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Classification of Human Failure in a Pharmaceutical Industry and its Various Corrective and Preventive Action – A Case Study on the Lessons Learned From the Past

Yudhistra kumar, A
Environment, health, and safety (EHS), Porus Labs pvt ltd, India

Abstract: *The incident / Accident in the pharmaceutical company is a major concern in the modern world. It is very important to know the various causes of the injury / accident while handling the deadly chemicals in the pharmaceutical sector. The collection of data for the incidents / accidents will help us to learn lessons from the past. The incident / Accident data is collected from the pharmaceutical industry from October 2017 to September 2021 in the Attibele, Bangalore, southern part of India. During the period there were 20 recorded incident / accident in the factory. Human failure for the classification for the various incidents / accidents are classified based on the Error by humans and violations in the seven different blocks, these are further classified as minor, major and dangerous. The percentage of the failure of the cause of the incident / accident are presented in the article. The incidents/ accidents were reported in the intermediate block > outside Intermediate block > Finished goods block > Pilot plant = Research & development block = Stores area = Effluent treatment plant area. These types of incidents / accidents, which were minor occurrences are two numbers, major and dangerous occurrences are five and thirteen numbers, which is a major cause of the concern. The human failures are responsible for the incident / accident. Its percentage, which varied from 5 (Routine and slip) % to 37.5 (Lapses) %. Various corrective and preventive action for each of the incident / accident has been presented. The human failures can be avoided by adopting strict safety rules and regulation in all the concern departments.*

Keywords: *Incident/Accident, Human failures, Corrective and preventive action.*

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Introduction

Pharmaceutical industries playing a vital role in manufacturing of the lifesaving drugs in India. Human failure resulting in the incident / accident, which will happen when there is no proper process safety management (PSM). These incident / accidents are complex in nature. The importance reason for the incident or the accident to be investigated and recorded, so that the knowledge and awareness can be increased for the prevention of the future catastrophic accidents [1, 2, 3]. The objective of the case study is to focus on the difficulties, which we have faced in the occupational environment resulting in the incident / accident and its various corrective and preventive action taken to prevent the re-occurrence of the similar type of incident /accident. The global community has learned many lessons from the various incidents / accidents, which have happened across the world. The institution of chemical engineers (IChemE), which is located in the United Kingdom have recorded more than 13,000 accidents for learning lessons from the past.

There is no similar organisation in the Indian context, which is having a huge database like IChemE for sharing the information for the incident/accidents in the pharmaceutical industry, which has happened in the past.

The various accidents / incidents will result in the injuries, casualties and it leads to the environmental pollution [4]. Baybutt [5] have reported the various ways of handling the risk and its prevention in a pharmaceutical industry. Many of the government authorities and various research agencies have carried out extensive research for the various causes of the incidents and accidents in the pharmaceutical and chemical industry throughout the globe [6, 7, 8]. There are several accidents, which has happened in the recent past, 7th May 2021 Styrene monomer, where improper storage and handling operations error resulted in the accident at Vishakhapatnam India [9], which has resulted in the deaths of more than 13 people and 1000 people were exposed to the styrene gas. Recently the union labour ministry of India has informed to the parliament in March 2021 that around 6300 workers lost their life, while working in different sectors in various industries, ports and construction sites in the past five years. In this regard Indian ministry has set an expert panel for the recommendations and suggestions for prevention of the various incident and accidents [10]. On the 21st March 2019 in the Xiangshui, Jiangsu Province of China, explosion happened in the chemical plant due to the improper operation of the workers in the production process, which has resulted in the death of 78 people and injuring about 566 people [11]. Many of the deadly chemical explosion, which has happened in the state of Tehran, which has killed 50 people in the year of 2015, explosion of petrochemical plant in Mexico, which has resulted in the death of 37 people in the year of 2013, explosion in Oil Storage Depot at Hemel Hempstead, united kingdom in the year of 2005, which has resulted in the injuring of the 45 people, Methyl isocyanate leakage in Bhopal in India caused death for more than thousands of people in the year of 1984. Impact of the chemical explosion and accidents, which is having a very serious consequences [12], which leads to deadly effect [13]. Many of the Safety aspects can be improved by learning lessons from the various disastrous accidents [14]. It is very much important to gather the information of the individual causation of the incident / accidents from the past [15]. It has been observed that maintaining of the records for the minor, major and dangerous incidents / accidents in the pharmaceutical industry in Indian scenario has to go long way.

