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Global process safety incidents in the pharmaceutical industry

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ABSTRACT

The objective of this research is to analyse global process safety incidents within the pharmaceutical industry in terms of their consequences and factors contributing to the incidents. There were 73 process safety incidents leading to 108 fatalities found between 1985 and 2019. Trends between the number of incidents, number of fatalities, location, and contributing factors were identified and summarized. The most reported fatalities occurred in 2018 & 2019. 83% of fatalities occurred in China and India. Explosions were associated with 71% of incidents, which resulted in 89% of fatalities. For most of the international incidents, incident investigations were not available and thus insufficient details were available to determine the causes. Contributing factors were available or estimated from available data for about half of the incidents, with the following most common: hazard awareness & identification; operating procedures; design; safeguards, controls & layers of protection; safety culture; and preventive maintenance. These findings can be used as a basis to improve process safety performance in the pharmaceutical industry.

1. Introduction

While many associate process safety related incidents with oil, gas and chemical operations, such fires, explosions and leaks, occur in a wide variety of industries. A recent publication (Bhusari et al., 2020), cites process safety related incidents across 14 industries, including agriculture, food, manufacturing … and the pharmaceutical industry. Two recent incidents from 2018 & 2019 are cited that resulted in 29 fatalities in pharmaceutical operations.

A recognized challenge to the process safety profession is the lack of a global multi-industry database of process safety incidents, whereby factors contributing to incidents can be identified and serve as a basis for organizations to improve their safety management systems. Many attempts have been made to develop various incident databases, as summarized by Kannan et al., 2016. These databases have various shortcomings such as industry, region, limited reporting and update process. This study provides the first database of pharmaceutical process safety incidents, that the authors are aware of, which can be analysed to determine common causes and lead to process safety improvement opportunities.

According to IBIS World, the pharmaceutical industry generated ~ $1260 trillion in revenue in 2019. (IBIS World, 2019). The reactors and equipment used to manufacture large quantities of drugs must be designed, operated and maintained properly, with the potential for malfunction, potentially resulting in process failures. Such failures may result in process safety incidents, which can be a non-toxic gas release, or a major reactor failure resulting from a violent chemical reaction, which may eventually result in an explosion or fire with catastrophic results. Process safety incidents may take place due to inadequate proper safety measures, human error, and other procedural and behavioural factors. Leading pharmaceutical companies employ process safety professionals to address such issues, particularly when planning to manufacture a new product.

Seventy-three process safety incidents have been found and analysed in this study. The focus is on manufacturing operations, including pilot plants, but not laboratory incidents, with the latter generally a unique set of circumstances. These incidents resulted in fatalities, injuries, environmental, infrastructure and equipment damage. Analysing the incidents for contributing factors, companies can work to improve both process safety, as well as the safety of their workers and surrounding communities.

2. Development of incident database

A database of process safety incidents was developed for the pharmaceutical industry, included as Supplemental Information. The primary databases used to find incidents are as follows:

ASM (Abnormal Situation Management) Consortium: This is a

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database which has information related to current process safety incidents, case studies, presentations relevant to abnormal situation management, publications, and recordings. ASM Consortium is a searchable database like Google, that provides links to articles corresponding to process safety incidents. ASM is not listed as a reference in the database here, but instead the source articles are provided with relevant incident information. Most recent incidents were found through ASM consortium (Consortium, 2020).

FiercePharma: This is a source of world-wide pharmaceutical industry news. Using keywords like chemical leaks, toxic gas/liquid release, reactor blast, and runaway reaction on this platform narrowed the search and helped find reported incidents. Subsequently, a Google search for an incident with the date and location provided more information through primarily media websites. Similar to ASM, FiercePharma is generally not listed as a reference in the database, but instead articles are referenced from subsequent Google searches. Two exceptions are incidents (39 & 46) where the Google search provided no further information. Unfortunately, the database only has incidents dating back to 2002 (FiercePharma, 2020).

