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Review Article

ENVIRONMENTAL IMPACT AND REGULATORY COMPLIANCE: A COMPREHENSIVE APPROACH IN MANAGING INSTITUTIONAL PHARMACEUTICAL WASTE

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ABSTRACT

Apart from the pharmaceutical industries, pharmaceutical institutes are also producing the various types of waste which is a complex issue and that raises several challenges to environmental sustainability as well as public health. Waste produced by pharmaceutical institutes includes chemicals, reagents, biological waste, papers, office supplies and electronic waste, etc. Key topics include the identification and classification of pharmaceutical waste which have potential harm to the ecosystem. Pharmaceutical waste can reach the environment through excretion and improper disposal methods which leads the water contamination, soil pollution and air emission. Surrounding environment directly affect the living things who suffers from infections and diseases from pharmaceutical waste materials. Regulatory frameworks play an important part in defining waste management protocols and proper waste depositories. Compliance with environmental laws and regulations pertaining to pharmaceutical waste disposal is an essential part of pharmacy management. The cost for regulatory compliance in the form of charges are paid by pharmaceutical institutes to comply various laws, rules and standards set by government agencies for waste management. If any institute are fails to comply with the standards of waste management, they have to pay penalties and fines for their improper handling of guidelines. The paper addresses advancements in waste treatment technologies, exploring innovative approaches like autoclaving, microwaving, plasma pyrolysis, incineration and chemical treatments. Understanding of the proper storage and disposal of garbage to prevent contamination and infection.

Keywords: Disposal, Environment, Pharmaceutical, Pharmaceutical institute, Waste

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INTRODUCTION

A pharmaceutical institute, often associated with pharmaceutical research and education dedicated to the advancement of knowledge and innovation in the field of pharmacy for scientific and medical developments. Pharmaceutical institutes serve as discovery engines, operating laboratories, conducting research trials, and producing experimental drugs. pharmaceutical institutes play an important role in researching and producing innovative solutions to worldwide health problems [1]. However, their goal is to improve the well-being of people, but with possible outcomes they also generate huge amounts of waste materials during the development of new drugs, medical treatments and the training of professionals for industrialization. Proper waste control and prevention have become crucial factors not only for environmental sustainability, but also for these institutions' financial well-being [2]. There are 4,050 pharmacy colleges in India, with 1,961 being privately owned, 287 government owned and 78 public-private owned colleges [3]. During the research performance and experimentation various forms of waste are produced such as chemical waste, testing waste, formulation waste and analytical waste. To manage these wastes, pharmaceutical institutions must be following specific guidelines and regulations. guidelines help to ensure proper handling, storage and disposal of hazardous waste generated in academic laboratories [4].

The structure of the review article was designed based on keywords, namely pharmacy colleges, pharmaceutical waste, waste management, regulatory authorities, laboratory waste, e-waste management, waste treatment and waste disposal. Articles from peer-reviewed journals focusing on waste management practices for more than 30 y were considered. Articles discussing both hazardous and non-hazardous waste management in Indian pharmaceutical institutes and other relevant global contexts and regulations for waste management were selected.

Types of waste generated in pharmaceutical institutes

Waste generated throughout the pharmaceutical institution either by production of products, testing of them, distribution of products or during the use of them. They produce hazardous waste material or non-hazardous waste material at the time of processing. Hazardous waste is generated in pharmaceutical institutes by wastage of chemotherapy drugs and its related substances, spent solvents, chemical sludges and leachate from various processes. Non-hazardous is generated through expired dosage forms, unused drugs, non-reworkable formulations, medicine delivery devices and liquid pharmaceutical waste. Hazardous waste material causes harmful effects on human health and environment, whereas non-hazardous waste material does not constitute a serious risk to public welfare or the ecosystem but can't be directly transferred [5]. Basically, laboratory waste and administrative waste are the two categories of waste generated in pharmaceutical institutes, as discussed below.

