



OCCUPATIONAL HEALTH HAZARDS IN THE PHARMACEUTICAL INDUSTRY

Dr. Sonali P. Mahaparale^{1*} and Shruti Vijay Hagawane²

¹HOD of Pharmaceutical Chemistry, Dr. DY Patil College of Pharmacy, Akurdi, Pune.

²Dept. of Pharmaceutical Quality Assurance Dr. DY Patil College of Pharmacy, Akurdi, Pune.

*Corresponding Author: Dr. Sonali P. Mahaparale

HOD of Pharmaceutical Chemistry, Dr. DY Patil College of Pharmacy, Akurdi, Pune.

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ABSTRACT

The rate of globalization has contributed to an increase in employment in the informal sector, usually characterized by flexibility, hazardous and precarious work, which poses a major risk to the well- workers. The pharmaceutical industry plays an important role in healthcare systems around the world engaged in the discovery, development, manufacture, and marketing of medicinal products for human as well as animal health. Formulation and development of a new dosage form involve ingredients and APIs, including various corrosive and irritant agents. Like acid- oxidizing and reducing agents, etc. In recent years, the pharmaceutical industry has come to occupy a unique position on the issues of industrial hygiene and toxicology. The government and stakeholders should, therefore, develop an occupational health and safety system and encourage industry to reduce the level of hazards associated with their employment. Musculoskeletal disorder is one of the occupational health hazards seen in the pharmaceutical industry.

KEYWORDS: Hazards, OSHA, GHS, NIOSH, ACGIH.

INTRODUCTION

Hazard is a condition that poses a risk to life, health, property, and the environment. Hazardous waste sites pose a multitude of health and safety concerns, all of which could result in serious injury or death.

Occupational hazard can be defined as a risk to a person usually arising from a job. It may also refer to work, material, substance, process or situation that predisposes or causes accidents or illnesses in the workplace. The history of awareness about occupational hazard can be traced back to the 18th century, when Bernadino Ramazzini, who is referred to as the father of occupational medicine, recognized the role of occupation in health and disease dynamics. Over the last decade, industry, government and the general public have become increasingly conscious of the need or need to study the growing hazardous waste problems.^[1,2,3]

Occupational hazards pose long-term and short-term risks to the industrial environment.^[4] It is a field of study in the field of occupational safety and health and public health. OSHA establishes an act to prevent injuries and illnesses in the workplace. OSHA Guidelines are used as a protective approach to the management of safety and health in the industrial environment.^[5] The pharmaceutical industry is a major contributor to the health of workers in the working environment. The industry presents particular challenges to occupational

health professionals involved in the transfer of effective occupational health services.^[6,7]

For the Management and regulation of occupational health, hazards involve various guidelines such as,

- Occupational safety and health administration (OSHA)
- National institute for occupational safety and health (NIOSH)
- American Conference of Governmental Industrial Hygienists (ACGIH) (Used to determine TLVs limit).

Objectives of Health Regulation

Highlighted below are a few of the health education objectives:

1. To develop desirable health practices and health habits;
2. To develop the health attitudes within the people;
3. To develop the health consciousness in the workers and the community;
4. To eradicate the diseases through health drive programs;
5. To provide a healthy environment for physical and mental growth.^[8,9]

An occupational hazard is experienced in various industries such as:

- Hazards may cause serious injury or death
- May not be immediately obvious or identifiable.
- May vary according to the location on-site and the task being performed.
- May change as site activities progress.

Types of occupational hazards

1. Chemical Hazards
2. Biological Hazards (Bio Hazards)
3. Physical Hazards,
4. Psycho-social Hazards.

A) Chemical Hazard

Chemical hazards are occupational hazards that may be caused by exposure to chemicals in the workplace. Hundreds of hazardous chemicals, including immune agents, dermatological agents, carcinogens, neurotoxins and reproductive toxins, sensitizers, and systemic toxins are also hazardous chemicals. Chemical hazards present a wide range of health hazards (such as irritation, sensitization, and carcinogenicity) as well as physical hazards (such as flammability, corrosion, and explosives).^[10,11]

