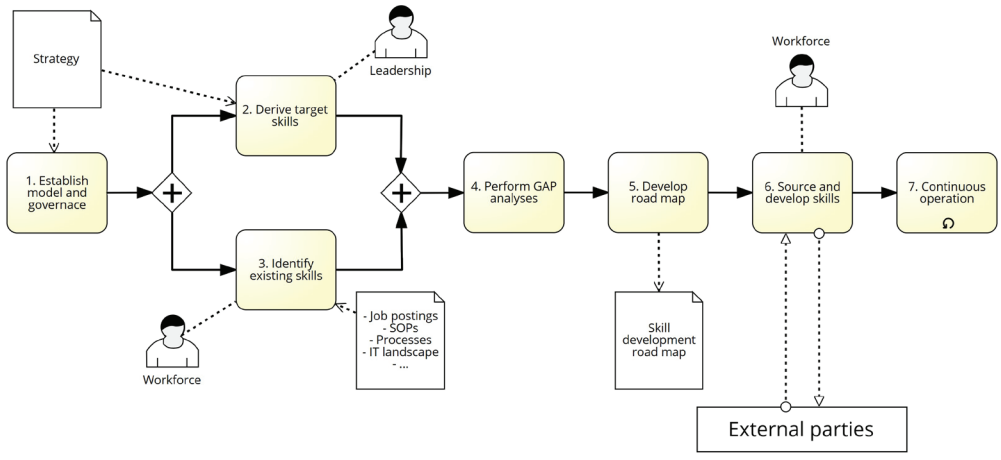
In conventional pharmaceutical organizations, the responsibility for skill development is often fragmented. Traditional approaches struggle to combine strategic business needs, learning methodology, technical expertise, and operational reality. The described development toward Pharma 4.0™, with its complexity, further increases the demand for a fundamental shift in ownership and a comprehensive approach to skill management.

Analysis of pharmaceutical organizations aiming toward Pharma 4.0™ reveals significant limitations in traditional skill development approaches. These limitations manifest in three critical dimensions that hinder successful digital transformation (see Table 1).

Table 1: Critical dimensions in Pharma 4.0™ skill management

Dimension	What?	Where?	Source
Digital Transformation vs. GxP Compliance	• Technology awareness and foresight • Validation of new digital systems • Implementation of electronic batch records • Data integrity • Continuous process verification	• Strategy • Quality assurance • Validation teams • IT departments • Manufacturing units	[2]
Technical and Process Integration	• Deep process understanding • Digital technology expertise • Cross-functional coordination • Regulatory knowledge	• Manufacturing operations teams • Quality management • Technical services • Process development groups	[3]
Strategic-Operational Alignment	• Incomplete technology adoption • Resistance to change • Inefficient resource allocation • Suboptimal business process integration	• Top management • Shop floor operations • Middle management • Project teams	[4]

Figure 1: Strategic skill management framework [5]



Emerging technologies of Pharma 4.0™ augment the toolset for pharmaceutical operations and skill development alike. Unlocking this potential requires effective integration of the end-to-end skill management process and thoughtful consideration of the critical perspectives: strategic business objectives, operational technical requirements, and learning experience.

Many organizations are aware of these new modalities but struggle to adopt them holistically [2]. This article builds upon a previously proposed strategic skill management framework [5]. It provides a tangible application in the form of a relatable case study based on the authors' collective knowledge as industry leaders. The article aims to support organizations in adopting holistic skill management and therefore ease transformation toward Pharma 4.0™.

CASE STUDY INTRODUCTION

The case study follows the fictious NewCo and its project to extend production by adding multiple new lines at an established production site. In parallel to engineering, this requires the identification and development of additional skills in the workforce. Here, NewCo takes the holistic approach toward skill management, following a dedicated framework (see Figure 1).

STEP I: ESTABLISHING A MODEL AND GOVERNANCE

A sound strategic skill management requires strong governance, particularly focusing on the integration of GxP requirements with digital transformation needs. The framework provides a structured way to bring together business leaders, operational managers, and HR professionals to develop a future-ready workforce. In the integrated approach, business leaders orchestrate the convergence of multiple perspectives and capabilities.

In their site expansion, NewCo aims to implement Pharma 4.0™ technologies to fundamentally change how they operate. The 8th thesis of Pharma 4.0™ states: "Pharma 4.0™ is not an IT project" [6].

Although previous digital transformation initiatives focused on technological aspects, NewCo recognizes workforce skills as an equally critical dimension. The company establishes clear and well-communicated governance, characterized by three interconnected core mechanisms that ensure effective implementation: business-led orchestration, cross-functional integration, and compliance-integrated development.

