

## Advancing Green Pharmaceuticals: Sustainable Biomanufacturing Practices Across Asia Pacific

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**The pharmaceutical industry is at a critical juncture, urgently needing to transform towards sustainability to reduce its environmental footprint. Sustainable biomanufacturing is a key focus within this context, primarily aiming to produce pharmaceutical products such as drugs, vaccines, and biologics using processes with minimal environmental impact. This includes resource conservation, waste reduction and greenhouse gas (GHG) emissions reduction, renewable materials and energy deployment, and greener operations throughout the sourcing, manufacturing, and distribution processes.**

According to WHO, modern health systems contribute around 5% of global carbon emissions. Around half of these emissions originate in manufacturing supply chains, including from the Asian region, considering the high presence of pharmaceutical manufacturers. A research study in Japan outlined that healthcare activities account for about 5% of national GHG emissions, with pharmaceuticals alone contributing an estimated 11.3 MtCO<sub>2</sub>-e (27% of healthcare emissions). Besides GHG emissions, pharma manufacturing can also result in air and water pollution through various solvents, effluent discharge, and waste generation. It is well-known that waste generated by antibiotic manufacturing can potentially create environmental hotspots of antimicrobial resistance, a public health concern. APIs (active pharmaceutical ingredients) released in wastewater are also a cause of concern, potentially leading to drug-resistant microbes, directly linking environmental stewardship and drug efficacy.

Governments and international bodies are playing a pivotal role in promoting sustainability in the pharmaceutical industry. They are actively integrating sustainability targets in regulations and setting industry standards. Regulatory bodies in the Asia Pacific (APAC) region are aligning themselves with international climate change goals and agreements. Initiatives such as Japan's net-zero emission targets for 2050, China's "Blue Sky" initiatives, and India's draft rules to limit antibiotic discharge

are spurring pharmaceutical companies to set their emission reduction targets. With US and European customers considering environmental criteria in procurement, sustainability efforts are becoming a pivotal requirement for market access for APAC API and generic drug manufacturers and suppliers.

Pharma and biotech companies are starting to respond to the expectations of their customers and investors, integrating carbon neutrality and eco-efficiency as part of their strategic goals. Stakeholder efforts such as the Carbon Disclosure Project (CDP) and Science Based Targets Initiative (SBTi) have gained significant traction in the industry. Japanese pharma companies are leading climate assessment efforts, especially in transparent sustainability reporting and goal setting. In APAC, there is a burgeoning interest in “green pharma” that can encourage manufacturers to adopt sustainable biomanufacturing as a means of competitive differentiation and innovation.

Sustainable biomanufacturing is not just about environmental benefits; it also offers significant economic advantages. Efficient bioprocesses can reduce waste and energy consumption, leading to lower operating costs in the long run. Companies are increasingly viewing sustainability and cost-efficiency as aligned goals, as resource optimization and yield improvement are both economically and environmentally favorable. With emissions trading schemes gaining momentum, reducing GHG emissions can translate to direct cost savings and potentially reduce future carbon taxes. Implementing greener biomanufacturing processes allows companies to gain an advantage over anticipated regulations and gain time to establish resilient operations. For Asian countries that still import high volumes of drugs and/ or raw materials, establishing resilient operations will boost local, sustainable production and improve self-sufficiency, making the transition to sustainable biomanufacturing advantageous from an environmental, regulatory, and business angle.

### **Technological Advances Enabling Sustainable Biomanufacturing**

Advances in biotechnology and engineering are providing the pharma industry with new tools and processes to make sustainable biomanufacturing feasible. Technology advances are widespread, including process innovations, green chemistry, recycling and waste reduction, and circular approaches.

Traditionally, pharmaceuticals, especially biologics such as therapeutic proteins, are manufactured using batch processes, which are intensive and time-consuming. Shifting from batch to continuous manufacturing can improve efficiency and eliminate downtime between batches, and using smaller reactors can help achieve a higher product yield per unit volume and reduce energy and water requirements. Continuous manufacturing integrated with automation technologies can maintain high purity levels while reducing water and energy consumption. While maintaining high purity levels. Process intensification includes high-cell-density fermentation, perfusion cell culture, and high-efficiency bioreactors to increase manufacturing output and productivity while reducing resource input. Companies like Samsung Biologics’ are incorporating process integration and advanced automation to reduce energy requirements in line with its net-zero emissions goals.