Laboratory waste

Laboratories of pharmaceutical institutes generate various kinds of chemical and reagent-related waste during manufacturing, testing and research which includes expired or unused chemicals, reaction residues, spill cleanup materials and also from empty chemical containers. Expired or unused chemicals are needed to proper identification and segregation from useful chemicals as they are inactive to give proper results otherwise more hazardous compared to functional chemicals. Cleaning materials like absorbents or neutralizing agents may contaminate the manufacturing or testing process [7]. To avoid unnecessary negative repercussions, residues created during chemical reactions or medication manufacture should be carefully handled and damaged or empty containers that previously carried chemicals should be properly disposed of according to guidelines [8]. In microbiological research performance generated waste includes expired and contaminated biological fluids, decaying animals, tissues and microbiological cultures. These waste products are contagious, posing health risks and also contaminating the environment. That should be treated and disposed of according to established protocols to prevent the spread of infections [9].

Administrative waste

Administrative waste in a pharmaceutical institute frequently comprises typical office equipment and materials. Here's a

breakdown of administrative waste with a focus on paper and office supplies as well as electronic waste which have been utilized for documentation or recording of experiments. Papers are used in pharmaceutical institutes to specify all materials, listing out of the all chemicals, solvents and reagents, personal information, contacts of staff members and students, methods of manufacturing and control, Standard Operating Procedures (SOPs) for every instrument and equipment, Master Production and Control Records (MPCR), Master Formula Record (MFR), Batch Production and Control Records (BPCR), Batch Production Records (BPR), calibration and validation records, log books, Good Manufacturing Practices (GMP) documents, audit records, practical journals, research papers and so on [6]. When institutes need to update the information, exchanging of these documents and records may be indirectly termed as waste but contains sensitive and confidential information regarding the institute. Requires to discard them by careful consideration and adherence to data privacy and security protocols [10]. As current generation is moving continuously towards electronics, digitalization and remote access to ease the workloads of professors and that will address the e-waste challenges. Electronic items such as computers, laptops, batteries, power Supplies, cables and accessories where computers and laptops are used to operate a number of instruments such as High-Performance Liquid Chromatography (HPLC), Liquid Chromatography-Mass Spectroscopy (LC-MS), Gas Chromatography (GC), Ultraviolet (UV) Spectrophotometry, Infrared (IR) Spectroscopy, etc. In pharmaceutical institutes, electronic items are used to store softcopies of documents and forms which is a digital version of information opposite of hard copy. During the improper working or damage of the electronics it becomes waste and needs to be discarded through e-waste management programs to recover valuable materials and prevent environmental contamination [11].

Below given fig. 1 represents the various types of waste generated by pharmaceutical institutes and its impact on the surrounding ecosystem [12, 13].

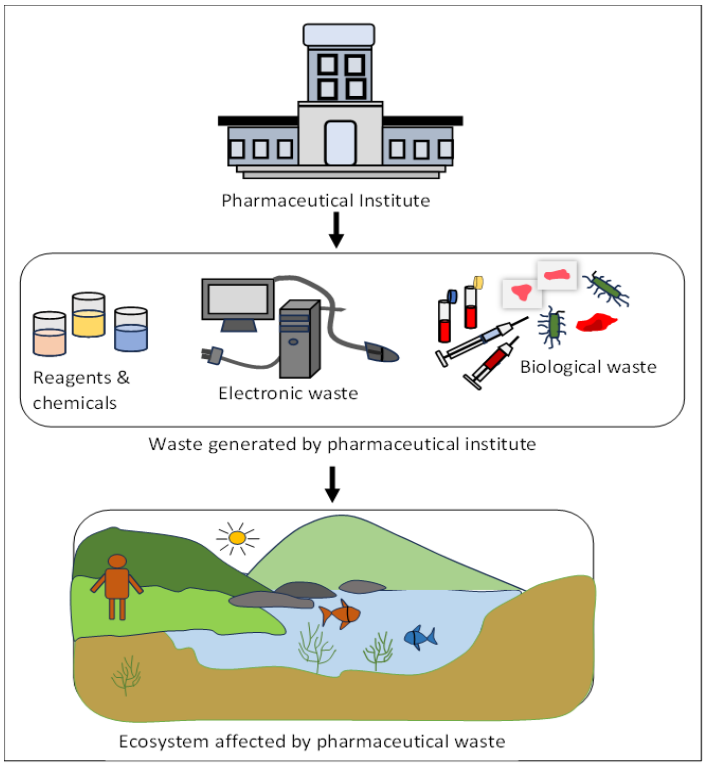

Fig. 1: Waste generated by pharmaceutical institute which has direct impact on ecosystem (Designed by Authors)