These three mechanisms work synergistically to create a robust implementation approach that bridges the previously identified gaps between strategic intent and operational reality. The business-led orchestration provides direction and accountability, whereas cross-functional integration ensures comprehensive stakeholder engagement. Simultaneously, compliance-integrated development preserves the critical balance between innovation and regulatory requirements, which is essential in pharmaceutical manufacturing.

Business-Led Orchestration

This approach establishes clear leadership accountability for skill development. It ensures direct connection to operational excellence and integrates skill development with business planning cycles. As demonstrated by recent surveys [2], such business leadership proves essential for maintaining momentum in digital transformation while ensuring GxP compliance.

Cross-Functional Integration

This represents the second critical mechanism, characterized by systematic stakeholder involvement across organizational units. This integration comes with clear role definitions and responsibilities, supported by a coordinated implementation approach. Evidence from pharmaceutical manufacturing environments suggests that this systematic integration significantly reduces implementation barriers and enhances adoption rates of new skills [3].

Table 2: Relevant stakeholders for Pharma 4.0™ skill identification

Level	Stakeholders	Focus Areas
Strategic	• CEO/board members • Head of manufacturing • Head of quality • Chief digital officer • Head of compliance	• Digital strategy alignment • Investment priorities • Quality vision • Market requirements
Operational	• Production managers • Quality managers • Validation managers • Technical services leads • Process development heads	• Technical requirements • GxP integration • Process optimization • Validation needs • Operating excellence • Lean Six Sigma
Support	• HR business partners • Training managers • Knowledge management leads • Change management experts	• Development programs • Training documentation • Knowledge transfer • Change readiness • Process optimization and lessons

Compliance-Integrated Development

This addresses the unique requirements of pharmaceutical organizations. By embedding GxP requirements directly into skill development processes and integrating regulatory considerations into skill development pathways, organizations can maintain compliance while driving innovation. This integration extends to quality systems, ensuring that skill development aligns with both regulatory requirements and operational excellence objectives [4].

NewCo's Approach

Aligned with the goals from the second mechanism, NewCo decided to set up a dedicated team for holistic skill management. The site expansion affects core processes rather than peripheral activities. Therefore, the development of new skills must be connected to both technical requirements and business implications. The central learning organization facilitated this by providing the latest learning methods and tools, supported by key team members.

Foresight into skill requirements requires a high level of strategic understanding. Business leaders, with their direct market exposure and organizational oversight, define both the technology strategy and project roadmap. From there, they are best positioned to identify future skill requirements in cooperation with central learning departments.

Technical training content on new digital technologies can typically be fully understood only by the dedicated subject matter experts (SMEs) responsible for the plant's operations. This includes considerations such as data integrity, electronic batch records, and automated quality control systems. At the same time, developing knowledge and training silos per site is to be avoided—for example, by establishing communities of practices and facilitating knowledge management.

Learning governance, methods, and tools are managed by the central learning organization of NewCo. This enables continuous awareness, scalability, and harmonization of effective methods, such as virtual reality (VR) and augmented reality (AR). In addition, an application for skill management is implemented to provide a harmonized setup and base skill model. In such, application-specific roles and skills are defined and accounted for by the respective SMEs.

As a result of the first step, NewCo established a clear governance and team. In addition, a base model to structure skills is available and embedded in a skill management application.

STEPS 2 AND 3: TARGET AND EXISTING SKILLS

Next, NewCo enters the exploratory phase to develop a comprehensive understanding of current skills and future requirements through systematic data collection and analysis. Following established methodological approaches in organizational research [7], the interdisciplinary team conducts semi-structured interviews with stakeholders across organizational levels. Based on extensive implementation experience in pharmaceutical organizations, the interview analysis requires careful consideration of different organizational perspectives and their unique insights into Pharma 4.0™ skill requirements [8].

Strategic leaders provide valuable insights into market dynamics and regulatory trends while being less focused on operational details. Their responses often reveal gaps between strategic vision and implementation reality, particularly regarding digital transformation priorities and compliance requirements.

Operational managers prove most valuable in identifying specific skills needs and practical implementation challenges. Their daily interaction with GxP requirements and digital technologies makes them essential for understanding where skill development is most critical. They can precisely identify where digital transformation initiatives intersect with compliance requirements and where traditional training approaches fall short.