European Commission eMARS (online Major Accident Reporting System): This source is European based and has the same format as FiercePharma. Following the same procedure as before yielded similar results. Many of the incidents had already been found, but eMARS helped provide incidents that dated nearly two or three decades earlier. This helped extend the timeline of incidents and expand the sample size to find trends over more years. An issue with eMARS is that it does not provide the details of the location or the company where the incident occurred, likely for privacy reasons and to encourage reporting. While most incidents are likely European, their process includes OECD (Organization for Economic Cooperation and Development) countries and is thus potentially broad. It does, however, give a detailed description of the incident and the results. European Commission, 2020)

OSHA: This source was used to find incidents in the U.S., given that most of the previous search results yielded incidents in Asia and Europe. The OSHA, 2020 database was searched for pharmaceutical related fires, explosions and gas releases – not the customary personnel incidents that make up most of the reported incidents. Ten incidents were added to the database, with additional information obtained for an incident found in earlier searches. For perspective, these ten U.S. incidents are associated with two fatalities, compared to the 106 fatalities found in the other searches and 63 incidents.

Of the 73 incidents listed in the Supplemental Information database, eMARS is cited as a reference for ten, OSHA another ten, FiercePharma for two and ASM for none, with the latter two relying on articles located with subsequent Google searches. Most incidents were identified in this fashion. One additional incident was from a Chemical Safety Board investigation, and a few others were provided by private communications from industry experts e.g., Flanagan, 2019. In addition, at times news articles listed other regional or company incidents, which led to further Google searches, many unsuccessful.

Other than OSHA, no additional government regulatory databases of incidents were used, should they exist. Thus, incidents in the database are not from various government incident reporting requirements which may vary by country, but rather from news coverage. While industrial fires, explosions and fatalities are likely newsworthy globally, there is perhaps more coverage in developed countries vs. emerging or developing countries.

Development of the database was a laborious process. The 73 incidents are associated with 108 fatalities. There is no reason to believe that ALL global incidents have been captured, particularly incidents with limited consequence that aren't newsworthy. With that said, this is a sound starting point for compiling incidents associated with pharmaceutical operations and analysing for lessons learned to prevent future incidents.

3. Analysis of process safety incidents

Figure 1 depicts the number of reported pharmaceutical related incidents and fatalities that occurred from 1985 to 2019, a 34-year period. During the past decade the number of reported incidents averaged about five. The most fatalities occurred in 2018 and 2019, impacted by 19 fatalities in one incident in 2018, and 10 fatalities in a 2019 incident. While injuries were captured as part of the incident database, since there is no clear global definition of what constitutes an injury, they were not evaluated further.

Figure 2 depicts the number of incidents that occurred in the U.S. as compared to internationally (i.e., outside the U.S.) from 1985 to 2019, with incidents from eMARS shown separately, with location unknown. The bars to the left may look large, but reflect incidents over 5 and 10-years, averaging approximately an incident per year. During the past decade the majority of reported incidents occurred internationally. This may at least partially be due to outsourcing and shift of manufacturing from the U.S. to international sites.

The distribution of reported global incidents and fatalities are shown in Figure 3and Figure 4, respectively. About half of the incidents occurred in developing countries (49%), where safety process evaluation is still at its infancy. The following quotes from articles describing incidents are sobering:

- *Boasted as a global destiny for manufacturers of bulk drugs, active pharmaceutical ingredients and intermediaries by both the developer of this sector specific Economic Zone, the JNPC (India) has turned into a veritable death trap for many a labourer working in pharma units. Scores of fatal accidents in the recent past lend credence to it. In all, 26 workers died and 66 were injured in about 30 accidents in just a five-year span* since 2013 mostly *in JNPC unit* …. Post, 2017
- *… in China where local safety authorities and the fire service have little power to really enforce safety standards and ensure that factories, storage facilities and other potentially hazardous workplaces are up to code …* CLB, 2018

The correlation between the number of incidents and quantity of drug manufactured in various countries was explored. Intuitively one might suspect that the larger share of pharmaceutical incidents in developing countries is consistent with the shift of manufacturing from the U.S. to overseas. However, this is a challenging question to quantify, with drugs separated as APIs (active pharmaceutical ingredient), biosimilars, generics, finished drugs, … and no clear distribution by country. For example, multiple sources indicated that 80% of APIs sold in the U.S. were made in India & China (Los Angeles Times, 2018). Directionally this is consistent with twice as many incidents occurring in India and China (49%) compared with the U.S. (23%).

