

EXECUTION OF ENVIRONMENT, HEALTH AND SAFETY (EHS) IN PHARMACEUTICAL INDUSTRIES

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ABSTRACT

Sales, employment, and GDP are only some of the metrics that have led to claims that the pharmaceutical business is vibrant and expanding. Businesses, governments, and academics all work together in this sector to ensure that their products are safe for consumers and the environment. While industrialization is essential to a country's development, it also produces significant quantities of pollution and trash. Thus, Environmental, Health, and Safety (EHS) must be a top priority in the manufacturing industry. The manufacturing sector is expected, and often required by law, to follow the regulations and standards set forth by regulatory organizations in the area of EHS. Good Manufacturing Practices (GMP) and worker safety depend on EHS more than anything else. A robust EHS management system may do wonders for an organization's productivity, in addition to making the workplace safer and healthier for workers. In this article, it has been tried to provide the basic correlation between the Pharmaceutical industries and EHS for smooth operation in the manufacturing plants.

INTRODUCTION

The worldwide medicines and vaccines sector is significantly influenced by India's contributions. It is the most important supplier of generic medications in the entire world. The country is responsible for the production of around sixty percent of the world's vaccines and has a share of twenty per-

cent of the total volume of the worldwide supply. In terms of volume, India is the third largest country in the world, while in terms of value, it is the fourteenth largest (Fig. 1). Over-the-counter medicines, generics, active pharmaceutical ingredients, vaccines, biosimilars, and Custom Research Manufacturing (CRM) are some of the most important sub-sectors of the Indian pharmaceutical business.

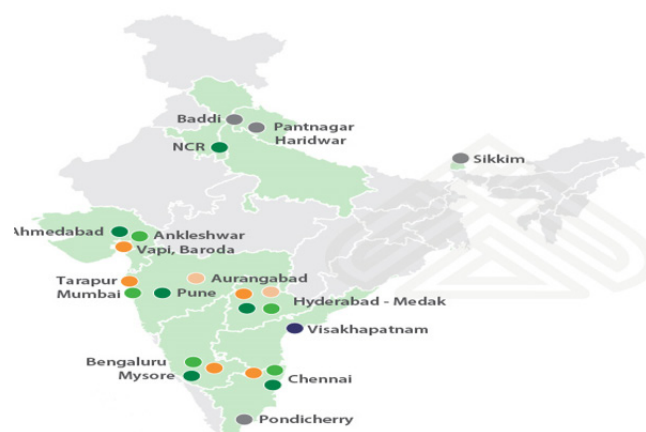


Fig. 1 Pharmaceutical clusters in india. **Note:** ■ Captive RandD units; ■ Contract R and D units; ■ Established bulk drug cluster; ■ Established formulation cluster ; ■ Emerging bulk drug cluster; ■ Emerging formulation cluster.

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MATERIALS AND METHODS

North America, Africa, the European Union, the Association of Southeast Asian Nations (ASEAN), Latin America and the Caribbean (LAC), the Middle East, Asia, the Commonwealth of Independent States (CIS), and other European regions all receive pharmaceutical products from India. NAFTA, Europe, and Africa together account for about two thirds of India's total exports (Figs.2 and 3). The United States of America, the United Kingdom, South Africa, and Russia were the top five export destinations for the Indian Pharmaceutical Industry in the years 2021-22.

741 establishments have been granted approval by the US Food and Drug Administration as of the month of August 2021. In addition to this, the number of ANDAs that Indian companies have been awarded as of December 2020 is 4,346. The COVID epidemic prevented the USFDA from carrying out inspections over the past couple of years; however, the inspections have begun again recently and it is anticipated that they will lead to an even greater increase in Indian exports to the United States.

The percentage of the worldwide market that is comprised of medicines and drugs that is owned by India is 5.92%. After drug intermediates and bulk medicines, formulations and biologics made up the largest amount of India's exports, accounting for 73.31 percent of the country's total, respectively. The country's pharmaceutical product exports brought in US\$ 24.62 billion in 2021-

22, which was the same amount as the previous year (Fig.4). The value of exports increased to \$24.4 billion, representing an 18% year-on-year increase. This impressive achievement was accomplished in spite of the disruptions to the global supply chain, lockdown, and the depressed manufacturing. The amount of money that India made through the sale of medicines and other drugs increased by 23 percent from February 2023, when it was worth 1.97 billion dollars, to March 2023, when it was worth 2.4 billion dollars. The United States of America, the United Kingdom, South Africa, and Russia are the top five destinations for India's exports. Even in the midst of a global health emergency, India was able to demonstrate its capacity to be a constant and reliable supplier of pharmaceuticals to the rest of the world thanks to its pivotal involvement in the COVID-19 outbreak.