Support function interviews, particularly with the learning department, reveal systemic challenges in skill development and insights on latest learning methods. Their perspective helps understand existing development frameworks and their limitations in addressing Pharma 4.0™ requirements. However, their input must be aligned with operational realities. Table 1 outlines stakeholders, their levels, and their focus areas in more depth.

The analysis focusses on identifying patterns across these perspectives. Common themes emerge around the following:

- Compliance–innovation balance
- Technical skill gaps
- Process integration challenges
- Documentation requirements
- Change management needs
- New ways of learning

The key is synthesizing these different perspectives into actionable insights while maintaining GxP compliance. Experience shows that successful analysis requires particular attention to areas where

strategic vision and operational reality diverge, as these often represent critical implementation challenges. Achieving tangible results is ensured by transparent definition of required roles; their associated skill sets and underlining skills. Extracting and documenting this information in a skill management application unlocks the required transparency and contributes toward general commitment.

With steps 2 and 3, New Co identified and documented its current roles and skills. Furthermore, a harmonized understanding of the upcoming required roles and skills for the site expansion and technological upgrade toward Pharma 4.0™ is established and documented.

STEP 4: SKILL GAP ANALYSIS

The established data foundation from the definition of current and target skills allows NewCo a data-driven skill gap analysis. Data is held in an application allowing for direct quantitative analytics. This includes the number of people and the "width" of the skill gap. In combination with available training formats, this leads to the training effort. The impact of a skill gap derives from its criticality and possibility to be mitigated, e.g., by temporarily relying on external talent or partners. In a portfolio approach, an impact–effort matrix is setup for different skill areas (Figure 2).

The gained insights are augmented with expert judgements and additional sources, such as analysis from manufacturing deviations/incidents and continual improvement. Existing formats of knowledge management bring insights from other plants and on future training opportunities. With that, NewCo systematically identifies several action areas for targeted skill development and hiring of new talents. For NewCo, the analysis shows a critical skill gap around aseptic manufacturing. The workforce should receive their base training and gain their qualification during line training prior to production. However, a delay in engineering reduces the time window for on-site qualification. The stakes are high, as this might become a bottleneck in the overall project timeline.

As a result from step 4, gaps are identified and evaluated. The skill development demand is clearly communicated to the involved business leaders and ambitions are high to solve the challenge around the critical skill gap in aseptic manufacturing.

STEP 5: DEVELOPING A ROADMAP

The sound gap analysis in step 4 allows NewCo to develop specific actions to secure the project timeline. The critical knowledge gap around aseptic manufacturing is tackled by the cross-functional team. As the on-site facilities are not available for training, the learning organization—with its expertise in modern training methods—proposes to leverage VR and AR. After consolidation with experts from Takeda, they present the concepts and best practices.

Leveraging Pharmaceutical Manufacturing Training with VR

Enhancing learning through immersion and safety

VR is transforming pharmaceutical manufacturing training by providing an immersive, interactive learning environment. With advanced VR headsets and hand controllers, users can engage with digital simulations, experiencing complex cleanroom procedures in a risk-free setting.

A major advantage of VR in cleanroom operator training is its ability to make the invisible visible, transforming complex processes into clear, tangible experiences. Trainees gain a deeper understanding of cleanroom protocols, equipment handling, and operational procedures through realistic, interactive simulations. By offering hands-on experience in a controlled digital space, VR reduces the risks and stress associated with real-world training, ensuring that employees are well-prepared before entering a real cleanroom.

Anytime, anywhere training with real-time feedback

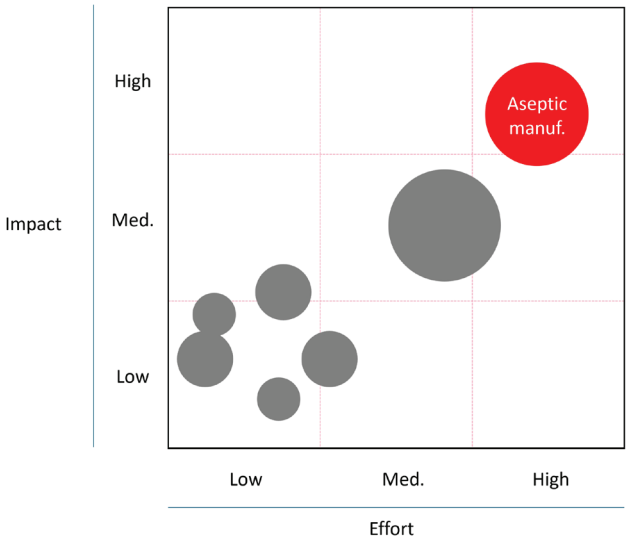
The flexibility of VR training enables trainees to access learning modules at any time, accommodating different time zones and work shifts. This 24/7 availability ensures continuous learning without disrupting critical cleanroom operations. Additionally, VR provides real-time feedback on performance, instantly identifying errors and guiding trainees to correct their mistakes. This enhances knowledge retention while reinforcing proper protocol adherence.

