A SKILL MANAGEMENT FRAMEWORK for a Pharma 4.0™ Workforce

By Vinzenz Zauner, Kai Reinhardt, PhD, Yvonne Duckworth, PE, and Paige Kane, PhD

Pharma 4.0™ is driving fundamental industry changes and requires a comprehensive approach to workforce development. This article proposes a skill management framework aimed at empowering companies to develop a future-ready workforce, including practical insights within the context of Pharma 4.0™.

The framework includes establishing a skill model and governance, deriving the target state, identifying existing skills, conducting a gap analysis, and developing a skill development roadmap. Organizations can greatly benefit from systematic skill management, which aims to increase operational efficiency, enhance flexibility, and improve employee retention. By fostering innovation and supporting corporate strategy, strategic skill management enables pharmaceutical companies to thrive in the Pharma 4.0™ era. Organizations can greatly benefit from systematic skill management, which seeks to increase operational efficiency, enhance flexibility, and improve employee retention.

RESEARCH MOTIVATION AND CONTEXT

The fourth industrial revolution, marked by the integration of digital, physical, and biological technologies [1, 2], is driving fundamental changes in the global VUCA (volatility, uncertainty, complexity, ambiguity) world [3, 4]. This transformation is particularly profound in the pharmaceutical industry, where technologies such as artificial intelligence, big data analytics, and the Internet of Things (IoT) are reshaping the sector. Members of ISPE have developed a holistic approach to the fourth industrial revolution, Pharma 4.0™, tailored to the uniquely regulated environment of the pharmaceutical industry.

In 2023, ISPE published the *ISPE Baseline® Guide Vol 8: Pharma 4.0™* (First Edition) which highlights the importance of people, organization, and culture in this transformation [5, 6]. Research highlights the "technological-organizational paradigm shift" [7] requiring that companies fundamentally reconfigure their skills and processes to remain competitive [8]. To effectively harness the potential of Pharma 4.0™, pharmaceutical companies must adopt a comprehensive approach to workforce development and the management of its skill landscape.

A mixed author team was assembled for this article, bringing together perspectives and knowledge from technology to human resources (HR) from across academia, consulting end users, to bridge theory and practice. This article proposes a skill management framework designed to empower companies in developing a future-ready workforce. The framework is presented in the context of Pharma 4.0™ to provide practical insight.

BENEFITS OF STRATEGIC SKILL MANAGEMENT

Beyond research interest, organizations can greatly benefit from systematic skill management. Active skill management can be an essential enabler toward the wider aim to cultural excellence [9]. It aims to increase operational efficiency in daily HR, training, and leadership tasks. Further, data-driven insights and transparency unlock new ways to efficient workforce planning [10–12]. If set up successfully, the following impact and use cases are possible.

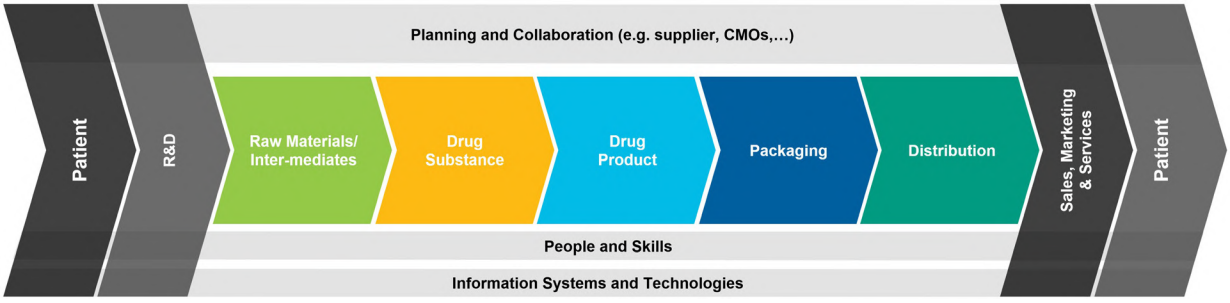
Increased Efficiency

Effective skill management enhances organizational efficiency by ensuring employees possess the necessary skills to perform their tasks effectively. This leads to improved performance, productivity, and operational efficiency, resulting in better-prepared employees who contribute significantly to overall organizational success.

