DEVELOPMENT OF A MODEL TO MINIMIZE DUST EXPLOSION IMPACTS IN PHARMACEUTICAL INDUSTRY

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ABSTRACT

DEVELOPMENT OF A MODEL TO MINIMIZE DUST EXPLOSION IMPACTS IN PHARMACEUTICAL INDUSTRY

Dust explosion is a major industrial disaster which result catastrophic outcomes if not controlled with necessary enforcements. Various industries which handled powdered materials are associated with dust explosion risk. Food, Tobacco, Plastics, Wood, Paper and pulp, Rubber, Pesticides, and Pharmaceutical are some of the industries associated with dust explosion risk. All the powder types does not responsible for dust explosions though particle size, dimension of particles, moisture content, upper and lower ignition limits, powder resistivity and charge relaxation time of combustible powders has a direct correlation with dust explosions. Dust explosions, initiated with the formation of dust explosion pentagon, which comprises with Combustible dust, Oxidant, Ignition source, Dust cloud and Confinement of dust.

However, the comprehensive literature review reveals that there is lack of studies on dust explosion scenarios, it's impacts, in-depth investigations in to causes and strategies to minimize the impacts of dust explosions in pharmaceutical industry. Therefore, the aim of this research is to develop a model to minimize the dust explosions and its subsequent impacts in pharmaceutical industry. The research objectives were achieved through mixed research approach by using semi structured interviews with experts in pharmaceutical industry and through the direct observations made during the site visit of pharmaceutical plant visits. The data collected during the structured interviews and site visits were collated in to tabulated and graphical mode to create a comparative analysis of three pharmaceutical manufacturing plants belongs to same mother company in three different countries. The findings of the research revealed the risk profiles of three pharmaceutical plants were differentiated with the combustible nature of the powdered raw materials used for each products in plant, quantity of those materials stored at plant and the risk associated with each activity or unit operation. Combustible nature depends on the minimum ignition energy of the material, and quantity of materials stored at plant depends on the batch size, chemical quantity of that particular chemical used for a batch. Finally the risk related to activity depends on the frequency of operation, no of peoples involve for the activity and the nature of the activity and the powder type.

Causes of dust explosions were analysed using the investigations done for dust explosion incidents happened at three pharmaceutical manufacturing plants. Causes identified were categorized in to three causes types immediate, underline and root causes. The root causes which need to be eliminated to prevent the dust explosions were identified as inadequate risk assessments, inadequate housekeeping inadequate training and deficiencies in change management. Failure to eliminate these root causes will effect health and safety, environmental and business impacts which could directly affect to the continuation of business. Impacts of dust explosions in pharmaceutical industries can be controlled through disaster cycle approach which includes prevention, preparedness, response and recovery strategies. A single model which discuss the causes and impacts of dust explosions and the strategies to minimize the impacts of dust explosion using disaster cycle was developed to be used in pharmaceutical industries.

To my Beloved Father

for spending his entire life for position me to this level today

and Dr. C.W.W Kannangara for introducing free education for this country,

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This research was completed with much dedication and full of support and assistance received from many people, who contributed in many ways. I express my heartiest gratitude to each and every individual for their encouragement, values and ideas, assistance and specially their commitment towards this research to make it a success.

First and foremost, I would like to pay my heartiest gratitude to my thesis adviser, head of the department, department of building economics Dr. (Mrs.) Yasangika Sandanayaka, for her gentle guidance, advices and encouragement with her busy work to make this research a successful one.

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Special thanks go to my immediate supervisor Mr. Asanka Palamakumbura for allowing me to do site visits to conduct the expert interviews and to all the expert interviewees, industry practitioners for spending their time to support me to complete a successful data collection by sharing their valuable knowledge with me. Finally, I express my heartfelt gratitude to my family, my batch mates and all others who were with me during this study for giving their utmost support, genuine advices and continuously motivating me to carry out the work successfully.

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ABBREVIATIONS

CSB	- Chemical Safety Board
FMEA	- Failure Mode Effect Analysis
GSK	- GlaxoSmithKline
HAC	- Hazard Area Classification
HAZOP	- Hazard and Operability Study
LOPA	- Layer of Protection Analysis
MIE	- Minimum Ignition Energy
PHIRA	- Process Hazard Identification and Risk Assessment
RCA	- Root Cause Analysis

CHAPTER 01

1.0 INTRODUCTION

1.1 Background

Dust explosion is a major industrial disaster that would result a catastrophic impact if the likelihood of the hazard not controlled adequately. History of recorded dust explosion scenarios goes up to the year 1785 and according to the statistics, since 2012, more than 2000 cases reported globally and most of the reported cases have been occurred in developed countries (Amyotte, Yuana, Khakzad, Khan, 2015). During the period of 1980 to 2005, Chemical Safety Board in United States have collected dust explosion related information of 197 incidents, which reported only in the US. The outcome of these incidents were caused 109 fatalities and 592 injuries collectively (Chemical Safety Board, 2006). Analysis and prevention of dust explosion scenarios are utmost important as, it always operates with highest severity in qualitative risk assessment frameworks.

