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Workforce 4.0:
The Long-Term Success of the Biopharmaceutical Industry

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A Public-Private Approach to Workforce 4.0 Development

Biopharmaceutical companies are actively adopting the principles of Industry 4.0, a convergence of technologies representing the future of drug manufacturing.[1] Publicly introduced in 2011, the term is shorthand for the "Fourth Industrial Revolution."[2] Industry 4.0 encompasses a wide range of advances and disciplines including digital technologies, artificial intelligence (AI), machine learning (ML), automation, and analytics performed on vast amounts of data. It also applies the principles of lean manufacturing to generate greater output and improve returns on investment, and sustainability.[3] Embracing the concepts of Industry 4.0, also referred to as "Biopharma 4.0", drug developers and manufacturers are transitioning from conventional factories to "smart" manufacturing facilities.

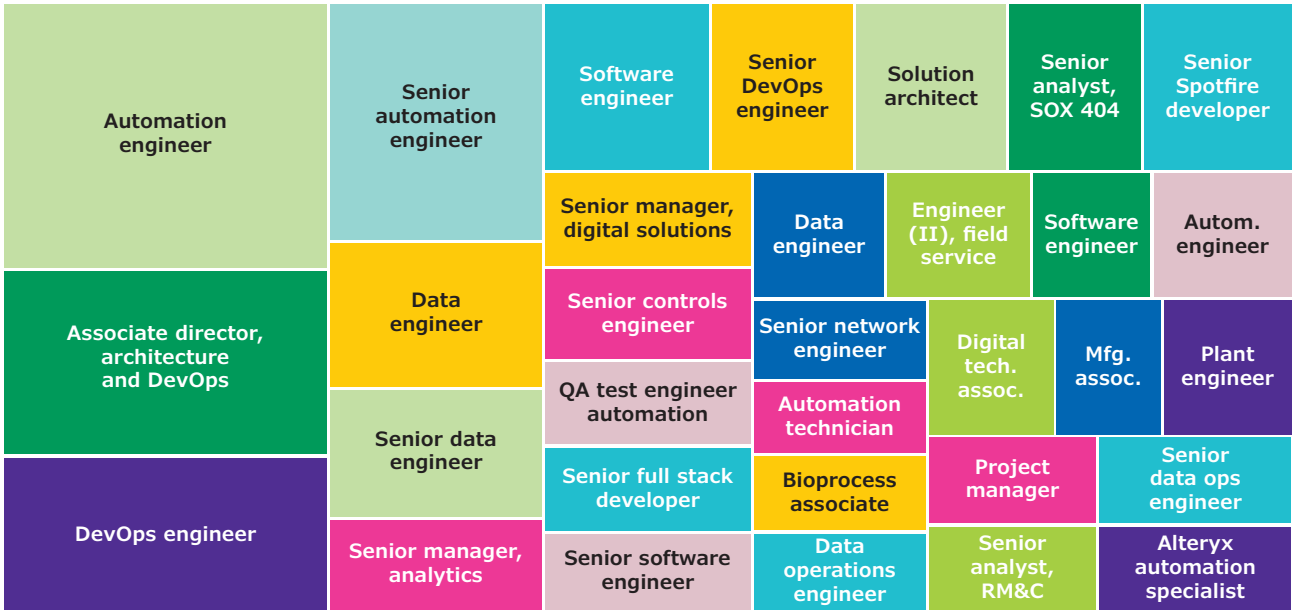
The Need for Workforce Evolution

The evolution to Biopharma 4.0 requires a workforce with new skills, new ways of thinking, and creative problem-solving capabilities. In addition to expertise in the science of biopharmaceutical research and development, companies need employees with an understanding of advanced, digitalized, lean, and sustainable biomanufacturing. Today, gaps in the skillsets of new hires and a shortage of trained employees threaten to considerably slow down the transition and transformation biopharmaceutical companies are undertaking toward digitalization and automation.

To shape the biopharmaceutical workforce companies must address the skill gaps among new hires and existing employees, and prepare future generations. Collaborations between industry, governments, and educational institutions are essential to develop and deploy targeted and specialized training programs that encompass not only traditional scientific disciplines but also digital competencies and practical experience. The traditional focus on biology, biochemistry, pharmacology, and industrial engineering is no longer sufficient and must be supplemented with training on information and operational technology, supported by real-world experience enabled by internships and other hands-on opportunities. In parallel, drug manufacturing companies must foster continuous learning for existing employees, offer internship/apprentice opportunities to provide practical experience, and guide academic institutions as they seek to better prepare graduates for employment at Industry 4.0 facilities.

In this article, we provide insights and perspectives on the workforce challenges presented by Industry 4.0 and highlight a new public-private approach in France for addressing these needs. This framework can serve as a playbook for participants in the biopharmaceutical ecosystem to help ensure a successful evolution to biopharma 4.0 and to set the stage for the long-term success of the industry.