Enhanced Flexibility

In today's dynamic business environment, flexibility is crucial. A robust skill management system allows organizations to quickly adapt to market changes, technological advancements, and evolving

Figure 1: Schematic representation of the end-to-end product supply value chain in the pharmaceutical industry influenced by Pharma 4.0™ [14]



customer needs. This agility helps maintain competitiveness and ensures that the organization can respond promptly to new challenges and opportunities.

Targeted Hiring

With clear insights into existing skills and future requirements, organizations can harmonize job postings and actively source the right talent. This targeted approach to hiring ensures that new employees possess the skills needed to meet current and future demands, aligning with the organization's strategic goals.

Improved Employee Retention

Focusing on skill development creates an engaging and supportive work environment. Employees who see opportunities for growth and development are more likely to stay with the company, which reduces turnover costs and contributes to a stable, experienced workforce. This fosters a culture of continuous improvement and loyalty.

Targeted Enablement

Data-driven insights reveal skill gaps with growing demand. Organizations can develop dedicated courses for relevant individuals, going beyond generic training available in overcrowded marketplaces. This targeted enablement ensures employees acquire the specific skills needed to excel in their roles.

Supported Corporate Strategy

Competency models aligned with the company's strategy ensure that the workforce can achieve long-term goals. By developing the specific skills necessary for strategic initiatives, organizations are better prepared for future challenges and can exploit new opportunities effectively.

Fostering Innovation

Systematic development of new skills promotes a culture of innovation. When employees acquire new skills and knowledge, they are more likely to contribute innovative ideas and solutions. Encouraging innovation helps the organization stay ahead of the competition, respond to changing customer needs, and explore new markets. These are essential for growth and long-term success.

Advanced Staffing

Organization-wide skill insights enable identification and staffing of optimal project teams. A project member chosen for technical expertise might hold that new role for the first time and then upskills in project management. After the project, the employee retains and documents the new skills, making them an identifiable valuable asset for future opportunities.

Embedded Regulatory Understanding

In regulated industries, employees and managers need to be aware of the regulatory framework of their company, processes, and products to meaningfully explore innovation, flexibility, and agility. Actively managing these critical skills helps in finding efficient ways to implement Pharma 4.0™ initiatives while ensuring compliance.

Overall, strategic skill management aims to bring immense value and improvements to workforce management as well as workforce spirit. These benefits make strategic skill management a central component of modern human resource management and organizational development strategies.

FROM STRATEGIC MANAGEMENT TO SKILL MANAGEMENT

Strategic management is paramount in navigating the complexities of global VUCA conditions and the fourth industrial revolution [2]. Building on dynamic capabilities theory [7], organizations must develop both the ability to sense new opportunities and the capacity to transform their operations accordingly. By formulating the business strategy, top management sets the organization's trajectory within this evolving landscape [2].

Changes coming with the adaptation of Pharma 4.0™ resonate throughout the end-to-end pharmaceutical value chain and its respective ecosystem capabilities in the context of people, processes, manufacturing plants, and organizations. This encompasses not only internal operations, but also external stakeholders, including suppliers, research partners, and regulatory bodies [13] (see Figure 1).

Table 1: Skill management impact areas within Pharma 4.0™

Impact Area	Guiding Questions
Digital Literacy and Data Fluency	• To what extent does the workforce understand core digital concepts such as data integrity, cloud computing, cybersecurity, and modular automation? • Are people enabled and willing to work with digital platforms and software commonly used in Pharma 4.0™, such as Laboratory Information Management System (LIMS), Manufacturing Execution System (MES), or Enterprise Resource Planning (ERP) systems?
Technical Skills for Automation and Advanced Technologies	• Does the workforce possess the skills to operate, maintain, and troubleshoot automated equipment, robotics, and other advanced technologies used in pharmaceutical manufacturing? • Is there relevant experience with technologies like artificial intelligence/machine learning (AI/ML) for drug discovery, process optimization, or predictive maintenance?
Skill Gaps and Upskilling/ Reskilling Timelines	• What are the most critical skill gaps hindering the implementation of specific Pharma 4.0™ initiatives (e.g., continuous manufacturing, real-time release testing, personalized medicine)? • Can existing training programs be adapted to address these gaps, or are new programs needed? If so, what is the timeline for development?
Concentration and Availability of Specialized Skills	• Is critical knowledge in areas like drug discovery, bioprocess engineering, or cybersecurity concentrated on few individuals, creating potential bottlenecks, knowledge silos, and risk? • Are these specialized skills resilient within the organization, or is there a need to recruit new talent or collaborate in novel ways?
Future Skills for Emerging Technologies	• How can the organization anticipate and prepare for the skills needed to implement Pharma 4.0™ technologies like 3D printing for drug manufacturing or digital twins for advanced process simulation? • What initiatives can be put in place to monitor technological advancements and proactively identify future skill requirements (e.g., industry partnerships, participation in conferences, horizon scanning)?
Internal vs. External Sourcing of Skills	• Which skills are more efficiently sourced externally through collaborations with technology providers, universities, or specialized consultants (e.g., advanced AI/ML, specialized automation engineering)? • What strategies can be used to balance internal skill development with external partnerships to ensure robust access to the most critical expertise?