Environmental impact of pharmaceutical institute waste

Pharmaceutical waste can have significant environmental impacts, including water contamination, soil pollution and air emissions. Pharmaceutical waste can pollute the environment through various means, such as human and pet secretion and improper disposal methods such as flushing drugs down sinks or toilets, throwing them away in regular trash, or washing them down the drain. Pharmaceutical waste can also contain Active Pharmaceutical Ingredients (APIs) that can be discharged into the environment and pose environmental risks even in small concentrations. APIs can be observed in effluent water, groundwater, surface water, air, soil and biota ranging from sub-ng/l to greater than µg/l. Pharmaceutical waste can impact ecosystems by contaminating water, soil and air [14, 15].

Local environmental impact

Pharmaceutical institution waste can have substantial implications on the local environment, including water contamination, soil pollution and air quality issues. Incorrect disposal of pharmaceutical waste is finding their way into local water bodies through inadequate waste management practices. Presence of these contaminants can harm aquatic ecosystems, disrupt the balance of water quality and impact the availability of safe drinking water. These types of waste can have a significant effect on soil quality resulting in severe consequences on plant growth and agricultural output [16]. The improper incineration methods or release of Volatile Organic Compounds (VOCs) from working laboratories releases the pollutants into the air and contributes to the air quality issues. Releasing pollutants in the form of hazardous gases and particulate matter, which can be inhaled by nearby people will constitute the severe health hazard [17].

Impact on surrounding communities

Surrounding communities including all living beings in the context of pharmaceutical institute waste all suffers from the health risk and quality of life. Direct or indirect contact of pharmaceutical contaminants are susceptible to infection and diseases which may cause respiratory issues, cancer, hormonal deviations, suppression

of immune responses and neurological effects. Proper management and disposal of pharmaceutical waste from institutes are essential to prevent local environmental impacts and ensure the safety of the community and the environment. Healthcare administrators should develop and instruct personnel on the complete waste management strategy that complies with the DEA and state standards [18, 19].

Ecosystem and biodiversity concerns

Essentially, ecosystems are separated into aquatic and terrestrial categories, which comprise all living things (plants, animals and creatures) interact with each other in non-living circumstances (weather, climate, earth, soil, sun and atmosphere). The release of pharmaceutical compounds from the institution by incorrect waste disposal method into water bodies in lower concentration but frequently can cause a gradual increase in their concentrations [20]. Laboratory waste effluent is high in pH and contains a trace number of heavy metals. Effluents pH disturbs the soil pH and affects the fertility of it. Also, contaminated water bodies impact aquatic organisms and the environment in mild to severe ways. This can have an impact on fish populations, change the behaviour of aquatic creatures, and contribute to biodiversity loss. Continuous pharmaceutical residues may build up in organisms over time, leading to bioaccumulation. Furthermore, these chemicals can biomagnify and result in higher quantities at higher trophic levels. This represents a risk to predators at the top of the food chain and resulting in habitat degradation due to release of pharmaceutical waste [21]. The presence of pharmaceuticals may diminish ecosystem resilience, making them susceptible to other disturbances such as climate change or pollution from other sources [22].

Economic effects of waste production

The economic effects of waste production can be significant in regards to both, the costs expenses with waste management and the potential impacts on economic growth through regulatory Consequences. Understanding of the effectively managing of operational costs such as waste disposal, administrative expenses, equipment maintenance, and implementing waste minimization strategies. It is crucial for pharmaceutical institutions to view waste management not just as a regulatory necessity but also as an opportunity to optimize operations, reduce costs and contribute positively to environmental sustainability. Operational cost involves the waste management expenses and regulatory compliance costs are detailed below:

Waste management expenses

Pharmaceutical colleges generate laboratory waste, which requires proper disposal that led towards expenses associated with specific containers, transportation and disposal sites that comply with regulations. Pharmaceutical waste requires rigorous segregation and treatment, which necessitates an investment of specialist equipment and disposal techniques [23]. Investing in specialized containers and disposal equipment, such as incinerators or autoclaves, allows for the safe disposal of hazardous substances and helps to reduce contamination. Put effort in suitable Personal Protective Equipment (PPE) and staff training programs to enable successful garbage segregation and management for personnel safety and compliance [24]. Arranging and paying for waste transportation to specific disposal places. Coordinating with transportation for the safe and effective movement of garbage from the source of generation to the recycling site [25].

