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NAVIGATING ENVIRONMENTAL SUSTAINABILITY IN PHARMACEUTICALS: A REGULATORY FRAMEWORK IN UNITED STATES AND EUROPE

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ABSTRACT

It is the pharmaceutical industry that is vital in maintaining us all in good health, but it is also a major contributor to environmental pollution. From high material and water use to toxic waste and greenhouse gas emissions, the industry's environmental record is increasingly under the spotlight. This paper addresses the challenges and progress towards environmentally sustainable pharmaceutical manufacturing and supply chains. Case studies from major pharmaceuticals and examples from the leading pharmaceutical companies illustrate that sustainability can be sustainable for the planet, profitable for companies.

Keywords: Environmental Sustainability, Pharmaceutical Industry, Green Chemistry, Sustainable Manufacturing, Waste Management.

1. INTRODUCTION

The pharmaceutical sector is a key component of worldwide health systems, however the production of pharmaceuticals, even when it serves the good and demands of vallied patients, usually result in high environmental impact. In recent times due attention has also been given to sustainability in the pharmaceutical industry [1].

The release of pharmaceuticals into the environment occurs through diverse, interconnected routes, underscoring the growing challenge. These routes can be broadly classified as direct industrial discharge, indirect anthropogenic release through excretion, or improper disposal of unused drugs [2].

1.1. Environmental Sustainability in the Pharmaceutical Industry

Environmental sustainability in the pharmaceutical context means making, using, and disposing of pharmaceutical products in a way that safeguards natural resources and the environment, allowing for long-term ecological balance, and does all this in a manner that maintains product performance, safety, and efficacy.

In today's pharma industry, "sustainable pharmaceuticals" means doing business that is good for the environment by emphasizing reduced environmental impact, while simultaneously focusing on public health and social responsibility. This ranges from sustainable production, minimising waste and sustainable disposal. It drives home the point that companies must consider both profitability and environmental and social concerns to create a healthier, more sustainable future. Pharma environmental issues are critical because production, consumption and disposal of pharma products have a major impact affecting both the environment and human health. This includes waterway contamination, manufacturing process pollution, and the emergence of antibiotic resistance. By making sustainability a top priority in the pharmaceutical industry, we can lessen these adverse effects, save ecosystems, and preserve public health for coming generations. Concerns about the substantial effects of pharmaceuticals on ecosystems around the world are growing in the wake of increased environmental consciousness. Every phase of the pharmaceutical lifecycle, from production procedures to disposal, has potential risks that require immediate attention [3].

Maintaining a sustainable environmental impact is just as crucial as maintaining public health. The weather, biodiversity, temperatures, and sea levels are all changing due to climate change, which is creating serious problems.

We can gain from sustainable drug production methods in a few ways. They can conserve resources and maintain ecosystems. They can also enhance the industry's image and reputation.

Lastly, they can guarantee the long-term sustainability of the sector. Therefore, a crucial component of pharmaceutical production is environmental sustainability [4]. During production, use, and disposal, pharmaceutical product residues may find their way into the environment. The transformation of conventional pharmaceutical manufacturing may be crucial for the environment given the growing trend toward sustainable practices [5].

1.2. Pharmaceutical Products as Pollutants:

Chemicals or microorganisms that damage the soil, water, or air are known as pollutants. The ecosystem is harmed by them. According to recent research, psychotropic medications, NSAIDs, and antibiotics are frequently found in aquatic environments. There are various ways that pharmaceutical products contribute to pollution.

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These consist of agricultural use, medication disposal, medical waste disposal, and manufacturing processes. There are several ways that pharmaceutical contaminants can get into aquatic systems. Water becomes contaminated when leftover medication is flushed down the toilet.

After going through the wastewater treatment plant, it enters rivers and the ocean. The whole marine ecosystem is harmed by this. It pollutes the soil when it is dumped in a dustbin or on the ground. High drug use causes some pollution because it leaves traces in faeces. Aquatic life is killed by this tainted water. Additionally, it damages people and results in numerous diseases.

2. DRIVING ENVIRONMENTAL INNOVATION

1. **Green chemistry,**
2. **Waste management**
3. **Sustainable packaging**

1. Green chemistry:

Green chemistry emphasizes designing chemicals and methods in a way that reduces or avoids the generation and application of hazardous materials. Design here reflects a conscious decision, not an accidental occurrence. It encompasses originality, preparation, through systematic and purposeful thinking, the Twelve Principles of Green Chemistry serve as guidelines, scientists with guidelines for pursuing sustainability.