Considering the present case study, we have recorded the various incidents / the accidents in the different blocks, which has happened in the past due the human failures and the various corrective and preventive action (CAPA) have been presented. Training to the employees has been provided in the handling of the process by implementing the standard operating procedure (SOP), wearing of the suitable Personal Protective Equipment (PPE) has been made compulsory during operations.

Methodology

The incident / accident report has been used for collecting the data from a pharmaceutical industry from October 2017 to September 2021 in the Attibele, Bangalore, southern India in the seven different blocks such as Intermediate block (IM block), outside IM block, finished goods block (FG block), Research & Development block (R&D block), stores block, pilot plant block and adjacent to the Effluent treatment plant (ETP) area. The various incident / accident was classified as Minor / Major / Dangerous occurrences. According to the UK'S Health and Safety Executive, human failure can be classified as error by human or due to violations (Figure. 1). Similar methodology has been used for assessing the human failures for the various accidents in the chemical industry in south Korea [16]. The errors due to action are classified as slips and lapses. These are the people who are having lower skills and untrained people performing the activity. Errors due to thinking leads to rule-based mistake or knowledge-based mistake. Rule based mistake occurs due to the deviations, whereas in case of knowledge-based mistake, where people are not properly trained to gain the knowledge for performing the given task. The human failure resulting in violation may be routine,

situation dependent and exceptional. After identifying the human failure for the cause of the incidents/accident, its CAPA for the various incident/accident has been presented in this paper.

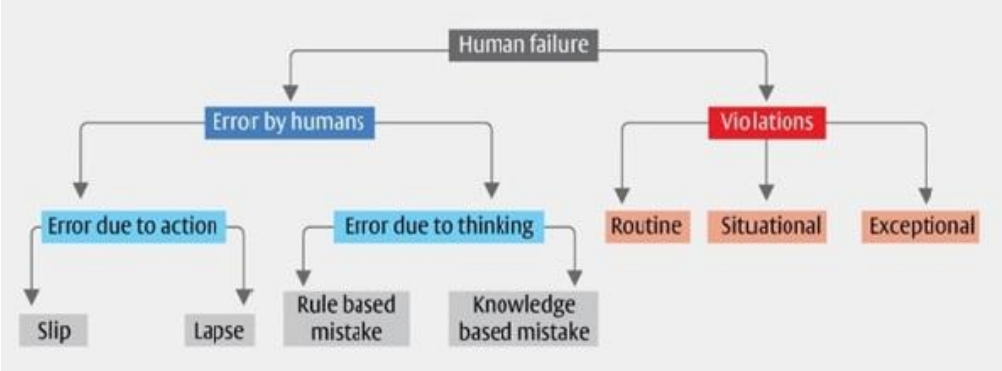

Figure. 1 Human failure classification

Results

The recordable incident/accident, which occurred in the year 2017 to 2021 were 20 numbers. The various causes of the incident / accident and its consequences were given in the Table. 1.

