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The New Three-Dimensional Safety Approach for the Implementation of Process Safety Management (PSM) and Improving Safety Aspects for the Pharmaceutical Industry in India – An Overview

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ABSTRACT

Implementation of the fourteen elements of process safety management (PSM) helps to build a good safety culture in the organization. The new three-dimensional approach, which consists of good safety practices, safety precautions, and frequent checking of the process equipment and its devices has been applied to the various elements of the process safety management. The elements of process safety management are six, four, and three are good safety practices, safety precautions, and frequent checking of process equipment and its devices but one of the elements is the combination of all the three-dimensional approach, which is a trade secret, which insists that all the people in the organization should follow all the documented procedures from two to thirteen elements of the process safety management, the controlled copy should only be used inside the company premises. We have taken secondary published data for assessing the deviations of the three-dimensional safety approach for the human failures in the pharmaceutical industry, which has led to various incidents/accidents from October 2017 to September 2021. The deviation, which we have observed for the good safety practices, safety precautions, and frequent checking of process equipment and its devices was ten, nine, and one numbers before implementation of the process safety management. After the implantation of the process safety management, the incidents were reduced to three numbers from January 2022 to August 2023, in which deviation has been found in the two and one for the good safety practices and safety precautions.

INTRODUCTION

The Pharmaceutical industry uses various hazardous chemicals and solvents in the process to achieve the desired final product. Many of the chemicals and solvents, which are used in the process are highly flammable, toxic, Irritant, Carcinogenic, and environmentally hazardous in nature (Bhusnure et al., 2018). The new three-dimensional safety approach, which consists of good safety practices (GSP), safety precautions, and frequent checking of process equipment and its devices, has helped in implementing Process Safety Management (PSM). The PSM fourteen elements were implemented and followed according to the guidelines, which are given in the Occupational safety health administration (OSHA) Part number 1910.119 (Wang et al., 2023).

The PSM culture in the pharmaceutical industry helps in building a GSP and reduces incidents/accidents in the organization (Kwon et al., 2016; Shariff et al., 2016; Nwankwo et al., 2020). Many of the industries have carried out investigations for the Incidents/accidents happening in the different industrial sectors but they were not reported in India (Prasad & Suresh, 2023). Maniar et al., 2020 reported that human failure in the incidents/accidents happening in the occupational environment of the pharmaceutical industry has resulted in 73 process safety incidents, which have led to 108 fatalities between the years 1985 and

2019 were studied considering the various minor, major, and dangerous occurrences.

Further, he has also reported that 83 % of the accidents, which are happen in South Asian countries like China and India. We have done a deep study and identified a three-dimensional safety approach, which focuses on the reduction of incidents/accidents in the pharmaceutical industry. We have strictly adhered to the interdependent behavior to be followed in the pharmaceutical and chemical industry to avoid incidents/accidents in the working environment. This article has a cutting edge for the safety professions in the form of a new three-dimensional safety approach, which has resulted not only in reducing the incidents/ accidents but also it helped in facing the global environment, health, and Safety audit for our active pharmaceutical ingredients (API) customers such as Johnson and Johson, Pfizer and Sanofi. We would like to share our experience in this article so that the global community can use the same concept for avoiding the incident/Accidents, which are happening due to the innumerable causes while working in the occupational environment in the various pharmaceutical industries, so risk-based process safety management is important to avoid the various incidents/accidents (Zwetsloot et al., 2020). The new three-dimensional safety approach for avoiding incidents/accidents in the chemical and pharmaceutical industries includes good safety practices, safety precautions, and frequent checking of the mechanical instrumentation and its devices.

Globally there are many studies carried out for solvent vapors, reaction mass, and combustible dust explosions in the chemical and pharmaceutical industries (Wu et al., 2023). Studies regarding the solvent vapor explosion in America and dust explosion in Germany were carried out by Cartwright et al., 2021, lower flammability limits of ethanol, acetone, and ethyl acetate vapor mixtures in the air were studied by Zhang et al., 2022, prediction of lower explosion limit of liquid fuel aerosol were reported by Jia et al., 2023, explosion studies were carried out due to the increase of temperature/pressure while handling the methane/ coal were studied by Yu et al., 2023. various factors for avoiding the explosion in the process batch reactors were studied by Wu et al., 2023, further, he has also studied safe handling of the hazardous chemicals, which are used in the batch process in the API (Wu et al., 2023).

