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Review Article

Chemical hazards and safety management in pharmaceutical industry

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ABSTRACT

Chemical hazards are a major occupational health and safety (OHS) issue in Pharma industry. Management of chemical hazards requires the combined efforts of OHS specialists, including generalist OHS professionals, occupational hygienists, and occupational health practitioners. This paper is about industrial chemicals, the manner in which their toxicity is assessed and the use of such assessments in regulatory decision-making. It begins with general points concerning toxicological data availability and hazard identification, then moves on to risk assessment and occupational exposure limits, and finally looks briefly at three specific toxicological issues, asthma, chronic toxic encephalopathy, and ''low toxicity'' dust effects on the lung, where the science is far from resolved after brief consideration of the historical context of chemical reactivity and toxicity issues, acute and chronic exposure, chemical hazard classification systems, and the identification, risk assessment, and control of chemical hazards. Preventing exposure to toxic chemicals is a primary concern at hazardous waste sites. Most sites contain a variety of chemical substances in gaseous, liquid, or solid form. These substances can enter the unprotected body by inhalation, skin absorption, ingestion, or through a puncture wound (injection). Emphasis is placed on the importance of working with a range of OHS specialists to ensure a range of skills is directed at preventing fatality, injury, disease, and ill health arising from this complex area of OHS.

KEY WORDS: Dangerous goods, Globally harmonized system, Hazardous chemical, Hazardous substance, Occupational exposure standard, Occupational hygiene

INTRODUCTION

Chemicals are used to make virtually every man-made product and play an important role in the everyday life of people around the world. The chemical industry is the third largest industrial sector in the world. It is also a major economic force. Worldwide, it employs some 10 million people and generates billions of euros in shareholder value and tax revenue for governments. The pharmaceutical industry has been described as dynamic and growing, in terms of sales, number of employees, and gross domestic product (GDP). It is an industry in which companies, government regulators and researchers focus on the "safety" of the products and their effects on end users and the environment.

Chemical hazards produce by chemical synthesis or manufacturing, processing, transportation and that effect on the human and environmental condition. A chemical hazard is a type of occupational hazard caused by exposure to chemicals in the workplace. Exposure to chemicals in the workplace can cause acute or long-term detrimental health effects. There are many types of hazardous chemicals, including neurotoxins, immune agents, dermatologic agents, carcinogens, reproductive toxins, systemic toxins, asthma genes, pneumoconiotic agents, and sensitizers.[1,2]

Little is known about the health risks of working in the pharmaceutical industry. On the surface, the industry looks clean. The production of medicinals demands a carefully maintained and sterile working environment and the white lab coats worn by workers add to the illusion of safety. The appearances are deceptive, though producing drugs and other medicinals may involve exposure to toxic industrial chemicals. And while the finished products may be lifesaving medications for sick people, they can be dangerous to healthy workers who are inhaling or absorbing

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them during the production process. Hazard is a term associated with a substance that is likelihood to cause an injury in a given environment or situation. Industrial hazard may be defined as any condition produced by industries that may cause injury or death to personnel or loss of product or property. Safety in simple terms means freedom from the occurrence of risk or injury or loss. Industrial safety refers to the protection of workers from the danger of industrial accidents.

These paper aim is that how to reduces the chemical hazards that management, responsibility precaution, safety guideline, how to identified hazards and how to protect from hazards, specific guideline regulation, responsibility, and lagout tagout chain. In pharmaceutical industry safety system in India that principle responsibility also challenges for risk assessment and safety hazards.

OBJECTIVES OF INDUSTRIAL SAFETY

- Understand the harmful effects of industrial hazards.
- Define the relationship between hazard and risk.
- Explore the routes of exposure to industrial hazards.
- Shed lights on type of toxicity by industrial hazards.
- Know the most toxic environmental hazardous substances.
- Industrial safety is needed to check all the possible chances of accidents for preventing loss of life and permanent disability of any industrial employee, any damage to machine and material as it leads to the loss to the whole establishment.
- It is needed to eliminate accidents causing work stoppage and production loss.
- It is needed to prevent accidents in industry by reducing any hazard to minimum.
- It is needed to reduce workman's compensation, insurance rate and all the cost of accidents.
- It is required to educate all members regarding the safety principles to avoid accidents in industry.
- It is needed to achieve better morale of the industrial employees.
- It is required to have better human relations within the industry.
- It is needed to increase production means to a higher standard of living.

TYPES OF HAZARDS

Chemical hazards are toxic, corrosive, irritant, carcinogenic, flammable, and mutagenic [Table 1].

According to workplace hazardous materials information, chemical hazards are classified as.[3,4]

Class A

- Compressed gas.
- Dissolved gas or liquefied gas.

Class B [Figure 1]

- Flammable gases.
- Flammable and combustible liquids.
- Flammable solid.
- Flammable aerosols.
- Reactive flammable material.

Class C

- Oxidizing materials - oxidizer and organic peroxide.
- Oxidizer: Chlorates, nitric oxide, peroxides, permanganates, perchlorates, nitrites, nitrates, and easily oxidize metal powder.
- Organic peroxide: Tetra hydro furan, diethyl ether, dioxane, and methyl isobutyl ether.

Class D

- Poisonous and infectious materials.

e.g.: Cyanides, tea salts, and asbestos.

Class E

- Corrosive materials.

e.g.: Inorganic acids and bases, hydrogen fluoride.

Class F

- Dangerous reactive materials.

e.g.: Ethylene dioxide, organic azides, Na, Li, Ca.