Per Figure 4 India and China account for 49% and 34% of fatalities,

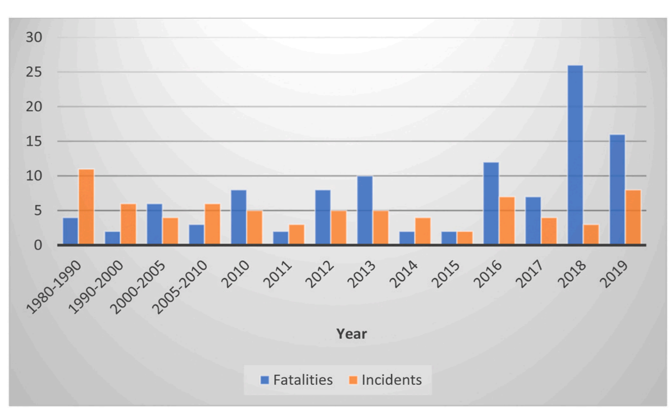

Fig. 1. Number of Fatalities & Incidents vs. Time Period that Occurred Globally in the Pharmaceutical Industry.

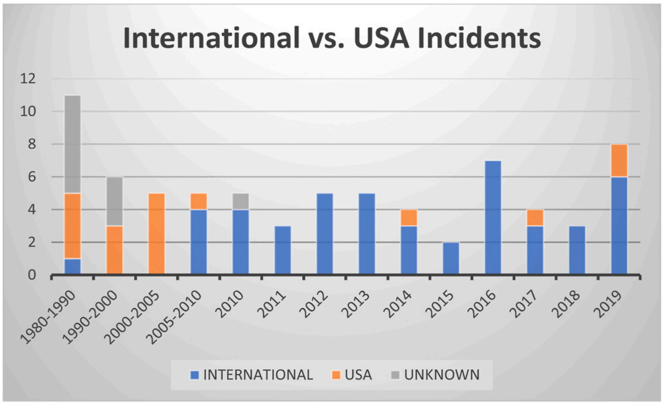

Fig. 2. Number of international, U.S. and site unknown incidents in the pharmaceutical database.

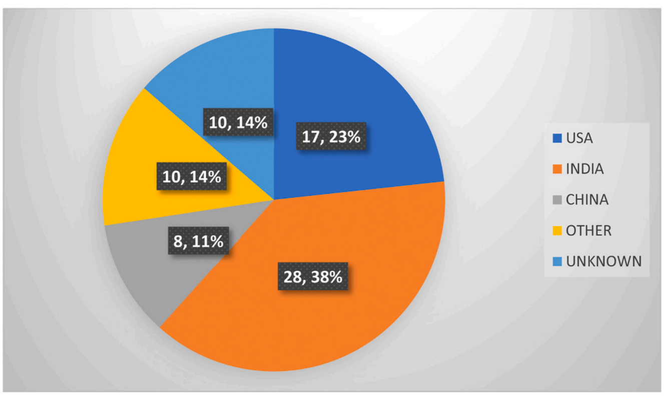

Fig. 3. Number of Incidents and Corresponding Percentage in the U.S., India, China, Other, and site unknown.

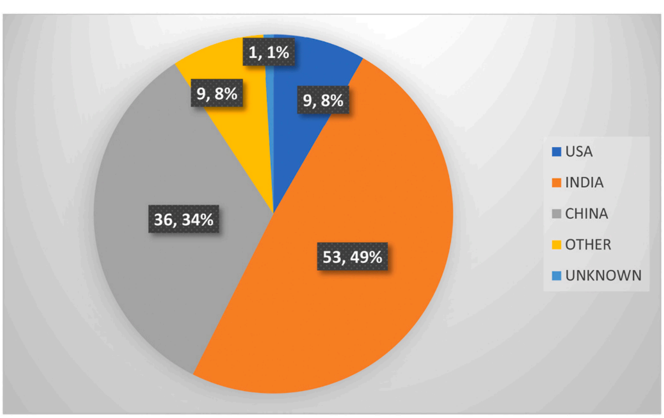

Fig. 4. Number of Fatalities and Corresponding Percentage in the U.S., India, China, Other, and site unknown.

respectively, or 83% of fatalities compared with 49% of incidents. Further, comparing reported incidents and fatalities by region, there is quite a disparity with ~4 fatalities per incident in China, compared with ~2 for India and ~0.5 for the U.S. It is unlikely that less severe incidents are being captured in developing countries.