The dust explosion studies with respect to the handling of the fusion reaction have been studied by Lu et al., 2023 and the various causations of dust explosion with respect to the high content of volatile matter were studied by Moron & Ferens (2024). The various studies with respect to the mitigation of the dust explosion studies were carried out by Wei et al., 2020. There is very little information about the various explosion hazards, that are incurred during the handling of the different solvents, reaction mass, and the combustible dust caused during the drying, Jet milling, Multi milling, and shifter, which are used in the powder processing in the pharmaceutical industry (Bu et al, 2022; Eckhoff, 2019; Eckhoff & Li, 2021).

Pharmaceutical industries lead to runaway reactions due to uncontrolled reactions (Dakkoune et al., 2019). Proper safe handling of the reactions is necessary for handling the chemicals and performing its operations according to OSHA (Yu et al., 2017). Electrostatic energy causes huge explosions in the chemical and pharmaceutical industries due to its accumulation of charged particles, which are not dissipated and discharged properly (Egan, 2017; Chen et al., 2021; Ebadat & Cartwright, 2023). To dissipate and discharge the electrostatic energy to the ground we can use double earthing, jumpers to the operation equipment, earth rite system, touch pads, wrist straps, personal tester, and electrostatic energy discharge (ESD) flooring (Yang et al., 2021; Zhang et al., 2023).

It is necessary to perform process hazard analysis (PHA) for the products, which are manufactured in the API to know the various risks (Haleem et., 2015), that are involved in handling and indulging in the operation of the process equipment. There is less collective safety information about the initial studies to be performed before starting the process (Wang et al., 2023). The studies will help us to know the nature of the behavior of each of the molecules in the reaction synthesis, which helps in avoiding explosions (Cheng et al., 2020). The various types of process safety studies, which are performed before starting the process are minimum ignition energy (MIE), fall hammer test, and Maximum temperature for synthesis reactions (MTSR) for our API manufactured products such as Alprazolam,

midazolam, Bromazepam, Clobazam, Haloperidol, Clonazepam and Loperamide, which are manufactured in our company.

Process safety studies such as MTSR play a vital role in knowing the runaway reactions in the chemical process industries (Behie et al., 2023). The GSP, safety precautions, and frequent checking of process equipment have helped us to achieve the objectives of the PSM and it reduces incidents/ accidents in the pharmaceutical industries. Various safety precautions are taken by wearing the appropriate PPE (Liaw, 2023) while working in the occupational environment and following the instruction given in the batch management record (BMR), which has resulted in the GSP, frequent checking of the process equipment and its devices has been followed as per the standards, which are given in the Indian factory act 1948.

We have successfully assessed the GSP, safety precautions, and frequent checks of process equipment and devices and correlated with the PSM. We have identified human failures for the various incidents/accidents, that happened in the seven different blocks such as the 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), its various corrective and preventive action (CAPA) has been reported previously in an international journal**,** the new extensive approach for avoiding the incidents/accidents by applying the new concept known as three-dimensional safety approach has helped us in avoiding the incidents/accidents, finally, it has resulted in building an excellent safety culture in the organization.

METHODS

We have implemented the fourteen elements of PSM as per the OSHA 29 CFR 1910.119 guidelines for achieving a safety culture and reducing incidents/accidents in the organization. The PSM fourteen elements were correlated with the new three-dimensional safety approach and its importance has been presented. The new three-dimensional safety approach deviation of the GSP, various safety precautions, and frequent checking of the process equipment and its devices have been applied to the secondary published data of the human failures in the pharmaceutical industries, which has resulted in the various incidents/ accidents from October 2017 to September 2021 has been presented. Further, we have investigated the incidents/accidents from January 2022 to August 2023 after the implementation of the PSM fourteen elements. Identification of the other general safety aspects, which are other than fourteen elements of PSM has been correlated with the new three-dimensional safety approach.

RESULTS AND DISCUSSION

People working in the pharmaceutical industries are trained for following the fourteen elements of the PSM as per the OSHA Part number 1910.119 standards (Wang et al., 2023). Each of the elements of the PSM is correlated with one of the elements of the new three-dimensional safety approach, which are GSP, Various safety precautions, and frequent checking of the process equipment and its devices. The PSI is one of the key elements of the PSM. We have collected the PSI information for each of the chemicals and solvents used in the process, which has resulted in achieving the GSP (Table 1). The PSI, which is extracted from the secondary data from the material safety data sheet (MSDS) is listed below.