- Pyrophosphoric materials.

e.g.: White phosphorous, diethyl aluminum chloride, and lithium.[3,4]

Carcinogens

The identification of carcinogenic agents was based on the IARC classification and corresponding IARC monographs.[5,6] Only agents belonging to Group 1 were considered, i.e., agents for which there is sufficient evidence of carcinogenicity in humans, and therefore, a causal relationship between agent and increased incidence of malignant neoplasms has been established. The estimates of the number of specific exposures of a worker were taken from the database carcinogens exposure.[7] These estimates correspond to the exposure period 1990–1993 across 55 industrial sectors for the EU-15 countries.[7,8]

Sensitizing and Reprotoxic Substances

The identification of sensitizing substances was based on the list of compounds published in 2013 by the German Commission for the Investigation of Health Hazards of Chemical Compounds (MAK-Commission)[9,10] Sensitizing substances,

Table 1: Chemical and that exposure limit

Chemical	Exposure limit
Ethyl alcohol	1000 ppm
acetone	1000 ppm
Methylene chloride	125 ppm
Isopropyl alcohol	400 ppm

Table 2: Pictograms used in chemical hazards

Picture			
Indicating words Name of the symbol	E Explosive	O Oxidizing	F, F+ Highly flammable or extremely flammable
Picture			
Indicating words Name of the symbol	T, T+ Toxic or very toxic	Xn, Xi Harmful or irritant	B Harmful or irritant
Picture			
Indicating words Name of the symbol	B Biohazards	N Dangerous for the environment	R Radioactive

i.e., substances capable of inducing an immunological response to an otherwise innocuous antigen,[11] are classified either as "Sa," "Sh," or "SP." The label "Sh" designates substances that can cause allergic or irritant reactions of the skin and the mucosa close to the skin (skin sensitizing) such as irritant contact dermatitis, allergic contact dermatitis, protein contact dermatitis, and contact urticaria.[12,13] The label "Sa" designates substances causing airway sensitization.

These involve allergic reactions such as bronchial asthma or rhinoconjunctivitis, and other effects associated with systemic reactions (anaphylaxis). The label "SP" designates substances causing photo contact sensitization, i.e., an allergic reaction of the skin due to the interaction of the substance with ultraviolet radiation.[14] In general, the classification of a substance as sensitizing is based on either sufficient empirical evidence of allergenic and/or irritant effects or in cases where the allergenic effect can be considered probable on the basis of appropriate empirical evidence.[15]

Mutagenic

According to Annex 6 of the council directive 67/548/ECC mutagenic substances refer to substances giving rise to an enhanced occurrence of genetic mutations that may be transmitted to the offspring, i.e., permanent changes in the amount of the genetic material resulting in a change of the phenotypic characteristics of the organism and its offspring.

Substances toxic to reproduction refer to substances causing either impaired fertility ("RF") or subsequent developmental effects in the progeny.[16]

Chemical exposures are generally divided into two categories: Acute and chronic. Symptoms resulting from acute exposures usually occur during or shortly after exposure to a sufficiently high concentration of a contaminant.[17] The number of exposures for a given contaminant, the symptoms of an acute exposure may be completely different from those resulting from chronic exposure.[18]

For either chronic or acute exposure, the toxic effect may be temporary and reversible or may be permanent (disability or death). Some chemicals may cause obvious symptoms such as burning, coughing, nausea, tearing eyes, or rashes. Other chemicals may cause health.

EFFECTS OF CHEMICALS EXPOSURE ON HUMAN BODY

- Skin burn,
- Ache,
- Anthrax,
- Ulcer in hand, nose, etc.
- Cancer,
- Irritation on windpipe,
- Many chemicals can cause severe burns, if they come in contact with living tissue,

- Living tissue may be destroyed by following chemical reactions:
  - o Dehydration by strong dehydrating agents,
  - o Digestion by strong acids and bases,
  - o Oxidation by strong oxidizing agent.[19]

Chemical Hazards Can Enter and Harm the Body by Four Main Routes

- Absorption through the skin;
- Inhalation;
- Injection; and
- Ingestion.[20]

DIFFERENT WAYS OF CHEMICAL HAZARDS CAUSE HARM

- Catching fire.
- Explosive or reactive.
- Corrosive.
- Irritant.
- Causing chronic organ damage over time.
- Causing an allergic reaction.
- Causing genetic or reproductive harm.[20]

The effects of exposure not only depend on the chemical, its concentration, route of entry, and duration of exposure, but may also be influenced by personal factors such as the individual's smoking habits, alcohol consumption, medication use, nutrition, age, and sex.

An important exposure route of concern at a hazardous waste site is inhalation. The lungs are extremely vulnerable to chemical agents. Even substances that do not directly affect the lungs may pass through lung tissue into the bloodstream, where they are transported to other vulnerable areas of the body. Some toxic chemicals present in the atmosphere may not be detected by human senses, i.e., they may be colorless, odorless, and their toxic effects may not produce any immediate symptoms. Respiratory protection is, therefore, extremely important if 2-3 there is a possibility that the work-site atmosphere may contain such hazardous substances. Chemicals can also enter the respiratory tract through punctured eardrums. Direct contact of the skin and eyes by hazardous substances is another important route of exposure. Some chemicals directly injure the skin. Some pass through the skin into the bloodstream where they are transported to vulnerable organs. Skin absorption is enhanced by abrasions, cuts, heat, and moisture. The eye is particularly vulnerable because airborne chemicals can dissolve in its moist surface and be carried to the rest of the body through the bloodstream (capillaries are very close to the surface of the eye). Wearing protective equipment, not using contact lenses in contaminated atmospheres (since they may trap chemicals against the eye surface), keeping hands away from the face, and minimize contact with liquid and solid chemicals can help protect against skin and eye contact.