At the skill management level, the leadership of each organization faces crucial questions about workforce readiness for Pharma 4.0™ (see Table 1).

Strategic skill management includes methods to address the questions highlighted in Table 1. It enables pharmaceutical companies to proactively identify, prioritize, develop, and retain the skills essential for thriving in the Pharma 4.0™ era.

A FRAMEWORK FOR STRATEGIC SKILL MANAGEMENT IN PHARMA 4.0™

This article proposes a novel framework to systematically implement and operate strategic skill management within an organization. This includes the required governance, identification of target and existing skills, formulation of a consistent roadmap, and sustainable operationalization for lasting organizational success. The framework is universal in nature but is applied and discussed here in the context of Pharma 4.0™.

Existing literature extensively explores the theoretical dimensions of skill management [15–17]. The presented framework bridges theory and practice, providing a sound approach accessible to leaders and professionals, independent of a background in human resource management or organizational psychology (see Figure 2).

Step 1: Establishing a Skill Model and Governance

Skill management functions as a dynamic and integrated decision-making tool for modern management [11, 12]. To start, foundational work is required to ensure success and organizational fit. The initiative can be targeted to specific areas undergoing transformation or applied across the whole organization.

Organizational setup

The organization setup considers the initial implementation project team as well as the later integration into the line organization. The initial setup necessitates a collaborative project approach, incorporating input from the following:

- Top management: defining strategic direction and scope
- HR: designing and implementing the model
- Department heads: identifying specific skill requirements
- Employees: providing input on their skills and needs
- Quality and regulatory: embedding compliance

Data model

The effectiveness of skill management is based on a structured data model. Early definition is required to structure the later data aggregation and usage. The authors propose roles, associated skill sets, and underlying skills. Roles are a powerful tool in

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Figure 2: A strategic skill management framework

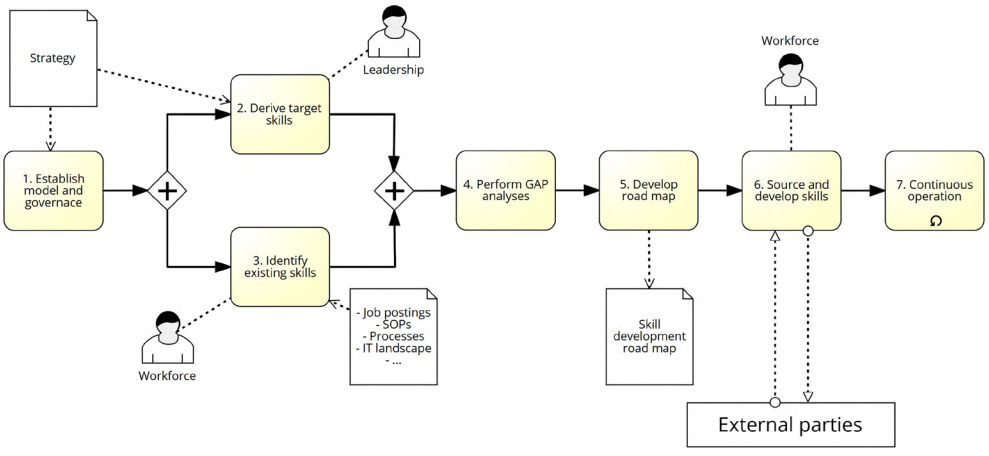
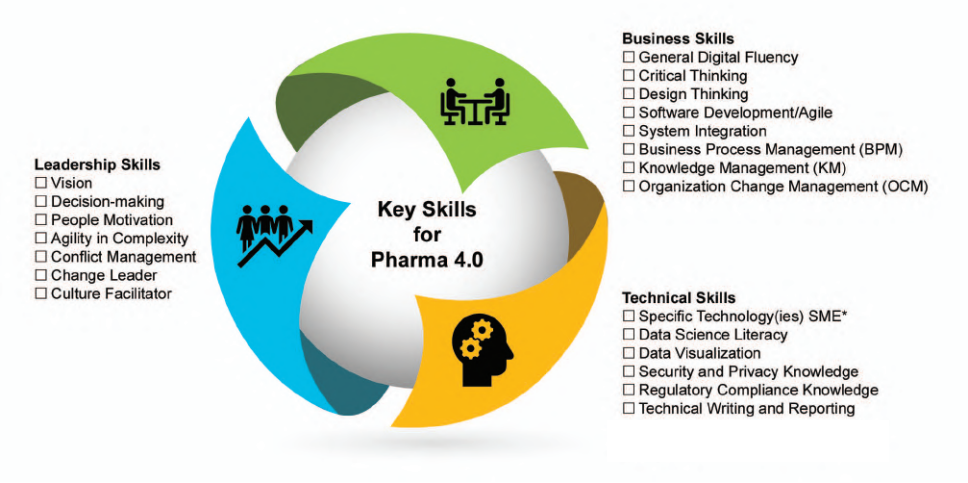