Physical properties are chemical abstract series, state of appearance, odour, molecular weight, molecular formula, melting point, boiling point, vapour density, reactivity with water, reactivity with air, light sensitivity, and stability. The Toxicity data, which includes threshold level values (TLV), handling restrictions for carcinogens, Immediate death for life and health (IDLH), reproductive toxicity, mutagen and occupational exposure level (OEL). Ignition and Explosion data consist of flash point, minimum ignition energy (MIE), auto-ignition temperature (AIT), lower explosion limit (LEL), upper explosion limit (UEL), and shock sensitivity. Thermal stability relates to the decomposition temperature. The Reactivity with other chemicals, which are reactive or non-reactive – a comparison approach.

The PHA has been performed to know the risks, which are involved in handling the chemicals and its usage during the various operations, which are carried out in the different batches at different temperatures and pressures as per the instructions, which are given in the BMR. The PHA, includes qualitative and quantitative approaches to risk

assessment (Herrera et al., 2015). Hazard and operability (HAZOP) study analysis is a qualitative approach and failure mode effective analysis (FMEA) and fault tree analysis is a quantitative and qualitative approaches to risk assessment. We have performed HAZOP for our API products such as Alprazolam, midazolam, Haloperidol, Clobazam, Haloperidol, Clonazepam, and Loperamide, which consist of seven, five, six, six, five, five and four stages and these batch processes are manufactured in the IM block, drying block and finally the finished goods are produced in a clean room of the FG block. By conducting the PHA and PSM, we have taken the highest safety precautions before starting the batch (Table 1) according to the OSHA 29 CFR 1910.119.

The PHA should be performed every five years once. Strict operating procedures have been followed as per the instructions, which are given in the standard operating procedure (SOP), which is in the form of a BMR for the API industry, which has resulted in the GSP in the occupational environment (Table. 1). Similarly, the GSP has been followed by training the employees and contractors as per the contractors and employees safety training schedule, which has resulted in the increase in the knowledge of the safety aspects and reduction of the incidents/ accidents in the industry. The Pre-start up safety review (PSSR) plays as vital role, which checking the functionality of the new process mechanical equipment and its devices before it is used for operations, which is one of the key elements of the new three-dimensional safety approach, similarly the mechanical integrity plays a vital role in checking of the process equipment's integration of mechanical parts of various equipment's such as reactors, centrifuges, dryers, jet milling, multi milling, and shifters before starting of the batches, so that we can avoid the leakages of the solvents, chemicals, reaction mass material and hazardous fugitive emission to the environment (Table 1). Many people have suggested PSSR in the form of preliminary consequence analysis (PCA), preliminary hazard analysis (PHA), and concept safety review (CSR).

Table 1. Fourteen elements of PSM with their benefits and correlating with one of the elements of the new three-dimensional safety approach

No	PSM Elements	Benefits	Elements of Three-Dimensional Safety Approach
1	Employee Involvement	All the employees are involved in the PSM	GSP
2	PSI	Helps to know the hazards of the molecules used in the process	Safety precaution
3	PHA	The study of the chemical process by using risk analysis such as what if or HAZOP or FMEA or Fault tree analysis	Safety precaution
4	Operating procedures	We have SOP / BMR for each of the operations of our manufactured products. The operator also knows to correct the deviation, which are incurred during operations	GSP
5	Training	Safety training has helped us to carry out the operations in a safer way and avoiding incidents.	GSP
6	Contactor safety	The Company has evaluated the contractor's safety performance; the contractor has taken highest safety precaution while carrying out the activity	GSP
7	PSSR	PSSR have been carried for all the new installed equipment and devices for the safe operations in the different blocks	Checking of process equipment and its devices
8	Mechanical integrity	The mechanical parts of the equipment's used in the process had followed good engineering practices for	Checking of process equipment and its

		smooth and safe operations	devices
9	Hot work permit	We have taken user, executer, EHS, and plant head clearance before starting any hot work such as welding, soldering, and cutting activities.	Safety precautions
10	MOC	Any of the changes in the usage of the chemical, process, or equipment have been properly evaluated and documented for the MOC and approved by the QA department	Checking of the process equipment
11	Incident investigation	Root cause for the incident/accident, which has taken place in the factory during the operations and its corrective and preventive action (CAPA) has been implemented	GSP
12	Emergency planning and response	Emergency control with the help of the various emergency controllers and incident controller are responsible for tackling an emergency situation arises.	Safety precautions
13	Compliance	All the safety audit recommendation points have been complied	GSP
14	Trade secrets	It is mandatory that all the employees and contractors have been involved in the PSM and follow from second to thirteen elements, so that they can also access all the PSM documents inside the factory premises only	Three-dimensional safety approach