Figure 1: Gas state chemicals will be inhaled or liquid state chemicals can be absorbed by the skin

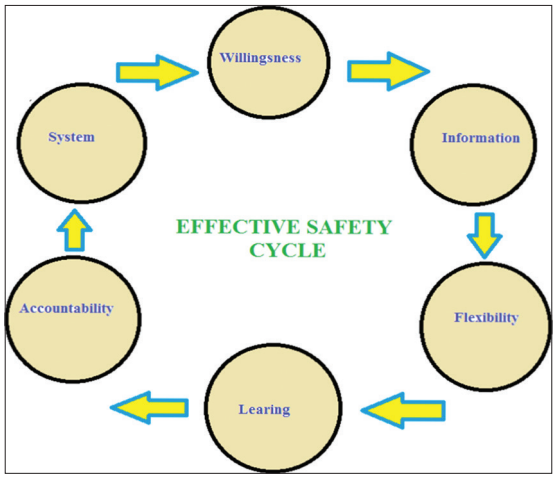

Figure 2: Effective safety cycle

Although ingestion should be the least significant route of exposure at a site, it is important to be aware of how this type of exposure can occur. Deliberate ingestion of chemicals is unlikely, however, personal habits such as chewing gum or tobacco, drinking, eating, smoking cigarettes, and applying cosmetics on site may provide a route of entry for chemicals.[20]

The last primary route of chemical exposure is injection, whereby chemicals are introduced into the body through puncture wounds (for example, by stepping or tripping and failing onto contaminated sharp objects). Wearing safety shoes, avoiding physical hazards, and taking common-sense precautions are important protective measures against injection.[20]

CHEMICALS HAZARDOUS REGULATION

Under the WHS regulations, a hazardous chemical is any substance, mixture or article that satisfies the criteria of one or more globally harmonized system of classification and labeling of chemicals (GHS) hazard classes, including a classification in Schedule 6 of the WHS regulations.

Most substances and mixtures that are dangerous goods under the ADG Code are hazardous chemicals, except those that have only radioactive hazards (Class 7 dangerous goods), infectious substances (division 6.2), and most Class 9 (miscellaneous) dangerous goods.

A comparison of dangerous goods classifications under the ADG code with those under the GHS is provided in Appendix B. To manage risk under the WHS Regulations, a duty holder must:

- Identify reasonably foreseeable hazards that could give rise to the risk.
- Eliminate the risk so far as is reasonably practicable.
- If it is not reasonably practicable to eliminate the risk - minimize the risk so far as is reasonably practicable by implementing control measures in accordance with the hierarchy of risk control.
- Maintain the implemented control measure so that it remains effective.
- Review, and if necessary revise all risk control measures so as to maintain, so far as is reasonably practicable, a work environment that is without risks to health and safety.[20]

Adverse Effect

Health hazards

These are properties of a chemical that have the potential to cause adverse health effects. Exposure usually occurs through inhalation, skin contact, or ingestion. Adverse health effects can be acute (short-term) or chronic (long-term). Typical acute health effects include headaches, nausea or vomiting, and skin corrosion, while chronic health effects include asthma, dermatitis, nerve damage, or cancer.[20,21]

Physicochemical hazards

These are physical or chemical properties of the substance, mixture or article that pose risks to workers other than health risks, as they do not occur as a consequence of the biological interaction of the chemical with people. They arise through inappropriate handling or use and can often result in injury to people and/or damage to property as a result of the intrinsic physical hazard. Examples of physicochemical hazards include flammable, corrosive, explosive, chemically reactive, and oxidizing chemical.[20,21]

Source of chemical hazards

Air born toxics

- Irritants,
- Ipecac, podophyllum, etc.
- Asphyxiants,
- Carbon dioxide, monoxide, methane, ethane, and hydrogen cyanide,
- Hydrogen sulfide, helium, nitrogen, etc.,
- Narcotics/anesthetics,
- Acetone, ether, chloroform, methyl ethyl ketone, etc.

Carcinogens

- Coal tar, creosote oil, anthracene oil, paraffin oils, and chromium,
- Nickel, cobalt, etc.,
- Hazards may arise when impure or contaminated chemicals are used.

Sources of hazards in pharma

- Handling and storage of huge quantity hazardous chemicals.
- Transferring, loading and unloading of solvents and chemicals to reaction vessels.
- Human errors while handling hazardous chemicals.
- Emission of hazardous air pollutants from reaction vessels due to overloading or under designed reaction vessels.
- Volatile organic compounds (VOCs) releases from uncontained (or not connected to scrubbers).
- Reaction vessels and most common VOCs include methanol, dichloromethane, toluene, ethylene glycol, N, ndimethylformamide, and acetonitrile.
- Leaks of effluents from wastewater treatment plants or from effluent collection sumps from process area.[20,21]

The hazards of organic synthesis

Organic chemical synthesis presents industrial hazards of three main types. First, the active agents used to attack and modify the structure of organic compounds are, by their very nature, exceptionally able to attack and modify the organic compounds of the human body, thus producing highly poisonous effects. Second, the intermediate compounds in most organic syntheses are often characterized by the readiness with which they enter into chemical combination with other organic matter; they are active. This often confers toxic properties of great variety on them. Third, the final products, though they are medicines designed to be introduced into the human body, may nevertheless produce severe poisoning under conditions of industrial exposure.[22]

Sulfonating Agents

The sulfonating agents, chlorosulfonic acid (HOSO2CI) is extensively used in the manufacture of p-acetylamino benzene sulfonyl chloride. The fumes of the acid itself are highly irritating, and in many sulfonation reactions, HCI gas and SO2 are given off. It is often not economically feasible to trap these irritant by-products in a small synthesis, and they are often vented into the outside air. This is a bad practice, which will cause a large amount of bronchitis and conjunctivitis under adverse wind and weather conditions. Scrubbing towers of simple and cheap design, or very high stacks, are usually required to eliminate the nuisance.[22]