The data were then analysed in terms of incident type, such as fire, explosion, gas/chemical leak (Figure 5). 'Explosions' reflect those incidents reported solely as explosions, as well as those where a fire preceded or followed the explosion, while 'fires' reflects incidents solely reported as a fire. 'Releases' reflect incidents with gas or chemical

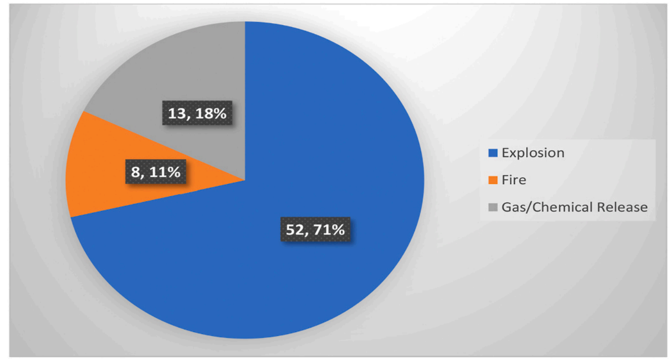

Fig. 5. Number of Incidents and Corresponding Percentage vs. Incident Type.

releases, regardless as to whether a fire or explosion followed (2 resulted in explosions). Figure 6 shows the number of fatalities associated with each incident type. A key observation from Figure 5 is that most reported incidents (71%) were explosions and per Figure 6, these incidents resulted in the vast majority of reported fatalities (89%). Note that while gas/chemical releases and fires accounted for 18% and 11% of incidents, respectively, these resulted in only 9% and 2% of fatalities, respectively.

Examining the incident data more closely: of the 52 total explosions, 14 were reactor blasts and 10 were dust explosions. The remaining 28 explosions were due to a wide variety of causes such as electric shorts, static electricity spark and equipment malfunction. Several chemicals were involved in the 13 gas/chemical releases, such as ammonia, ethylene oxide, methylene chloride, phosgene, and chlorine. In addition, a nitrogen asphyxiation was reported.

In addition to fatalities, the magnitude of an incident can also be viewed in terms of its impact on the public, beyond the plant boundaries including destruction of nearby businesses and homes. Unfortunately, 20% of the incident descriptions were unclear as to such broader impact. Of the remaining 80% of incidents, 58% reported no such impact, while only 22% (16 incidents) indicated impact beyond the facility's boundary. For the U.S., only two of 16 incidents or 13% had broader impact.

4. Contributing Factors

A key aspect of this study was assessing the contributing factors of incidents to determine which are most prevalent, including which countries most commonly had such shortcomings. Such learnings would focus where steps should be taken by industry to reduce such incidents. For the ten incidents reported by eMARS and one by CSB, thorough incident investigations were performed. While less rigorous, causes were generally available for the eleven incidents from the OSHA database. For other incidents, one must rely on newspaper coverage, which depends on the specific individual(s) interviewed and subjectivity of the reporter. In addition to the 22 incidents with investigations and from OSHA, a

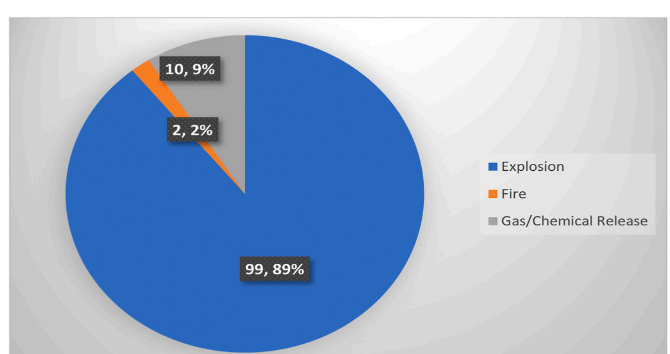

Fig. 6. Number of Fatalities and Corresponding Percentage vs. Incident Type.

best attempt was made to provide the causes for 19 others based on statements by plant personnel, while key causes are not provided for the remaining 32 incidents studied. Thus 56% of incidents were further analysed for factors contributing to the incidents.