The field of green chemistry emphasizes creating molecular structures and synthetic processes that lower potential hazards.

The three key aspects of the Green Chemistry framework can be outlined as:

1) Green Chemistry plans for every phase of the chemical life cycle.
2) The aim of green chemistry is to minimize the dangers linked to chemical processes and products by embedding safety into their design.
3) Green chemistry serves as a cohesive framework of guiding principles for sustainable design.

12 Fundamental Guidelines of Green Chemistry

1) Eliminating Unnecessary Waste

It is better to stop waste from being generated in the first place than to manage or discard it after its formation.

2) Efficient Use of Atoms

The design of synthetic methods should focus on so that the maximum proportion of reactants is incorporated into the final product, minimizing by-products and waste.

3) Safer Chemical Synthesis

Chemical processes should be developed so that the use and production of substances harmful to people or the environment are minimized or avoided.

4) Developing Safer Chemical Substances

Chemical products should be developed to carry out their intended function effectively while at the same time reducing toxicity to humans and ecosystems.

5) Safer Use of Solvents and Auxiliaries

Auxiliary materials such as solvents, separation agents, or other processing aids should be used sparingly, and only when essential. When their use is unavoidable, they should be chosen to ensure the least possible risk to health and the environment.

6) Energy-Efficient Design

Processes should be planned to consume as little energy as possible. Wherever feasible, chemical reactions should be done at normal environmental temperature and atmospheric pressure rather than under extreme conditions.

7) Utilization of Renewable Raw Materials

Raw materials or feedstocks should come from renewable sources instead of non-renewable ones, provided this is both technically practical and economically viable.

8) Reduction of Derivatives

Minimizing or eliminating unnecessary steps such as blocking or protecting groups is important, as these processes often increase waste and reagent consumption.

9) Catalysis

Compared to stoichiometric reagents, which are used up completely during a reaction, catalytic reagents are preferred since they provide higher selectivity and efficiency.

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10) Sustainable Design for Safe Disposal

The design of chemical products should ensure they break down into environmentally safe and non-toxic byproducts after use, so they do not persist and cause environmental harm.

11) Continuous Monitoring to Prevent Pollution

Testing procedures should be applied during the process to enable immediate monitoring and control, preventing the formation of harmful by-products.

12) Safer Chemicals and Processes to Prevent Accidents

Chemicals and their physical forms should be selected to minimize the risk of hazards such as explosions, fires, or accidental releases [6,17).

2. Waste management in pharmaceutical industry:

Waste refers to materials that are no longer needed or usable and are therefore discarded. Such materials are either intended for disposal or have already been thrown away. Proper and timely disposal of waste is essential to prevent serious risks to human health and environmental safety. Otherwise, waste should be recycled into new, useful products.

Syringes are just one of many possible sources of pharmaceutical waste in the healthcare system; intravenous (IV) preparations.

A) Pharmaceutical waste is generally divided into three main categories:

a) Hazardous Waste – includes medicines and products that pose risks to human health or the environment if not properly handled.

b) Non-Hazardous Waste – pharmaceutical items that are safe to dispose of with minimal risk but still require proper management.

c) Chemotherapy (Chemo) Waste – waste generated from chemotherapy drugs and any contaminated materials associated with their use.

B) Management and Disposal of Pharmaceutical Waste

1) Incineration:

In this efficient waste disposal technique, solid organic wastes are burned to produce residue and gaseous products. The method is applicable for the disposal of byproducts generated from solid waste and wastewater treatment.

2) Autoclaving:

This method of sterilization uses saturated steam that comes into direct contact with the BMW in a pressure vessel for periods of time and at temperatures high enough to destroy the pathogens. The Biomedical Waste Rules specify minimum autoclave temperatures, pressures, and residence times for safe disinfection.

3) Microwaving:

By applying an electromagnetic field over the BMW, the waste's liquid oscillates and heats up, eliminating the infectious elements through conduction. If the waste material is exposed to ultraviolet light, this technology works.

4) Disinfection with chemicals:

Blood, urine, faeces, and sewage from medical facilities are among the liquid wastes that chemical disinfection works best for.

5) Deep burial:

According to the Biomedical Waste Management Rules, human and animal anatomical waste should be disposed of by deep burial in rural areas and in towns with populations under 500,000. The burial site must be a pit or trench about two meters deep, located in an area with impermeable soil, away from human habitation, shallow wells, or surface water sources, and safe from erosion or flooding, to minimize the risk of contamination.