Date	Place of the icident / accident	Causes of the Incident / Accident	Consequences	Minor/Major/ Dangerous occurances
06-10-2017	IM block	Earthing provision is not there	Short circuit	Dangerous
27-10-2017	FG Incident	Not worn air suit	Giddiness	Major
09-12-2017	Out side IM block	Inertization of nitrogen not provided	Resulting in the spark	Dangerous
07-02-2018	Out side IM block	Leakage of chlorine gas	Resulting in unconscious	Dangerous
15-03-2018	Out side IM block	Old civil structure	Sun shade has fallen down	Dangerous
14-08-2018	IM block	Face shield not worn	Face injury	Major
28-08-2018	FG block	Air suit has bot been used	Resulted in unconscious	Major
28-08-2018	FG block	Negligence	Injury to the fingure	Minor
29-2-2019	Out side IM block	No proper lifting device used	Spillage of Thionyl chloride	Major
02-05-2019	IM block	Not worn safety Goggles	Eye irritation	Dangerous
03-06-2019	IM block	Not worn safety Helmet	Injury to the head	Minor
09-07-2019	IM block	Safety deviation	Resulted in the compound facture	Dangerous
02-02-2020	Pilot plant	Failure of mechanical integerity	Exposure to the corossive vapours	Dangerous
21-05-2020	R&D block	SOP not followed	Explosion of the round bottom flask	Dangerous
14-06-2020	IM block	Mishandling of the pipe line	Bumping of the hot water	Major
09-06-2020	Stores block	Negligence	Spillage of the Dimethyl sulphate	Dangerous
28-09-2020	IM block	No proper earthing	Resulted in blue flamr	Dangerous
17-03-2021	IM block	Electrical short circuit	Resulted in spark	Dangerous
04-05-2021	ETP area	No proper supervision	Burning of dry grass	Dangerous
25-09-2021	IM block	Mechanical failure	Explosion of the reactor	Dangerous

Table. 1. Various causation and consequences for the incidents / accidents from October 2017 to September 2021

There were two, five and thirteen numbers of incident / accidents, which were minor, major, and dangerous occurrences. The highest incident / accident was reported in the IM block and the lowest in the pilot plant, R&D, stores and ETP area (Figure.2). The percentage classification of human failure, which has resulted in the incident / accident has been given in the Figure. 3.

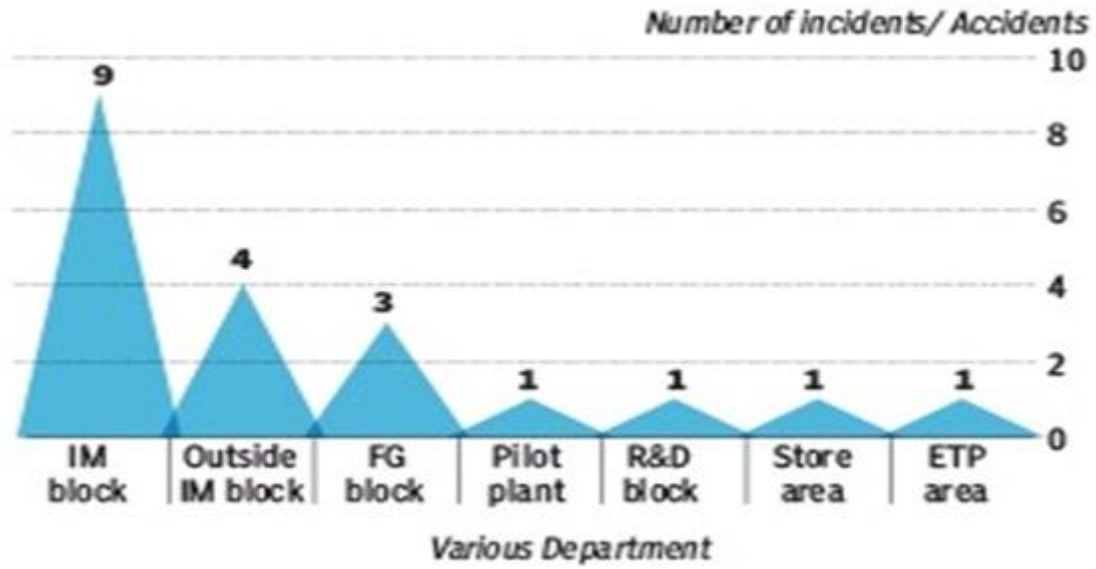

Figure. 2. The number of incidents / accidents, which are taken place at the various locations.