Regulatory compliance costs

Regulatory compliance costs are the charges paid by institutions to comply with numerous laws, rules and standards set by government agencies. These costs are related to ensuring that an organization's operations comply with legal standards. Depending on the type of waste produced, pharmaceutical colleges may be forced to pay disposal fees when disposing of hazardous or special trash at permitted sites. The regulatory compliance landscape is dynamic and organizations must constantly adjust to changes in laws and regulations. Improper disposal processes can lead to legal action, with victims or regulatory organizations filing legal action against the college. Non-compliance with waste management standards may result in penalties and fines. Several organizations see compliance as a critical component of their risk management and corporate governance initiatives [26].

Regulatory authorities for pharmaceutical institute waste

Environmental Protection Agency (EPA)

The EPA is a regulatory body in the United States that is primarily concerned with protecting human health and the environment by enforcing compliance with environmental laws and regulations. Pharmaceutical institutes must be aware of EPA standards for governing hazardous materials and waste management. It emerged in 1970 under the Environmental Protection Agency Act [27]. The EPA regulates hazardous waste disposal under the Resource Conservation and Recovery Act (RCRA). It encourages reduction and recycling efforts to lessen the environmental impact of garbage disposal. The EPA sets air and water quality standards to avoid pollution by regulating emissions and discharges from numerous companies and institutions [28].

Food and Drug Administration (FDA) or equivalent health agencies

The FDA's primary mission is public health, with a particular emphasis on the safety and efficacy of food, pharmaceuticals, medical devices and other products. The FDA publishes drug disposal guidelines and recommendations for the correct disposal of pharmaceutical items, including expired or unused medications, in order to prevent injury and environmental pollution [29]. The FDA manages the development, production and marketing of medications, which ensure that they are safe and effective for consumer use. Institutions must follow standards for the correct disposal of controlled substances, is potential for abuse to prevent diversion and misuse. It regulates pharmaceutical recalls and returns goods, which include correct methods for managing and disposing of to avoid potential harm to customers and the environment [30].

Occupational safety and health administration (OSHA)

OSHA is a federal agency of labour which was established by the Occupational Safety and health act of 1970 with the primary goal of ensuring safe and healthy working conditions for employees. These regulations cover a wide range of industries and organizations address various hazards to protect workers from injuries, illnesses and fatalities. OSHA sets and enforces standards provides training, outreach, education and assistance to employers and employees. It has reporting requirements for severe injuries and fatalities. OSHA uses this information to track workplace safety trends and improve safety standards [31].

Department of environmental quality or environmental agency

The primary focus of environmental agencies or departments of environmental quality is the protection and preservation of the environment. This includes regulating and enforcing standards for air and water quality, managing waste and addressing issues related to pollution and environmental degradation. It provides information about the process to dispose of medical waste and requirement that medical/infectious waste be converted into non-infectious via steam sterilization, chemical disinfection, or another similarly effective treatment method before being disposed of in a municipal solid waste landfill [32].

Ministry of health or health department

Agency has first priority is to focus on public health issues and improving the health of communities, preventing the spread of diseases and ensuring access to healthcare services. It promotes and protects public health through various programs and initiatives, including disease prevention, health education and healthcare delivery. This can include licensing healthcare facilities, monitoring food safety, conducting disease surveillance and implementing health-related regulations to protect the well-being of the population [33].

Pharmaceutical waste treatment and disposal

The Indian government's pharmaceutical waste rules and regulations specify the technologies for treating and disposing of

pharmaceutical waste. It strives to reduce the environmental impact and public health concerns associated with pharmaceutical waste by ensuring correct management, treatment and disposal. For the management of waste, staff of the institution needs to include an operator to keep records of the generation, collection, storage, treatment and disposal of waste material [34]. There are several specific processes for treating and disposing of pharmaceutical waste, including incineration, autoclaving, chemical neutralization and inertization and encapsulation. It emphasizes the necessity of good waste management methods, such as meticulous stock keeping, appropriate inventory control and waste minimization measures, in reducing pharmaceutical waste generation.