OSHA's Hazard Communication Standard (HCS) 29 CFR 1910.1200, 1915.1200, 1917.28, 1918.90, and 1926.59 is designed to ensure that information about chemicals and toxic substance hazards in the workplace and associated protective measures are disseminated to workers.^[12,13]

To ensure chemical safety at the workplace, information on the identity and hazards of chemicals must be made available and understood by workers. The OSHA Hazard Communications Standard (HCS) requires that such information be developed and disseminated.^[14,15]

It is anticipated that chemical manufacturers and importers will assess the hazards of the chemicals they produce or import and prepare labels and safety data sheets to communicate hazard information to their downstream consumers as well as to train workers to handle the chemicals properly. Training for employees must include information on the hazards of chemicals in their work area and the measures to be used to protect themselves.^[16]

Table 1: Different types of chemical hazards.^[17]

Hazardous Substance or Chemical Group	Compounds	Uses	Target Organs	Potential Health Effects	Medical Monitoring
Aromatic Hydrocarbons	-Benzene -Ethyl Benzene -Toluene -Xylene	Used as a commercial solvent in pharmaceutical industry	Blood, Bone Marrow, CNS, Eyes, Skin, Liver, Kidney.	CNS depression, Defatting dermatitis, Chronic exposure can cause leukemia, Bone marrow suppression	Occupational and general medical history concerning the exposure of these or other toxic agents.
Halogenated Aliphatic Hydrocarbons	CCl ₄ , Chloroform, Ethyl Bromide, Methyl Bromide, Vinyl Chloride, CH ₃ Cl ₂	Commercial solvent and intermediate organic synthesis	CNS, Kidney, Liver, Skin	CNS depression, Kidney changes- Decreased urine flow, Anaemia Liver Changes- Fatigue, Dark urine, Jaundice	A medical examination on the liver, kidney, nervous system, skin. Laboratory testing- for liver and kidney, CBC & Platelet count
Heavy Metals	Arsenic Cadmium Chromium Lead Mercury	Wide variety of industrial and commercial users.	Blood, Kidney, Liver, Lungs, CNS, Skin	All are toxic to the kidney. Lead causes decreased mental ability, Weakness, Headache, Cadmium causes kidney and lung disease.	Laboratory testing- Metallic content in body fluid and tissue. Measurement of kidney and liver function.
Polychlorinated Biphenyls (PCBs)		Wide variety of industrial uses.	Liver, CNS, Skin, Respiratory system	Various skin ailments, including chloracne; may cause liver toxicity and carcinogenic to animals.	Physical examination on skin and liver. Laboratory tests- Serum PCB level, Triglycerides, and cholesterol Measurement of liver function.

B) Biological Hazard

Biological hazards include bacteria, fungi, and viruses. Nail salon workers can be exposed to blood Borne pathogens, such as hepatitis B, hepatitis C, and human

immunodeficiency virus (HIV), if they come into contact with infected blood from a co-worker or client it may be harmful to others. Workers may also be exposed to fungal infections of the nails and feet by touching

infected customer's skin or by using uncleaned equipment.^[18,19]

Table 2: Different types of biological hazards (Viruses, bacteria, fungi, and plants).

	Infection	Infection zoonosis ¹	Allergic response	Respir- able toxin	Toxin	Carcinogenic
Bacteria						
Rickettsiae,Chlamydiae,Spiral bacteria		X				
Gram-negative bacteria	x	x	x	X(e) ²		
Gram-positive Cocci		x	x			
Spore forming bacilli		x	x	x		
Fungi						
Molds	x		x	X(m) ³		X
dermatopytes	x	x	x			
Yeast-like geophilic	x	x				
Endogenous yeasts	x					
Parasites of wheat			x			
Mushrooms			x			
viruses	x	x				

1. Infection-zoonosis: usually causes infection or invasion of vertebrate animals (zoonosis)
2. e-Endotoxin
3. m-Mycotoxin