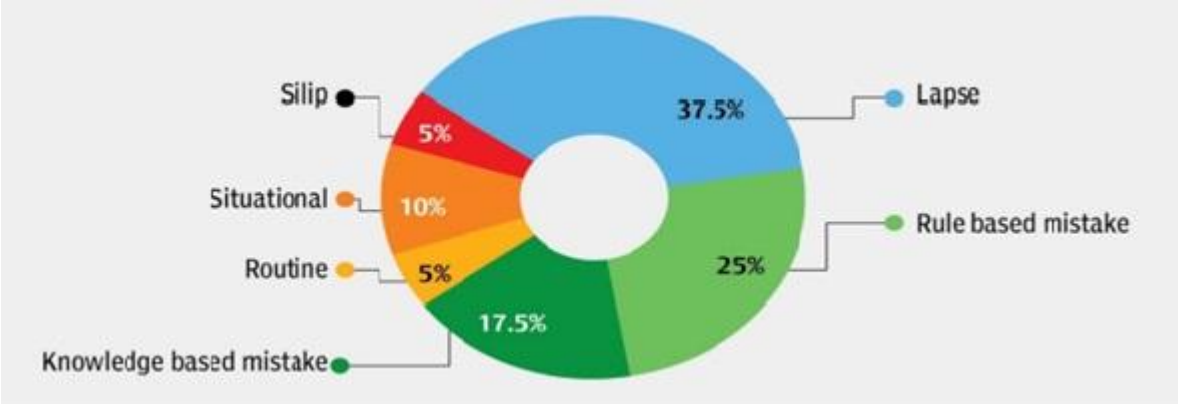

Figure. 3. Percentage of human failure classification for the various incidents and accidents, which occurred during the year of 2017 to 2021**.**

category of Incident/Accident

Minor Incident

There are two minor incidents reported. On 28th August 2018 in the FG block, the painter opened the exit door of the Primary change room, Tr. officer has kept the left-hand finger between the door and the frame, which has resulted in the injury of his left-hand finger. The injured Tr. officer has been treated with the first aid. Safety training has been provided to the employees to avoid the lapses while indulging in the activity. The Tr. Officer has not worn the safety helmet resulted in the hitting of the forehead to the bottom valve of the reactor (R17) on 3rd June 2019. First aid has been given to the injured person. Training has been provided for wearing all the required PPE during the working environment, so that we can avoid the lapses of behaviour in the working environment.

Major incident / Accident

The inhalation of the Haloperidol on 27th October 2017 occurred due to the not wearing of the air suit by the Sr. Executive while performing sieving activity in the FG block, which has resulted in the giddiness. He has been taken to the open place and provided with plenty of drinking water. Safety training has been provided for wearing the air suit and its various advantages has been explained, so that we can avoid the lapses of the incident. On 14th August 2018 the technician has opened the reactor (R12) manhole, which contains Clonazepam stage -3 reaction mass in the IM block without wearing the face shield, which has resulted in face injury due to the release of the corrosive vapours from the reaction mass. It was made compulsory that shift in charges in their respective block must see that face shield has been worn while performing the activity, so that we can avoid the situational violation. On 28th August 2018 the Sr. Executive have indulged in routine violations, by not wearing the PPE while performing multi milling for Alprazolam - Final stage material in the FG block, which has resulted in unconscious. Immediately he has been taken to the open air and given primary treatment. Departmental people were trained to start the exhaust blower before fifteen minutes of starting the multi milling and compulsory wear air suit while performing the activity. On 29th February 2019 incident is caused due to human error in mishandling of the thionyl chloride 45 kg outside the IM block, which has accidently slipped from the drum trolley resulting in the spillage. Caustic potash has been spilled on the thionyl chloride area and the vapours of thionyl chloride has been arrested. Training has been given to the workers for carrying the thionyl chloride on the four-wheeler trolley instead of drum trolley, so that we can avoid the slippery incident. On 14th June 2020 where reactor (R19) condensed stream hose pipe is not inserted Properly into the stream header line, which has resulted in bumping of the hot water. It has resulted in injury of the left-hand shoulder of the worker. The injured shoulder was washed with cold water and applied ointment. The workers were trained for handling the condensate stream from the reactor to avoid knowledge-based mistake.