6) Safe filling of land:

Solid biomedical wastes (BMWs) are commonly managed through secure landfilling, a specialized landfill system designed to safely handle hazardous materials. Under the Biomedical Waste Management Rules, solid chemical waste, cytotoxic drugs, and incineration ash must be disposed of only in designated secure sites. Landfilling, which involves burying waste in the ground, remains the most widely used method of disposal in many countries.

C) Techniques for immobilizing waste:

1) Encapsulation:

- Drugs are immobilized in a solid block inside steel or plastic drums that have been cleaned and cleared of any potentially dangerous residue.

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- Drugs, either solid or semi-solid, fill drums to 75% of their capacity. A medium, such as bituminous sand, cement, lime, or plastic foam, fills the remaining space.
- To fill the drum, lime, cement, and water are added in a 15:15:5 ratio, making sure the mixture reaches the appropriate consistency.
- New municipal waste is spread over sealed steel drums that are positioned at the bottom of a landfill. Drums can be palletized for convenience of transportation.

2) Inertization:

- Inertization involves removing pharmaceuticals from their packaging, such as blister packs, grinding them, and then combining them with lime, cement, and water to create a paste.
- Because of the possibility of dust hazards, worker protection (masks, clothing) is crucial.
- Concrete mixer trucks are used to carry the liquid paste to a landfill, where it is poured into municipal waste and allowed to solidify within the solid waste mass. This technique is cost-effective and requires only simple materials such as water, cement, lime, a concrete mixer, and a grinder.

3) Sewer:

Some liquid medicines, like syrups and IV fluids, may be safely diluted with water and released into the sewage system in small quantities, as this usually does not cause serious harm to public health or the environment [7].

3. Pharmaceutical Industry Sustainable Packaging:

A) Adopting Biodegradable Materials

- A major change in the pharmaceutical industry's packaging strategy is the move to biodegradable materials.
- When compared to conventional packaging made of plastic or metal, these materials which are frequently derived from plant sources have a significantly smaller environmental impact.
- They are made to break down organically over time, leaving no toxic residues and drastically lowering the amount of waste that accumulates.
- Moulded pulp, which is made from recycled paper and cardboard, and plant-based plastics like polylactic acid (PLA) and polyhydroxyalkanoates (PHA) are examples of biodegradable materials frequently used in pharmaceutical packaging.

B) Reducing Packaging Waste

- By using optimized packaging designs, businesses are using less material.
- Minimalist strategies emphasize sufficient protection with fewer materials.
- Reusable and refillable packaging approaches contribute to advancing circular economy practices.
- Incentives for customers promote the return of containers for reuse and sterilization.

C) Funding Recycling Initiatives

- Packaging, office, and production waste are separated by internal facility recycling; lower raw material costs and resource conservation are among the economic advantages; and proper waste segregation guarantees that materials reach the right recycling facilities.
- Improves the company’s standing as an environmentally conscious one.

D) Using green technologies to innovate

- Biodegradable substitutes are provided by bioplastics made from renewable resources.
- Green technologies reduce waste, energy use, and emissions; • Eco-friendly printing techniques (digital printing, water-based inks) minimize chemical use; • Materials preserve required performance while enhancing environmental profile [8].

3. REGULATIONS ON ENVIRONMENTAL SUSTAINABILITY IN USA AND EU

3.1. In USA:

A) Environmental Protection Agency (EPA) Regulations

a) Clean Water Act

The Clean Water Act (CWA) provides the primary legal framework for regulating the discharge of pollutants into U.S. as well as for defining criteria to regulate the quality of surface waters. Originally enacted in 1948 as the Federal Water Pollution Control Act, it was significantly revised and expanded in 1972, after which it became commonly known as the Clean Water Act.

- Under this law, the Environmental Protection Agency (EPA) has introduced several pollution control programs, such as industry-specific wastewater standards and national water quality criteria for various contaminants in surface waters. [9].

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b) Clean Air Act

This legislation is built on several core provisions designed to control air pollution and protect human health. A central element is the National Ambient Air Quality Standards (NAAQS), which establish acceptable concentration levels for pollutants including carbon monoxide, lead, nitrogen dioxide, ozone, particulate matter, and sulfur dioxide.

- These standards aim to preserve environmental quality while protecting public health, with special attention given to vulnerable populations such as children and the elderly. (16).
- Another key provision assigns the Environmental Protection Agency (EPA) the responsibility of identifying and regulating harmful air pollutants.
- This involves preparing an official list of hazardous substances that pose risks to human health and the environment and setting technology-based emission standards for various industries.
- To ensure these rules remain effective, the act also requires the EPA to periodically review and revise the standards considering new scientific and technological advancements [10].

c) Toxic Substances Control Act (TSCA)

The Environmental Protection Agency ("EPA") is empowered to regulate hazardous waste from the start of a process until its disposal. This indicates that hazardous waste products are transported, stored, and disposed of with EPA's assistance. Guidelines for the management of non-hazardous solid wastes are also provided by the RCRA.