Green chemistry principles are being considered for manufacturing processes using safer solvents, fewer steps, and less waste. Biocatalysis and fermentation to manufacture generic APIs and enzymatic processes for synthesizing drugs like statins and antibiotics are gaining momentum. Synthetic biology advances to produce pharmaceutical compounds from renewable feedstocks are being undertaken on a small scale. Technology such as that of ASTAR and MojiaBio, which uses engineered microbial pathways to convert low-cost renewable feedstocks to high-value molecules, can be used in the pharma industry. Biotechnological approaches that leverage algae or CO<sub>2</sub>-utilising microbes and enzymatic synthesis to manufacture APIs are being investigated. Biocon is utilizing enzymatic processing for some of its biopharmaceutical production to improve yields and reduce chemical usage; pharma companies are also using enzymatic catalysis for drug synthesis. Dr. Reddy’s Laboratories, India, has a dedicated Process Innovation group to re-engineer several of the company’s bulk drug syntheses to reduce waste. The company implemented a catalytic route for an antiviral API that cut solvent usage by half and eliminated a toxic reagent, showcasing the company’s commitment to green chemistry.

The use of single-use (disposable) bioreactor systems is a matter of debate; however, it must be accepted that they provide flexibility and eliminate energy-intensive cleaning and sterilization. These systems also allow smaller, modular designs that can be scaled with a lower capital investment with the trade-off of potential waste generated due to disposable components. However, with the increased use of bio-based or recyclable single-use materials and recycling programs, single-use bioreactors can gain acceptance in the next three to five years. With APAC countries being a leading manufacturer of single-use components such as disposable bioprocess bags, filters, etc., regional efforts can go a long way to establish processes that can make sustainable single-use bioprocessing systems.

Digital technologies, including sensors, automation, artificial intelligence (AI), and data analytics, have been established to play a vital role in ensuring sustainability in biomanufacturing processes. Biomanufacturing 4.0 and 5.0 leverage these

technologies to monitor and control manufacturing processes in real-time and optimize to reduce waste and resources. Integrating Process Analytical Technology (PAT) and automation can reduce batch failures and improve yields. Consortia, such as BioPIPS in Singapore, focus on leveraging data analytics, digital twins, and others to enhance productivity and sustainability in manufacturing.

It's well-known that manufacturing drugs and other pharmaceutical compounds generate a lot of waste streams; deploying advanced water and wastewater treatment technologies such as advanced oxidation and membrane bioreactors can drastically reduce the impact on local ecosystems. Integrating advanced catalysis, solvent recovery systems, and Zero Liquid Discharge (ZLD) are being considered to improve sustainability.

### **Rising stakeholder interest in sustainable biomanufacturing**

There is a growing interest amongst APAC pharma companies in incorporating sustainability efforts into their business operations. Japanese and Korean companies actively deploy sustainability and ESG strategies and devise ambitious targets. For example, Takeda is working towards achieving “carbon zero” by 2040. Many of the top 10 Japanese pharma companies, including Astellas and Chugai, aim to cut 20–55% of emissions by around 2030–2040, with a path towards net zero by 2050. Biocon and Samsung Biologics are other examples of stakeholders actively integrating sustainability practices in all their operations. GenScript Biotech has also committed to emissions reduction targets validated by the SBTi. Pharma players are not restricting themselves to carbon reduction emissions alone; they are actively involved in pollution, water stewardship, and waste reduction.

These efforts are actively supported by initiatives from industrial consortia and associations whose focus covers the entirety of the pharma operations from R&D to retail, including supply chain and infrastructure. The AMR Industry Alliance has developed an environmental framework to reduce antibiotic manufacturing pollution, and some of the Indian manufacturers have initiated self-reported compliance in line with its discharge targets. APAC manufacturers also participate in initiatives such as the United Nations Global Compact and local green industry programs. Singapore's Pharma Innovation Programme (PIPS) and its extension, BioPIPS, are examples where regional arms of companies like GSK, Sanofi, and local biotechs collaborate with ASTAR to test and trial new sustainability efforts in real-world settings. Pharma companies are also building coalitions to promote sustainability; one example is the joint initiative of various Japanese pharma companies such as Astellas, Eisai, Daiichi Sankyo, and Takeda to reduce packaging waste and incorporate eco-friendly materials.

