

Sustainable Practices in Pharmaceutical Manufacturing

Kibibi Muthoni L.

Faculty of Science and Technology Kampala International University Uganda

ABSTRACT

Sustainable pharmaceutical manufacturing integrates green chemistry, energy efficiency, and responsible resource management to minimize environmental impact. The industry faces challenges such as high greenhouse gas emissions, extensive water usage, and hazardous waste generation. Regulatory frameworks enforce sustainability but are often perceived as burdensome. Companies adopting eco-friendly technologies benefit from cost savings, improved efficiency, and enhanced market competitiveness. Sustainable sourcing, circular economy principles, and case studies highlight best practices, while financial and regulatory barriers remain obstacles. Future trends focus on pollution prevention, eco-design, and advanced research, driving a more sustainable pharmaceutical sector.

Keywords: Sustainable manufacturing, green chemistry, pharmaceutical waste management, energy efficiency, regulatory compliance, circular economy.

INTRODUCTION

The growing focus on sustainable practices across industries is clear. Organizations must mitigate adverse effects on human health and the environment stemming from their production methods by adhering to ecological balances and relevant principles. Yet, many emerging bio-economy firms overlook the benefits of integrating innovative, clean, and energy-efficient technologies, especially in their early stages. This study seeks to increase awareness among these companies about the advantages of green practices, such as green chemistry, green engineering, and biomass pre-treatment. The goal of implementing these green practices is to minimize environmental impact. However, traditional chemical, thermochemical, and enzymatic pre-treatment methods can harm the environment by releasing hazardous gases and toxic waste. A more sustainable approach is to adapt biomass processing to side-stream valorisation. Innovative technologies enable a more streamlined, efficient, and cleaner production process. Implementing green practices may yield significant benefits like reduced raw material, energy, and water use and less environmental waste impact. By fostering interdisciplinary collaboration and enhancing the efficiency of bio-economy production, integrated biorefineries can notably bolster a company's market position, attract new clients, and secure funding, which is especially vital for smaller firms with limited financial resources. Often, industries only address these aspects in response to regulatory mandates [1, 2].

Environmental Impact of Pharmaceutical Manufacturing

The pharmaceutical industry can significantly contribute to pollution and ecological degradation, mainly the concerned of the environmental impacts of pharmaceutical industry keeping in mind that there is no way to avoid completely all the environment. The environment will remain at the cost of industry's progress and there will be always a necessity for waste management, Pollution in one form or other needs to be accepted as an integral part of industry will point out the sources of pollution, likely areas of increase in pollution load due to proposed intensive manufacturing activities and the measures planned to be adopted for eco-friendly management of both existing and proposed project activities related to the project. The pharmaceutical industry has grown tremendously and plays a major role in the economic development of a country. The global pharmaceuticals sector is approximately equal in size to the U.S economy as a whole, and this wealth makes the pharmaceutical industry a tempting target for measures

that would not be considered elsewhere due to its high pollution load contributing significantly to the actual problems of pollution in soil, water, and air. An increased burden on the ecosystem in terms of consumption of depletable resources and greater pollution and physiochemical waste. Understanding the potential impacts can guide the pharmaceutical industry in its efforts to undertake life cycle assessment to inform the improvements of existing practice as well as future decisions in the manufacture of pharmaceutical products. Each section of the pharmaceutical lifecycle has identified the potential environmental influences that present the industry a roadmap toward cost-effective, greener practices. The objectives for the measures regarding aspects which are of increasingly concern to the environmental impacts of the pharmaceutical activity: the emissions of greenhouse gas and coolants, the potentially release of pharmaceutical products into the environment, mainly waters, the production of solid waste, as well as water and packaging materials treatment, and, finally, the operation of effective initiatives aimed at further greening other products and activities within the pharmaceutical industry. On the other hand, it is now widely acknowledged that industry, in general, can contribute significantly to pollution and ecological degradation. In recent years, the issue of environmental degradation has become so acute that stringent measures are being initiated by regulatory authorities to force industry leaders to adopt environmentally sound technology [3, 4].