Dangerous Incident / Accident

Short circuit of the temperature indicator of the reactor (R7) happened on 6th October 2017. We have switched on the emergency shut down button of the reactor. The short circuit happened because of the loose connection in the wiring and earthing has not been provided. Electrical department has ensured that the Proper wiring and earthing has been provided to all the temperature indicator in the IM block, so that we can avoid the knowledge-based mistake. The technician who has involved in changing the hose pipe of the empty N- Butyllithium (NBL) cylinder on 9th December 2017 outside the IM block, which has resulted in small leakage of NBL solution from the nozzle of the cylinder, the NBL solution touches the Teflon tape and exposed to the oxygen concentration resulted in the fire. Immediately dry chemical powder (DCP) has been used to stop the fire. While removing the hose pipe of the empty NBL cylinder it is recommended to give nitrogen supply to the pipeline, so that we can avoid the rule-based mistake. Outside of the IM block on 7th February 2018 chlorine gas cylinder has leaked while opening the adopter of the empty cylinder, while keeping the spindle in the slightly open mode. The maintenance technician though that the spindle was in the closed mode. The maintenance technician has exposed to the chlorine gas concentration have become unconscious for few minutes. While investigating the incident it was found that the spindle was worn out and the technician was wearing the dust mask. It is recommended to wear chlorine gas mask while handling the chlorine cylinders and check the empty weight of the chlorine cylinder. Safety department has been made mandatory to check the spindle of the chlorine cylinder, so that we can avoid the lapses in the judgement in handling of the empty chlorine cylinder. On the 15th March 2018 beam top sun shade has fallen down, which has resulted in heavy sound outside the IM block. This is due to the old civil structure. The incident is a rule-based mistake. The building stability certification has been performed and its recommendations has