The highest safety precautions have been taken while issuing the hot work permit as the API industry consists of highly flammable chemicals, which are stored in the manufacturing area. This hot work permit is to be signed by the user, executor, and EHS department and finally, it is signed by the plant head after thorough verification, then only clearance is given for starting the hot work in that area, where there are no flammable chemicals are stored. Xin (2023) studied the various regulations and standards to be applied in the hot work area, where gas welding, cutting, and brazing, are performed in the hazardous industries in China. The Management of change (MOC) means any change in the process, which results in checking of the equipment, and its devices (Table 2), the MOC document has been initiated before starting the process, we have got approval from all the concern department due to the changes in the product mix, change in chemical used or change in process lines., then finally it is approved by the quality assurance (QA) department before starting the process.

The incident investigation of the PSM plays a vital for investigating the various incidents/ accidents, that happen in the occupational environment. The various causes of human failure for the different incident/accident data in the pharmaceutical industry were collected from the recently published international journal, where the collected secondary data has been used for knowing the deviations in GSP, safety precautions and the frequent checking of the safety deviations of the new three- dimensional ideological approach was ten, nine and one numbers between October 2017 to September 2021 (Table 2), which consist of two, five, and thirteen numbers of minor, major, and dangerous incidents/accidents (Table 2) but now after following the three-dimensional safety approach, we have reduced the incidents/accidents from twenty to three numbers, which consist of two minor and one major incidents from January 2022 to August 2023 (Table 3), its deviation of the three-dimensional approach has been presented in Table 3. Xin et al., 2023 & Bai et al., 2023 reported that there are minor and major accidents happened in the China due to the deviation of the PSM perspective. We are trying our level best to achieve zero incidents/accidents for the year 2024-2025.

Table 2. Deviation of one of the elements of the new three-dimensional safety approach, which has led to the various incidents/accidents from October 2017 to September 2021

Date	Place of the incident/ accident	Cause of the incident/accident	Minor/Major/ Dangerous occurrences	Deviation of the three-dimensional approach
06-10-2017	IM block	Short circuit in the temperature indicator wiring line	Dangerous	GSP
27-10-2017	FG Incident	Inhalation of the Haloperidol	Major	GSP
09-12-2017	Outside IM block	The spark generated while removing the hose pipe from the empty N- Butyllithium (NBL) cylinder	Dangerous	Safety precautions
07-02-2018	Outside IM block	Leakage of the chlorine gas cylinder	Dangerous	Safety precautions
15-03-2018	Outside IM block	Beam top of the sunshade has been fallen down	Dangerous	GSP
14-08-2018	IM block	Exposure of the corrosive vapours while opening reactor manhole	Major	Safety precautions
28-08-2018	FG block	Not wearing PPE while performing Jet milling	Major	GSP
28-08-2018	FG block	Fingers struck between the frame and the door	Minor	Safety precautions
29-2-2019	Outside IM block	Spillage of Thionyl chloride	Major	Safety precautions
02-05-2019	IM block	Inhalation of vapours of 4-Dimethylamino cinnamaldehyde	Dangerous	GSP
03-06-2019	IM block	The reactor bottom valve hit the head of the trainee officer	Minor	Safety precautions
09-07-2019	IM block	Not wearing the safety belt while working on the roof top	Dangerous	Safety precautions
02-02-2020	Pilot plant	Leakages of the hazardous chemicals from flange joints	Dangerous	Checking of the process equipment and its devices
21-05-2020	R&D block	Explosion of the round bottom flask	Dangerous	Safety precautions
14-06-2020	IM block	Hot water bumped off from the stream header line	Major	GSP
09-06-2020	Stores block	Spillage of the Dimethyl sulphate	Dangerous	GSP
28-09-2020	IM block	The top dish hit the centrifuge dome, resulted in the spark	Dangerous	GSP
17-03-2021	IM block	Electrical short circuit in the cable tray wiring, which has resulted in a spark	Dangerous	GSP
04-05-2021	ETP area	Welding burr has fallen on the dry grass, which has resulted in a fire	Dangerous	Safety precautions
25-09-2021	IM block	Explosion of the reactor	Dangerous	GSP