Greenhouse Gas Emissions

In light of stricter environmental regulations, reducing Greenhouse Gas (GHG) emissions poses a significant challenge for the pharmaceutical industry. Pharmaceutical synthesis produces several kilograms of waste per kilogram of product, making it one of the most energy-intensive sectors in the chemical industry, accounting for 20% of overall industrial energy use. Recent studies have focused on the carbon footprints of various products, emphasizing the need for the chemical sector to decrease its emissions due to growing environmental awareness. Carbon emissions are key contributors to climate change, with the pharmaceutical and Fine Chemicals (FC) sectors responsible for around 5% of GHG emissions in the chemical industry. Pharmaceutical production emits between 200 and 800 kg of CO₂ per kg of active substance, while NO_x emissions range from 10 to 30 g. Most existing analyses target other sectors, such as cement and steel, leading to pharmaceutical emissions being grouped in the broader “other chemical production” category, which may not accurately represent their specific impact. The anticipated legislative pressures, combined with the financial risks associated with emissions, highlight the necessity for focused research in this area. [5, 6].

Water Usage and Pollution

Water is assumed; it's everywhere on Earth. Yet, only a very small proportion can be used by humans. There are currently 1.1 billion people who lack access to safe water supplies and over 2.6 billion people without adequate sanitation. By 2025, it is predicted that two-thirds of the world will suffer moderate to severe water shortages. As the population grows and water resources become scarcer, there will be increased competition for the world's already strained water supplies. Concerns heighten further when considering the amount of agricultural expansion in water-scarce regions and the likelihood of high-water consumption. Water is essential for the pharmaceutical industry – production cannot take place without it. This document will examine the water-related risks to this sector. An average pharmaceutical plant has a water intake of 47 m³ per tonne of product, a much greater demand than the food industry at 2 m³ per tonne and the automotive industry at 1.5 m³ per tonne. It also generates an average wastewater effluent of 9 m³ per tonne of product. Like the textile product, the majority of this wastewater consists of suspended particles and chemicals such as phenols, nitrates, and, more commonly, heavy metals. The wastewater discharge from this sector can often have a high color concentration. Most of these chemicals are considered toxic and often carcinogenic. Hence, without treatment, this effluent is deleterious to aquatic life and poses high risks to plants, animals, and humans. This point is especially important as many industries are located close to rivers and canals, which are commonly used water sources [7, 8].

Waste Generation and Management

Pharmaceutical manufacturing generates various types of waste, including solid, liquid, and gaseous effluents. Depending on the processes, waste can be inorganic (reagents, catalysts), organic (solvents, consumables), aqueous (solvents, acids), or gas (emitting CO₂, NO_x, SO_x). Hazardous waste, characterized as flammable, corrosive, reactive, or toxic, requires special management due to its severe health and environmental impacts. This waste largely comprises different formulations, and improper disposal can harm ecosystems. Wastewater containing pharmaceutical residues significantly affects flora and fauna, making waste management crucial for the industry. Effective practices can lessen negative

impacts on health and the environment. It's expected that 80% of products will exhibit negative properties after their initial use, necessitating a redefined approach to managing waste and implementing recycling strategies to prolong product life cycles. The pharmaceutical sector, particularly in Bangladesh, is rapidly expanding, with medium and small industries driving its growth. The Bangladeshi regulatory authority is enhancing GMP activities and promoting awareness for improved waste management in pharmaceutical industries [9, 10].

Regulatory Frameworks and Guidelines

Numerous regulations govern pharmaceutical manufacturing's environmental impacts. International regulations include ICH E6 and current Good Practices (GxP), as well as the EU's GMP and EudraLex Vol. 4, with global legislation enabling enforcement bodies for chemical production control. In regions lacking specific regulations, entities like the FDA and EMEA are often viewed as de facto regulators. Pharmaceutical manufacturers must comply with all regulations, distinguishing between compliance (mandatory) and sustainability goals (optional). Non-compliance endangers products and patients, yet companies can pursue sustainability beyond minimum legal requirements. Guidance documents assist in creating sustainable processes within the legal framework. While regulations may drive innovation, many see them as obstacles due to compliance demands. Current trends in legislation indicate a shift towards enhanced environmental protection and resource efficiency, fostering potential collaboration between the pharmaceutical sector and regulatory bodies. As regulatory pressures escalate, it's advantageous for companies to precede compliance expectations, thereby leveraging synergies between compliance and continuous improvement [11, 12].