Incident descriptions were analysed in terms of a list of 15 contributing factors of chemical processing incidents, as provided in Table 1, along with their definitions. These were developed as part of a companion project examining the causes of process safety incidents across 14 industries, Bhusari et al., 2020. They are referred to as 'contributing factors' rather than 'root causes', since sufficient information is generally not available to ascertain true root causes. It shouldn't be surprising that several of the causes (7) are elements of OSHA's Process Safety Management System (OSHA, 1992), e.g., mechanical integrity, process hazards analysis, operating procedures, training, management of change, work permits and emergency response. Several other causes are prevalent in incidents in developing countries such as safety culture and hazard awareness. The Bhusari paper listed 14 contributing factors, to which a 15th 'safeguards, controls & layers of protection' was added based on this work, being a key deficiency and cause of pharmaceutical incidents.

Figure 7 depicts the contributing factors of incidents that occurred in the U.S., India, China, as well as the eMARS database, where incident locations are not specified. Hazard awareness and identification towers over all other causes, as a significant factor in incidents in India, the U.S. and eMARS. Operating procedures are the second most common cause, followed by design, the latter being particularly prevalent in U.S. incidents. Safeguards, controls and layers of protection, safety culture, and preventative maintenance are the next most common. Other causes follow, and if more were known of many international incidents, regulations and regulatory oversight, training, mechanical integrity, and others to the right of Figure 7 likely played a role in many. In fact, it is often difficult to separate hazard awareness, PHAs, safety culture and safeguards as key factors contributing to incidents when limited information is available. Comparing the figure with the list of 15 causes in Table 1, one may note that only management of change does not appear from the incidents examined. If further details were available about the incidents, one would expect that this played a role in some incidents.

5. Select pharmaceutical process safety incidents

The most well-known pharmaceutical industry incidents are generally explosions, such as those at: Aarti, Yibin Hengda and Qilu Tianhi Huishi plants. As examples, these three incidents will be discussed in further detail, as they are representative of pharmaceutical incidents, in terms of damage and cause. The 2003 West Pharmaceutical incident in the U.S., was thoroughly investigated by the U.S. Chemical Safety Board, but not elaborated on here, since it was due to a dust explosion which occurred in a pharmaceutical rubber compounding operation, unlike most other incidents found in this study which were more closely related to the pharmaceutical manufacturing process.

5.1. Aarti chemical plant explosion (Hindustantimes, 2013; Nair, 2013; News18, 2013)

Aarti Chemical Industries is a leading Indian manufacturer of speciality chemicals and pharmaceuticals. Its pharmaceutical branch is one of India's top 100 drug manufacturers, and mainly produces vitamins, anti-arthritis, anti-fungal, antibiotics, and angiotensin-converting inhibitors. An explosion occurred at its factory at Boisar in the Thane district, Mumbai, India on March 13, 2013. This chemical plant, owned by Aarti Drugs, manufactured methyl nitro imidazole, a chemical used in the production of pharmaceuticals. The incident resulted in five fatalities and 18 injuries. It was reported that the explosion happened during a nitration reaction, as brownish fumes were seen prior to the blast. Some additional minor blasts continued after the fire started. Seven persons, including some senior officers, were charged with culpable

Table 1
List of contributing factors, definitions and descriptions (Bhusari et al., 2020).

No.	Contributing Factors	Definition or Description
1	**Safety Culture**	CCPS defines safety culture as 'the common set of values, behaviour and norms at all levels in a facility or in the wider organization that affect process safety.' A weak safety culture implies lack of leadership, lack of a common understanding of everyone's responsibilities regarding safety, ineffective supervisory oversight, placing production before safety, ineffective safe management systems and not measuring proper personnel and process safety metrics.
2	**PHA**	PHAs (Process Hazard Analysis) use methodologies including but not limited to Checklist, What if, HAZOP (Hazard and Operability) study and FMEA (Failure Mode and Effects Analysis). They are commonly facilitated by the engineering organization, with a team consisting of representatives of operations, engineering, and maintenance. In the US, compliance with OSHA PSM requires they be performed at least every five years.
3	**Mechanical Integrity**	Mechanical integrity expectations are set by senior mgmt. in terms of acceptable level of risk, engineering design standards, and ultimately the need for refurbishment/ replacement as equipment reaches its useful life. The inspection, testing and maintenance of process equipment must consider the hazards and risks of the operations, including such equipment as vessels, storage tanks, piping systems, relief systems, controls, alarms, and emergency shutdown systems. Best practices include a documented mechanical integrity program, written procedures and a schedule for inspections and testing to ensure fitness for use during equipment lifetime.
4	**Emergency and Preparedness Response**	Equipment, processes and training must be capable of handling emergencies such as spills, fires, explosions, hurricanes, and security breaches. Best practices include written procedures, defined teams with clear roles and periodic training and drills, which may include appropriate external parties.
5	**Personnel Training**	Comprehensive program of on the job training (OJT) and informative/technical training of employees and contractors (including supervisors). Program must be documented and include periodic refresher training and assessment of competency.
6	**Operating Procedures**	Written operating procedures aligned with process safety that provide clear step-by-step instructions for safely performing tasks involved in each process. Typically include operating limits, safety and health considerations and safety systems, for multiple operating modes - initial start-up, normal operations, shutdown et al. as noted by OSHA PSM.
7	**Preventive Maintenance**	Preventive maintenance is the periodic inspection of equipment by plant personnel to reduce the likelihood of its failure or performance degradation. This is to ensure the equipment is safe to operate and to fix issues thus preventing major hazards due to equipment malfunctioning.
8	**Management of Change**	CCPS defines Management of Change (MOC) as 'a process to ensure changes do not inadvertently introduce new hazards or unknowingly increase risk of existing hazards.' MOC includes a review and authorization process for evaluating proposed adjustments to facility design, operations, organization, or activities prior to