Efforts extend to establishing green manufacturing and infrastructural facilities. Pharma companies are working with suppliers to shift to renewable energy and cleaner processes. Programs like China's collaborative model of renewable energy procurement and India's Energize can help companies access renewable energy and facilitate a smooth transition. Factories are also being remodeled, retrofitted, or built to high environmental standards, showing the region's interest in adopting sustainable biomanufacturing. Wuxi, for example, is upgrading its facilities in China by installing solvent recovery in its chemical labs, using energy-efficient freezers and HVAC in biologics facilities, and actively participating in China's Green Manufacturing Initiative. WuXi Biologics' latest biologics plant in Jiangsu is equipped for continuous processing and uses heat pumps instead of conventional boilers for process heating.

### **Governmental efforts to boost sustainability act as a growth lever**

Japan's Ministry of Economy, Trade and Industry (METI) has established subsidies for energy-saving equipment in pharma factories. South Korea's Ministry of Trade, Industry and Energy (MOTIE) launched initiatives under its Bioeconomy blueprint, including green biomanufacturing. The government provides tax incentives for companies to reduce energy use or obtain EMS certifications. The New Energy and Industrial Technology Development Organization (NEDO) has funded biocatalyst projects for drug synthesis and energy-efficient biologics production methods.

South Korea is pushing for a hydrogen economy and fuel cells, which has implications for the pharma industry. In line with these efforts, SK Pharmteco, a CDMO, has announced plans to pilot fuel cells to reduce grid dependency. The Chinese government has enforced pollution control norms on API manufacturers. The country's Five-Year Plans have explicitly mentioned green development in the pharmaceutical and chemical sectors. The 14<sup>th</sup> Five-Year Plan (2021–2025) calls for cleaner production techniques and developing a green manufacturing system. The Chinese government also initiated grants for the adoption of green technology; a subsidy program in Jiangsu province helps pharma factories install solvent recovery and VOC (volatile organic compound) emission controls.

Singapore Green Plan 2030 emphasizes sustainable industry as a key pillar with biopharmaceuticals as a key part of the effort. The government, through its Economic Development Board (EDB) and A\*STAR, has launched various initiatives to infuse sustainability into biomanufacturing and has partnered with industrial players to establish the Sustainable Biomanufacturing Technology Platform (SBTP) to develop new bioconversion processes using renewable feedstocks. The Indian government introduced a draft policy in 2019 to set limits on antibiotic concentrations in pharmaceutical effluent, one of the first in the world, and has also actively enforced existing environmental norms, emphasizing that companies must install ZLD (Zero Liquid Discharge) in sensitive zones. It's National Manufacturing Policy and Pharma Sector Vision include support for sustainability, which includes subsidies for common effluent plants in pharma clusters and funding for the development of greener processes through its Department of Biotechnology schemes.

Other Asian countries are engaged in promoting sustainable biomanufacturing in their ways. To establish itself in pharma manufacturing, Malaysia has been promoting bio-based manufacturing, such as encouraging the production of biologics (like insulin or vaccines) using modern, efficient technology. Under its National Investment Aspirations for the chemical and pharma industry, it aims to attract investments in high-tech, sustainable manufacturing. Thailand has explicitly included medical and wellness as one of four priority areas in its Bio-Circular-Green (BCG) Economy Model. Under the model (2021–2026 action plan), the country is investing in biotechnology for healthcare with a focus on vaccines and biopharmaceuticals. It emphasizes that facilities and processes should use resources efficiently and minimize waste.

### **Challenges in Implementation and Way Forward**

Despite the apparent benefits and growing interest, implementing sustainable biomanufacturing practices is difficult. Stakeholders face a variety of hurdles in making their biopharma industries greener.