In the powder industry, a material is announced as a "powder" if the particle size of that material is less than 1000 µm (16 BS mesh size), whereas a material is announced as dust, if the particle size of that material is less than 76 µm (200 BS mesh size)(Tasneem and Abbasi, 2006). All the dust would not create explosions, however the dust only with combustible in nature create explosions. If this combustible dust suspended in air, in the correct concentration, under correct conditions, can become explosible (Tasneem and Abbasi, 2006). Even materials that do not burn in larger pieces, such as aluminium or iron, given the proper conditions, can be explosible in dust form (Occupational Safety and Health Administration US, 2008). When a sufficiently energetic ignition source is present in a controlled volume at a time where combustible dust is suspended can result a dust explosion and the consequences of this explosion often similar to those arising from a gas explosion in terms of impact on people, physical assets and business production (Amyotte and Eckhoff, 2010).

Dust explosion demands two more factors to be linked together to initiate explosion, other than the factors, which initiate fire triangle. That is mixing (of dust and air), and confinement (of the dust cloud) (Eckhoff, 1996). The 'dust explosion pentagon' is formed when these five factors (a) Presence of combustible dust in finely divided form (Fuel), (b) Oxidant, (c) ignition source, (d) mixing of the fuel and oxidant and (e) Confinement of the resulting mixture (Dust Cloud) combined together (Tasneem and Abbasi, 2006).

Consequences of dust explosion, like any other explosion, can be defined as a sudden release of stored energy, resulting in the generation of pressure effects, blast waves and missiles. An explosion results when a fuel ignites within a confined area. On ignition, the flame begins to propagate through the fuel-air atmosphere as a spherically expanding flame front a few millimeters wide but at a speed of 10 ms-1(GSK Technical Manual 707-T1-101, 2003), this not only create catastrophic incidents like fire and explosion, but also the risk of releasing toxic gases, especially in pharmaceutical industry.

Combustible dust is identified in various industries as form of raw materials, by-products and waste (Amyotte, Yuana, Khakzad, Khan, 2015) coal powder in coal mines and wood dust generated as a waste material in the wood industry. Sugar powder and corn powder in food processing industry and powdered chemicals in pharmaceutical manufacturing plants. Dust explosion may result violent chemical reactions that may release toxic gases apart from the high pressures and temperatures generate from the dust explosion (Eckhoff, 2003). Hence, dust explosions involve significant threat not only as fire and explosion risk, but also the health risk to people.

Incidents like Imperial Sugar Company Port Wentworth, Georgia, sugar dust explosion happened in February 7, 2008, killed 14 and 36 injured (CSB, 2006). In Kunshan Zhongrong Metal Products Co, Ltd China, metal powder explosion fire occurred in August 2, 2014 killed 146 people and injured 114. Formosa Fun Coast, New Taipei, Taiwan in June 27, 2015 killed 14 and injured 498 from the incident were some of the very recent cases of catastrophic consequences of dust explosions (Amyotte et al., 2015). The most serious dust explosion incident reported in history was happened in 1942 at China in Liaoning province. This incident resulted 1594 deaths and 246 injuries in a coal mine. (Amyotte et al., 2015).

Depends on the dust explosion sequence, there are two types named primary explosion and secondary explosion. Primary explosion is the initial ignition of the explosive powder due to the creation of dust pentagon (Glaxo SmithKline Technical Manual 707-T1-101, 2003). This initial ignition causes to disperse powders, which are stagnated on environment, initiating the secondary explosion (GSK TM, 2003). Most vulnerable locations where dust explosions can occur in process equipment such as mills, dryers, mixers, classifiers, conveyors, storage silos and hoppers. Secondary explosion depends on various factors such as (a) the primary particle size distribution of the dust, (b) the degree of de agglomeration of the dust particles in the cloud, (c) the dust concentration distribution in the cloud, and (d) the cloud turbulence (Eckhoff, 2008). The elements which required to be combined to develop as a dust explosion is mapped together in one polygon can explained as a dust explosion pentagon. In-order prevent a dust explosion it is obvious that we need to remove either one or more elements from the dust explosion pentagon. (Eckhoff, 2008).

While it is relatively straight forward to prevent or mitigate a dust explosion by simply removing one of the pentagon elements, the field of dust explosion risk reduction is more complex. Ideally, explosion risk is identified and prevented at an early stage of process design, called inherently safer design approach (GSK TM, 2003). Dust explosion risk cannot be completely eliminated in practice. Process design should be done with consideration of layer of protection system with right combination of preventive and protective actions (Amyotte, Pegg, Khan, 2009). Furthermore, some of the process safety risks reduction tools like PHIRA (Process Hazard Identification & Risk Assessment), HAZOP (Hazard and Operability Study), What-if, FMEA (Failure Mode Effect Analysis) and LOPA (Layer of Protection) are being practiced in the industry to maintain the dust explosion risk as far as low that it does not cause any catastrophic consequences (Pekalaski, Zevenbergen, Lemkowitz, Pasma, 2005).