(*continued on next page*)

Table 1 (*continued*)

No.	Contributing Factors	Definition or Description
		implementation to make certain that no unforeseen new hazards are introduced and that the risk of existing hazards to employees, the public, or the environment is not unknowingly increased.
9	**Work Permit System**	A work permit system is a formal written system used to control certain types of work (e.g., hot work, work at height or confined spaces) that are not part of routine operations and potentially hazardous. The document typically specifies the work to be done and the precautions to be taken to mitigate hazards, typically reviewed and signed off on by site supervision.
10	**Regulations and Regulatory Oversight**	There are a variety of regulations (e.g., OSHA, EPA, DHS) that protect people in and outside the site, as well as the environment. May include periodic regulatory inspections/ audits. While this doesn't directly cause incidents, regulations set a minimum standard for operators.
11	**Design**	Designs should consider RAGAGEP (Recognized and Generally Accepted Good Engineering Practices), reflecting hazards, safety systems and instrumentation. It is often subsequent modifications to the design that lead to the introduction of unintended hazards.
12	**Human Factors**	Human and organizational issues, such as equipment related (e.g., valve location, lighting), sufficient staffing, as well as broader organizational issues. Shortcomings can result in accepted 'normalization of deviance' by operators.
13	**Safeguards, Controls & Layers of Protection**	Insufficient, unreliable or lack of safeguards, such as instrumentation and control hierarchy. Lack of consideration of inherently safer design.
14	**Hazard Awareness and Identification**	It is imperative that day-to-day operations staff identify and resolve workplace hazards. Elements may include a hazard assessment survey of operations, process safety information like safety data sheets (SDS), proper housekeeping for cleaner and safer workplace, equipment and materials, recording incidents and near misses.
15	**Facility Siting**	Proximity of facilities to the public, as well as location of on-site plant personnel to hazards. Considers analysis of consequences of flammable and/or toxic hazardous materials.

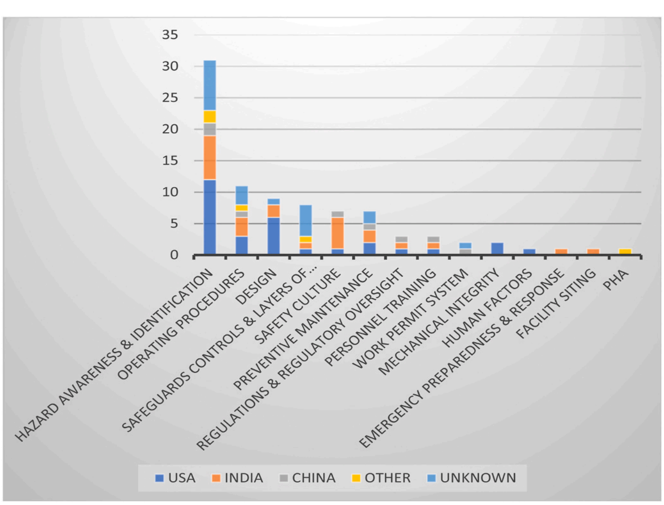

Fig. 7. Number of Incidents vs. Contributing Factors (per country).

homicide for negligence in connection with this explosion. The administrative office where the victims were seated was too close to the 2000 kg chemical tank which exploded. The contributing cause was the rise in temperature inside the chemical tank that was unnoticed. The causes for this incident include a poor safety culture, facility siting, hazard awareness and design based on press reports of the incident.