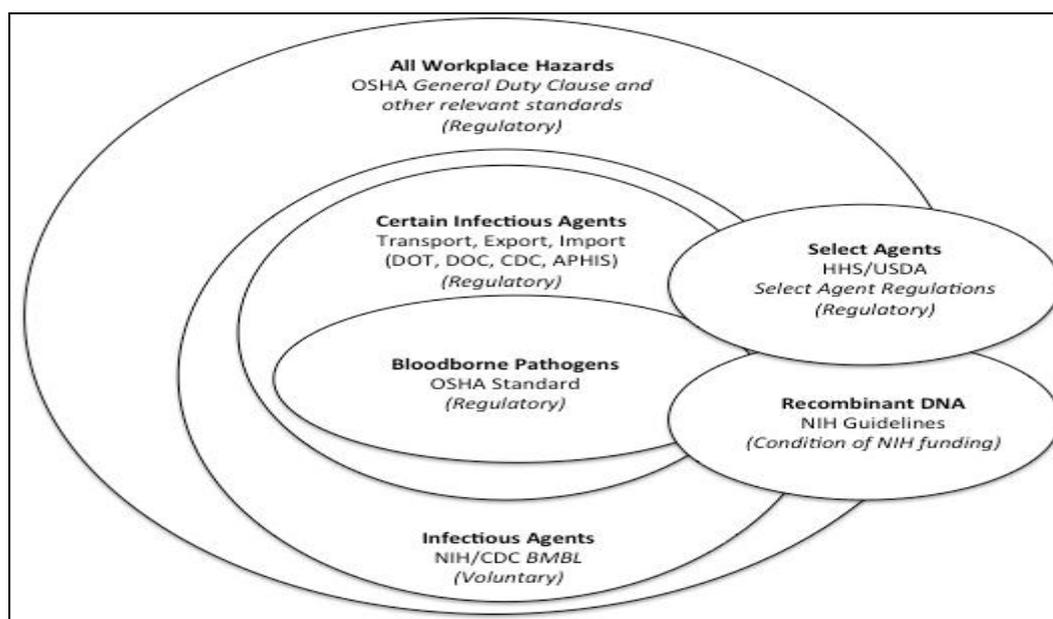


Figure 1: (variety of agencies and regulations).

As noted in the figure-1, a variety of agencies and regulations touch on various aspects of biological materials oversight in research. The next sections will highlight the major federal regulations and guidelines for biological materials oversight in research.^[20]

C) Physical hazards

An agent, factor or circumstance that can cause harm without contact is a physical hazard. Physical hazards include ergonomic hazards, noise hazards, radiation hazards, heat and cold stress, and vibration hazards.

Controls of engineering are often used to mitigate physical hazards. Physical hazards are a common cause of injury in many industries. In some pharmaceutical industries, such as the manufacture of APIs, the production of alcohol-based medicines that are highly explosive may be unavoidable, but over time, people have developed safety methods and procedures to manage risks of physical hazards in the workplace.^[21, 22]

D) Psychological hazards

Psychosocial hazards or job psychological issues are occupational hazards that affect employees

'psychological and physical well-being, including, among others, their ability to engage in the workplace. Psychosocial hazards relate to how work is designed, organized and managed, as well as to the economic and social context of work. They are associated with psychiatric, psychological disorders such as occupational burnout, anxiety disorders such as depression, hypertension, and cardiovascular disease. Psychosocial risks are linked to the organization of work as well as to occupational violence and are internationally recognized as major challenges to occupational safety and health as well as to production.^[21]

Occupational Safety and Health Administration

More than 500,000 workers are employed in laboratories in the United States. Laboratory working people are exposed to a wide range of potential hazards including chemical, biological, physical and radioactive hazards and musculoskeletal stress is subject to various OSHA supervision (Roy 2000). Laboratory safety is governed by several local, state and federal regulations (Azmi Mohd and Norafneeza). Over the years, OSHA has enacted rules and published guidance to make laboratories increasingly safe for staff (Krienitz). Several primary OSHA standards apply to laboratories as well as other OSHA standards that apply to different aspects of laboratory activities, including OSHA Bloodborne Pathogen and OSHA Hazard Communication (Kuruvilla 2010, 2011, Traynor 2012).^[23]