The worldwide pharmaceutical business is continuing to expand, resulting in a spectacular increase of \$1.4 trillion in revenue in 2021 (Fig.5). This growth is being fueled by the introduction of new products as well as an aging population. Because new pharmaceuticals are consistently being developed, approved, and put on the market, the market overall is seeing substantial expansion. The pharmaceutical industry has shown resilience in the face of setbacks brought on by the COVID-19 pandemic, and in 2021, the FDA approved a total of 50 new pharmaceuticals, making it the fourth-best year in terms of drug approvals behind 2018 (59 drugs), 1996, and 2020 respectively (53 each).

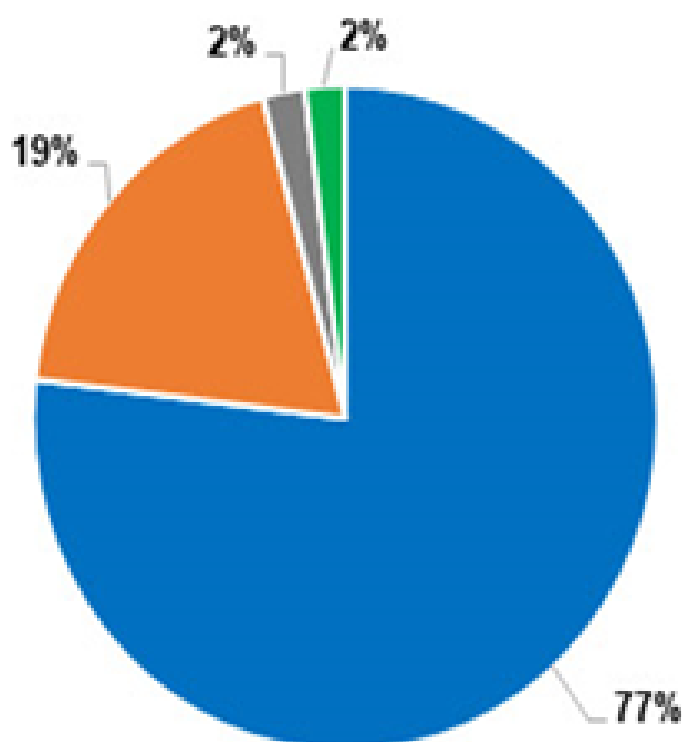


Fig. 2 India's category wise export share in the World. **Note:** ■ Drug formulations and biologics; ■ Bulk drugs and drug intermediates; ■ Surgicals; ■ Ayush and herbals products;

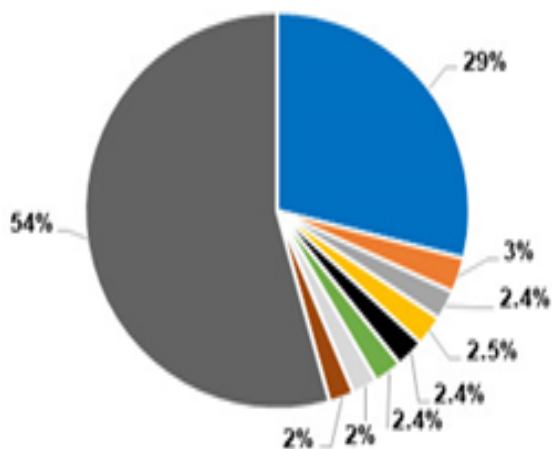


Fig. 3 Country-wise share of drugs, pharmaceutical and fine-chemicals exports 2021-22. Note: The US; The UK ; Russia ; South Africa; Nigeria; Brazil; Germany; France; Others;



Fig. 4 Export trends of drugs and pharmaceuticals of india.