Final Products of Synthesis

Mepacrine and acriflavine

Among the final products of organic synthesis, mepacrine itself deserves mention as an especially

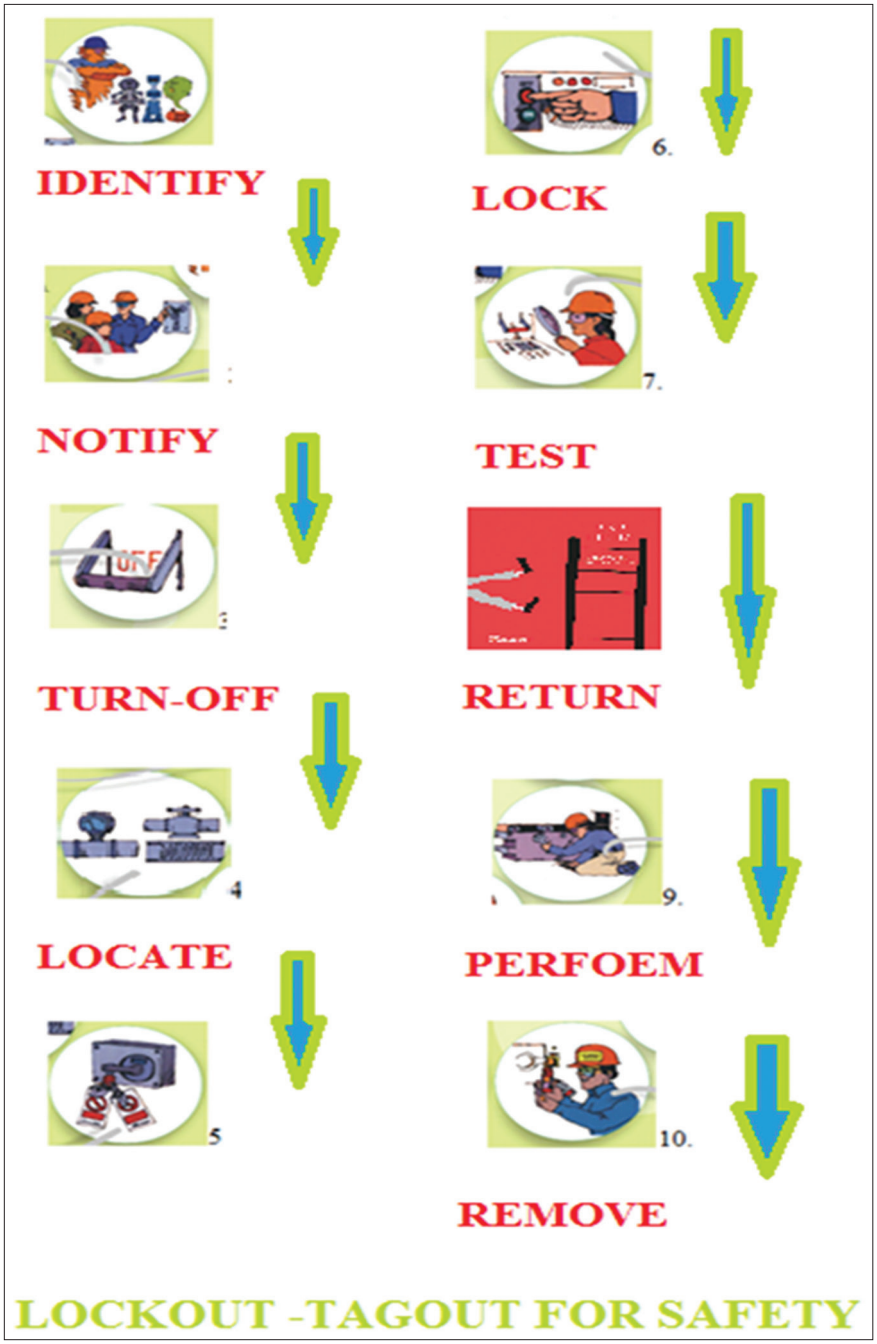

Figure 3: Lockout tagout chain for safety management

troublesome primary irritant and sensitizer. Rather extensive compressing and grinding, thrice repeated, are necessary to prepare the material in the form of tablets; dust control during these operations is mandatory, but extremely difficult, because of the structure of the machines involved. In a study made at the Abbott Laboratories (Watrous, 1944), exposure to the dust at levels between 035 and 4–2 µg/l was sufficient to cause conjunctivitis in more than half of the workmen, and dermatitis, rhinitis, and stomatitis in about a third. Similar symptoms have recently been described by Barlow *et al*. (1946). Acriflavine another dye of the acridine series, possesses similar, though weaker, irritant properties; workers bottling tablets of this dye often suffer from a conjunctivitis of considerable severity if they transfer the material to their eyes by injudicious rubbing with dust-stained hands.[22]

Nicotinic acid

Nicotinic acid and its salts have a peculiar effect on the skin of certain workers who handle these chemicals in bulk: This consists of a diffuse erythema on the exposed parts of the skin, usually not accompanied by itching, and resembling sunburn in appearance. It is usually transient, disappearing in from 12 to 24 h,