According to the above discussion it is evident that dust explosion is one of the major industrial disasters that would result a catastrophic impact if not controlled adequately using dust explosion risk prevention tools. Many research studies have done globally to identify general conditions, different parameters require for dust explosion and different models, which can be used to prevent dust explosions and to minimize the occurrence of dust explosions.

1.2 Problem Statement

Dust and hybrid-mixture explosions continue to occur in industrial processes that handle fine powders and flammable gases (Abuswer, Amyotte and Khan, 2011). Considerable amounts of researches are therefore conducted throughout the world with the objective of both preventing the occurrence and mitigating the consequences of such events. Although there have been many incidents happened related to dust explosions in global arena, there is only few recorded significant incidents happened in Sri Lanka related to dust explosion incidents. This may be either due to lack reporting or lack of knowledge among the industrial professionals about the dust explosion scenarios. Moreover, there is a lack of studies in dust explosion scenarios and its impacts such as fire and explosion risk, environmental impacts and the health implications in pharmaceutical industry.

Although industrial professionals and researchers have been trying to develop effective measures to assess and to develop effective mitigation strategies for dust explosions in various industries (Abuswer, et al 2011, Amyotte, et al 2009, Amyotte, et al 2015), there is a lack of an in-depth investigation in to causes of dust explosion and strategies to minimize the impacts of dust explosions in pharmaceutical industry. There is therefore a need to investigate the causes of dust explosion and strategies to minimize the impacts of dust explosions in pharmaceutical industry.

1.3 Aim

The aim of this research is to develop a model to minimize the dust explosions and its subsequent impacts in pharmaceutical industry.

1.4 Objectives

Sequential fulfilment of following objectives would reach the above aim.

1. Review of dust explosions and their impacts in powder based industries
2. Investigate the dust explosion risk profile in pharmaceutical industry
3. Examine the dust explosion incidents and their impacts in pharmaceutical industry
4. Analyse the root causes of dust explosion incidents in pharmaceutical industry
5. Propose strategies to minimize dust explosions and its subsequent impacts in pharmaceutical industry

1.5 Research Methodology

A comprehensive literature survey was carried out by referring books, journals, technical manuals, accident investigation reports, scholarly articles and publications to enhance the knowledge on dust explosion scenarios, factors / causes associated with explosions, its impact and the strategies to minimize its impact.

Multiple case studies were analysed in three pharmaceutical manufacturing facilities in Sri Lanka, India and Bangladesh belongs to one parent company. Data collection was done through site visits, observations, reviewing accident investigation reports and archival records and mainly by conducting interviews with the subject matter experts in the selected facilities using a data collection instrument. Data analysis was done using manual content analysis.

1.6 Scope and Limitation

Date collection of this study was limited to Sri Lanka, India and Bangladesh due to lack of pharmaceutical manufacturers in Sri Lanka. Scope was further narrowed down to pharmaceutical manufacturing process from powder sampling point to tablet packing point as they are the most vulnerable operations, which may create dust cloud, leads to an explosion. Non availability of reported dust explosion incidents in local pharmaceutical companies, case selection had to be taken from three pharmaceutical plants belongs to one mother-company.

1.7 Chapter Breakdown

Chapter one of this research dissertations presents a general overview of the dissertation consisting of the research background, aims and objectives and the methodology adopted. It further gives a general guide to the contents of the study. Chapter two mainly focuses on literature findings related to the concept of dust explosion and associated risk. Chapter three explains the research methodology and discusses the analysis method adopted for this study. Chapter four presents the research findings of the case studies and analysis of the result. The chapter further presents the dust explosion risk prevention model for pharmaceutical industry. Chapter five summarizes the findings and provides conclusions and recommendations. Finally, it concludes with the recommendation to further research directions.

1.8 Summary

Dust explosions are industrial accidents with higher severity and lower probability. Combustible dust is identified in various industries as form of raw materials, by-products and waste (Amyotte, Yuana, Khakzad, Khan, 2015) coal powder in coal mines and wood dust generated as a waste material in the wood industry. Sugar powder and corn powder in food processing industry and powdered chemicals in pharmaceutical manufacturing plants. Formation of dust explosion pentagon initiates a dust explosion and there have been many reported incidents in the history, which leads to many deaths and fatalities. Dust explosions happen in pharmaceutical industries not only has in the risk of fire and explosion but also the health risk associated with the release of toxic gases. Hence, studying of this phenomenon is utmost important to pharmaceutical industry.

CHAPTER 02

2.0 LITERATURE REVIEW

2.1 Introduction

Apart from the vapour cloud explosions (VCE) and boiling liquid expanding vapour explosions (BLEVE), dust explosions can identified as the serious explosion hazards in the process industry. (Tasneem and Abbasi, 2006). Apart from serious fatalities, dust explosions almost always lead to serious financial losses in terms of damage to facilities and down time.

