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2023 PHARMACEUTICAL MANUFACTURING TRENDS

The pharmaceutical manufacturing industry has entered a period of rapid innovation and modernization. Life sciences companies are expected to produce and deliver pharmaceuticals at faster rates than ever before. The Covid-19 pandemic and the adoption of Industry 4.0 have brought a multitude of changes to the industry. Furthermore, regulatory inspections are ramping up again and it's essential that companies maintain Current Good Manufacturing Practices (cGMP).

Moving into 2023 and beyond, life sciences companies must continue to find innovative ways to overcome the unique challenges that they face in order to maintain a competitive advantage in the pharmaceutical manufacturing industry.

In this report, we outline five pharmaceutical manufacturing industry trends for 2023:



LABOR SHORTAGES



SUPPLY CHAIN CHALLENGES



RECESSION READINESS



AUTOMATION & BIG DATA



CONTINUOUS MANUFACTURING



LABOR SHORTAGES

As new technologies emerge and demand increases, it's essential to grow the talent pipeline. The pharmaceutical industry is entering gene and cell therapy. Process development and manufacturing cell and gene therapies require new technologies and processes and, therefore, highly skilled and specialized knowledge. Because of this, it's critical to retain and attract specially skilled talent. However, given the emerging nature of the market, the labor pool is limited and highly competitive, leaving jobs unfilled. Some companies are competing with titles and salaries, but ultimately, finding the right knowledge and cultural fit specific to an organization is challenging regardless of the attraction tactics.

Cell and gene therapy companies are not alone in facing labor shortages. Across the board, pharmaceutical companies have struggled to get the right talent in the right place at the right time. Taking advantage of some layoffs in the tech sector and with Big Pharma in late 2022 and early 2023 may provide some much-needed relief.

In addition, digitization and [automation](#) will play a role in addressing the labor shortage. Digitization is transforming manufacturing and can be leveraged to streamline processes and onboard employees. Moving paper-based processes into systems is a simple first step. More advanced applications include using systems for training by simulating real production processes and creating comprehensive knowledge management systems.

While there's no easy solution to the labor shortage, companies can take steps to help close the gap. Onboarding [training and upskilling](#) needs will be different from traditional methods. Companies may need to bring in employees with applicable skills and provide focused, technology-specific training after they are hired to stay competitive and meet growing demand. It's essential to forecast and understand the changing workforce needs and imperative that employees develop robust skill sets.

The manufacturing industry could face a shortage of skills and staff that will cost the U.S. economy \$1 trillion in 2031.

SOURCE



SUPPLY CHAIN CHALLENGES

The Covid-19 pandemic caused a major disruption in the supply chain, and the pharmaceutical industry is no exception. As we move into coexisting with the virus, we may also have to coexist with this challenging [supply chain](#). The industry is now reassessing their manufacturing

networks and strategies. The weaknesses in the global supply chain have become evident and shown the importance of diversifying the supplier base and manufacturing base. [Supply chain resilience](#) is necessary and more important than ever.

The U.S. is largely dependent on foreign manufacturers, which has led to some key drug shortages over the past few years, as most Active Pharmaceutical Ingredients (APIs) come from China and India. There has been an increasing push to bring API manufacturing and contract manufacturing back to the United States in order to strengthen the domestic supply chain. Additionally, building a national stockpile has become a more pressing concern. These can be difficult challenges to take on while fighting to keep up in the current environment.

The need for better [supply chain visibility](#) has also become clear, which is particularly important for cold chain supply. Real-time visibility solutions will help manufacturers better predict the supply chain and react to disruptions. Implementing these solutions will allow businesses to optimize and adapt processes in real-time. New technologies will play a role in addressing supply chain problems and help to build a resilient and robust supply chain.

The IQVIA Institute for Human Data Science estimates that the biopharma industry loses \$34 billion annually due to supply chain temperature-control failures.