International Regulations

The pharmaceutical manufacturing industry can be influenced by international agreements, standards, regulations, and guidelines applicable worldwide. Composed of a variety of formulations, the industry's goal is to research, develop, produce, distribute, and market medications. Global agreements shape industry practices, sustainability standards, and increasing compliance requirements for companies. Industry responsibly and voluntarily follows compliant actions and procedures, considering a variety of actions in sustainability initiatives. Governed by the Food and Drug Association (FDA), companies working in pharmaceutical manufacturing must ensure the health of patients who use the medicines. Inspections, control over drugs, and regulations of the overseas solidity of pharmaceutical medicinal control may burden and generally lessen the requirements of international. Performances by the manufacturer are regulated worldwide by a series of guidelines, regulations, and standards that have been established by international organizations. In addition to the industry working standards, guidelines have also been set in place for pharmaceutical drugs. International pharmaceutical manufacturers, the pharmaceutical industry, and Public Health Organizations (PHO). As the industry rapidly changes based on new technologies, medical products, procedures, and policies also rapidly evolve. This calls for manufacturers to adapt rapidly to the worldwide changes in regulations, standards, and industrial procedures. There is a growing global demand for medicines. Pharmaceutical companies continue to research, develop, and produce various cures for diseases, improving public health. Pharmaceutical production is inherently energy, material, and resource intensive. However, striving for compliance also detracts from the sustainability initiatives that many companies are increasingly implementing. Globally, the invention of future cures for various diseases and environmental, energy, and sustainability development can be coexistent. Over the last few decades, pharmaceutical companies, one of the largest energy consumers in the industrial sector, have now been trying to develop a commitment to the environment and more corporate responsibility along with compliance. This new behavior is also in line with the goals of the United Nations when addressing sustainable development [13, 14].

Industry Standards

Sustainable practices within pharmaceutical manufacturing have been highlighted, along with the co-benefits and potential trade-offs of such practices. The implementation of this research encompasses a novel review method to summarize the key literature. Sustainability guidelines given by 11 pharmaceutical organizations have also been reviewed in line with the Standards Comparator software. Through summarizing the literature and the guidelines in terms of water, energy, materials, recycling, carbon emission, energy, green practices, and USP474, guidelines are shown to guide companies to optimize manufacturing processes, thus promoting sustainability and a zero-waste production. For the biopharmaceutical industry, 409 guidelines were found after reviewing 14 articles and the guidelines given by eight organizations. The templates are designed in the format of tables to facilitate the use of

this work for the biopharmaceutical manufacturing industry. For the chemical and pharmaceutical industries, 279 guidelines are also found based on the review of three articles and the guidelines given by three organizations. The comparison includes seven organizations and the summarization of their guidelines and requirements in such different companies could rapidly evaluate their current working practices, as well as their suppliers and CMOs, according to these sustainability guidelines. Successful industry case examples are presented to highlight the benefits of adhering to such guidelines. Nevertheless, some challenges are also found to face companies to align with the guidelines as sustainable practices vary regarding regions with different environmental legislation and industry standards based on the regional cultures and resources. Multiple standards also need to be followed under this condition, thus leading to difficulties in working up to the environmental ambition as well as the commitment to quality and responsibility for the environment. Furthermore, the advances in technology are changing quickly, thus demanding the evolvement of the guidelines continuously. The biopharmaceutical organizations are urged to update their guidelines and requirements regularly, considering the technological changes and the new resources available. The newly developed software can compare the sustainability guidelines provided by the companies and the large-scale biopharmaceutical companies. Companies are expected to assess their existing practices and suppliers using the software after carrying out such practices to ensure greater consistency and to continuously update it with the evolving sustainability practice. Furthermore, the success in implementing the guidelines could also benefit companies, environmentally enhancing the company reputation as well as saving costs [15, 16].

Energy Efficiency in Pharmaceutical Manufacturing

Active substances in pharmaceuticals are mainly produced through organic chemical syntheses, which require high energy for stirring, evaporation, and cooling. This often leads to local overheating, particularly in tropical regions, necessitating energy-intensive refrigeration plants typically using CFCs. These plants contribute to the greenhouse effect, making their replacement with ammonia-operated systems a priority for energy management in pharmaceutical plants. Energy analyses reveal high costs for cooling, drying, and ventilation, indicating that reducing cooling and air-conditioning loads can lead to significant cost savings as well as improved reliability and work environments. Keywords like energy efficiency, greenhouse gases (GHG), and regulatory compliance can deter organizations from improving energy management. The challenge lies in balancing energy costs and ROI while integrating energy efficiency with GMP guidelines. Electric energy serves multiple functions in the industry, including water production and heating, while boilers produce steam for heating and sterilization. This work evaluates the electric and thermal demands of pharmaceutical production and lighting, suggesting energy-saving opportunities. Waste heat produced in processes like refrigeration and cogeneration can be recovered for preheating feedwater or air, thereby significantly reducing overall energy demand [17, 18].