Figure 3: Key skill sets and skills for Pharma 4.0™ [5]



achieving a shift from rigid, power-based hierarchies and static job descriptions to a more agile and dynamic organizational structure. A person can hold one or more roles, and roles should be held by multiple people to avoid knowledge concentration. A role typically holds multiple skill sets, reflecting areas of knowledge relevant to the organization and providing a structuring middle layer.

A skill set consists of multiple skills. Skills form the foundational level. They are tangible, described in detail, and subject to individual development and evaluation. For example, the role "digital compliance specialist" might hold a skill set "regulatory" with a skill in "International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use regulations" and a skill set "digital" with skills in "data integrity" and "Rust programming." An example of this logical structure is provided in the *ISPE Baseline Guide Vol. 8: Pharma 4.0™ (First Edition)* [5] (see Figure 3).

In addition, the scope of the skill model is to be defined. There are multiple dimensions to categorize discussed in literature [10, 18, 19]. One example is shown in Table 2.

Data management

Strategic skill management produces and requires the management of large amounts of data. Although a spreadsheet can support initial pilots or small organizations, leveraging software for skill management is recommended. Common corporate workforce management applications such as SAP SuccessFactors, Workday, Oracle HCM, and Personio, as well as dedicated providers such as Growify, ensure relevant data structure. Data become an actionable asset with searches and reports, such as skill bubble maps, skill

Table 2: Differentiation of skills across different dimensions with definition, examples, and importance

Dimension	Definition	Examples	Importance
Technical Skill	Referring to the specialized knowledge and practical skills	• Mastering Java or Python • Understanding aseptic processing or freeze drying	Fundamental for any professional role; influences the ability to effectively perform specialized tasks
Methodological Skill	Ability to apply appropriate techniques and methods	• Applying Scrum or Lean Six Sigma • Document and transfer insights into knowledge	Essential to promote innovation, strategic thinking, and investigation of deviations
Social Skill	Skills for effective interpersonal interactions	• Promoting collaboration • Mediating team conflicts • Inspiring leadership	Important in environments that rely on teamwork, dynamics, and culture
Self-Skill	Ability to manage oneself in various professional contexts	• Adapting to a fast-paced work environment • Working productively under pressure • Independent decision-making	Crucial in roles requiring a high degree of autonomy, such as leadership positions or independent work environments

matrices for team staffing, and skill timelines indicating when skills will leave the organization. These insights provide immediate value by enabling data-driven decisions in daily operations.

Dedicated change management

Implementing effective change management strategies is crucial to ensure smooth transitions and minimize resistance. Clear communication of the "why" with benefits and goals helps align all stakeholders, foster a supportive environment for change, and increase workforce motivation. Effective communication and change management strategies are vital to fostering a culture that embraces innovation and continuous improvement. Current employees may be accustomed to legacy systems and processes, making it essential to address resistance to change.