Standardized, Scalable, and validated VR training

The Takeda VR program establishes a globally standardized and scalable training framework across all sites, ensuring that cleanroom operators receive consistent, high-quality training aligned with industry's best practices and regulatory standards.

A key aspect of the program is platform validation, which ensures compliance with Good Manufacturing Practices (GMP) and other regulatory requirements. This includes meeting regulatory

Figure 2: Impact–effort matrix on identified skill gaps and development areas. The red circle marks a high-impact, high-effort skill gap in aseptic manufacturing.



compliance with the US FDA, EudraLex, and US Pharmacopeia (USP) standards, seamlessly integrating with the Takeda learning management system (LMS) for tracking training records, and maintaining compliance documentation.

LMS integration ensures training consistency and effectiveness by automating training records, supporting Sharable Content Object Reference Model (SCORM)-compliant learning paths, and enabling centralized monitoring for large-scale deployment across multiple sites.

Additionally, content validation is crucial to maintaining training accuracy and regulatory compliance. Training modules follow a structured framework that defines learning objectives, maps out interactive step-by-step training procedures, and incorporates both correct and incorrect scenarios to reinforce error prevention. By embedding validation mechanisms, content validation ensures that VR-based cleanroom training remains effective, scalable, and aligned with the highest industry and regulatory standards.

The future of training in pharmaceutical manufacturing

By integrating VR technology into cleanroom training, the pharmaceutical industry is embracing a new era of education that is immersive, flexible, and highly effective. VR not only enhances learning outcomes, but it also improves compliance, minimizes human errors, and boosts operational efficiency. As this technology continues to evolve, its role in workforce training and development will become increasingly indispensable, setting new standards for excellence in pharmaceutical manufacturing.

AR: Transforming Digital Instruction, Remote Assistance, and Training

Enhancing digital instruction with AR

AR is revolutionizing digital instruction by providing real-time, interactive guidance that improves how complex procedures are followed. Traditional standard operating procedures (SOPs) often rely on static manuals or written documentation, which can be difficult to interpret and are prone to human error. AR changes this by overlaying digital information directly onto the physical environment, making instructions more intuitive and accessible.

Takeda has a fully GxP-validated version of AR using Microsoft HoloLens, with a validated platform to deploy digital instructions in full compliance with GxP standards. This solution is part of a comprehensive global program, ensuring seamless deployment and adherence to industry regulations.

With AR-enabled devices, employees can receive step-by-step visual guidance while performing their tasks, eliminating the need to pause and referring to printed instructions. This hands-free approach ensures smoother workflow execution and reduces the likelihood of errors. Updates to procedures can be made instantly in AR systems, ensuring that employees always have access to the latest instructions. By making digital instruction more interactive and engaging, AR significantly improves compliance, efficiency, and accuracy in pharmaceutical productions, where precision is critical.

Augmented reality significantly improves compliance, efficiency, and accuracy in pharmaceutical productions, where precision is critical.

Revolutionizing remote assistance with AR

One of the most impactful applications of augmented reality (AR) is in remote troubleshooting and technical assistance. Traditional troubleshooting methods often require experts to be physically present on-site, leading to delays and increased costs. AR changes this dynamic by enabling real-time, remote collaboration, where specialists can guide field workers through repairs and maintenance from anywhere in the world.

Through "see-what-I-see" technology, remote experts can view exactly what the on-site worker sees and provide real-time visual instructions. AR overlays can highlight specific parts, provide animated guidance, or display relevant data to help resolve issues more efficiently. This reduces downtime and increases productivity, as problems can be diagnosed and fixed faster without waiting for a technician to arrive in person. Using remote assistance in our productions can maintain high operational efficiency while reducing service interruptions.

Immersive training for workforce development

AR is revolutionizing employee training by providing immersive, hands-on learning experiences. Traditional methods often focus on theory, making it difficult for employees to apply knowledge in real-world scenarios. AR allows employees to practice complex procedures in simulated environments before executing them in real life, improving confidence and competence. Interactive AR modules enhance understanding of workflows and equipment, ensuring better knowledge retention. The benefit from AR is the ability to reduce errors and enhance safety.