All types of powders do not create explosions and it is only the combustible in nature initiate this phenomenon. More than 70% of dusts processed in industry are combustible (Tasneem and Abbasi, 2006). Many materials, which are combustible, can generate a dust explosions. Some of the examples are coal and sawdust. In addition, many mundane organic materials such as grain, flour, starch, sugar, powdered milk, cocoa, coffee, and pollen can also be dispersed into a dangerous dust cloud (Eckhoff, 2003). Powdered metals such as aluminium, magnesium, and titanium can form explosive suspensions in air, if finely divided (CSB, 2006).

There had been serious accidents happened in the past due to the dust explosion scenarios in different industries resulting many deaths and millions of financial losses. Literature review of this research discussed in detail the nature of dust explosion, the land mark cases of dust explosions in history, mechanism, theory and causes behind the dust explosions, the effects of dust explosions in pharmaceutical industry and the prevention of dust explosions.

2.2 Nature of Dust Explosion

2.2.1 The Phenomenon

Sudden release of chemical energy can simply be defined as the explosion, though if scientifically explained, an explosion can be explained as sudden release of exothermal chemical energy at isochoric condition (Eckhoff, 2003). Simply a sudden pressure rise in a controlled volume due to the ignition of combustible dust is known as dust explosion.

2.2.2 The Dust

Materials with particle size less than 1000 µm (16 BS mesh size) are defined as 'powders' as well as particles with diameter less than 76 µm (200 BS mesh size), are referred to as 'dust' (Tasneem and Abbasi, 2006). All the dust would not create explosions; it is the dust only with combustible in nature. As per the OSHA-US definition, a solid material composed of distinct particles or pieces, regardless of size, shape, or chemical composition, which presents a fire or deflagration hazard when suspended in air or some other oxidizing medium over a range of concentrations is defined as combustible material. If such a dust is suspended in air in the right concentration, under certain conditions, it can become explosible. Even materials that do not burn in larger pieces such as aluminium or iron, given the proper conditions, can be explosible in dust form.

A wide verity of dust can be exploded in various industries such as food (e.g., candy, sugar, spice, starch, flour, feed, grain), tobacco, plastics, wood, paper and pulp, rubber, pesticides, pharmaceutical powders, coal, metals (e.g., aluminium, chromium, iron, magnesium, and zinc), provided with necessary conditions (OSHA, 2019).

2.2.3 Dust Explosions

A dust explosion, like any other explosion, can be defined as a sudden release of stored energy, resulting in the generation of pressure effects, blast waves and missiles (Eckhoff, 2003). An explosion results when a fuel ignites within a confined area. On ignition, the flame begins to propagate through the fuel-air atmosphere as a spherically expanding flame front a few millimeters wide but at a speed of 10 m s^{-1}. Ignition of unconfined fuel produces what is described as a "flash fire" (Eckhoff, 2006). There are generally regarded to be two types of dust explosion, primary and secondary, as described below.

2.2.3.1 Primary Explosion

Primary explosions occur when an explosive concentration of dust is ignited within the confine environment. This initial explosion may initiate an explosion in other interconnected components such as mills, ductwork, etc.

As the primary explosion develops, pressure will rapidly increase within the plant items, normally achieving a maximum pressure of 7-10 bar, though this could be greater depending on the specifications of the material (GSK TM, 2003). With this magnitude of pressure, and associated rapid pressure rise, the plant item will need to be a pressure vessel constructed of sufficient strength to retain the pressure and confine the explosion:

- allow the release of the pressure through specifically designed and installed vents which operate at low pressure, typically 0.1 bar;
- have a suppression system installed so as to quench the explosion as it occurs;
- inert the vessel so as to prevent the explosion in the first place, or;
- suffer catastrophic failure to allow the release of pressure directly into the workspace (GSK TM, 2003).

2.2.3.2 Secondary Explosion

If during the explosion, the plant item ruptures due to catastrophic failure, a pressure wave will emerge followed by a cloud of yet unburned powder. Behind this will be the flame front that rapidly consumes the ejected powder. A fireball is formed and ignites any other powder within the environment, which may have been raised into a suspension in the atmosphere from the floor or dislodged from roof trusses or suspended light fittings by the preceding pressure wave, and continues to increase in size while there are sufficient dust and oxygen available to sustain combustion.

In the event of this, fireball occurs within the confines of a room or building, the magnitude of the associated pressure wave, known as a “secondary explosion”, (GSK TM, 2003), will normally be sufficient to cause walls, ceilings and windows to be blown out. In extreme cases, more serious structural damage is liable to occur. The room/building in which the secondary explosion occurs effectively becomes the vessel, like that in the primary explosion.

In factories, it is the effect of this pressure wave directly on employees, or via debris from damaged plant and buildings, which results in the vast majority of injuries and deaths when dust explosions occur (CSB, 2006).