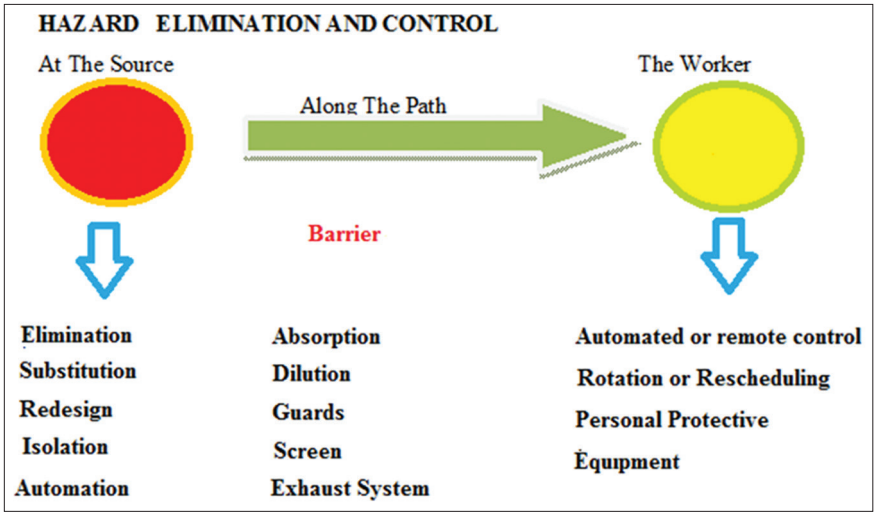

Figure 4: Hazards elimination and control

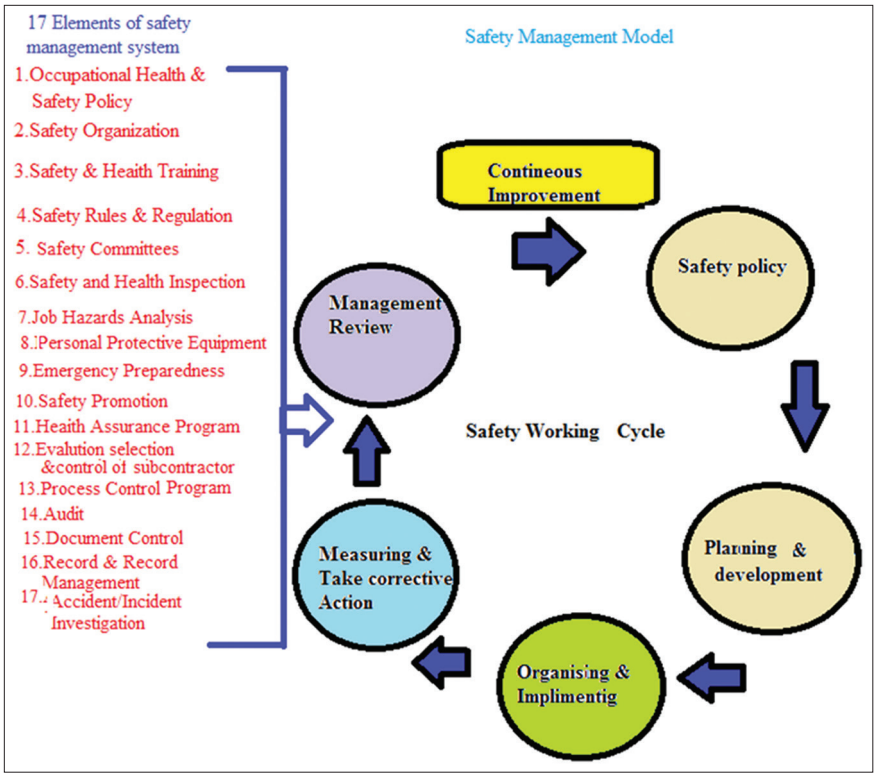

Figure 5: Elements and safety model of chemical hazards

though sometimes it assumes a popular character on the 2nd day and lasts several days.[22]

Powdered penicillin

Dry powdered penicillin has proved to be a potent sensitizer and skin irritant in all the American factories where it is handled. It may produce follicular erythema, diffuse; popular rashes on the exposed parts of the body, or, in some cases, severe generalized urticaria which persists for days or weeks after exposure ceases. In the latter cases, it seems probable that a generalized sensitivity has been created by the previous contact with the substance, and that the urticaria results from systemic absorption of the powdered drug by inhalation. In a series of four cases showing industrial dermatitis from exposure to penicillin, Friedlaender *et al*. (1946) found the patients to be sensitive to pure crystalline penicillin rather than to any particular impurity in the commercial product.[22]

Local anesthetics

The local anesthetics, procaine, butyl (butacaine sulfate), and butesin (n-butyl aminobenzoate), form a group of substances more or less prone to cause sensitization and dermatitis on prolonged contact with the skin. The tendency for procaine to sensitize the skin

of dentists and others who frequently spilled solutions on their hands were recognized many years ago and was one of the factors which made prepared solutions in cartridges so popular with dentists. Women engaged in filling cartridges with sterile solutions of procaine are subject to a characteristic occupational dermatitis caused by excess solution overflowing from the tubes and running down their arms.[22]

Neoarsphehamine

Neoarsphenamine, sensitization of the skin in those who pack it in ampoules. In such cases, the minute amount of dust which settles on the skin during the process may cause popular rashes on the exposed skin areas. In one such case, the skin was so sensitive to contact with the drug that a patch test made with a few milligrams of the powder exhibited vesiculation within 12 h. Such marked reactions, however, are rare; patch tests are usually negative, but many mild dermatoses of this kind subside when contact with the drug ceases and recur when it is resumed. Neoarsphenamine may also act as a primary irritant if it is allowed to accumulate under the nails of those handling it.[22]

2-methyl-1, 4-naphthoquinone

-2-methyl-1, 4-naphthoquinone, a synthetic form of Vitamin K, has the property of sensitizing the skin and producing dermatitis. Workers who handle this chemical present a dark-brown staining of the skin, and may later show popular or eczematoid dermatitis.[22]

Sulfonechloramides

At least two sulfonechloramides which are used as antiseptics or disinfectants have rather unusual properties as local irritants and sensitizers.