Hazard Assessment

Once the presence and concentrations of specific chemicals or classes of chemicals have been determined, the hazards associated with these chemicals must be determined. This is done by referring to standard reference sources for data and guidance on permissible exposure levels, flammability, etc.^[24]

Threshold Limit Value (TLV) ®

TLVs can be used as a guidance to determine the appropriate level of protection for workers. These values have been derived for many substances and can be found in Threshold Limit Values for Chemical Substances and Physical Agents, which is published annually by the American Conference of Governmental Industrial Hygienists (ACGIH) 121. The ACGIH defines three categories of TLVs: time-weighted average (TWA); short-term exposure limit (STEL); and ceiling (C). All three categories may be useful in selecting levels of protection at hazardous waste sites. For additional details see Threshold Limit values for chemical substances and physical agents.^[25,26]

Permissible Exposure Limit (PEL)

Permissible exposure limits are enforceable standards enacted by OSHA. In many cases, these are derived from TLVs published in 1968. The PEL for a substance is the average or ceiling concentration of 8 hours over which workers may not be exposed. Although personal protective equipment may not be required for exposures below the PEL, its use may be advisable where there is a potential for over-exposure. See tables and substance-specific standards in 29 CFR Part 1910, Subpart Z for further details.^[27]

Recommended Exposure Limit (REL)

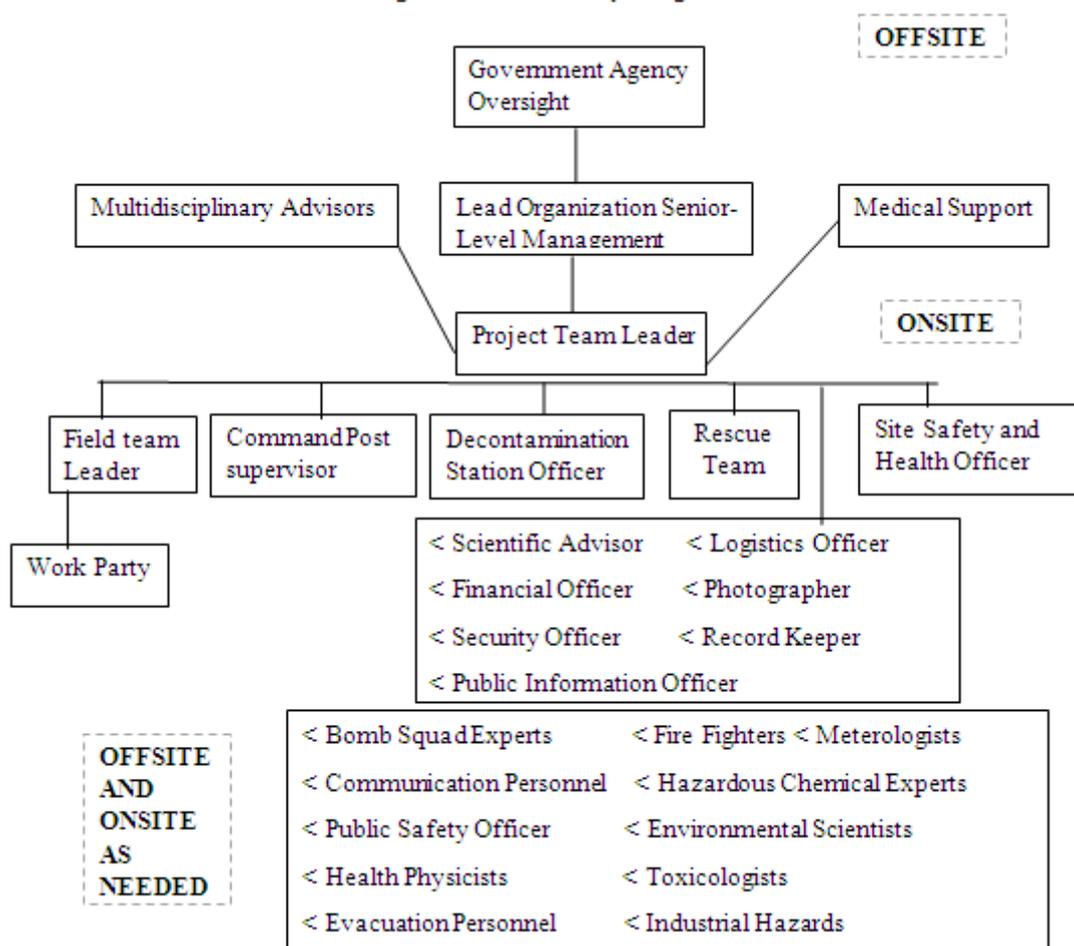
The NIOSH recommended exposure limit (REL) is the occupational exposure concentration recommended by NIOSH for the recovery of OSHA as a PEL but not enforceable as OSHA PEL. In some cases, NIOSH described time-weighted average concentrations as 10-hours instead of 8-hour averages.^[27]