Green Chemistry in Pharmaceutical Manufacturing

Green chemistry, or sustainable chemistry, involves designing, manufacturing, and using chemical products in a safe and environmentally friendly manner. It considers environmental health and safety throughout a chemical's lifecycle. Key principles include safer reaction conditions, atom economy, renewable feedstocks, energy efficiency, and pollution prevention through safer solvents. This paper highlights cleaner chemistry, focusing on transforming feedstocks and reagents into products like pharmaceutical ingredients, which are essential in the synthesis of new drugs. A considerable amount of industrial waste arises from batch-wise synthesis of active pharmaceutical ingredients, using excess reagents and non-selective, unsustainable methods. Green chemistry reduces synthetic waste in this sector by replacing hazardous materials, promoting bio-based feedstocks, and developing safer synthetic processes while managing emissions effectively. It's noteworthy that batch syntheses generate more environmental impact compared to continuous micro-tub reactions, resulting in significant by-products, often exceeding 30% of the mass commercially. Thus, employing sustainable chemistry via flow micro-tubular reactions can greatly reduce pharmaceutical waste and lower capital costs.

Sustainable Sourcing and Supply Chain Management

Pharmaceutical products rely heavily on complex supply chains. This means that the supply chains, in general, contribute significantly to the overall sustainability impact of the products as pharmaceuticals. Creation of the actual pharmaceutical formulation is the very last step, and preparing the formulation for delivery on a global scale demands a massive logistics distribution setup all over the world. Therefore, efforts should also be put (besides the sourcing of raw materials) on how to improve environmental management; re-checking and selecting logistic partners are an important part of being responsible. The

majority of environmental pollution is caused by the large number of moving things all over the world: shipping, flying, or even driving trucks. On the other hand, there are indeed some legal requirements to be observed to guarantee the quality of pharmaceutical products but besides those, it is also quite a common (and at times almost a necessary) practice in the competition-driven pharma field, to coordinate and collaborate with the supply chain partners in terms of joint demands on environmental and sustainable practice goals. In a pharmaceutical case, as an example, communication in the direction of procuring only raw materials that have the description of Non-Containment of Genetically Modified Organisms in the Specification Table is a viable way of exchanging information on this issue. Similarly, planning the regular audits of selected suppliers in terms of energy, water management, waste handling, or other sustainable requirements. Pharma companies may drop certain suppliers who are not meeting sustainability demands, which might also lead to improvement on the supplier's sustainable practices, or having benefits for the entire sector. There are already pharmaceutical companies who have been certified with environmental and energy systems, which also sets an example or puts pressure on the competition environment on the latter. There are also safe transport certifications known in the global pharmaceutical industry that guarantee the product's integrity during distribution. On the other hand, there are some case studies found from academic research already covering successful sustainable sourcing practices in the pharmaceutical sector. The case studies discuss sustainable practices through the value chain, focusing on responsible sourcing of raw materials [19, 20].

Circular Economy Approaches in Pharmaceutical Manufacturing

Wastage in the supply chain adversely affects the Circular Economy. Pharmaceuticals represent 10% of healthcare expenditures in developed nations. The industry is vital for medicine development, necessitating ongoing enhancements through technological innovations. Pharmaceutical contribution to GDP is low due to protection given its chemical composition. The UN has advocated for protective practices in this sector. Manufacturing is complex, involving various operations where inadequate cleaning can lead to residue. For every 100 grams of active pharmaceutical ingredient (API), a maximum of 10 micrograms of other substances is allowed. Increasing pollution prevention demands and strict regulations are pushing manufacturers to reduce losses. However, complete recovery is unattainable. The global low-price pharmaceutical market is valued at \$240 billion. During the Global Financial Crisis, pharmaceutical contributions to GDP reached \$17.70 billion, indicating future demand potential. Companies often depend on external services. High energy levels for production activities mean spare parts and raw materials cannot always be reprocessed or recycled. Effluent treatment systems require monitoring for impurities to meet government standards. Unfortunately, current physical-chemical methods do not allow for the technological recovery of waste API [21, 22].