Pharmaceutical waste disposal technologies are enlisted in detailed below:

Incineration

Incineration is a waste treatment process which is for combustion of organic form of solid waste at high temperature and converting them into gaseous materials and residue. It is commonly used for the treatment of various types of pharmaceutical waste such as biomedical waste and hazardous waste in the context of pharmaceutical waste management [35]. Incineration is effective in destroying pathogens, bacteria; viruses are present in biomedical waste. It may be employed to safely dispose of expired or unused medications, contaminated materials and other pharmaceutical residues. In this procedure, within 20 to 30 percent of the mass is reduced from its initial amount. It can also be referred to as heat treatment [36].

Autoclaving

Autoclaving is a process of treatment that uses steam to sterilize waste materials. It is a common method used for the treatment of biomedical waste, including pharmaceutical waste. Autoclaves treat the waste in combination of high-pressure steam and heat to achieve the necessary temperature and pressure conditions for effectively killing microorganisms, including bacteria, viruses and spores, which result in sterilization. Materials suitable for autoclaving are glassware, surgical instruments, laboratory equipment and certain types of pharmaceutical waste, such as used vials, syringes and other heat-resistant materials. Basically, autoclaving is used to reduce microbial load from these waste materials before disposal to avoid subsequent contaminations [37].

Microwaving

Microwaving, as a waste treatment method, involves using electromagnetic wave frequency to generate heat within waste material and disinfection process carried out. It is for specific types of waste, including certain biomedical and pharmaceutical waste. The primary goal of microwaving for waste treatment is to sterilize or disinfect the waste by raising its temperature sufficiently to kill microorganisms, including bacteria and viruses [38].

Chemical treatment

Chemical treatment is a waste management method that involves the use of various chemicals to treat and neutralize waste materials. The primary goal of chemical treatment is to alter the chemical composition of the waste, rendering it less harmful, non-toxic or non-hazardous. Chemical treatment is carried out by oxidation or reduction processes, which takes place by adding oxidizing agents or reducing agents which can break down or reduce harmfulness of the waste. Treatment is also carried out by using precipitation and neutralization, where chemicals are added into waste materials to induce the formation of solid precipitates in case of precipitation process of treatment, while, neutralization involves the addition of acids or bases to adjust the pH of the waste to a neutral or less corrosive level [39].

Shredding and disposal in landfills

Shredding and disposal in landfills are a waste management method that involves mechanically shredding waste materials into smaller pieces of more manageable pieces before disposing of them in designated landfills. This approach is often used for non-hazardous and non-biomedical waste. Shredding is effective in reducing the volume of waste, making it more compact and easier to transport and dispose of in landfills. Shredding is commonly applied to a wide range of materials, including paper, cardboard, plastics, textiles and other non-hazardous solid waste [40].

Plasma pyrolysis

Plasma pyrolysis is an advanced waste treatment technology that involves the use of plasma, which is converted into an ionized gas with high energy through air or steam at extremely high temperatures exceeding 3000 ^{0}C using an electric arc or other energy sources. This results in the formation of a highly energized state of matter with ions, electrons and excited neutral particles which is used to thermally decompose organic compounds of waste materials. This process is also known as plasma gasification or plasma arc gasification [41].

Encapsulation

Technology used for hazardous waste management where waste is physically immobilized to prevent contact with leaching agents such as water. Goal of the technology is to coat the waste with inert materials such as polybutadiene, sulphur polymer and high-density polyethylene [40]. Treatment method is to reduce the hazard potential of the waste itself and limit its environmental impact. Disposal of sharps and mercury-contaminated hazardous wastes that require burial or storage. It provides high resistance to corrosive environments such as acids and salts [42].

CONCLUSION

In conclusion, managing institutional pharmaceutical waste requires a comprehensive approach that considers both environmental effect and regulatory compliance. Recognizing the complexities of pharmaceutical waste, institutions must incorporate effective waste management procedures into their operations. Adherence to local, national, and international rules ensures that institutions function within legal structures, thereby lowering the risk of penalties and legal consequences. This includes implementing sustainable disposal procedures and researching new methods for the remediation of pharmaceutical residue. By performing this way, institutions can help to reduce their ecological impact while also protecting the surrounding ecosystem. Institutions that embrace their duty as responsible defenders of the environment contribute not only to sustainable waste management but also to the larger global activity to protect ecosystems and public health.

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CONFLICT OF INTERESTS

Declared none

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