The Resource Conservation and Recovery Act (RCRA) is built around three main objectives. These goals are:

- To preserve energy and natural resources;
- To lessen or completely eradicate the production of hazardous waste;
- To safeguard the environment and the people who inhabit it.

d) Toxic Substances Control Act (TSCA)

As a component of the EPA's New Chemical Program, the TSCA gives the EPA the authority to regulate and screen all chemicals produced or imported into the US. This is done to make sure that the risks that imported chemical substances pose to the environment and human health are recognized and sufficiently addressed before those substances are produced or transported into the US.

- A chemical substance that is manufactured or imported but has not yet been added to the TSCA Chemical Substance Inventory is referred to as a new chemical [11].

B) 21 CFR part 25

As per FDA regulation 21 CFR Part 25, applicants must include Environmental Assessments (EAs) with certain regulatory submissions. This category covers new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologics license applications, supplements to these submissions, investigational new drug applications (INDs), and other designated actions, unless the activity falls under a categorical exclusion. [12].

3.2. In EU:

A) Water Framework Directive (WFD) 2000/60/EC:

On October 23, 2000, the European Parliament and the Council introduced Directive 2000/60/EC, which created a unified framework for water policy across the European Union [13].

Article 4 of the Water Framework Directive (WFD) defines its core objectives. It requires EU Member States to implement Programs of Measures (PoMs) and River Basin Management Plans (RBMPs) to prevent further deterioration of water bodies. In addition, they must protect, maintain, and, where necessary, restore these waters so that they achieve a good status, which includes both ecological integrity and chemical quality [14].

B) REACH Regulation (EC No. 1907/2006):

REACH guidelines for the European Parliament and Council's Regulation (EC) No. 1907/2006 of December 18, 2006, pertaining to the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH). It became operative on June 1st, 2007.

C) Action Plan for the EU Green Deal and Circular Economy:

The European Commission introduced the Circular Economy Action Plan (CEAP) in March 2020 as part of the European Green Deal to support Europe's shift toward sustainability. The shift to a circular economy is expected to generate employment, drive long-term economic development, and decrease reliance on finite resources. At the same time, it contributes to protecting biodiversity and supports the EU's commitment to reach climate neutrality by 2050 [15].

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4. CASE STUDY

Merck & Co., Inc. – Continuous Manufacturing of KEYTRUDA®

Issue:

Traditional biopharmaceutical production is batch-based, where engineered cells grow for weeks before the protein drug is harvested in a single filtration step. This method requires large facilities, high energy and water use, and significant raw material consumption. Such inefficiencies increase costs and environmental impact, including higher greenhouse gas emissions.

Actions Taken:

a) Merck adopted a continuous production system for KEYTRUDA® (pembrolizumab), its PD-1 immunotherapy, marking a significant process innovation.

b) How It Works:

- The revised method allows for continuous removal of pembrolizumab from cells during production, replacing the traditional end-of-batch filtration.
- This innovation allows more protein per reactor volume.

c) Operational Benefits:

- Smaller equipment is needed, which reduces facility size and energy demand.
- Consumables (e.g., filters) are used more efficiently.

Results:

- 4.5× less energy consumption for pembrolizumab synthesis.
- 4× reduction in water use.
- ~2× less raw material consumption.
- A reduced physical footprint lowers facility emissions and helps minimize pollution.
- Industry Recognition: This breakthrough earned Merck the 2024 U.S. EPA Green Chemistry Challenge Award in the Greener Synthetic Pathways category (18).

5. CONCLUSION

In the pharmaceutical sector, environmental sustainability is now a strategic necessity rather than a side issue. The industry's environmental impact is growing along with it in response to the demands of global healthcare, as evidenced by its high-water consumption, energy-intensive procedures, and production of hazardous waste.

Several pharmaceutical companies have started to embrace sustainability, which is encouraging, by coordinating their operations with international agreements like the Paris Accord and the UN Sustainable Development Goals, as well as environmental standards and regulatory frameworks like those established by the FDA and EPA. Technological advancements in digital monitoring tools, biodegradable materials, and process intensification are showing that environmental responsibility and sustainability can coexist with both product quality and economic performance.Finally, it is essential to bring environmental stewardship to all aspects of pharmaceutical development to promote the health of people as well as of the planet.

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