Table 3: Guidelines for Assessing Chemical and Physical Hazards.^[27]

Hazard	Guideline	Explanation	Sources For Values	
Inhalation of airborne contaminant	TLV	Threshold Limit Value	One of three categories of chemical exposure levels, defined as follows:	
	TLV-TWA	Threshold Limit Value-Time-Weighted Average	The time-weighted average concentration for a normal 8-hour workday and a 40-hour workweek, to which nearly all workers may be repeatedly exposed without adverse effect, Should be used as an exposure guide rather than an absolute threshold.	ACGIH
	TLV-STEL	Threshold Limit Value-Short-Term Exposure Limit	A 15-minute time-weighted average exposure that should not be exceeded at any time during the workday.	ACGIH
	PEL	Permissible Exposure Limit	Time-weighted average and ceiling concentrations similar to (and in many cases derived from) the threshold limit values Published in 1968.	OSHA
	IDLH	Immediately Dangerous to Life or Health	The maximum level from which a worker could escape without any escape-impairing symptoms or any irreversible health effects.	NIOSH
	REL	Recommended	Time-weighted averages and ceiling concentrations based	NIOSH

		Exposure Limit	on NIOSH evaluations.	
Carcinogens	TLV	Threshold Limit Value	Some carcinogens have an assigned TLV.	ACGIH
	PEL	Permissible Exposure Limit	OSHA has individual standards for some specific carcinogens.	OSHA
	REL	Recommended Exposure Limit	NIOSH makes recommendations regarding exposures to carcinogens.	NIOSH
Noise	TLV	Threshold Limit Value	Sound pressure levels and durations of exposure that represent conditions to which it is believed that nearly all workers may be repeatedly exposed without an adverse effect on their ability to hear and understand normal speech.	ACGIH
	PEL	Permissible Exposure Limit	Limits for acceptable noise exposure.	OSHA
	REL	Recommended Exposure Limit	Limits for acceptable noise exposure.	NIOSH
Fire	Flash Point	The lowest temperature at which the vapour of a combustible liquid can be made to ignite momentarily in the air.		NFPA

Organization of Safety Programme



Management of Occupational Health Hazards

There are many health hazards in the workplace, such as noise, vibration, radiation, chemicals, extreme temperatures, and biological agents. Exposure to health hazards may result in occupational or occupational disorders. Many of these are insidious and manifest only after a prolonged period of exposure to hazards; some are irreversible and have no cure. Occupational health is

concerned with the management of occupational health hazards and those who are exposed to such hazards or suffer from occupational illnesses or ill health.^[28,29]

The Workplace Safety and Health Act (WSH) and its subsidiary regulations set standards for the safety, health, and well-being of workers at work in all workplaces. The Act specifies the duties of various stakeholders:

1. Employers: ensure the safety and health of all the people at work
2. Occupiers: ensure the workplace is safe and without risks to health
3. Principals: ensure the health and safety of contractors and subcontractors engaged at work