Table 3. Two minor and one major incident, which has happened between January 2022 to August 2023

Date	Place of the Incident/Accident	Cause of the Incident/Accident	Minor/Major/ Dangerous occurrences	Deviation of the elements of the three-dimensional approach
03-4-2022	FG block	Slippery floor resulting in the fall injury	Minor	GSP
21-3-2023	IM block	Leakage in the hydrogen cylinder	Major	Safety precautions
09-6-2023	Outside IM block	Not wearing of helmet, which has resulted in a head injury	Minor	Safety precautions

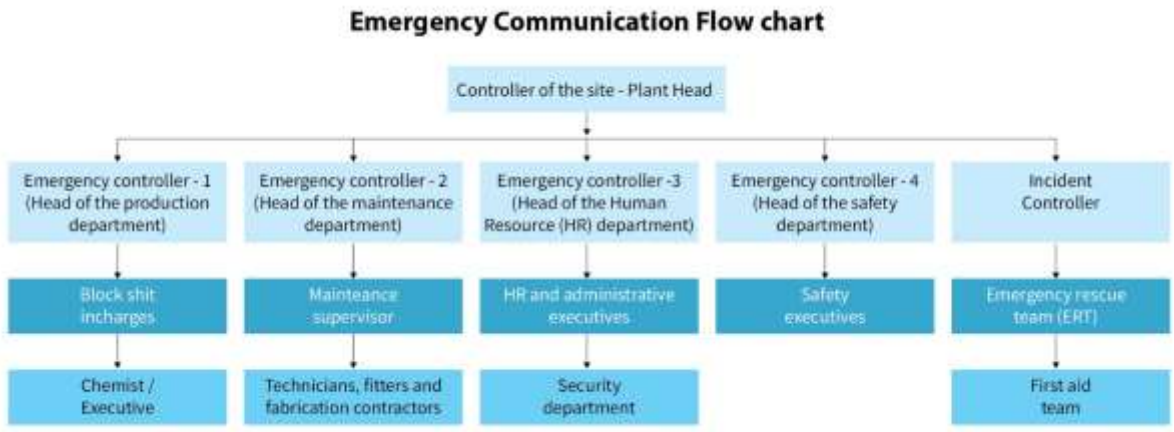

Figure 1. Communication during an Emergency situation in the occupational environment.

Emergency planning and response is one of the GSP to be followed to tackle an emergency that arises in the occupational environment. The incident observer first informs the concerned departmental heads, the head of the department will inform the site head and the same will be informed to an incident controller to tackle an emergency that arises in the pharmaceutical industry. The Emergency communication chart for handling the emergency has been presented in the Figure. 2. We have further practiced the mock drill to tackle the emergency situation in the pharmaceutical industry. In this mock drill, we have demonstrated the various techniques for lifting an injured person, which are listed below.

1. One person lift carrying method
2. Pack strap carrying method
3. Two hand carrying method
4. Three hand carrying method
5. Three hands carrying - Right Leg with Right Hand carrying method
6. Three hands carrying - Left Leg with left hand carrying method
7. Four hand carrying method.
8. Pick a back and Fire man's lifting method
9. Pick a back reverse method - Pregnant woman.
10. Single human crutch method, when there is less space.
11. Double man crutch method, when the causality is able to walk with an assistance.
12. Fore & aft method, where the causality is unable to walk.
13. Three men carrying method.
14. Ankle dragging method.
15. Collar pull dragging method
16. Shoulder pull dragging method.
17. Toe dragging method - During smoke and fumes.
18. Knee Dragging method - During smoke and fumes.
19. Figure of 8 - Best technique during the smoke and fumes.

