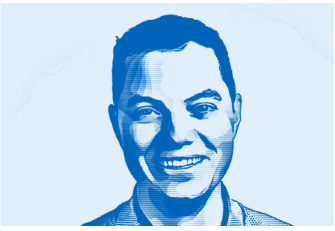

# The Impact of Artificial Intelligence in Biopharmaceutical Manufacturing

Stefan Hyde
*Automation Manager*

Stefan received his Master of Science (M.S.) in Mechanical Engineering with a field of study on controls and an Engineering Management Minor from Northwestern University.

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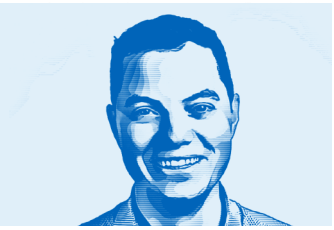
Every year, leaders in the biopharmaceutical industry speculate then invest in technology and methods they believe will benefit the sector as well as patients. The question is whether these yearly investments result in trends that eventually fade out or become foundational staples in better development, productivity, performance, and consumer benefits. Artificial intelligence was first introduced in the 1950s, however, with the advancement of machine and deep learning, it wasn't until the early 2000s that AI was fully applicable in drug discovery as well as the research and development of medicine.[1] AI's applications became even more prevalent – and its value more visible – to enterprises as governments raced to push the Covid-19 vaccine to fruition during the pandemic.


*"AI's applications became even more prevalent – and its value more visible – to enterprises as governments raced to push the Covid-19 vaccine to fruition during the pandemic.*

In the past year, we saw a surge of interest and money flowing into AI among big tech conglomerates; the biopharmaceutical industry was no different, particularly in the infrastructure of pharmaceutical manufacturing and bioprocessing. As we delve into 2024, strategic innovations in biopharma will be more competitive than ever. Without the implementation of AI in newly evolved business models striving for better product delivery and excelled patient experience, companies including manufacturers, will find it harder to gain headway in productivity and optimized value ahead of their competitors.

Historically, biopharma enterprises have been shown to face "a complex and challenging environment due to increased competition and R&D cycle times, shorter time in market, expiring patents, declining peak sales, pressure around reimbursement and mounting regulatory scrutiny"[2] These obstacles contributed to an increased fallout in "projected return on investment that large biopharma companies might expect to achieve from their late stage pipelines."[3] Many of these bottlenecks have been reversed as biopharma enterprises utilize its large data volumes through complex and ever-evolving learning systems to provide solutions in diagnosing its production stages.

[1] https://www.giejournal.org/article/S0016-5107(20)34466-7/fulltext.
[2] https://www2.deloitte.com/us/en/insights/industry/life-sciences/rise-of-artificial-intelligence-in-biopharma-industry.html.
[3] https://www2.deloitte.com/us/en/insights/industry/life-sciences/rise-of-artificial-intelligence-in-biopharma-industry.html



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Entering the realm of Industry 4.0, also referred to as the Pharma 4.0™ Operating Model by the International Society for Pharmaceutical Engineering (ISPE), we venture further away from human powered applications and dive into the integration of big data. Focusing on pharmaceutical development and manufacturing, AI and ML "already represent an important aspect of how modern contract development and manufacturing organizations operate."[4]

Here are several ways in which AI is impacting biopharmaceutical manufacturing:

## ROBOTICS AND AUTOMATION

**Robotic Process Automation (RPA)**: AI-driven robots automate and streamline industrial repetitive processes otherwise done manually. Manufacturers will often make more than one product so an elevated sort of automated workflow such as matrix production systems in comparison to linear systems are more beneficial. This type of machine learning lowers error rates, increases safety, and raises productivity ultimately minimizing costs, matching and even exceeding supply for an increasing amount of demand we see in therapeutics. A more enhanced form of AI and robotics in manufacturing means "more personalized medicine, more diseases treated, and treatment of a larger population. According to a 2021 survey by Deloitte, in manufacturing, 75% of life sciences leaders say AI is a priority investment in the next five years."[5]

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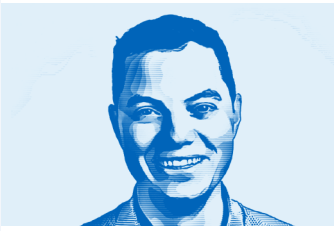
## PROCESS OPTIMIZATION

**Bioprocess Optimization**: "Unlike the chemical process…bioprocess has high time scale variability of different stages and phases because of the different inoculation size, seed age, or culture conditions"[6] giving way to challenges in recognizing and targeting exact and accurate bioprocess phases. To enhance yield and lower production costs, AI improves bioprocessing parameters by identifying and generating new insights into fermentation conditions and culture media composition.

[4] https://www.genengnews.com/insights/growth-of-artificial-intelligence-in-pharma-manufacturing/
[5] https://www.pharmexec.com/view/ai-to-impact-clinical-trials-and-manufacturing-in-life-sciences
[6] https://www.sciencedirect.com/science/article/abs/pii/S0960852422017849



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**Real-time Monitoring**: Real-time data on numerous process parameters is provided by AI-enabled sensors and monitoring devices. AI can diagnose issues in the entire manufacturing process including detecting failures in machinery, forecasting possible breakdowns in production lines, as well as identifying and reducing the consumption of energy. This guarantees that the production process is running smoothly and allows for quick modifications. Automated inspection involving computer vision systems driven by AI means pharmaceutical items can be inspected automatically. This ensures consistency and identifies flaws more precisely than with conventional techniques. According to a recent study done by McKinsey, "25% of inspection costs and 10% of annual maintenance could be reduced if AI is used."[7]

## SUPPLY CHAIN MANAGEMENT

**Demand Forecasting**: Due to the pandemic, the industry experienced supply chain issues due to global factory shutdowns and lack of workforce affecting production lines worldwide. Supply chain challenges were further fueled by the increasing demand for the Covid-19 vaccine giving light to how much the biopharma industry could use AI's ability to predict demand and mitigate risk. By examining previous and current datasets such as market trends, global events, weather movements, and other factors that could impact supply chain integrity, AI is able to predict the need for pharmaceutical products as well as prevent possible supply chain disruptions ultimately enabling increased productivity. This assists companies in combating shortages and excess inventory. Furthermore, AI optimizes supply chain logistics by streamlining the distribution and transportation of medical supplies, saving expenses and ensuring on-time product delivery.

*"Consequently, companies are investing in blockchain and AI technologies to improve security, transparency and traceability.*

The biopharma manufacturing industry is also seeing an influx in counterfeit products or drugs that fall below the standard of regulations. "For biopharma the importance of supply chain integrity goes beyond counterfeit products, as key product types need 'chain of identity' and 'chain of custody'. Consequently, companies are investing in blockchain and AI technologies to improve security, transparency and traceability."[8]

AI is likely to surge past the title of a mere market trend and will quickly become a mainstay for biopharma manufacturing. Not only does it prove immensely beneficial in all aspects of the business process from discovery to product delivery, but it also serves to optimize future operations.

**Questions?**

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[7] https://www.forbes.com/sites/forbesbusinesscouncil/2023/03/15/five-areas-where-ai-is-revolutionizing-the-biopharmaceutical industry/?sh=3fc7baa87087
[8] https://www2.deloitte.com/ch/en/pages/life-sciences-and-healthcare/articles/intelligent-drug-supply-chain.html.