



Executive Summary

The pharmaceutical industry is undergoing a transformative shift driven by expiring drug patents, rising cost pressures, and evolving global health demands. By 2030, over USD 100 billion in annual sales from blockbuster drugs will be at risk due to patent expirations, intensifying competition from generics and biosimilars. In response, pharma manufacturers are embracing advanced technologies and reimagining their manufacturing strategies to remain competitive and resilient.

This Point of View explores the key trends reshaping pharmaceutical manufacturing. Central to this transformation are advancements in biotechnology, including Cell and Gene Therapy (CGT), genomics, biosimilars, and nanomedicine. These innovations are enabling more personalized, patient-centric therapies but also demand specialized manufacturing capabilities, cleanroom environments, and updated standard operating procedures (SOPs).

Market forces are also influencing manufacturing strategies. Outsourcing to contract manufacturers is on the rise, especially in emerging markets, to reduce costs and improve accessibility. Simultaneously, sustainability is becoming a core focus, with green chemistry and biocatalysis gaining traction. Geopolitical shifts, such as trade tensions with China, are prompting companies to reassess supply chain dependencies and localization strategies.

On the technology front, **Industry 4.0** is revolutionizing operations. The adoption of **single-use technology**, **digital twins**, **AR/VR for workforce training**, cloud computing, and 3D/bioprinting is enhancing efficiency, reducing contamination risks, and enabling real-time decision-making. **Gen AI and Agentic AI** are further accelerating drug development, optimizing SOPs, and predicting deviations in manufacturing processes.

Smart packaging technologies, including radio-frequency identification (RFID), near field communication (NFC), and sensor-embedded materials, are improving traceability, patient engagement, and inventory management. These innovations, coupled with sustainable packaging materials, are reshaping the pharma supply chain.

In conclusion, the future of pharmaceutical manufacturing lies in agility, digitalization, and sustainability. Capgemini Invent India's Life Sciences team is well-positioned to guide organizations through this transformation, leveraging deep domain expertise and cutting-edge technology to drive innovation, reduce time-to-market, and ensure long-term growth.

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Trends in the pharmaceutical industry in reshaping manufacturing

Various trends are shaping up in the pharmaceutical and bio-pharma industry in the near to long term. The trends are broadly categorized as:

Introduction

The pharmaceutical industry is poised to face significant cost and supply chain challenges by 2030. Between 2020 and 2030, patents for over 15 blockbuster drugs—collectively generating over USD 100 billion in annual sales—are expected to expire. This will open the market to a surge of generics and biosimilars, putting pressure on margins for major pharmaceutical players.

As per Capgemini Next-Gen Pharma Lab Survey, October 2023, the need for faster drug development, digitalization, and a shift towards innovative therapies are impacting pharma organizations globally.

The COVID-19 pandemic also reignited focus on supply chain localization, with companies seeking to mitigate region-specific disruptions. Combined with increasing regulatory complexity and stringent quality controls, these dynamics are reshaping manufacturing priorities.

To navigate these challenges, pharma manufacturers are turning to disruptive technologies—Artificial Intelligence (AI), digital twins, predictive analytics, 5G, TinyML, generative AI (Gen AI), and cloud platforms—to reduce time to market, enhance cost efficiency, and build resilient supply chains.

This point of view explores the future trends and challenges shaping pharmaceutical manufacturing and highlights how the Life Sciences team at Capgemini Invent India can serve as a key enabler in driving digital transformation across this domain.



Advancements in biotechnology



Market forces



Manufacturing process / technology / digital / Industry 4.0



Impact of Gen Al



Packaging



Advancements in biotechnology

Pharma and bio-pharma manufacturing is witnessing increasing innovation as therapies become increasingly human-centric in nature. As a result, newer therapies such as Cell and Gene Therapy (CGT) have brought disruption in bio-pharma manufacturing as the CGT process develops drugs with patients at the center. This has helped develop novel therapies targeting critical illnesses, including cancer and autoimmune conditions.