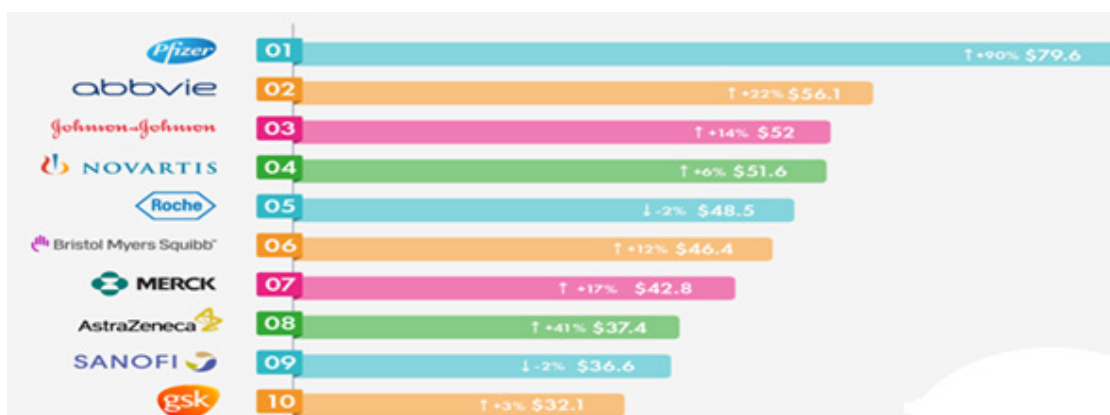


Fig. 5 Top 10 pharmaceutical companies and their revenue (USD Billions) in the world (2023).

When working in the pharmaceutical sector, it is vital to prioritize safety in three primary areas: when handling machinery and equipment, as well as when carefully working with medications and chemicals. In this day and age, it is obvious that an accident will cause damage to the factory as well as the company’s reputation, in addition to the need to pay out significant compensation and possibly the possibility of the factory being shut down.

In the pharmaceuticals sector, many different chemicals are managed through the utilization of a wide variety

of pieces of machinery, equipment, and processes that make use of electrical and mechanical tools. In addition, a wide variety of microorganisms are handled, both in the laboratory and during the production process. So, a comprehensive analysis of the entire setup, including the machinery, the process, the raw materials, the chemicals, and the microorganisms, is required. In order to avoid an accident, it is necessary to first recognize all of the potential risks and then to adopt safety precautions as well as corrective actions. In light of all of this, it is imperative

that all of these elements be taken into consideration for the sake of safety during the design and execution of the project. This contributes to the reduction of the likelihood of accidents occurring while the plant is in operation.

As businesses in every region of the world work to improve their standards of quality, Environmental Health and Safety (EHS) is rapidly becoming an industry standard. When it comes to the process of manufacturing outsourcing, a number of the regulatory bodies are choosing to prioritize EHS compliance as one of the most important requirements. In the pharmaceutical sector, the first thing that will automatically come to mind when thinking about how to produce new drugs is to invest heavily in Research and Development (R and D). Yet, careful and responsible management of chemicals as a step toward the EHS program is also viewed as a potential area for financial investment at this time (Gupta, 2001).

EHS makes the company more profitable, and the most of these practices have already been implemented by multi-national pharmaceutical corporations. As a result of considering the potential benefits of this decision, the majority of large pharmaceutical businesses in India are now completely compliant with all EHS regulations. Companies like as Ranbaxy Laboratories, Alembic, Dr. Reddy's Laboratories, Lupin, Zydus Cadila, and USV, amongst others, are instances of this tendency in the pharmaceutical industry (Gupta, 2001). A community may become concerned about the operations of the pharmaceutical business, and a well-designed and comprehensive Environmental Health and Safety (EHS) program may be able to assist in addressing these issues.

RESULTS AND DISCUSSION

Environmental Management System (EMS) in Pharmaceuticals Products

It is necessary to take into consideration the

environmental concerns that arise from the disposal of pharmaceutical items as the number of people who use these products rises. The pharmaceutical business, health care providers, environmental regulators, and members of the general public were among the several parties who participated in the process of addressing these environmental challenges. The pharmaceutical industry has a responsibility to the environment, and one of the goals of environmental management is to reduce the amount of pharmaceuticals and chemicals that are related to them that are found in our air, land, lakes, rivers, and streams (Fig.6) (Subrahmanyam,2005; Berry, et al., 2000).

Safety Management System (SMS)

Occupational health seeks to ensure that workers are as physically, mentally, and socially healthy as possible in the workplace, that they are safe from any hazards that could compromise their health, that they are shielded from any threats to their well-being on the job, and that they are kept in settings that are optimal for their specific needs (OHSAS:BS, 2007).

Concerns raised by members of the community as a result of activities carried out by the pharmaceutical industry can be alleviated with the assistance of an Environmental, Health, and Safety (EHS) program that is both well-designed and comprehensive (Krishnananda, et al., 2014).