Case Studies of Sustainable Practices in Pharmaceutical Manufacturing

The fourth chapter focuses on case studies of pharmaceutical companies regarding waste minimization, energy, water, and hazardous chemicals. Six companies participated in the pilot study, including both generic and originator firms. Visits lasting 2-4 hours were conducted with plant environmental engineers and senior sustainability managers between May 2009 and January 2010, covering 13 production lines, 11 of which were for solid dosage forms. Additionally, other case studies were included for broader insights on enhancing environmental performance. The results are presented by waste, water, energy, and environmental management systems, with energy being a significant contributor to CO₂ and air emissions. Interrelations among the three areas are summarized, highlighting cross-impacts between IMS and these domains [23, 24].

Challenges and Barriers to Implementing Sustainable Practices

The pharmaceutical industry can greatly benefit from sustainable practices that enhance energy and raw material efficiency while promoting the recycling of waste and by-products. This approach improves worker conditions, reduces pollution from effluent discharges, and mitigates waste disposal issues. Pharmaceutical manufacturing carries significant environmental burdens linked to its processes and products, making sustainability crucial. Stricter environmental regulations are prompting companies to adopt more transparent and efficient production methods. However, financial constraints pose major challenges to implementing standalone sustainability measures. Deciding where to focus efforts raises additional issues, such as the availability of clean technologies and potential funding for sustainability projects. Moreover, the highly regulated nature of biopharmaceutical manufacturing often hampers effective development. Transitioning to economically viable and eco-friendly production processes is complex and requires all stakeholders to recognize the transition's potential benefits. Unfortunately,

many pharmaceutical companies show indifference toward sustainable development, viewing it as merely an added cost. There is also a prevalent lack of awareness among top management and stakeholders about the various indirect benefits of adopting sustainability initiatives [25, 26].

Future Trends and Innovations in Sustainable Pharmaceutical Manufacturing

Sustainable practices in the manufacture of pharmaceuticals, active pharmaceutical ingredients, and excipients are complex and often intricate. These manufacturing processes can contribute to the emission of greenhouse gases, hazardous waste, the consumption of large quantities of water and energy, and the generation of plastic waste. The regulatory frameworks that govern the production of pharmaceuticals and related substances do not widely enforce the regulation of emissions and waste from the plants themselves, but instead, the impact of these emissions and waste on human health and the wider environment. Furthermore, the required conditions and constraints in pharmaceutical manufacturing can hinder sustainability criteria. For example, to guarantee patient safety, medicines should be produced in a controlled, reliable, and reproducible manner, in a sterile environment, with precise limit values regarding purity and stability. Moreover, manufacturing plants are designed with high containment requirements to allow for API synthesis at larger scales with highly potent molecules. Thus, maintaining a high containment of chemical compounds within the system under these conditions can make the implementation of traditional waste treatment processes especially challenging. Despite these challenges, the desire to reduce and improve the above-mentioned aspects is pushing companies involved in pharmaceutical manufacturing towards more sustainable paths. Major pharmaceutical companies have started developing and setting deadlines for sustainability roadmaps, and partnerships have been framed to tackle these issues. Operating improvements involving eco-design tools and staff knowledge are addressed, as well as preventive actions. Furthermore, industrial research and development into innovative processes and systems regarding pollution prevention, control methods, and disposal are actively pursued, either experimentally or through modelling and simulation of the process. There is a growing amount of consideration of impacts of manufacturing on the environment, most investigations focusing on the environmental impact of bio/pharmaceutical products, process development, or the pharmaceutical supply chain. However, there is no specific assessment of the environmental impacts of manufacturing technology, processes, and practices; only an understanding and labelling of green chemistry criteria in process design and development is achieved. This work bridges the current gap by developing a specific method extended from existing ones to evaluate the environmental sustainability of the overall API manufacturing process and practice, highlighting the methodology and application of the assessment to two practical case studies [27-32].

CONCLUSION

Sustainable practices in pharmaceutical manufacturing are crucial for reducing environmental impact while maintaining regulatory compliance. Companies that invest in green chemistry, energy-efficient processes, and waste management strategies not only minimize pollution but also enhance operational efficiency and market positioning. Although challenges such as financial constraints and regulatory complexities persist, emerging innovations in eco-design and circular economy approaches offer promising solutions. A collaborative effort among industry stakeholders, regulatory bodies, and research institutions will be key to advancing sustainability in pharmaceutical manufacturing.

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