Genomics is playing a big role in the development of personalized medicine as manufacturers are looking to move away from the "one size fits all" approach to drug development and manufacturing. For instance, **precision treatments** have been developed in the last few years to treat Human Epidermal Growth Factor Receptor 2 positive (HER-2-positive) breast cancer cells, thereby improving the prognosis of the disease.

Biosimilar are biologically similar products of biologics and are increasingly witnessing approvals by regulatory authorities to reduce overall healthcare costs, especially in the fields of oncology, inflammation, and nephrology. Industry analysts say that biosimilars are on track to reduce U.S. drug expenditure by USD 133 billion by 2025^[1].

Nanomedicine is also an upcoming area of therapy development and the development of nanoparticle-sized medicines and vaccines such as Messenger Ribonucleic Acid (mRNA) vaccine, which is expected to help in fighting viral-based diseases such as Human Immunodeficiency Virus (HIV) and Coronavirus Disease of 2019 (COVID-19).

These biotechnology advances are expected to impact the manufacturing process as they will lead to newer manufacturing processes with specialized equipment, cleanroombased manufacturing, and upgrading the existing manufacturing processes and standard operating procedures.

Market Forces

With an increasing focus on innovation and research & development (R&D) of high-margin medicines, manufacturing drugs have become a specialized function that is getting increasingly outsourced to **contract manufacturers**. For example, Pfizer is looking at contract manufacturing partners in emerging countries so that the products from Pfizer can be made available in low-income countries at affordable prices. Contract manufacturers such as Samsung Biologics and Catalent^[2] are investing in advanced high-end manufacturing systems to be able to partner with the big pharma companies for exclusive drug contracts.

Pharma manufacturers focus on the development of sustainable products, practices, and processes as climate goals take priority. Green Chemistry or **Biocatalysis** is increasingly preferred in developing Active Pharmaceutical Ingredients (APIs) as wastegenerating materials and substances are gradually being phased out in manufacturing and packaging medicines.

The recent trade wars of 2025 are shaping the geopolitical landscape of pharma manufacturing; China has emerged as a major source of APIs and promising drug candidates. Collaboration of big pharma companies with Chinese firms is expected to be impacted. For example, <u>Johnson & Johnson's</u> (J&J's) collaboration with Legend Biotech in China [3] could experience difficulties due to the tariffs.

The companies co-develop the **CAR T therapy Carvykti** for multiple myeloma and are expected to commercialize the same. AstraZeneca's USD 1 billion acquisition of Gracell Biotechnologies^[4], a Chinese cell therapy firm, could be impacted. AstraZeneca acquired Gracell Biotechnologies' investigational cell therapy GC012F, a dual-targeting autologous CAR-T therapy for multiple myeloma, other hematologic cancers, and autoimmune conditions like systemic lupus erythematosus.

Thus, market forces play a critical role in drug development strategies and business models, localization of supply chain, requirement of skilled labor, and focus on green material for manufacturing and packing and manufacturing by specialized contractors which in turn impacts pharma manufacturing in a major way.



Manufacturing process / technology / Industry 4.0 / Digital

The development of CGT has led to the adoption of **single-use process systems** in manufacturing. The rise in the adoption of single-use technologies is proving to reduce product cross-contamination risks by eliminating the need for cleaning between batches, making it more efficient and cost-effective. Single-use systems lower operating costs by offering 46 percent less water and energy reductions, a 35 percent more favorable CO2 footprint due to lower facility emissions, and a 40 percent lower initial investment cost. [5]

With the advent of newer technologies, there is a need for **advanced skillsets** which has led to the creation of a skill gap in the pharmaceutical industry and these new technologies themselves are expected to help in overcoming this gap in the near term. Pharma manufacturers are leveraging Augmented Reality / Virtual Reality (AR/VR) technologies for internal upskilling and crossfunctional training, thereby reducing dependency on external hiring.

Pharma companies are looking at **Digital Twins** as an efficient option for streamlining operations processes as well as drug development. Airbus, Capgemini, and Roche [6] have joined forces to develop and industrialize a digital ecosystem for industrial and manufacturing environments. The **Virtual IoT Manufacturing System (VIMS)** delivers detailed visualizations of manufacturing processes from single production lines to complete factories, thereby giving full control of production lines to operators, engineers, and managers.