Figure 1. Biopharma 4.0 talent demand in 2022 by job role (1,2); the larger the box, the higher the demand for that role.



[Key: autom. = automation, DevOps = software development and information-technology operations, eng. = engineering, mfg. = manufacturing, RM&C = resource monitoring and control, SOX 404 = Sarbanes-Oxley Act <404> compliance, QA = quality assurance.]

Source: Biopharma 4.0 — the Talent Evolution (Jason Beckwith, Robbie Dool, Paul Rooney, Manish Thilagar, Stephen Goldrick, William Nixon, and Stavros Kourtzidis)

The Challenges of Implementing Industry 4.0

Despite the substantial advantages that digital transformation can bring, biopharmaceutical manufacturers face challenges in its adoption and have deemed their systems, data and approaches to organization management inadequate for the transition.[4] In addition, a significant cultural shift is necessary. At all organizational levels, staff may need to embrace entirely new work approaches, as their labs and manufacturing facilities implement state-of-the-art technologies and processes for realizing operational efficiency.[5] Figure 1 provides a visualization of the shift in demand for talent in the biopharmaceutical industry.

Beyond traditional scientific education in such disciplines as biology and engineering, today's modern biopharmaceutical industry demands proficiency in data management and analytics, AI and automation. Transitioning to Industry 4.0 also calls for developing specific soft skills. Adaptability and agility are paramount. In an ever-evolving technological landscape, employees must engage continuously in learning, unlearning, and training to keep their skills in sync with workplace demands.[6]

Reskilling and upskilling are part of the solution and collaborations between businesses and educational institutions are critical—and time is of the essence.

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New and Potential Hires Are Not Prepared

While new university graduates know the latest scientific concepts, they often lack the full range of skills required to work in modern 4.0 facilities. As R&D, administrative and manufacturing operations evolve, the skills expected of new hires also evolve.[7] Adding to this imperative, biopharmaceutical companies compete aggressively for talent with many other employers in their own countries and at a global level.[8] As one observer put it, Industry 4.0 "has positioned the sector in direct competition with the high-tech industry" for talent.[9]

Another challenge is the fact that students perceive the biopharmaceutical industry to be less innovative than other high-tech sectors, which diminishes their interest in pursuing careers in "big pharma."[10]

Existing Employees are Not Prepared

In general, existing employees have the requisite industry experience within their communities of practice, but lack the skills or incentives for transitioning to Industry 4.0.[11] Lags related to sufficient workforce training and the skill gaps of many current employees as the industry advances toward the future are becoming increasingly evident.

In most cases, the growing use of data science, AI, machine learning (ML), process automation, and robotics will not necessarily supplant factory or laboratory workers. Rather, such usage will substantially alter the characteristics of many jobs, compelling employees to master a broader array of skills than traditionally needed.[12] Employees will have to take a multidisciplinary perspective and excel in activities like building and problem-solving that computers and IT systems execute less efficiently.[13] Such efforts will benefit from the availability of accessible and appropriately targeted training courses.

Strategies for Developing a Talent Pipeline

Automation and new job requirements could affect as much as 90 percent of today's biopharmaceutical manufacturing workforce.[14] To upskill the current workforce and successfully train future workers, employers and other public and private stakeholders need deliberate strategies. Such approaches include:

- **Hands-on Learning Environments:** Establish hands-on educational or proof-of-concept (PoC) spaces known as "learning/collaboration factories" where students can engage in real-world biomanufacturing processes with the latest solutions and technologies.
- **Diverse Hiring Practices:** Seek candidates with a mix of hard and soft skills to foster adaptability and creativity in problem-solving.
- **Promote 4.0-Specific Careers in Biopharmaceutical Manufacturing:** Implement targeted promotional campaigns that highlight the innovative and dynamic nature of careers in Biopharma 4.0.
- **Career Advancement Pathways:** Promote non-traditional routes for career development, including such as retraining workers from other industries including lateral entrants and career changes.
- **Strategic Workforce Planning:** Integrate workforce development into overall operations strategies to ensure alignment with Industry 4.0 requirements.
- **Adapting Existing Training Programs:** Continuously update existing training programs and create new ones[15] that reflect the latest technological advancements.

Targeted government support and strategies for workforce development also will help.[16] Governmental bodies in Europe and other regions have acknowledged as much and are striving to expedite implementation.

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Public–Private Training Initiatives

Developing new training programs in public-private partnerships is an effective approach to supporting the needs relative to biomanufacturing's future workforce.[17] By collaborating with industry, universities can keep job candidates up to date on equipment, processes, and regulatory and compliance issues within the industry.[18] Such collaboration also can help to align the requisite skill sets for workers in different entry roles.

Education 4.0 has thus emerged as a business priority and an investment in the future and, therefore, high on the political agenda. European political leaders have long recognized the strategic importance of training on digitalization in their institutes of higher learning.