It has been identified that it takes only a very small dust layer to provide sufficient fuel in the atmosphere, if sufficiently disturbed, to enable a secondary dust explosion to occur. As an example, it only requires a 1-mm layer of dust, typically with a bulk density of 500 kg m^{-3}, to create a flammable dust concentration of 100 g m^{-3} to a height of 5 m above the floor or surface level (GSK TM, 2003).

It is therefore of crucial importance that good housekeeping is applied to eliminate the risk of dust becoming involved in secondary explosions. Fortunately, within the healthcare industry, the standard of housekeeping in relation to dust deposits is excellent, if only by the very nature of legislative constraints on the manufacture of these healthcare products.

2.3 Significance of Dust Explosion Hazard

Dust explosion is a major industrial risk where its history of reported occurrence scenarios goes up to the year 1785 and according to the statistics, since 2012, more than 2000 cases reported globally and most of the reported cases have been occurred in developed countries (Amyotte et al., 2015).

Any combustible dust dispersed into the atmosphere has the potential to explode when:

- the combustible dust is dispersed in sufficient concentration to ensure the minimum explosive concentration is reached;
- the particle size of the dust is fine enough to enable flame propagation to occur;
- sufficient oxygen is present to support combustion;
- an ignition source is present (GSK TM, 2003).

Pictorial interpretation of above mechanism can explain as the dust explosion pentagon shown in Figure 2.1.

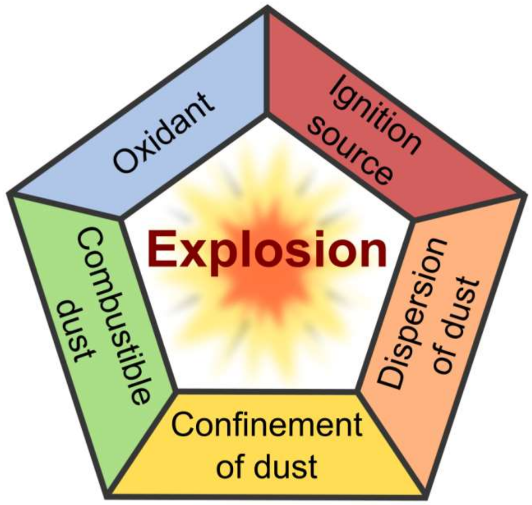


Figure 2-1 Dust Explosion Pentagon

If further elaborates, in order to initiate a fire, three elements should be combined together, that is oxygen, flammable material or fuel and ignition source. That is been announced as “fire triangle”. in-order to extend this further to a dust explosion, it requires two more factors to be combined with fire triangle that is dis and the confinement of dust. Hence the following five factors together is called as the “dust explosion pentagon”(Tasneem and Abbasi, 2006)

- Combustible dust,
- Ignition source,
- Dispersion of dust,
- Confinement of dust, and
- Oxidant.

2.3.1 Statistical Records of Dust Explosions

An illustrative list of dust explosions as demonstrated by Tasneem and Abbasi (2006) is given in annexure I. The statistical evidences in annexure I has proved at least one dust explosion incident have occurred in each year at industrialized countries.

2.3.2 Landmark Cases of Dust Explosions

As discussed above, there had been many industrial disasters occurred due to the dust explosion. Below are some of the landmark cases, which announced as black marks of the world history.

a. Imperial Sugar Plant Explosion

On February 7, 2008, at about 7:15 p.m., a series of sugar dust explosions occurred at the Imperial Sugar manufacturing facility in Port Wentworth, Georgia. As a result of this explosion 14 employees encounted with fatal injuries. Eight workers died at the scene and six others eventually capitulated to their injuries at the Joseph M. Still Burn Centre in Augusta, Georgia. This explosion resulted 36 workers with serious burns with permanent injuries and some could not return back to work due to their injuries. (CSB, 2008).

b. West Pharmaceuticals Explosion

On 29 January 2003, USA based west pharmaceutical (Kinston, NC) experienced a fire and explosion situation due to polyethylene dust. This explosion resulted 6 employees to their death and 38 others were injured. Two fire-fighters were among those killed. The impact of the massive blast spread over a large area and the suspended material due to the initial blast triggered secondary explosion which impacted around a large area of about 2 miles away. An unidentified reason has caused dust to become airborne above a suspended ceiling and an ignition source appeared in that area has led to this catastrophic event (Tasneem and Abbasi, 2006).

c. CTA Acoustics Manufacturing Plant Explosion

Seven workers were critically injured due to the fire and explosion incident occurred at Corbin, KY, in USA, On 20 February 2003. This dust explosion was occurred in a CTA Acoustics manufacturing plant and reason was identified as the resin dust, which was accumulated in production line, ignited during the cleaning activity. A thick dust cloud appeared due to the cleaning activities were ignited from the flames erupted in an open door oven. The resulting explosion travels through the plant causing secondary explosions, removing powdered resin dust from the surfaces and adding to the airborne fuel filler. (Frank, 2004)

d. Zhongrong Metal Production Company Explosion

On 2 August 2014, an explosion took place at Zhongrong Metal Production Company in Kunshan City, China causing 75 workers were killed and 185 were injured. The reason for explosion was investigated as the spark arising in the metal dust filled room and the metal powder had ignited to cause the explosion.
Photographs of above incidents are shown in Figure 2.2.