When these chemicals contaminate the working environment in the form of dust, they may produce dermatitis, rhinitis, conjunctivitis, and bronchitis in their capacity as primary irritants.[22]

Solvents

Methyl alcohol is not commonly used. Ethyl alcohol offers medical hazards only to the extent to which it is denatured with more toxic materials.

Benzene

Benzene itself is, unfortunately, such an excellent solvent for many active principles, as well as for numerous important synthetic chemicals, that it constitutes a major problem in the pharmaceutical industry. This is not the place to describe or discuss the well-known facts about acute and chronic benzene poisoning, except to affirm from my own experience that these well-established facts are still completely unknown or disregarded in more backward works, and that they cry out for more popular diffusion among workmen and foremen, even in the most progressive organizations.[22]

Chloroform and ethylene dichloride

Chloroform and ethylene dichloride (1,2-dichloroethane) are occasionally used to extract alkaloids and other fat-soluble principles. Both solvents are liver poisons, and men working with them under ordinary conditions may develop certain vague symptoms which are referable to the gastrointestinal tract and which suggest very slight liver damage. These consist of anorexia, a heavy feeling in the epigastrium, and fatigue. At this time the urine may give a positive test for urobilinogen, and in my experience, this is an indication for transferring the workman temporarily to other employment. By-products may accumulate relatively high concentrations in parts of the plant and cause unexpected effects.

In pharmaceutical industry, most of the dermatitis can be attributed to synthetic drugs, especially acridine and phenothiazines.

CHEMICAL SAFETY GUIDELINES

Always follow these guidelines when working with chemicals [Table 2 and Figure 2]:

- Assume that any unfamiliar chemical is hazardous and treat it as such.
- Know all the hazards of the chemicals with which you work. For example, perchloric acid is a corrosive, an oxidizer, and a reactive. Benzene is an irritant that is also flammable, toxic, and carcinogenic.
- Never underestimate the potential hazard of any chemical or combination of chemicals. Consider any mixture or reaction product to be at least as hazardous as - if not more hazardous than - its most hazardous component.
- Never use any substance that is not properly labeled. It may not be what you think it is date all chemicals when they are received and again when they are opened.

Follow all chemical safety instructions, such as those listed in material safety data sheets or on chemical container labels, and precisely.

- Minimize your exposure to any chemical, regardless of its hazard rating, and avoid repeated exposure.
- Use personal protective equipment (PPE), as appropriate for that chemical.
- Use the buddy system when working with hazardous chemicals. Do not work in the laboratory alone.[23]

HEALTH AND SAFETY MANAGEMENT DUTIES IN RELATION TO HAZARDOUS CHEMICALS

Under the WHS act, a person conducting a business or undertaking has the primary duty to ensure, so far as is reasonably practicable, that the health and safety

of workers and other persons are not put at risk from work carried out as part of the conduct of the business or undertaking. This includes ensuring the safe use, handling and storage of substances.

The WHS regulations include specific duties for a person conducting a business or undertaking to manage the risks to health and safety associated with using, handling, generating, and storing hazardous chemicals at a workplace.

The duties include:

- Correct labeling of containers and
- Pipework, using warning placards and
- Outer warning placards and displaying of safety signs.[24]

HAZARDOUS CHEMICALS GENERATED OR MANUFACTURED IN THE WORKPLACE

Some processes will produce hazardous chemicals as by-products or waste. These hazards may not be easily identified when generated at the workplace, for example, hydrogen sulfide in a sewer or diesel exhaust fume from truck engines. Information on by-products may be available from a SDS, but not always. Use of welding rods may liberate toxic fumes and vapors, grinding metals release toxic metal dust or fumes, off-gassing of solvent vapors from glues used to manufacture timber products such as Medium Density Fibre, and dusts released from machining timbers are hazardous to health or can present a dust explosion risk.[24]

Preventive Measures

- Solvents used in extraction, purification of synthetic drugs and chemical analysis should be handled with care.
- Flammable and explosive chemicals should be kept at a proper distance.
- Tolerance levels for toxic chemicals set by federal regulation have to be followed.
- Suitable label to the chemicals for proper handling.
- Personal protective cloth.
- Application of cream before the commencement of work.
- Use of goggles.[25]

MANAGEMENT OF OVEREXPOSURE TO CHEMICALS

Removal from Exposure

- Prompt removal of the person from the exposure site is the first step.
- Air respirators and lifelines are a mandatory first aid [Figure 3].

Resuscitation

Resuscitation means restoration of life of one who is apparently dead (collapsed or shocked). Further supportive care should be provided as with any other medical emergency.

Decontamination

A victim whose skin or clothing has been contaminated requires immediate removal of garments and shoes. Then, vigorous showering with soap and water, including attention to the fingernails and scalp is advised.[26]

Symptomatic Treatment

Acute overexposure may result in a variety of signs and symptoms that require general supportive medical management regardless of the specific agent. Examples include the control of convulsive seizures bronchospasm.[26]

TLV CONCEPT

- American Council of Government Industrial Hygienists has established Threshold Limit Values (TLV).
- TLV-time-weighted average time-weighted average concentration for a normal 8-h working day and a 40-h working week, to which nearly all workers may be repeatedly exposed day after day, without adverse effect.[27]
- TLV-short-term exposure limit.

It is defined as a 15-min, time-weighted average which should not be exceeded at any time during a working day, even if the 8-h time-weighted average is within the TLV.

The workers should not be exposed to the substances more than these limits.

TLVs are only guidelines and are not intended as absolute boundaries between safe and dangerous concentrations.