WSH (Risk Management) Regulations

In each workplace, the employer, the principal and the self-employed shall conduct a risk assessment on safety

and health risks at the workplace at least once every three years or on the occurrence of any injury to any person; or any significant change in working practices. They must take all reasonable steps to eliminate any foreseeable risks. Where this is not feasible, reasonably practicable measures must be put in place to minimize or control the risk in the control hierarchy below.^[30]

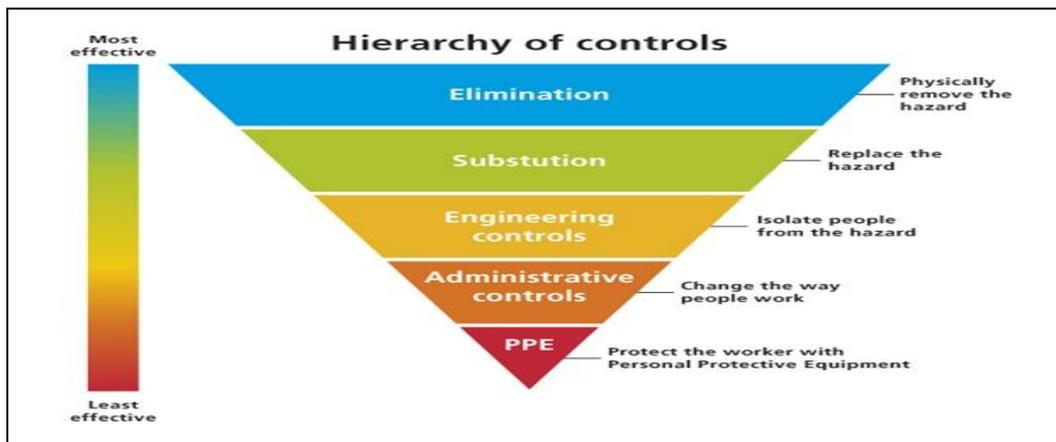


Figure 2: Hierarchy of controls.

WSH (Incident Reporting) Regulations

When an employee has an accident, injury at the workplace or an occupational illness specified in the Second Schedule of the WSH Act, the employer shall submit a report to MOM (Minister of Labour) within 10 days. Common occupational diseases include occupational skin diseases, noise-induced deafness, and musculoskeletal disorders^[31]

Management of Noise Hazards at Workplace

Noise is generated from machines, installations, works, operations, and processes. Extended exposure to excessive noise can cause noise-induced deafness or permanent hearing loss. Other harmful effects of excessive noise include tinnitus and acoustic trauma.

A person shall be considered to be exposed to excessive noise if the noise to which he or she would have been exposed in the absence of a hearing protector exceeds the permissible exposure limit set out in the Schedule of the WSH (Noise) Regulations.^[32]

To reduce noise, control measures can be carried out at:

- Source – install silencers, apply damping material, use vibration isolators
 - Path – enclose machines or processes, erect noise barriers, apply sound-absorbing materials
 - Receiver – isolate workers in control rooms, reduce exposure time through job rotation
- Key WSH (Noise) Regulations requirements are:

- Implement noise control measures to reduce the noise emitted from used equipment or machinery. Where it is not practicable to reduce the noise, limit the duration of exposure.
- Conduct noise monitoring every 3 years at least once. Where there are >10 workers exposed to excessive noise
- Appoint a noise control officer to advise on noise control measures. Where there are >50 workers exposed to excessive noise
- Provide suitable hearing protectors to workers and ensure that they are properly maintained and used.
- Display warning and PPE signs at all entrances to or at the periphery of noisy areas.
- Train workers annually.^[33]

Management of Hazardous Chemicals at Workplace

A wide variety of chemicals are used in many industries. It is important to ensure that chemicals are properly managed at work, as many of them are inherently hazardous, while others may pose hazards due to chemical incompatibility.

Hazardous chemicals are classified into 3 main classes:

- Physical hazards e.g. flammables, explosives, reactive
- Health hazards e.g. carcinogenic, toxic, corrosive, skin sensitizing
- Environmental hazards e.g. ozone depletion, aquatic toxicity^[34]

Under the WSH (Work safety and health) Regulations

- Hazardous substances should be kept, stored, used, handled or disposed of properly.
- Hazards should be communicated through the use of warning signs, container labeling, and safety data sheets.
- Hazardous substances must be placed under the control of a competent person who has adequate

knowledge of the properties of the substances and their dangers.