To support these training approaches, the European Commission has expanded funding for advanced biomanufacturing 4.0. Diverse biomanufacturing training initiatives in Europe are responding to this growing Industry 4.0 need.

MilliporeSigma contributes to onsite and remote training in advanced biomanufacturing through its global network of M Lab™ Collaboration Centers.[19] The M Lab™ Collaboration Centers give scientists access to new approaches and techniques, cutting-edge equipment, troubleshooting, analytical and modeling support, and other advice from MilliporeSigma engineering and scientific experts.

Interdisciplinary Academic Training

Universities can move toward interdisciplinary academic training so that graduates can work across multiple areas in biomanufacturing 4.0 and contribute to teams comprised of generalists and specialists. Students need hands-on training to acquire skills, knowledge, and real-world experiences, as such, learning-by-doing approaches must complement classroom learning. Within these programs, virtual tools can complement rather than replace other types of training.

The Lyon Consortium: Developing Innovative Bio-4.0 Training

The Lyon Consortium was established in 2023 with the goal of developing new approaches to training the biomanufacturing workforce of the future. The Consortium includes a supplier of bioprocessing equipment, expertise, and services such as MilliporeSigma, biopharmaceutical manufacturers, professors, and researchers from the Claude Bernard University of Lyon I, along with experts in financing innovative economic development projects.

The Lyon Consortium exemplifies a successful public-private partnership aimed at addressing the skills gap in the biopharmaceutical sector by leveraging the diversity of insights, perspectives, and experiences of the participants, and accomplished the following:

- Conducted extensive research, including interviews to identify skills gaps faced by employers in the biopharmaceutical sector; the findings serve as the foundation for developing targeted training programs.
- Identified the skills that graduates of public universities, notably Lyon I, acquire as they earn their degrees in biology, chemistry, and pharmacology, the fields in which universities normally train biopharmaceutical workers.
- Mapped these skills gaps and looked for innovative approaches to close them, such as developing new learning modules, deploying state-of-the-art equipment for 4.0 training, and creating special projects to give students opportunities to gain hands-on experience with adequate equipment.
- Aligned with broader French and European workforce development goals and collaborated with specialists to secure public financing for testing then potentially scaling the approach across France and beyond.

Format of Educational Programs

As outlined by the Consortium, training centers, universities, and other stakeholders can develop new training programs via different pathways, each presenting unique opportunities and challenges.

To provide training that meets the needs of Industry 4.0, the Consortium developed an innovative conceptual syllabus combining scientific and IT training. Representatives of two public universities, one private training center, and one biopharmaceutical innovator—all located in France—reviewed and endorsed the syllabus.

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The Lyon Consortium's project creatively, efficiently, and effectively addresses critical workforce training needs in France, in a sector of vital public interest, through hands-on training delivery. The project further explores new funding strategies for universities, providing them with access to specialized experts on fundraising for procuring the necessary equipment for their 4.0 training programs.

Financing

To address universities' financing challenges, the Consortium brought in a specialized consulting group, ABF Decisions, that helps secure French and European funding for projects.

The Lyon Consortium expects its project to create new training approaches for students, along with biopharmaceutical employees wishing to reskill or upskill. With this blended approach, universities could recuperate some of their costs by charging companies the market rate for sending their employees for training. This would require defining the credential earned and creating systems for its verification, in addition to promoting its value in the marketplace as credible and delivered by high-quality training institutes and centers.

Equipment

Having analyzed the training needs for biomanufacturing 4.0, the Lyon Consortium is working on procuring the relevant biopharmaceutical manufacturing equipment, in alignment with the proposed coursework to enable students to join the workforce of the future of the biopharma industry.

The project also brings forward the concept of creating and deploying novel virtual reality (VR) tools to train students on digitalized equipment. Companies are already using this approach to prepare employees for interacting appropriately with clean rooms and could apply it to other aspects of biomanufacturing.[20]

Monitoring and Evaluation

The Lyon Consortium is developing appropriate metrics and a methodology for collecting the necessary information to track the impact of these important initiatives. It plans to continue engaging with employers so that it can assess the relevance of the new and revised training programs and use this information to amend the programs iteratively over time if needed. This feedback, combined with data collection by organizations such as the Lyon Consortium and LEEM, the professional organization of pharmaceutical companies operating in France, will help to innovate new program features and, eventually, new programs.

The Way Forward

The Lyon Consortium's project creatively, efficiently, and effectively addresses critical workforce training needs in France, in a sector of vital public interest, through hands-on training delivery. The project further explores new funding strategies for universities, providing them with access to specialized experts on fundraising for procuring the necessary equipment for their 4.0 training programs.

The creation of a multistakeholder, public-private consortium to ensure new training models align with needs across the biopharmaceutical sector in France and, more broadly, in Europe will contribute to safeguarding the relevance of the new model. The approach can likely be replicated outside of Europe. The Lyon Consortium expects to report publicly on the project's progress to inform similar efforts.

Read the full paper

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