The use of highly skilled employees as early adopters of change is an opportunity to develop skills in the workforce. These individuals might view sharing knowledge as weakening their position. Building a culture of proactive knowledge sharing (e.g., by taking on an apprentice) is a necessity for advancement. At the end of this step, the implementation project is planned, the new line function is envisioned, and the data model developed.

Step 2: Deriving the Target State

Once the governance is in place, the target state is detailed. Input for the roles, skill sets, and skills should come from strategy and from across relevant business functions. When exploring the organization's target skill setup, it is beneficial to differentiate on relevant dimensions. This, for example, involves temporary organizational needs versus permanent skills for sustained operational effectiveness.

Models can be developed from templates or created from scratch [20] and should differentiate between the borrowed approach, the borrowed-and-tailored approach, and the tailored approach. From the first to the latter, the level of individualization and resources rises. Although each extreme might come with downsides in either being too generic or requiring too much development effort, companies face the decision where to balance themselves in between. At the end of this step, the skill model is filled with described target roles, skill sets, and skills. Skills are evaluated on a scale with the defined target level.

Step 3: Identifying Existing Skills

Identifying the current skills is carried out in parallel with, and in alignment to, the definition of the target state. Multiple sources are available for skill identification, greatly varying in required resources and insight. Some are centrally accessible and can be reviewed by the project team. Starting points are existing job profiles, organizational charts, and training materials. In the pharmaceutical industry, standard operating procedures are critical for quality and compliance and can be another valuable resource. In addition, established business process management (BPM), enterprise architecture management (EAM), or knowledge management (KM) systems should be leveraged to derive insight into existing skills.

Typically, these inputs are disconnected, resulting in a fragmented understanding on the skill landscape. To gain a complete picture and strengthen accountability, the workforce should be involved. Here, a combination of self-assessment and external evaluation is recommended. This ensures that the data collected is more representative of the entire organization.

Self-assessment empowers employees to reflect on their own skills, fostering ownership and responsibility for personal development. This method can be facilitated through questionnaires, competency matrices, or online platforms designed for self-evaluation. External evaluation provides an objective perspective on skills across the organization, often conducted by supervisors, peers, or

Table 3: Type of skill outlook with examples from Pharma 4.0™

Skill Outlook	Examples in Pharma 4.0™
I. Future Skills	• AI for drug discovery • Data analytics for clinical trial optimization • Cybersecurity expertise for protecting sensitive patient data
II. Increasingly Important Skills	• Quality control and data integrity • Process control and optimization using digital twins • Cybersecurity awareness and best practices for all employees • BPM • EAM • Organizational change management (OCM) • Knowledge Management
III. Stable Skills	• Core scientific knowledge (organic chemistry, pharmacology, toxicology) • Manufacturing practices and regulatory compliance expertise (GMP) • Project management
IV. Decreasingly Important Skills	• Manual data entry and traditional documentation practices • Certain laboratory techniques where inline measurement takes over
V. Phasing Out Skills	• Skills related to legacy manual work to be replaced by automated systems • Legacy software or systems expertise

external assessors. This can involve observation, interviews, skills tests, or 360-degree feedback mechanisms.

At the end of this step the existing roles, skill sets and skills are identified. Each member of the workforce is assigned to its roles and has their skills evaluated.

Step 4: Conducting Gap Analysis

After building a structured foundation, a gap analysis should be completed. A gap analysis is a systematic comparison of the organization's current skill set with the defined target skills. This analysis reveals discrepancies and highlights areas where skill development initiatives are needed. Depending on the applied tools, this can involve out-of-the-box analytics and reports or may require manual data processing. This data-driven approach provides reliable results for the upcoming management discussions and reflects on the readiness toward Pharma 4.0™. At the end of this step, the skill gaps are identified.

Step 5: Developing a Skill Development Roadmap

In the journey toward achieving the target state, developing a comprehensive roadmap is essential. This roadmap must address identified gaps and clearly differentiate between skills required on a short-term, project-based basis, and those that will become integral to the new line organization in the long term. In addition, the time dynamic of skills should be considered (see Table 3).

Another dimension should focus on the spread of skills across the organization. Although some skills may have existed in the organization for some time (like data integrity), with wider adoption of additional technology, there is a need for more individuals to become fluent, and for knowledge to not just be concentrated within a few experts. Here an individual categorization from universal skills to expert skills is recommended.