been implemented. On 2nd May 2019 the people in the IM block were involved in breaking the lumps of the 4-Dimethylamino cinnamaldehyde, which is a strong irritant. They have exposed to the allergies and eye irritation. Immediately they have been taken to the nearby hospital and given treatment. It is made mandatory to use the proper available exhaust facility in the IM block and wear the googles while performing the activity, so that we can avoid the lapses and the knowledge-based mistake. On 9th July 2019, the person working on the roof top at 30 feet height has fallen through the old poly carbonate sheet because he has not hooked the safety belt to the available lifeline while performing the activity. This has resulted in compound fracture to his right-hand elbow. We have provided safety training to the people who are working on the roof top, double hooking of the safety belt to the lifeline has been made necessary before starting any of the activity on the roof top, so that we can avoid the lapses of the incident. On 2nd February 2020 the executive has been exposed to the vapours of the Dimethyl sulphate (DMS) in the pilot plant due to the not wearing the face shield. The leakages in the flange joints have resulted in the incident. Immediately we have washed the pipeline by flushing with the water and tightened the flange joints. Training has been provided to wear the face shield and it was made mandatory to switch on the blower exhaust facility while performing the activity, so that we can avoid the lapses of the incident. The reaction mass, in the round bottom (RB) flask consist of Dimethyl sulfoxide (DMSO), Potassium hydroxide (KOH) and Nitromethane has bumped and exploded on 21st May 2020 in the R&D block while addition of stage 2 Dimalate intermediate material. While investigating it was found that fast addition of the stage 2 Dimalate material and proper cooling has not been given to the RB flask as per the standard operating procedure (SOP). Training has been provided to R&D people to follow the SOP while performing the activity, so that we can avoid the knowledge-based mistake. Three liters of the of the DMS has been dispensed into the bottle by the stores department and the cork of the bottle has not tightened properly on 9th June 2020, which has resulted in the spillages of the DMS on the left leg of the trainee officer. Immediately the lid of the bottle has been tightened. The injured left leg has been washed with water, sodium carbonate and ethanol and ointment has applied on the injured portion. Training has been provided for proper handling of the DMS, so that we avoid the lapses in handling the chemical bottle. The centrifuge (CF-11) has primary washed with plenty of water and methanol on 28th September 2020. The top dish of the CF-11 has been opened after washing the surface of the CF -11 with methanol, during that time the supported part of the dome has hit the surface of the CF-11, which has resulted in the friction causing the blue flame on the surface of the CF-11. Immediately DCP has been used to put off the blue flame. While investigating it was found that the static energy has resulted in the incident and further it was noticed that the double earthing has not been provided properly to the CF -11, Double earthing for all the equipment's has been checked and it has been made mandatory in all the blocks. Training has been provided for avoiding the washing of the centrifuges with methanol, so that we can avoid the knowledge-based mistake. There was a short circuit in the IM block on 17th March 2021. Immediately safe shut down procedures has been followed. The power was switched off. It was observed that the loose joints of the cables were tied with the electrical tapes have melted, which has led to the incident. Such type of incident happened due to the poor knowledge of the electrician. The entire cabling in the IM block has been checked and the main has been switched on. The welder was performing welding activity on 4th May 2021 for the stripper column at the ETP area. During that time the burr has fallen on the dry grass, which has resulted in the fire. The fire was extinguished by using the treated effluent and the DCP. It was made mandatory to all the employees to avoid performing welding activities in the dry grass area, so that we can avoid the lapses of the incident. The reactor (R7) has exploded on 25th September 2021 in the IM block. The incident taken place while performing the Dimalate stage 3 reaction, the reaction mass in the reactor consists of DMS, potassium hydroxide, nitromethane and stage -2 material. During investigation it was found that the fast addition of the of nitromethane and due to the power failure, suddenly chilling dropped

and the reaction mass temperature has raised, which has led to the un-controllable reaction and the reactor has exploded. The accident has taken place due to rule-based mistake. The Figure. 4 shows R7 reactor area before and after the blast and the environmental pollution due the blast. Three people have been severely injured. Fire and emergency rescue department has been rushed to the spot and extinguished the fire. Training has been provided to production people to handle the critical reactions in IM block.

Figure. 4. 1**.** R7 reactor area before the explosion, 2. R7 reactor area after the explosion and 3. Environmental pollution due to the explosion of the R7 reactor.

Discussion

Accidents or the incidents, which takes places due to the failure of eliminating the hazard, when the more hazardous chemicals not substituted with the less hazardous chemicals, mechanical integrity has not been followed and not wearing the appropriate PPE while carrying out various activity in the plant. Many of the studies have suggested the various disastrous and accidents, which have deadly consequence, which are caused by the human failures [16]. Henrich who is a pioneer in the safety philosophy described the various causation for the accidents and its various prevention methodology has been suggested for the minor and major accidents [17; 18]. The occupational injuries are more than 10 to 20 times higher in the developing countries [19]. It is unfortunate that only 5 to 10 % and 20 to 30 % in the developing and developed countries have access to the occupational health services [20].

Globally there are many such techniques, which are used for investigating the incidents or accidents such as root cause analysis (RCA) and its various CAPA, Failure mode and effective analysis (FMEA), Bow tie and Fish bone diagram, Petro tree analysis, 5-why analysis [21]. During the present study it was observed that most of the incidents / accidents, which are caused due to the lapses (37.5 %) due to not following the safety rules and regulations while working in the hazardous working environment and rule-based mistakes (25 %), which are occurred while improper handling of hazardous chemicals and not following the SOP while indulging in the operations. The safety training has been given to the operators involved in the operations, so that all the safety precautionary points have been penetrated deep into the inherent mind of the individuals, so that we can avoid the lapses, rule-based mistakes and other human errors leading to the incidents or

accidents in the occupational environment. Berhanemeskel et al. [22] reported that occupational injuries were 69.4, 56.5 and 50.6 % among the large, medium and small-scale industries, with an overall prevalence of 63 % in a year at the Bahir Dar city in Ethiopia, which is very less compared to our present case study.