Compliance with respect to all the process safety aspects in the organization played a vital role in resulting in the GSP. We have complied with the internal and external safety audit observations. Further, we have complied with the Indian Factory Act 1948 section and rules. It was enacted by the parliament of India to protect the workers working in the occupational environment (Pingle, 2016). Various equipment/devices have been tested as per the rules and sections, which are given in the Indian Factory Act 1948 (Table 4). Miadlicki & Pajor (2015) have communicated the importance of the testing of load lifting devices. we have maintained Form 8 report for the pressure vessels and Form 38 for the adequate equipment for fighting the fire in the factory premises so that the legal documents can be shown during the inspection by the Department of Factories Boilers Industrial Safety and Health. In the trade secret element of the PSM, it has been ensured that no document will be shared and given to people outside the industry premises, further, it has been seen that all the employees and contractors will be adhering to the two to thirteen elements of the PSM, which has finally resulted in the formation of the new three-dimensional safety approach. The safety precautions, GSP, and frequent checking of the process equipment and devices will not only increase the safety culture in the organization but also the productivity by following the proper SOP/ BMR during the operation of the process equipment. Chandwani et al. (2019); Sohrabi & Babamiri (2021) reported that a good workplace safety culture increases productivity and increases the brand image in the global community. Thus, practicing the highest safety in the organization, it shows the brand competence among the other competitors in the international arena. Workplace safety enhances Knowledge, attitude and GSP will build a safety culture in an organization (Oamen & Ihekoronye, 2022; Odu et al., 2023)**,** further, he has also reported that following the GSP spreads safety awareness in the organization, which helps in reducing the incidents/accidents in the occupational environment. To reduce the incidents/ accidents it is very much necessary for all the workers should have proper eye vision; and no stress-related problems and they should be trained in the proper working environment to perform the particular task (Murad et al., 2013).

Table 4. Indian Factory Act Rules 1948 for checking the various mechanical equipment and devices

No.	Equipment /Device	Rules and sections of the Indian Factory ACT 1948	Frequency of testing	Agency - Internal/ External competent person
1	Safety relief valve	Rule 56, section 31 (3)	Six months once	External
2	Pressure vessels /Reactor thickness testing		Six months once	Internal
3			Yearly once	External Competent person
4	Reactor/vessels hydraulic test with manhole		Four years once	External Competent person
5	Reactor/vessels hydraulic test without manhole		Two years once	External Competent person
6	Air /Nitrogen receivers		Six months once	External Competent person
7	Thermic fluid heater		Six months once	External Competent person
8	Cage Hoist	Rule 55 & 55 A, Section 28 & 29 (2)	Six months once	External Competent person
9	Battery hoist forklift truck		yearly once	External Competent person
10	Battery operated stacker		Yearly once	External Competent person

The fourteen elements of the PSM were compared to the different safety practices of the safety aspects with respect to the new three-dimensional safety approach in the pharmaceutical industry. The three-dimensional approach not only helps in implementing the fourteen elements of the PSM in the organization but also it improves the general safety aspects such as business continuity planning, following behavioral-based safety (BBS), secondary contamination provision in the tank farm area, proper dressing and cable routing, which are the GSP, whereas usage of appropriate PPE, having good ventilation, scrubbing system, emergency exit are free from blockages, maintaining the personal hygiene, display of caution board and SCBA kept ready for the usage in the emergency situation are the safety precautions, which are taken in the working environment. In this way, the new ideological approach will not only increase the process safety culture in an organization but also enhance the general safety aspects to build a strong ethical safety culture in the organization.

Fabiano & Bernatik (2023) reported that good safety principles will help to increase safety in the pharmaceutical industry. Lindqvist (2023) has stressed the importance of human factors, which has helped in building a good safety culture in the process and chemical industries in America. Above all strong belief by obeying the safety rules and regulations has been followed by penetrating deep into the minds of the people while working in the organization. In this way, we can say the new three-dimensional safety approach has not only helped us implement the fourteen elements of the PSM, further it also reduced the incidents /accidents in the organization, which has resulted in the GSP, safety precautions, and frequent checking of process equipment and devices in the pharmaceutical industry.

CONCLUSION

The new three-dimensional safety approach has good safety practices, safety precautions and frequent checking of the process equipment and its devices played a key instrumental role in the implementation of the process safety management. The fourteen elements of process safety management elements, which consist of six, four, and three, are good safety practices, safety precautions, and frequent checking of process equipment and its devices. The final element of the process safety management is the trade secret, which is the combination of the new three-dimensional safety approach. The new approach has helped us reduce incidents/accidents from twenty to three between October 2017 to September 2021 and January 2022 to August 2023. Further, we have identified the deviation of the elements of a new three-dimensional ideological approach, which has resulted in various incidents/accidents. It has been ensured that the incidents/accidents are not repeated in the occupational environment. Further, the three-dimensional approach we have practiced enhanced safety aspects required for the pharmaceutical industry, we can say that the new three elements of the new ideological approach have resulted in the implementation of process safety management, which are interrelated. Overall, it has increased the image of safety in the organization resulting in greater cooperation by achieving the production targets in the organization.

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