These additional dimensions align with the concept of organizational ambidexterity, which emphasizes the importance of simultaneously exploring new opportunities and exploiting existing capabilities [21]. By fostering ambidexterity in skill development, pharmaceutical organizations can effectively balance the need for innovation and adaptation with the need to maintain operational efficiency and leverage existing expertise from experts.

Implementing a robust skill development roadmap or workforce development program is crucial for equipping employees with new skill sets. This includes careful selection of appropriate training methods such as on-the-job training and focused apprenticeships to facilitate practical learning. Leveraging skills from other industries can bring diverse perspectives and expertise, enhancing the overall capability of the workforce.

One of the greatest challenges in skill development is preventing silos and eliminating redundancies. Adopting a matrix organization or establishing a Center of Excellence can provide specialized support at various points within the organization, promoting efficiency and collaboration. Emphasizing cross-functional training and development ensures that skills are transferable, and that knowledge is shared across the organization.

Special focus is required in brownfield facilities, which are existing sites undergoing modernization. Here skills of type IV and V are present, which require well-established teams to be upskilled or reskilled to adapt to new technologies and processes. This needs a strategic approach to training and development, ensuring that employees are equipped with the necessary skills to thrive in a digitally transformed environment.

In contrast, greenfield facilities, which are new sites built from the ground up, offer a blank slate for skill development. These facilities require building a workforce from scratch with the required skills of the present and future. Beginning staffing early, like during the planning phase, ensures alignment with the goals and allows for challenges and opportunities to be identified and proactive measures to address them to be enabled. At the end of this step, a dedicated skill development roadmap is developed, approved, and communicated.

Step 6: Sourcing and Developing Skills

During enablement, holistic alignment with the ecosystem's capabilities is required. For externally sourced skills, strategic partnerships with specialized providers are best suited. Effective vendor management involves setting clear expectations,

maintaining open and transparent communication channels, and implementing rigorous qualification processes. For ensuring long-term organizational success and stability, managing internal skills is indispensable. This process involves creating customized learning paths that are tailored to various skills.

In the special case of a new greenfield facility, introduction to the community is a critical step in building local support and attracting talent. Establishing partnerships within the local community, such as with educational institutions and industry organizations, can create a robust pipeline of skilled workers in line with identified needs. Additionally, seeking support from the wider organization ensures consistency and leverages existing resources.

For training, external sources for skill development include industry-specific training centers like the Jefferson Institute for Bioprocessing in Pennsylvania, the National Institute for Bioprocessing Research and Training in Dublin, the Biomanufacturing Training and Education Center in North Carolina, and the European Aseptic and Sterile Environment facility in Strasbourg, France, with cooperation to ISPE. These offer numerous training programs with state-of-the-art facilities to systematically address, develop, and identify future skills. Conferences from ISPE and other professional organizations provide networking opportunities with peers, instructors, and industry professionals who foster valuable relationships for development and collaboration. At the end of this step, strategic skill management is implemented and aligned with the aims of the organization. After initial setup, continuous operations are transferred to the line organization.

Step 7: Implementing Continuous Operations

Strategic skill management is an ongoing process that requires continuous assessment and adaptation. Identifying gaps and new or unexpected roles that may arise is essential to stay ahead of industry changes. New insights or strategic changes should feed back to the now established system. For line integration, it is recommended that the department responsible for training, often part of HR, holds administrative responsibility, whereas the individual functions in scope of the strategic skill management initiative are responsible for the content and up-to-date assessment.

Strong integration in operations and management ensures value and continuous commitment from leadership and workforce. The continuous operations cycle is summarized in Figure 4. From monitoring the dynamic internal and external environment, new demand emerges. Identified and planned adjustments to the skill landscape are communicated in the organization. Impacted members of the workforce take part in evaluation. Finally, insights and data-driven actions are taken to execute precise development.

This step does not end and ensures continuous excellence in strategic skill management.