Every occupational health professional should have a copy of the current TLVs. [28,29]

SAFETY AND HEALTH GOALS

- Provide workers with a safe work environment.
- Conduct routine/regular workplace inspections.
- Provide PPE.
- Develop and implement safe work procedures and rules.
- Provide on-going safety training.
- Enforce safety rules and appropriate discipline.
- Provide on-going property conservation practices.[30]

SAFETY MEASURES

- Before starting work with a chemical a “chemical hazard pocket guide” should be consulted for

necessary information about the chemical. It will give the type of reaction the chemical may produce, its inflammability, carcinogenicity, prevention, and treatment procedures, etc.
- No eating, drinking, or smoking where chemicals are used.
- Skin should be covered with protective clothing.
- Clothing should be removed immediately it gets wet or contaminated with a chemical.
- Eyes or skins should be washed with plenty of water after an accident.
- Face mask may be used in toxic dust or gases.
- Workers working in antibiotic-related products must be changed routinely so that an individual is not exposed to a certain antibiotic for a long period of time.
- Whenever a dust allergy or respiratory problem precipitates, the worker should immediately be removed from the workplace and put under proper health care.
- In case of inflammable gas or solvent leakage, the exhaust fans should be started, and all the source of fire should be extinguished.[31]

ROLE OF CONTROLLING HAZARDS

The next three sections (a planner's Guide, A Supervisor's Guide, and A Worker's Guide)

Provide detailed information on the roles and responsibilities in developing and implementing effective chemical management, based on the phase in which each person fits (i.e., planning, implementation, or execution). Each section serves as a standalone guide for each phase.[32]

Use the following descriptions to select the section that best applies to your role in the process:

A planner's guide (blue) is for those persons (planners) responsible for planning and initially designing the chemical management process. Planning roles include but are not limited to prime contractor, owner, owner's representative, licensee, operator, and supplier.

A supervisor's guide (red) is for those persons (implementers/supervisors) responsible for organizing workers and ensuring that the chemical management process gets done.

Implementation roles include but are not limited to supplier, supervisor, and site supervisor.

A worker's guide (green) is for those persons (executers/workers) who physically manage the chemicals on the job site and therefore are directly or indirectly exposed to the chemicals.

Execution roles include but are not limited to supervisor, worker, and driver. [32]

Control of Chemical Hazards

Priorities for control action [Figure 4]

Elimination

The most effective and reliable controls are those that result in the elimination of the hazardous chemical.

Substitution

Substitution of a hazardous chemical for a less hazardous one is the next control of choice; however, care must be taken to ensure that the substituted chemical does not introduce new hazards. Substitution also may involve using the chemical in a less hazardous form or process (e.g., use of the chemical in a pellet form rather than a dust).

Isolation

Isolation of the chemical in time or space from those potentially exposed can be an effective means of control (e.g., locating people in a protected control room, installing a buffer area around a chemical reactor, using the material when people are not in the vicinity).

Engineering controls

Engineering controls typically reduce exposure at the source (e.g., by enclosing the process in vessels or pipes, or by local exhaust ventilation). Prevention of uncontrolled releases is important; this may be achieved using strategies such as quantity reduction and segregation.

Administrative controls

In general, administrative controls will be required to supplement higher-level controls.

Administrative controls may include maintenance of equipment and training of workers and their managers in the operation of the equipment. Preventative maintenance is important in preventing uncontrolled releases. Work procedures may need to be developed to ensure that engineering controls function as designed; this includes any safe-handling procedures and special storage instructions.[33]

Personal protective equipment

Any residual risk may require workers to wear PPE to reduce exposure to chemicals absorbed through respiration or skin or eye contact.

Specialist knowledge may be required to ensure selection of the correct type of PPE for a specific chemical.

Selection of gloves for protection against chemicals absorbed through the skin requires reference to chemical resistance charts or databases and consideration of the potential for chemical permeation, penetration, and degradation of the PPE. In some situations, chemically

resistant safety footwear is required. Inappropriate or poorly maintained PPE itself can act as a source of chemical exposure (e.g. contaminated gloves can be a source of ongoing exposure through persistent permeation or occlusion of the chemical inside the gloves).

While it would be expected that the risk associated with tasks such as decanting of chemicals would be controlled through the enclosure or other engineering controls, some chemical handling tasks may require eye protection. Depending on the task, this may be safety goggles or full face protection.

There is a wide range of PPE for respiratory protection. While Australian standards provide information on appropriate selection of respirators, the interpretation of these standard and the selection of the appropriate respiratory protection require specialist Knowledge. Fitting, maintenance and user training are important for all types of PPE, but especially for respiratory protection.[34]

IDENTIFYING CHEMICAL HAZARDS

Chemical Label

Current labeling requirements in Australia vary according to the intended use of the material and is based on the classification of chemicals in accordance with the requirements of the Australian Code for the Transport of Dangerous Goods by Road and Rail (NTC, 2011) and/or the Standard for the Uniform Scheduling of Drugs and Poisons (TGA, 2007). 10. Introduction of the GHS, along with the national model work.

The manufacturer or importer is responsible for ensuring that any chemical or chemical product is classified and labeled according to current regulatory requirements. From the perspective of the OHS professional and the workplace user of the chemical, the important label components under the GHS are signal words, hazard statements, precautionary statements, and pictograms.[35]

Signal words are used to indicate the relative level of severity of a hazard. The GHS uses "danger" and "warning" as signal words. "Danger" is used for a more severe or significant hazard, while "warning" is used for the less severe hazards.

Hazard statements describe the nature of a hazard, including the degree of hazard, where appropriate. A unique hazard statement is assigned to each hazard class and category.[35]

Precautionary Statements

Precautionary statements are assigned to each hazard class and category.