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Bio-printing typically is a long-term process carried out on actual patients. Institutions have already started to print human ears and <u>Poietis</u>, a <u>French company is commercializing bio-printed skin for drug development or ingredient testing purposes [7]</u>.

Lack of end-to-end visibility in manufacturing processes and supply chain is one of the major challenges which is being addressed with the help of cloud computing and data analytics as these technologies help structure the data and increase the data interoperability by removing silos. Many big pharma companies such as J&J, and Novartis are looking to develop centralized control towers to improve the visibility and monitoring of data across the pharma value chain, thereby aiding in predictive analytics and predictive maintenance.

3D printing / Additive Manufacturing offers an eco-friendly method of medicine manufacture as formulations can be produced with little or no drug and excipient wastage. 3D printing is also helpful in manufacturing the drugs and/or part of complex equipment in a customized manner. 5G in telecommunication. EDGE/TinvML. **and Metaverse** are expected to speed up the manufacturing processes and bring in efficiency. 5G assists pharmaceutical products in moving through the supply chain using edge computing and blockchain technologies and also helps track and verify them. The metaverse leverage digital twins to reduce the cost and time required to run reliable clinical trials, through the development of virtual clinical trials.

The advent of digital technologies, analytics, digital twins, 3D printing, bio printing etc. will help in automating manufacturing processes leading to more efficient and productive manufacturing.

The adoption of newer equipment and processes, enabling faster commercialization of drug development, and enhancement of the skill level of workers will be impacting the manufacturing processes and technology.



Gen Al and Agentic Al

Gen AI has positively impacted the pharmaceutical industry as the industry focuses on reducing the drug development pipeline. Gen AI is expected to play a major role in virtual screening of drug candidates during drug development process and will also speed up the candidate selection process during clinical trials.

Gen AI is expected to improve the quality aspect in manufacturing by predicting impurities and deviations in a batch while manufacturing and automating documentation and real-time deviation alerts. Gen AI will be used in optimizing the manufacturing standard operating procedures (SOPs) to improve downtime and overall yield of the end-product. One notable example is of Insilico Medicine [8], a biotech company based in Hong Kong, who designed their pulmonary fibrosis drug using Gen AI in about half of the typical drug development timings and in 10% of the typical drug development costs. As per Capgemini experts, Gen

Al or Large Language Models are also helping in the development of Multimodal AI models for the Life Sciences sector, which helps in unlocking significant opportunities for deeper clinical and medical data analysis using various data types such as molecular and genetic information, electronic health records, diagnostic images from Magnetic Resonance Imaging (MRI) reports and Computed Tomography (CT) scans, and patient interaction recordings.

Agentic AI will enhance decision-making and bring in precision in manufacturing by end goals. Agentic AI can identify trends in operating data that point to wear and tear and decide to stop equipment before failure, thereby enabling maintenance workers to make repairs before a breakdown occurs.



Packaging



Pharma companies are adopting **smart packaging** solutions for more efficient processes. For instance, Sanofi, GSK, and other companies have introduced prefilled syringes in the market, which are dose accurate, sterile, convenient to administer, and affordable. Additionally, smart packaging includes initiatives to **track and trace** the inventory using **Radio-Frequency Identification (RFID) tags,** to discourage medicine counterfeiting.

Barcode scanning and Near Field Communication (NFC) tagging are expected to introduce intelligent packaging solutions, as the package information can be read by the patients with the help of smartphones and thereby helps in reducing wastage of labeling on secondary packaging. Packaging

material embedded with sensors uses microchip sensors to record data for accurate dosing and dose monitoring. As an example, whenever a patient removes a pill from the packaging, a built-in sensor will record this data and upload it to a cloud source, enabling real-time inventory tracking at the consumer end.

There is a growing emphasis on sustainable primary and secondary packaging materials, including bioplastics and biodegradable alternatives. Faster drug discovery, smart packaging and labeling, bioplastics, and an increase in supply chain visibility are some of the trends which will majorly impact the overall supply chain of the pharma industry to enable faster drug development and commercialization.

