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Manufacturers who recognize trends and practice risk mitigation will create solutions that become the industry standard

The Future of Biopharmaceuticals: Top Trends and Risks

The future trends and risks of biopharmaceutical manufacturing are foreshadowed by issues that arise from social and economic impact of its preceding climate. Trends introduced in recent years will evolve to have a more significant impact in the years to come and although the industry continues to improve on ways to advance the sector, it still needs to resolve the supply chain challenges ignited by COVID-19. With any new or accelerating trends, fresh ventures can create instability and risks may arise in the effort to resolve old issues. Manufacturers who recognize trends and practice risk mitigation will create solutions that become the industry standard. The following top trends and risks pave the way for what we believe to be a better biopharmaceutical future.



ADVANCING TECHNOLOGIES

Labor shortages reflected in the production side of biopharma manufacturing may be a thing of the past as machine learning (ML), artificial intelligence (AI), and the Internet of Things (IoT) play an integral part in streamlining drug development. “McKinsey researchers estimate that as much as 30% of biopharma’s production workforce – employees like manufacturing technicians and packaging operators – may be displaced by automation by 2030.”¹ Turning your facility into a smart factory cuts staffing expenditures, optimizes the downstream process, and mitigates human error for greater efficiencies. Integrations of Industry 4.0 not only streamline operations but also provide clearer visibility of supply chains by revealing weak points.

Digital pills also have the potential to make a substantial impact on the pharma industry. The first such pill was approved by the FDA in 2017² and is meant to serve as a digital tracker for patients with illnesses that require scheduled intake. Laboratories and manufacturing facilities will need to prepare to employ proper machinery, technology, and third-party vendors to produce the electronic circuits embedded in the pills.

¹ <https://blog.isa.org/the-top-4-biopharmaceutical-manufacturing-trends-in-2022>

² <https://medicalfuturist.com/top-10-trends-shaping-future-pharma/>



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GENERIC DRUGS

Although brand-name drug companies dominated media outlets and attracted investor interest during the pandemic, we've seen a massive surge of generic drugs in 2022 with the global generic drugs market estimated to hit \$574.63 billion by 2030.³

Driving factors behind generic drug growth in the marketplace include:

- » Declining generic drug costs as prescription prices for brand names increases.
- » Expiring patents forcing drug makers to release new medicines to grow profits – opening opportunities for generic drug producers to launch new drugs into the market.
- » Increasing support from the FDA – since the passing of the Generic Drug User Fee Amendments Reauthorization (GDUFA II) – as it looks to aid developers and producers of generic drugs.
- » Growing instances of chronic illness worldwide.



BREAKTHROUGH IMMUNOTHERAPIES

Oncology is one of the top three fastest-growing therapeutic areas. In fact, “the global market for oncology pharmaceuticals should grow from \$177.4 billion in 2021 to \$313.7 billion by 2026, at a compound annual growth rate (CAGR) of 12.1%.”⁴

Ground-breaking immunotherapy advancements in the treatment of cancer are influencing the landscape of manufacturing operations and supply chain. Although gene and cell therapy has shown the potential to treat rare and stubborn diseases, the industry is still in the beginning stages of supporting those treatment methods as they require more intricate and personalized supply chain types. Pharma companies seek to adopt a more customizable manufacturing approach to prepare for complex processing as “the number of personalized drugs is expected to double or even triple in the upcoming years.”⁵

³ <https://www.europeanpharmaceuticalreview.com/article/166397/generic-drug-market-growth-insights-to-2030/>

⁴ <https://www.businesswire.com/news/home/20220314005621/en/Global-Pharmaceuticals-Industry-2021-2022-and-Beyond---Huge-Opportunities-in-Precision-and-Genomic-Medicine---ResearchAndMarkets.com>

⁵ <https://www.businesswire.com/news/home/20220314005621/en/Global-Pharmaceuticals-Industry-2021-2022-and-Beyond---Huge-Opportunities-in-Precision-and-Genomic-Medicine---ResearchAndMarkets.com>



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SUPPLY AND DEMAND

Over the next few years, volatility will be prevalent on both the supply and demand sides of the industry. Unemployment and higher costs of living fueled by inflation will negatively impact consumer purchasing power, particularly for those who remain uninsured. Residual supply chain issues from the pandemic will continue to influence customer purchase decisions, potentially deterring them from their usual prescriptions due to a lack of inventory.

For biopharmaceutical manufacturers, inflation and economic fluctuation are constants. Therefore, as manufacturers navigate the financial and consumer challenges, it is also vital to prioritize efficiency in streamlining their process resulting in less waste, faster production output, and lower costs. In addition, to further combat supply chain disruptions, it is critical for companies to accurately predict consumer needs, increase inventory, and retain sources to minimize the possibility of shortages.

SUPPLY CHAIN AND LABOR CHALLENGES

Volatility in pharma supply chains due to COVID-19 has driven biopharmaceutical manufacturers to prioritize preventive measures and distribution efforts going forward. Factors that heavily contributed to supply chain issues were:



Policies
Global policies shutting down factories and ports



Location
Overseas distribution failures plus longer shipping times causing disruptions



Demand
Influx of consumer demand overran supply



Manpower
Labor shortages

The pandemic drove the industry to recognize initiatives that strategically combat all possible supply chain scenarios on a long-term scale, as supply chain experts believe these challenges aren't likely to end soon.⁶

Biopharmaceutical manufacturers that seek to strengthen their supply chain should focus on regional outsourcing. Contract manufacturing will play a pivotal role now more than ever, and this is particularly applicable for labor shortages as contract workers are flexible and easily facilitated during staffing constraints. Furthermore, closing the distance and bringing biopharma activity regional will benefit supply chains making them less susceptible to delay.⁷ Overall, enforcing vigilant management in logistics and adapting supply chain procedures will minimize flow disruption, increase visibility, and decrease waste.

⁶ <https://wtwww.rochester.edu/newscenter/what-is-supply-chain-issues-explained-525302/>

⁷ <https://www.rochester.edu/newscenter/what-is-supply-chain-issues-explained-525302/>



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Environmental-based initiatives within the manufacturing realm are crucial global objectives considering the limited resources available globally

Questions?

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CYBERSECURITY AND DATA BREACHES

Due to rapid advancements in technology, protecting consumer and industry data from cyber criminals is more crucial than ever. According to IBM's 2020 Cost of a Data Breach Report, "cyberattacks cost the industry more than \$5 million last year."⁸

The industry's adoption of IoTs, increased outsourcing to third-party supply chains, and data distribution across multi-cloud systems, including classified or intellectual property, are all reasons biopharma companies should be wary of data breaches. A manufacturer can increase protection by investing in solid cybersecurity, sensitive data protection, and better internal cybersecurity policies, including training for all staff members on-location and remote. In addition, integrating the proper resources to protect the integrity of your system internally and externally will decrease the risks of operational disruptions and malware.

The trends and risks we cover are just a fraction of what the future holds. In a consistently evolving industry, experts should prepare for increasing demand and aim to control potential pain points by monitoring industry advancements. Assessing trends and taking action ahead of time allows biopharma manufacturers to maximize ROI and mitigate risks.

For biopharmaceutical manufacturers, inflation and economic fluctuation are guaranteed constants. Therefore, as manufacturers navigate the financial and consumer challenges, it is also vital to prioritize efficiency in streamlining their process resulting in less waste, faster production output, and lower costs. In addition, to further combat supply chain disruptions, it is critical for companies to accurately predict consumer needs, increase inventory, and retain sources to minimize the possibility of shortages.

⁸ <https://www.ibm.com/security/data-breach>.