	
Imperial Sugar Plant Explosion	**West Pharmaceuticals Explosion**

	
CTA Acoustics Manufacturing Plant Explosion	**Zhongrong Metal Production Company Explosion**

Figure 2-2 Landmark Cases of Dust Explosion

2.4 Impacts of Dust Explosions in Powder Based Industry

More than 70% of dusts processed in industry are combustible (Tasneem and Abbasi, 2006). This implied significant portion of powder based industries have inherent risk for dust explosions. CSB has reported more than 2000 dust explosion incidents during past 200 years and it is evident that significant portion of dust explosions are in food processing industry. Dust explosions not only impacts to the health and safety of people, but also it negatively impacts on environment, business and society where industry operates.

2.4.1 Powder Based Industries at Risk of Dust Explosions

Factories, which associated with dust explosion hazard were divided into following industries manufacturers of food products, manufacturers of wood and wood products, manufacturers of metal products, manufacturers of rubber and plastics products, manufacturers of textiles and other products, the mining of coal and lignite including the mining of metal ores, other mining and quarrying, warehousing, electricity suppliers. According to the International Standard Industrial Classification of All Activities (United Nations, 2008. Figure 2.3 summarizes the explosions in various industry types in percentages and figure 2.4 summarizes the types of powders related to dust explosions.

2.4.2 Impacts of Dust Explosion to Health and Safety of People

Impacts of dust explosions as always categorized as a high severity situation in risk assessments due to the irreversible occurrences that may happen to the people near-by. Reviewing Table 2.1, it is evident that all the incidents happened has ended up with either death or fatal. Pressure waves generate as a result of dust explosion could spread, can kill the people around and collapse the structures, where the explosions happen. Generation of hazardous and toxic vapour created as a result of burning of different chemicals, initiated from the explosion can impact to the entire society where the operation exits. Specially in pharmaceutical industries where different types of active pharmaceutical ingredients are used can result significant impacts when the physical properties of those chemicals changed due to the high pressure and temperatures arise as a result of dust explosions.