Precautionary statements are separated into five categories:

- Prevention statements refer to precautions to be taken to prevent an accident or exposure.
- Response statements refer to instructions in case of an accident.
- Storage statements refer to instructions for safe storage of the chemical.
- Disposal statements refer to appropriate disposal instructions.
- General statements for use as appropriate.[35]

INDUSTRIAL SAFETY SYSTEM

The Industrial Safety System and Type

Industrial automation has minimized the human interaction with the machines but has not completely eliminated it. Industrial safety systems are introduced to protect the human who works in hazardous plants. Some examples of these are oil and gas, chemical, and nuclear plants. The industrial safety systems not only protect the humans but also protect the environment and the plant itself from the chemical reactions [Figure 5].

Process Control System

These systems do not control any process but in fact, come into play when it is not possible to control a process through normal means. They are rather installed as a protective measure and are quickly becoming the need of every working environment.[36]

They are installed for the monitoring of the manufacturing environment, and they control the manufacturing process electronically. A laser diode is used for the detection of liquid or gas present in the environment. If the gas or liquid is detected, then their particular frequency signature is converted to a digital signal and the processor identifies the signal received.[36]

Safety Shutdown System

These systems are particularly helpful in the state of emergency as they automatically shutdown a system to a safe state whenever they sense a danger. They can be connected to the fire and gas systems to achieve securer working environment.[36]

Fire and Gas Systems

These systems are highly sensitive and intelligent. They sense the inflammable gas, material, or liquid spill at an early stage. They also detect the fire within the working environment and give audible and visual signals of the threat detected. These systems can be activated automatically or manually.

There are other systems such as pressure safety valves and emergency shutdown systems that are widely used in the manufacturing industry.

The "Laboratory Standard," 29 CFR 1910.1450, requires a Chemical Hygiene Program and designated Chemical Hygiene Officer. The basic tenets of safe laboratory work will be found in your local Chemical Hygiene Program.[36]

General safety Guidelines and Rules

- Never work alone in the laboratory.
- Never mouth pipette.
- Wear safety glasses or goggles at all times in the laboratory.
- Practice personal hygiene rules (e.g., wash hands before leaving the laboratory).
- No eating or drinking in the laboratory.
- Use PPE - do not wear laboratory coats outside the laboratory area - wear closed toe, sturdy shoes.
- Practice good housekeeping techniques - keep walkways clear - label and date all containers.[36]

ROLES AND RESPONSIBILITIES IN IMPLEMENTING THE LABORATORY STANDARD

The following are the National Research Council's recommendations concerning the responsibilities of various individuals for chemical hygiene in laboratories.

Chief Executive Officer

- Bears ultimate responsibility for chemical hygiene within the facility.
- Provides continuing support for institutional chemical hygiene.[36]

Chemical Hygiene Officer

- Develops and implements appropriate chemical hygiene policies and practices.
- Monitors procurement, use, and disposal of chemicals used in the lab.
- Ensures that appropriate audits are maintained.
- Helps project directors develop precautions and adequate facilities.
- Knows the current legal requirements concerning regulated substances.
- Seeks ways to improve the chemical hygiene program.[36]

Laboratory Supervisors

- Laboratory supervisors have overall responsibility for chemical hygiene in the laboratory.
- Ensure that laboratory workers know and follow the chemical hygiene rules.
- Ensure that protective equipment is available and in working order.
- Ensure that appropriate training has been provided.
- Provide regular, formal chemical hygiene, and housekeeping inspections, including routine inspections of emergency equipment.
- Know the current legal requirements concerning regulated substances.
- Determine the required levels of PPE and equipment.
- Ensure that facilities and training for the use of any material being ordered are adequate.[36]

Laboratory Workers

- Plan and conduct each operation in accord with the facility's chemical hygiene procedures, including the use of PPE and engineering controls, as appropriate.
- Develop good personal chemical hygiene habits.
- Report all accidents and potential chemical exposures immediately.[36]

Basic Principles of Safety Management

- No employee should risk injury or death to do a job.
- Safety can and should be managed.
- Accident prevention leads to more efficient and profitable operations and improves the quality of life for employees.
- Each employee has a right and responsibility to help in the ongoing safety improvement process. Encourage your employees to help identify and resolve safety concerns as they arise.[36]

PROCESS SAFETY MANAGEMENT (PSM) IN INDIA

Current Trends in PSM in India

As per KPMG (2003), the Indian Chemical Industry contributes to 6.7% of India's GDP, with revenues of USD 28 billion. As per Indian Chemical Manufacturer's Organization (website, 2004), the industry has the following credits to its name:

The Indian fertilizer industry is the fourth largest in the World. It is the largest manufacturer of pesticides in Asia, second only to Japan the Indian pharmaceutical industry is the largest in the developing world. The large-scale players in the industry have been proactively adopting management systems for process safety, occupational health, and environment. Although the PSM system is not mandated by Indian law, a number of chemical industries in India are voluntarily adopting the PSM system developed by OSHA. USA PSM is increasingly being woven into business strategy, during the project conceptualization stage itself. While the large-scale players are systematically adopting best practices in PSM, the fragmented medium and small-scale manufacturing sector are yet to systematically adopt PSM.[37]

CHALLENGES

- Enhancing ratification and implementation of existing regulations.
- Expanding risk assessments and controls.
- Improving management capacity and raising awareness.

- Minimizing generation of hazardous chemicals and wastes.
- The adoption of more proactive and precautionary policies and management approaches is ultimately needed to achieve necessary environmental and human health protection standards.[38]

CONCLUSION

The concluded that knowing and understanding the risk of hazardous facility and hazard release are the most important segments of an optimal pharmaceutical safety management. An effective hazard and risk assessment allows developing an incident action plan and implement strategies and tactics. The bulk of societal costs, however, are actually being borne by the workers themselves. There is an urgent need of rethinking the production process by taking into account the health impact on workers from the very beginning.

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