CONCLUSION

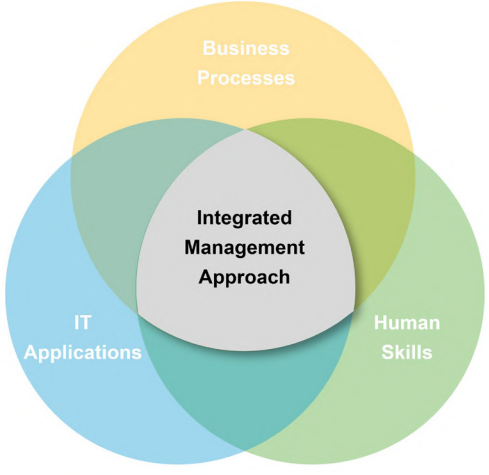
This article presents a framework for strategic skill management and details the steps from initial setup to sustainable integration. Initial execution is resource-intensive. Top management must demonstrate commitment and provide oversight while the project team executes. By embedding clear structures for roles and skills within a dynamic governance framework, pharmaceutical organizations can effectively manage their skill landscape while maintaining the high-quality standards essential to pharmaceutical manufacturing.

This framework empowers organizations to strategically manage skill development with data-driven methods. By implementing targeted solutions and leveraging the expertise of specialized consultants, companies can ensure their workforce is

Figure 4: Strategic skills management operating model



Figure 5: Integrated approach for management of processes, applications, and skills



prepared for future challenges. This forward-thinking, strategic approach helps build a dynamic and adaptable organization, while ensuring the organization continuously evolves and meets the demands of an ever-changing market.

Depending on an organization's readiness, an integrated approach combining business processes (BPM), IT applications (specifically, Enterprise Asset Management), and skills can leverage synergies (Figure 5). Each area includes mapping both current and future states and is characterized by holistic landscapes. During Pharma 4.0™ transformation, all three areas are deeply intertwined. For example, implementing a new manufacturing technology impacts business processes, IT applications, and required workforce skills. This integrated management approach fosters the organizations transformation management capabilities.

In summary, the framework provides a comprehensive approach to skill management, underpinned by strategic planning and coordination. This is vital for navigating the complexities of modern business environments and achieving sustained success. By proactively investing in strategic skill management, organizations position themselves to respond effectively to emerging challenges and opportunities, thereby securing a sustainable competitive advantage in the marketplace.

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About the authors

Vinzenz Zauner, MSc, MSc, is a consultant in digital transformation and business process management. He gained experience in bioprocess analytical technology with stations at Knick Elektronische Messgeräte GmbH, Joint Lab Bioelectronics TU Berlin, and the Department of Bioprocess Technology at TU Vienna. In 2024, he served as the Emerging Leaders Chair of the ISPE Pharma 4.0™ CoP Steering Committee and the Emerging Leader Representative for the ISPE Program Committee for Pharma 4.0™ Conference. He is a member of the editorial board for *Pharmaceutical Engineering* magazine. He joined ISPE in 2019.

Kai Reinhardt, PhD, is a professor of Business Administration at HTW Berlin in Germany. He specializes in digital transformation, strategic human resources, and competence management. He is an expert in future-oriented skill management, advancing this field through the development of agile, data-driven organizational models and the integration of AI in HR practices. He has collaborated with leading corporations such as Deutsche Bahn, SAP SE, and Siemens AG. He is the author of *Digital Transformation of Organizations* and *Competence Management in Practice*.

Yvonne Duckworth, PE, MBA, is a registered automation engineer with 33 years of technical design and project leadership experience within the pharmaceutical and biotech industries. She serves as a fellow in digital technology at CRB in Pennsylvania. Her expertise includes developing overall control system strategy, instrumentation design, process control system design, control system network architecture design, control system programming, commissioning, validation, construction, and start-up support activities. She serves as Co-Lead for the *ISPE Good Practice Guide: Holistic Digital Enablement* Task Team and as Secretary of the ISPE Pharma 4.0™ CoP Steering Committee. She joined ISPE in 1993.

Paige Kane, PhD, MSD, CPIP, is an industry leader with over 30 years of experience, including with the Genetics Institute, Wyeth, Pfizer, Merck, and the US government. She has led quality systems groups focusing on automation compliance, data integrity, computer validation, and change control during start-up and operations for biologics facilities in the US and Ireland. She frequently contributes to ISPE Good Practice Guide teams, including the recent *ISPE Good Practice Guide: Knowledge Management in the Pharmaceutical Industry* and multiple GAMP® guides. She joined ISPE in 2000.