SOURCE



RECESSION READINESS

A looming recession is threatening the economy, and the pharma industry must prepare for the challenges that come. The lasting effects of the pandemic, the [war in Ukraine](#), and [increased inflation](#) are leading to changes in the market and operations. Companies are tightening budgets and taking a cautious approach to Research and Development (R&D) efforts in response to the recession. In addition, drug pricing reform may disrupt the industry. Pharmaceutical manufacturers have been consolidating manufacturing capacity. In parallel, they're adopting more out-of-the-box cloud systems that will scale more easily and have low total cost of ownership.

Recession concerns are causing pharma companies to rethink the manner in which they execute their business strategies. [Focusing on scalability](#) is crucial and will require manufacturers to rely on new technologies. For example, [increased automation](#) in manufacturing and laboratories will allow for efficiency and also provide the data needed for insights and advancement. This can also be accomplished through biopharma partnerships,

which are becoming more standard across the industry and helpful in increasing scalability. In addition, creating reusable development and manufacturing methods and processes will play a role in scale-up. Machine learning and automation that have previously been used in academia can be utilized in this arena. Automation and reusability to scale efficiently has been a trend for the past two decades, and the recession will only increase these pressures.

48% of investors expect the U.S. to fall into a recession in the next year.

SOURCE



AUTOMATION & BIG DATA

Big data has the ability to minimize the risk of disruption through integration, efficiency, and innovation. The use of Industry 4.0 manufacturing concepts, such as digitalization, automation, robotics, and artificial intelligence (AI), is spreading across the life sciences industry. A prerequisite for [ISPE's Pharma 4.0 model](#) is an established Pharmaceutical Quality System (PQS) and controlled processes and products.

[AI has played a role in drug discovery](#) and is quickly becoming relevant in the manufacturing space. Creating a “smart factory” with enabling technologies and appropriate cybersecurity will be seen in the future.

Automation and AI have the potential to automatically optimize designs, improve decision-making, and increase throughput. Big data analytics and AI solutions will play a role in predictive quality measures.

With big data predictive analytics, manufacturers will be able to discover quality issues in real-time, and in turn minimize waste and increase cost savings. AI has already been used in pharmaceutical manufacturing in predictive equipment maintenance to [reduce disturbances, risks, and production downtime](#). AI can also be utilized to predict the optimal production schedule for a drug. The use of data-driven, proactive maintenance methods, along with good data hygiene and good [data integrity](#), is essential for growth and optimization.

The pharmaceutical automation market is projected to reach \$18.2 billion by 2029.

SOURCE



CONTINUOUS MANUFACTURING

While many drug manufacturers are moving toward personalized medicine and low-volume production, traditional manufacturers are expanding their use of [continuous manufacturing](#). The switch from batch manufacturing to continuous manufacturing comes with regulatory

challenges and the need for good quality control. Continuous manufacturing isn't a new idea; however, it's still emerging in the pharmaceutical industry and continues to play an important role in manufacturing plants.

The use of continuous manufacturing for generic drugs can increase production capacity and decrease costs. Continuous manufacturing could also play a role in strengthening the domestic supply chain. In developing a continuous manufacturing process, there are quality and regulatory considerations. Many companies have been slow to implement continuous manufacturing due to cost as well. However, the FDA supports the development and implementation of continuous manufacturing. In 2015, the [FDA approved the first continuous manufacturing drug product](#), and has since approved nine more. Continuous manufacturing has the power to increase throughput and is expected to continue growing.

According to the FDA, products using continuous manufacturing entered the market 12 months faster after regulatory submission and three months faster after approval when compared to batch applications.

[SOURCE](#)

CONCLUSION

Businesses are under pressure to fast-track production and deliver products to the market at faster rates than before. Implementing new technologies is difficult in such a highly regulated environment, but developing an innovative strategy is an essential step in overcoming the numerous challenges. Many of these challenges are driven by external factors, such as labor shortages, supply chain problems, and the recession. The emerging sector of cell and gene therapy will continue to grow and will require businesses to optimize processes and add advanced technologies. While many innovative technologies are on the horizon, higher levels of security will be needed.

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