5.2. Yibin Hengda explosion (Zhiling, 2018; CLB, 2018; Meng and Jourdan, 2018; Yan, 2018)

A series of seven explosions in 10 min occurred at Yibin Hengda Technology Co., a chemical plant in Yibin, Sichuan Province, China on July 12, 2018. Three buildings were reduced to steel frames and windows of nearby buildings were shattered due to the explosions. There were 19 fatalities and 12 others injured. Hengda was started in 2015 and registered as a chemical product manufacturer and distributor. The company makes 300 tonnes per year (tpy) of benzoic acid, which is used in food preservatives, and 2000 tpy of 5-nitroisophthalic acid, for medicines and dyes. According to Sichuan government's investigation report, the owner of the company started construction of the factory in July 2017 without permission from the local government. The Yibin work safety bureau requested they stop and go through the proper application procedure, but the company didn't comply. After the incident occurred, 15 people, including the legal representative, were arrested. The workers lacked basic knowledge of safe operating practices in the chemical industry. A deputy chief reportedly had only studied for three years in an elementary school. The contributing cause of the accident was a worker misplacing unlabelled chemical into a dehydration pool, causing the fire and explosion. The causes of the incident include a poor safety culture, lack of personnel training and certification, hazard awareness, negligence of law, illegal production and regulatory oversight.

5.3. Qilu Tianhi Huishi pharmaceuticals explosion (Palmer, 2019)

Qilu Tianhi Huishi Pharmaceuticals specializes in the manufacture of generic drugs and active pharmaceutical ingredients. On April 15, 2019 an explosion occurred at their chemical plant in Licheng, Jinan, Shandong, China. It was reported that welding of a pipe caused a heat transferring substance to ignite leading to an explosion. This resulted in 10 worker fatalities due to smoke inhalation and 12 others suffering minor injuries. Contributing factors appear to be hazard awareness and lacking work permit system. Further details are not available at this time.

6. Conclusions

Significant effort was extended to develop a database of 73 global process safety incidents. About half of the incidents occurred in developing countries, 38% in India. Unfortunately, explosions were associated with most incidents. The consequences of such incidents can be devastating with one-third of the 73 incidents resulting in multiple fatalities, and five with five or more fatalities. Less severe incidents do not appear to be reported internationally. Sufficient information to assess contributing factors was available for only about half of the incidents and for most incidents rigorous investigations were not complete or available. The majority of incidents were due to hazard awareness & identification, operating procedures, design, safeguards, controls & layers of protection, safety culture, and preventative maintenance.

6.1. Recommendations

The number of incidents and fatalities rises sharply in 2018 & 2019 with 11 incidents (9 international) and 42 fatalities. With many incidents and fatalities occurring in developing countries, one may wonder how many of the companies with incidents market their own products vs. produce for other companies to sell. For the latter, one might question whether further control and oversight should be provided by the companies purchasing these products for sale.

It was a challenging effort to develop the database of incidents shown as Supplemental Information. Readers are encouraged to share additional incidents they are aware of with Dr. Mentzer (rmentzer@Purdue.edu) so the database can be expanded, and learnings potentially enhanced. With the number of fatalities seemingly peaking in 2018 and 2019, the database should be updated every year or two to continue to examine the trends. Additional effort should be extended within the pharmaceutical industry to ensure incidents are being reported, analysed and shared, with increased transparency within the pharmaceutical industry so all can learn from the shortcomings.

Finally, the results from this analysis in terms of contributing factors should be shared within the pharmaceutical industry to encourage steps to prevent or mitigate future incidents. Individual companies should begin with an evaluation of the adequacy of existing processes for the ~6 most common contributing factors identified in this study.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jlp.2020.104279.

Author Statement

Apoorv Kumar began this project as an undergraduate at Purdue, conducting a thorough literature search resulting in ~36 pharma process safety incidents. Maaz Maniar, a student in the Professional Master's Program, then followed up on this work verifying the earlier work and citations and doubling the list of incidents. Both students worked under the direction of Professor Ray Mentzer.

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