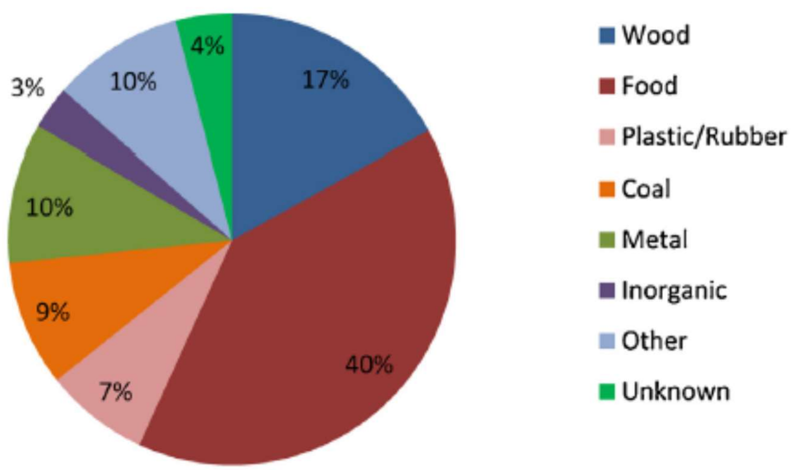


Figure 2-3 Dust Explosions Related to Various Dust Types

Source: United Nations, 2008

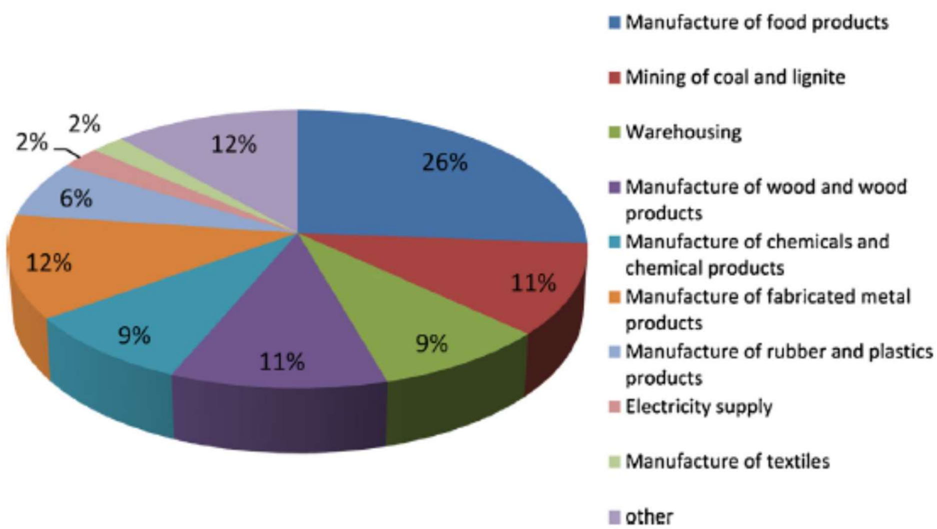


Figure 2-4 Dust Explosions Incidents Related Various Industries

Source: United Nations, 2008

2.4.3 Impacts of Dust Explosion to the Business

Dust explosion incidents happen in powder based industry can affect to the business in two ways that is, directly and indirectly.

Direct impacts can be:

1. Loss of lives or fatal injuries to employees belongs to the company would create legal prosecution and stoppage of business.
2. Critical damage to the buildings, structures and operations would result significant time to recover the business
3. Damage to the products, employee morale and the costs associated with recovery.

Indirect impacts can be:

1. Loss of reputation, market share and shareholders due to the incident
2. Loss of employee morale would result the reduction of productivity, profit and reduction of new employee affection to the business etc.
3. Loss of customer good will, damage to public image and business reputation

(HSE-UK, 2010)

Repercussions of the dust explosions sever to a small scale business as it might result the shutting down of business due to its inability to recover from the damage. Hence it is utmost important for all the powder based industries to identify the importance of preventing dust explosions by introducing necessary controls to the business.

2.5 Causes of Dust Explosions

Causes of dust explosion can simply be explained as combination of dust explosion pentagon or allowing the elements of dust explosion pentagon to form though in theory there are various factors which can influence the dust explosions.

2.5.1 Dust and Dust Cloud Properties to Influence the Explosions

A variety of parameters related to the characteristic of the material and its environment can influence the sensitivity of the material to various sources of ignition. These parameters can also affect the characteristic of the dust explosion following ignition (Eckhoff, 2003).

2.5.1.1 Combustibility

The first stage in the assessment of dust explosion hazards is to identify whether the material has, or has not, the ability to explode as a dust cloud. A material that is capable of producing a dust cloud that can propagate flame or combustion has been variously described as "flammable", "explosible", or "Group A". Those that cannot exhibit this characteristic have been described as "non-flammable", "non-explosible", or "Group B" (GSK TM, 2003).

The most widely accepted convention, and that preferred by GSK, is classification into Groups, in which:

Group A – Explosible dusts – comprises those that ignite and propagate a flame away from an ignition source;

Group B – Non-explosible dusts – comprises those that do not propagate a flame away from an ignition source;

(GSK TM, 2003)

It should be noted that this convention is only applicable up to an ambient temperature of 110°C. Within general industry, whilst a very large proportion of dusts handled are recognised as being in Group A, there are a substantial number classified as Group B. However, within the pharmaceutical industry, it is almost exclusively Group A dusts that are handled. The occurrence of a Group B dust is viewed very much as the exception (GSK TM, 2003).

2.5.1.2 Particle Size

One of the major factors influencing the course of a dust explosion is the particle size, which can vary greatly within a sample of a particular material. Any solid material that can burn in air will do so with a speed and violence that increases with continuing sub-division of the material. This is because heat transfer and combustion during an explosion take place at the surface of the particle (Tasneem and Abbasi, 2006).

For example, a piece of wood once ignited burns slowly, releasing its heat over a long period of time. When it is divided into small pieces, the combustion rate increases, because the total contact area between the wood and air has been increased as shown in Figure 2.3. Further, the ignition of the wood becomes easier in the divided condition (Eckhoff, 2003).

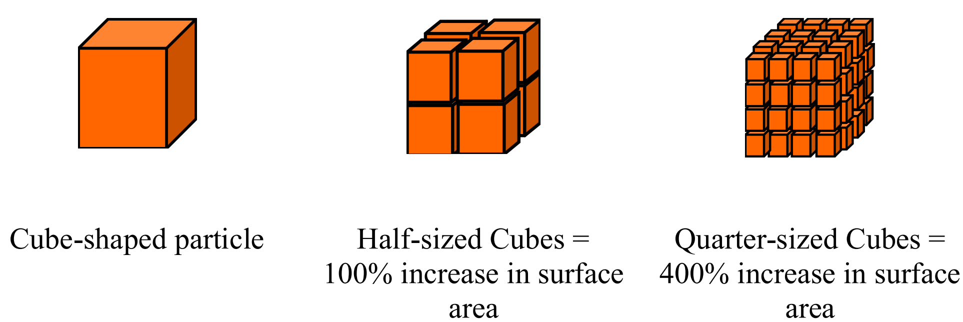


Figure 2-5 Increase of Surface Area with Subdivision

Therefore, as the particle size decreases, the maximum explosion pressure and rate of pressure rise (K_{st}) or $\left(\frac{dP}{dt}\right)_{max}$ will increase while the Minimum Ignition Temperature (MIT) and Minimum Ignition Energy (MIE) will decrease (Eckhoff, 2003). For example, the maximum rate of pressure rise of a polythene dust explosion increases from 150 bar s^{-1} to greater than 400 bar s^{-1} when the mean particle size is reduced from 100 μ to 25 μ. Explanation of above terms described in below Table 2.1