A key challenge is the investment cost of adopting new technology or upgrading facilities. Many biomanufacturing and sustainable solutions are cost-prohibitive compared to conventional approaches, and it is difficult for companies operating on thin margins to deploy them without external support. The payback period for some sustainable efforts, such as the use of advanced bioreactors and the shift to renewable energy, might be longer than what companies are usually accustomed to in a highly competitive and, to a certain extent, fragmented market. Often, companies must choose to balance these costs against other R&D or capacity expansion costs. This becomes even more challenging when there is increasing pressure to normalize drug prices. Balancing between quality, safety, and sustainability is a significant task, and ensuring that changes don't compromise regulatory compliance is essential.

Governments are offering subsidies, grants, or tax breaks for sustainability efforts. For example, Singapore's EDB offers co-funding for companies investing in energy-efficient equipment or renewable energy integration. The Indian government is considering offering low-interest "green loans" to pharma MSMEs (micro, small & medium enterprises) to encourage installing pollution control or energy-saving systems. Public-private partnerships (PPPs) are gaining traction to pool resources and establish technology transfer, licensing, or sharing to mitigate risks and share innovation costs. International cooperation, such as OECD and UNIDO, which have knowledge-sharing and transfer programs, can speed technology adoption.

The WHO's call for greener pharma regulation emphasizes creating regulatory pathways encouraging sustainable innovation. The ASEAN Pharmaceutical Product Working Group could potentially integrate environmental standards in its harmonization efforts, though in its nascent stages, to develop a standardized common framework that aligns with global requirements. Governments are trying to set clear environmental standards for pharma manufacturing to ensure harmonization, such as India's API effluent limits or China's emission norms.

Despite renewed interest in technology development and R&D efforts, a skill gap in many parts of APAC makes implementing advanced sustainable biomanufacturing challenging. Besides conducting regular training programs and educational initiatives, bridging the skill and knowledge gap requires continuous and integrated efforts. Companies are establishing Centers of Excellence as internal training centers while fostering stakeholder collaborations. National labs such as South Korea's KRIBB (Korea Research Institute of Bioscience & Biotechnology) and others that pioneer research and developmental efforts to integrate sustainability in biotech processes by working with local companies can help in skill development and hands-on training.

It is established that a high percentage of the pharmaceutical industry's environmental footprint lies in its interlinked and complicated supply chain. This makes compliance with sustainability goals a significant challenge, considering the Scope 3 emissions. It also makes end-to-end trackability and traceability a concern. Aligning the entire supply chain with sustainable biomanufacturing can be solved by a single stakeholder but requires the active participation of the entire industry.

Incorporating environmental criteria into supplier qualification and audits and continued initiatives such as including ESG score as supplier selection criteria can help in better traceability across the supply chain.

To address the perceived trade-off between quality and sustainability, companies are increasingly integrating sustainability protocols into their pharmaceutical Quality Management Systems rather than considering them separate protocols. Implementing robust risk management and validation techniques can also ensure that newer processes meet all quality parameters.

### **Future Trajectory for Sustainable Biomanufacturing in Asia Pacific**

Industrial stakeholders are converging with governments, associations, and trade organizations. Industry and society must establish sustainable biomanufacturing practices, and the momentum will likely grow. Following the path of Japanese and Korean companies, more companies from India, China, and others in the Asia Pacific are expected to commit to net-zero emissions targets in the coming years, in timelines around 2040–2050, as governments push for national decarbonization goals such as that of China's 2060 neutrality goal and India's 2070 goal.

Continued focus on technology development and collaborations for R&D and knowledge transfer can improve adoption prospects, especially those related to Biomanufacturing 4.0 and 5.0 and biotechnological approaches such as cell-free expression systems and indigenous technologies leveraging regional and local feedstock for drug and API manufacture.

Sustainable biomanufacturing is no longer an added consideration; it is increasingly becoming a critical pillar of innovation and social responsibility in the pharmaceutical industry. In APAC, sustainable manufacturing is an area of immense opportunity and challenge that will help companies innovate and lead toward a new paradigm in the pharmaceutical industry.

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