The explosion in the Reactor (R7) in the IM block on 25th September 2021 has resulted in sever injury for the three persons and the blast that has polluted the environment [23]. These could have been avoided if there was a safety relief valve and rupture disk of the reactor connected to the dump tank. This clearly indicates that the accident has taken place due to the failure of mechanical integrity, which is one of the causes of concern. The safety device should be checked during the design stage [24] and Prestart up safety review (PSSR) to be conducted before commissioning of the equipment's in the various manufacturing blocks. Amine Dakkoune et al. [25] reported that the run-away reactions, which resulted in the deaths of 4 % of the people working in the working environment and three people died due to the explosion caused by the thermal run-away reaction in the French chemical industry. There are no deaths have been reported during the present case study. Shobit Srivastava [26] reported that the accident, which has taken place in the Dahej, Bharuch district, Gujarat in India on 3rd June 2020 in a chemical fertilizer company, which has killed eight people and injured 50 workers, which are caused due to the lapses and rule-based mistake, which clearly indicates the human failure in handling of the chemicals and its operations. We should be more cautious while handling the deadly solvents and chemicals in the pharmaceutical industry otherwise it will lead to the grave consequences. The management and mangers of the chemical company must take a lead role to improve the safety culture of the organisations, so that we can avoid the incidents and accidents [27]. The managers of the chemical and pharmaceutical company should see that the laid safety rules and regulations are followed properly in the occupational environment to avoid any incident or accidents in the factory premises [28]. Further it is also necessary to update the knowledge on the safety aspects and awareness required to prevent the catastrophic event in the future [3]. `

Hazard communication playing a vital role in the pharmaceutical industry. The potential hazard of the chemicals, which are used in the process to be understood [29]. Hazard is recognized by reading and understanding the Material science data sheet (MSDS) or safety data sheet (SDS) and chemical labelling system [30]. Occupants must be familiar with the hazard of the chemicals, which are pasted on the drums and bags. Various safety precautions to be taken while handling the deadly harmful chemicals to be known. The hazard communication, which are in the form of Flammability, Oxidizers, Toxic, Irritant, Corrosive, Compressed gas, Environmental hazard, Health hazard and Explosive in nature. The labelling procedure of Globally humanized system (GHS) has been adopted in the year of 2002 with the help of United Nations economic and social council, the technical committee has given guidelines for the classification of the chemicals, which is in the form of a GHS purple book. We have adopted the GHS labelling procedure. It includes the H (Hazard) and P (precautionary) statement and the hazard communication, so that we can avoid the incidents or the accidents while handling and usage of the chemicals in the pharmaceutical industry.

CONCLUSION

During the case study we have identified total 20 recordable incidents / Accidents in the seven different locations in the pharmaceutical industry for the period of October 2017 to September 2021. The incidents / accidents at various locations were IM block, Outside IM block, FG block, pilot plant, R&D block, Stores area and ETP area are 9, 4, 3, 1, 1, 1 &1. The incident / accident, which are classified as Minor (2 no's), Major (5 no's) and dangerous (13 no's). The percentage of incident / accident, which are caused due to the form of human failure are in the form of Lapses (37.5 %), Rule based mistake (25 %), Knowledge based mistake (17.5 %), Situational (10 %), Routine (5 %) and Slip (5 %). Various CAPA for the 20 incident / accident have been presented.

We have followed the GHS labelling system for identifying the hazards and precautions to be taken while handling the deadly chemicals. Further the human failure has been avoided by following the strict safety regulation, safety training and mechanical integrity in the pharmaceutical industry to avoid the incidents / accidents in the future.

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