AR as a strategic asset

The integration of augemented reality into digital instruction, remote troubleshooting, and workforce training is reshaping industry operations by increasing efficiency, minimizing downtime, and improving workforce capabilities. By embracing AR technology, organizations are not only improving operational processes but also setting a new standard for workforce development and innovation.

NewCo's Use of VR and AR

At NewCo, the cross-functional team received the AR and VR input well and completed it with further sources and case studies [8]. The cross-functional team is tasked with developing optimal training formats for key users (Table 3). The learning organization provides knowledge on VR and AR technology. The on-site SMEs specify the targeted training content, and the business leadership ensures strategic alignment and budget commitment.

In step 5, NewCo developed a solid roadmap for addressing identified skill gaps. Applying modern learning technologies is quickly established and facilitated by systematic argumentation and the cross-functional team setup.

STEP 6: SKILL SOURCING AND DEVELOPMENT

As developed in the roadmap in step 5, applying advanced Pharma 4.0™ learning technologies such as VR and AR support efficiently closing the identified skill gaps. The skill development portfolio is systematically addressed. With a combination of internal and external support, the workforce is successfully qualified in time with facility construction.

STEP 7: ONGOING EVALUATION AND LEARNING ORGANIZATION

Driven by project demands, NewCo adopted a systematic approach to skill management and explored VR and AR technologies. To ensure lasting impact, NewCo integrated the gained insights in their programs on knowledge management (KM) and organizational change management (OCM). KM is an area of practice that encompasses the capture, curation, and dissemination of information and knowledge (not data) that can then be turned into action (learning or a task). This is key when considering identification and strategic implementation of skills management in the Pharma 4.0™ environment. The practice of KM—in the spirit of information and knowledge findability and availability—also can be supported by large language models (LLMs) and AI to better enable search and create insights. The practice of KM is typically very human centric and has strong ties to OCM, communication, and culture [9].

OCM and KM lay the foundation for mindsets and culture. Key considerations for a mindset and culture of adaptability include continuous learning, adaptability, and reskilling and upskilling. Continuous learning requires embracing continuous learning to keep pace with rapid technological advancements. Adaptability must be developed so teams and processes can adjust to changing roles and responsibilities in the Pharma 4.0™ landscape. Reskilling and upskilling both encourage proactively seeking opportunities for training to stay relevant in the evolving job market.

KM, digital communication and collaboration tools, and skills development are closely interconnected. Examples include:

- Digital platforms: Gaining proficiency in tools that support digital communication and collaboration in connected environments.
- Remote collaboration: Developing skills for remote collaboration across distributed manufacturing sites.
- Information sharing: Using digital tools to share information and knowledge efficiently across the manufacturing ecosystem

Table 3: Virtual reality and augmented reality training formats, users, and limitations

Training Aspect	Virtual Reality	Augmented Reality
Best Training Formats	Guided on-the-job training: Real-world overlays for step-by-step guidance	Cleanroom and machinery simulations: Immersive sterile environment training with virtual replicas of equipment for practice
	Real-time troubleshooting and maintenance: Hands-free visual instructions for equipment servicing, with potential guidance by remote experts	Emergency response and hazard training: Simulated chemical spills, airflow disruptions, etc.
Best-Suited Users	Line operators and technicians: Hands-free access to procedural steps	New employees and trainees: Safe, immersive learning environment
	Maintenance and engineering teams: Faster troubleshooting with digital overlays	Cleanroom operators: Virtual gowning and contamination control practice
		Emergency response teams: High-risk scenario training
Limitations	Less effective for theoretical training: Not ideal for GMP principles or compliance courses	Not ideal for on-the-job training: Disconnected from real-world machines
	Lacks physical dexterity training: Limited tactile feedback for manual skills	Setup time and motion sickness risks: VR sessions require preparation and adaptation
	Limited use in controlled environments: AR headsets may not be allowed in sterile zones	Impractical for quick refreshers: Setting up VR is time intensive for short sessions

After successful plant completion, NewCo integrates strategic skill management at the corporate level. Further projects will apply similar concepts, and the skill management application is planned to be rolled out across the organization. Skill management is then integrated into the OCM and KM concepts of the organization to enable systematic and data-driven management of current and future skills.

CONCLUSION

The article describes how NewCo applies strategic skill management to enable timely skill development within a project, utilizing modern AR and VR learning methods. It demonstrates how an interdisciplinary team and an integrated, holistic approach to skill management facilitate the adoption of new learning technologies and data-driven decision-making. Organizations can leverage these approaches to address the complexities of Pharma 4.0™ transformation while appropriately considering workforce needs.

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