The impact of trends on pharma manufacturing

| | Trends | Complexity | Capital Expenditure | Adaptability | Capability |
|--|--------------------------------------|------------|------------------------|--------------|------------|
| Advancement in Biotechnology | Cell and Gene Therapy | | | | |
| | Genomics | | | | |
| | Biosimilars | | | | |
| | Nano Medicine | | | | |
| Market Forces | Contract Manufacturing | | | | |
| | Bio Catalysis | | | | |
| Manufacturing Process / Technology / Industry 4.0 / Digital | Single Use technology | | | | |
| | Resources training with AR/VR | | | | |
| | Digital twin | | | | |
| | Bioprinting | | | | |
| | Cloud Computing and Data Analytics | | | | |
| | 3D printing / Additive Manufacturing | | | | |
| | Edge Tiny ML and Metaverse | | | | |
| Gen Al and Agentic Al | Gen Al | | | | |
| | Agentic Al | | | | |
| Packaging | Smart Packaging | | | | |
| | Barcode scanning and NFC tagging | | | | |
| | Sustainable materials | | | | |

| Parameter | Meaning | Range |
|---------------------|--------------------------------|--|
| Complexity | Ease of implementation | Easily implementable |
| | | Moderate complexity |
| | | Quite Complex, need new infrastructure |
| Capital Expenditure | Cost of Implementation | Cost effective |
| | | Moderate Costinvolved |
| | | Cost intensive |
| Adaptability | Adoption of trend across globe | Low adoption |
| | | Medium adoption |
| | | Rapid adoption |
| Capability | Upskilling required | Current Skillset is enough |
| | | Need upskilling |
| | | Complete new skillset is required |





Conclusion

In conclusion, the future of pharmaceutical manufacturing will be shaped by rapid technological evolution, shifting market dynamics, and increasing regulatory and sustainability demands. From advancements in biotechnology to the rise of AI, digital twins, and smart packaging, pharma organizations must adopt agile and intelligent manufacturing strategies to remain competitive.

The Life Sciences team at Capgemini Invent India, with its deep domain expertise and technology leadership, is well-positioned to support pharmaceutical enterprises in navigating these transformative shifts—driving innovation, accelerating time-to-market, and ensuring sustainable growth.

Authors:



Prathmesh Limaye Manager – Life Sciences, Capgemini Invent India prathmesh.limaye@capgemini.com

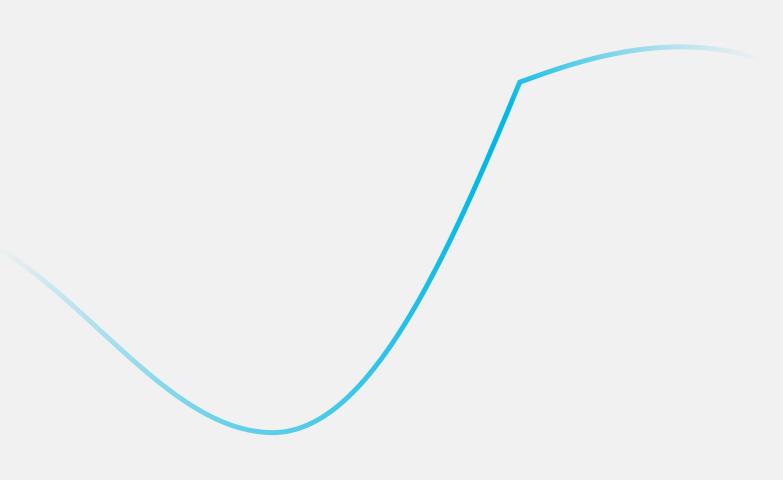


Abhijit Wakodikar Senior Manager – Life Sciences, Capgemini Invent India abhijit.wakodikar@capgemini.com

Reviewer:



Dr. Sarika Vanarse Senior Director – Life Sciences, Capgemini Invent India sarika.vanarse@capgemini.com



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