The management of pharmaceutical companies ought to have the expectation that their environmental, health, and safety program would keep employee and community exposures at the lowest levels that are reasonably possible (Fig.7). Because of this, they will be able to reap the benefits of enhanced staff morale, positive views in the community and media, and the minimizing of costs

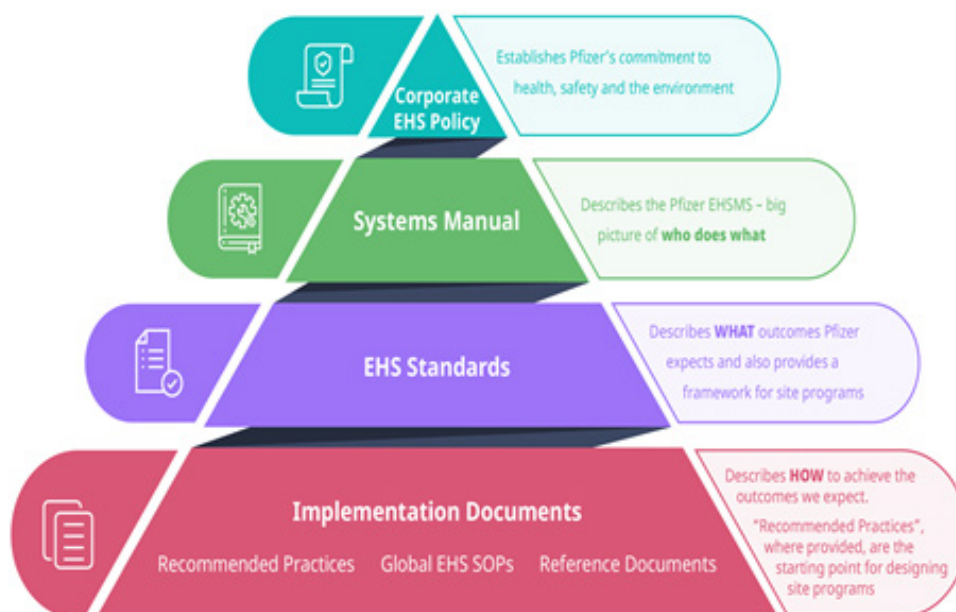


Fig. 6 EHS management system.



Fig. 7 Legal Ways to understand the system for Indian constitution.

connected with unexpected incidents.

Safety at Workplace can be achieved through the Following Steps

- Risk analysis and hazard research.
- “Work Permit” Procedure.
- Management Strategy for Fire Protection.
- Electrical Risk Management Procedures.
- Enough Personal Protective Equipment.
- Employees should receive extensive safety education.

Basic Safety Rules Required at Workplace to Ensure Safe Man-hours

- While on duty, all personnel must dress in full uniform, including a clean cap.
- The factory is a smoke-free zone.
- Everyone on staff has been handed a safety helmet, goggles, and gloves, all of which must be worn at all times.
- While working with dangerous chemicals, it's important to wear protective gear like acid-proof aprons and goggles.
- All production materials are extremely costly and potentially dangerous; be sure there is some waste and spillage. Learn the Material Safety Data Sheets (MSDS) for every chemicals you use.
- Safety belts are required when operating at elevated levels.
- Do not go aboard any watercraft without the required entrance permits.
- No hot work or welding is allowed without a fire

permit.

- Any upkeep work requires a valid work permit.
- Do not begin work without the proper authorization.
- Any excavation work requires an authorized excursion.

Contingency Plan to Control Safety

It is important to have a “Contingency Plan” ready in the event of an industrial disaster that could cause serious harm to workers and nearby residents. Hence, each sector must create an “Emergency Management Plan” for the workplace, outlining what must be done and by whom in the event of an emergency. All control methods necessary to prevent damage to life should be described in full, as should the problem, its rapid control, and any action to prevent further escalation.

CONCLUSION

In order to reap the benefits of improved employee morale, positive community and media perceptions, and the minimization of costs associated with unexpected events, management at pharmaceutical companies should expect their Environmental, Health, and Safety program to maintain employee and community exposures at as low a level as is reasonably achievable. This expectation applies to research and development as well as manufacturing. So, pharmacists have moral obligations to ensure the health and safety of both their profession and the general public. This is the most important thing that can be done right now to save water, cut down on waste, slow down the rate at which the earth is warming, and preserve the amount of natural resources that are available.

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