- Regular workplace monitoring should be conducted and workers should not be exposed to toxic substances above their permissible exposure levels specified in the Regulations.^[35]

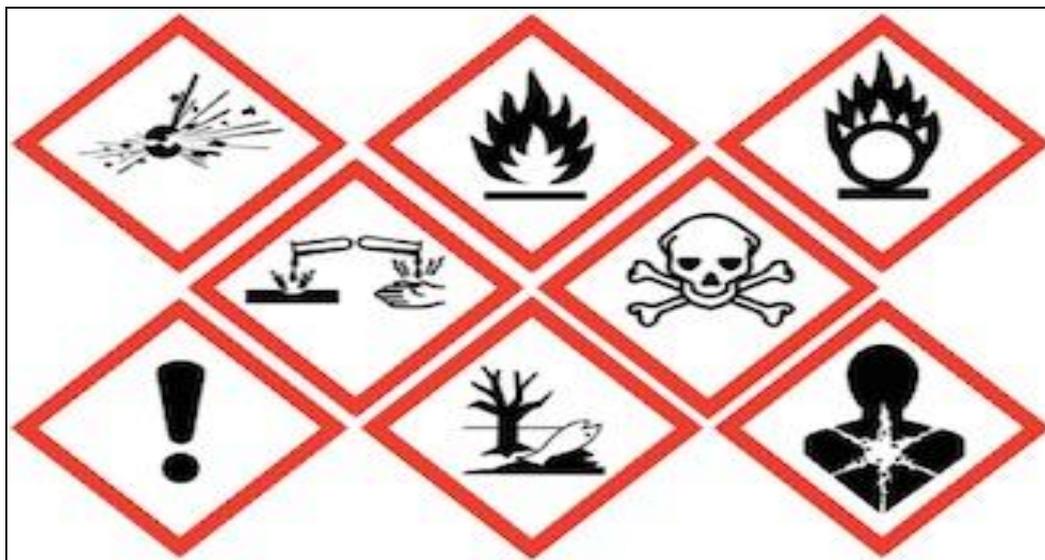


Figure 3: Symbols of industrial safety.

Management of Heat Stress at Work.^[36]

Being in a tropical environment, workers are more prone to heat stress which can result in heat exhaustion, heat cramps, and heatstroke.

The risk factors include

- Physical work capacity
- Susceptible individuals
- Un-acclimatized persons

Preventive measures to reduce the risk of stress from heat include

- Allowing new workers to acclimatize to the hot weather
- Provision of drinking facilities
- Heavy physical work arrangements to be done during cooler part of the day.
- Provision of shaded areas for work and rest during breaks
- Training of workers on heat-related disorders and appropriate preventive measures.^[37-40]

Following the WSH (General Provisions) Regulations, the occupant shall take reasonably practicable measures to ensure that persons at work are protected from excessive heat and harmful radiation.

The Wet Bulb Globe Temperature (WBGT) is a key indicator for the assessment of heat stress levels. WBGT

measures environmental factors and is associated with deep body temperature and physiological response to heat stress.

CONCLUSION

Industrial hazards are anything that endangers the welfare of employees and must be addressed through safety measures. It should be evident from the above that any pharmaceutical industry, large or small, is particularly in need of expert advice in matters affecting the worker's health. Identifying industrial hazards enables employers to protect their workers from accidents, injuries, and fatalities. Safety in simple terms means freedom from risk or injury or loss. It is recommended that literature invest more in the area of application and relevance of guidelines and practices some new practices have recently been applied to the pharmaceutical industry, although they are widely used in non-pharmaceutical industries, such as lean manufacturing; Six Sigma; total quality management. Both managers in the pharmaceutical industry and the literature should focus on the adoption of such practices in the pharmaceutical industry, making use of previous research in the non-pharmaceutical sector. New case studies should be conducted to demonstrate the feasibility of such practices.

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