Table 2-1 Important Parameters Related to Dust Explosions

Source: Amyotte and Eckhoff (2009)

Parameter	Typical units	Description	Risk component addressed	Example test methodology	Example industrial applications (Figure 1)
P_{max}	bar(g)	Maximum explosion pressure in constant-volume explosion	Consequence severity	ASTM E1226-05	Containment, venting, suppression, isolation, partial inerting
$(dP/dt)_{max}$	bar/s	Maximum rate of pressure rise in constant-volume explosion	Consequence severity	ASTM E1226-05	As per P_{max}
K_{St}	bar m/s	Volume-normalized (or standardized) maximum rate of pressure rise in constant-volume explosion	Consequence severity	ASTM E1226-05	As per P_{max}
MEC	g/m^3	Minimum explosible (or explosive) dust concentration	Likelihood of occurrence	ASTM E1515-07	Control of dust concentrations
MIE	mJ	Minimum ignition energy of dust cloud (electric spark)	Likelihood of occurrence	ASTM E2019-03	Removal of ignition sources. Grounding and bonding
MIT	°C	Minimum ignition temperature of dust cloud	Likelihood of occurrence	ASTM E1491-06	Control of process and surface temperatures (dust clouds)
LIT	°C	Minimum ignition temperature of dust layer or dust deposit	Likelihood of occurrence	ASTM E2021-06	Control of process and surface temperatures (dust layers)
MOC (LOC)	volume%	Minimum (or limiting) oxygen concentration in the atmosphere for flame propagation in dust cloud	Likelihood of occurrence	ASTM WK1680	Inerting (with inert gas)

The converse is also true. Since the dust must be capable of being suspended in the air at the moment of ignition if an explosion is to occur, the larger the particles the less likely they are to become airborne. Also, as the particle size increases, the quicker they will settle and hence decrease the risk of a dust explosion occurring.

2.5.1.3 Particle Dimension

The degree of sub-division of a solid is normally expressed in terms of the particle size. However, since the speed and violence of an explosion is a function of the available surface area in contact with the air, the physical dimension of the particles will also influence the propagation of the explosion (Eckhoff, 2008*)*.

If a cubic particle of unit volume is sub-divided into eight cubes of half the linear dimension of the original cube, the total surface area has doubled, which indicates that the so-called "specific" surface area of the subdivided material open to the air is simply the reciprocal of the linear dimension of the cube. This concept can be generalized to define a "specific surface area", *S*, which is the total surface area of a collection of particles each of linear dimension *x* and together totalling unit volume. The dimension *x* varies according to the shape of the particle as shown in Table 2.2

Table 2-3 Calculating Specific Surface Area

Source: GSK TM (2003)

Shape of Particle	Dimension *x*	Specific Surface Area *S*
Cubic	Length of side	$S = 6/x$
Spherical	Diameter	$S = 6/x$
Flake (thickness much smaller than the length and breadth)	Thickness	$S = 2/x$
Fibrous (large length-to-diameter ratio)	Diameter	$S = 4/x$

As the particles get smaller, inter-particle forces play an increasingly important role in the suspension of dusts compared with gravitational forces. In a given practical situation, the dust in a dust cloud may not necessarily be dispersed into the small individual primary particles, but rather into larger agglomerates, or lumps. The effective particle size will therefore be larger and the effective specific surface area smaller than if the primary particles had been completely dispersed (Sanchirico, Russo, Sarli, Benedetto, 2014).

2.5.1.4 Moisture Content

The moisture content of the dust can have a significant effect on the sensitivity to ignition and severity (violence) of a dust explosion. As the moisture content of the dust increases, the severity (violence) of the explosion decreases until the point is eventually reached when the dust is no longer explosible (Eckhoff, 2003).

A general guide to the potential effects of various moisture contents is as follows:

0–5%	little observed effect;
5–10%	decrease in sensitivity;
10–25%	significant decrease in sensitivity;
>25%	the dust is unlikely to be held in suspension. (GSK TM, 2003)

Although the sample must be representative of the expected lowest moisture content if it is to avoid unrealistic data being produced, it is important when classifying dusts that tests are not performed on over dried material (Eckhoff, 2006) on samples containing less than the minimum moisture content found under the expected process conditions.

In processes where the moisture content can be closely defined, explosibility testing to determine the sensitivity under process conditions should be carried out using a sample representative of the minimum moisture content found in the process (Abuswer, et al 2011).

2.5.1.5 Lower Explosive Limit

The Lower Explosive Limit (LEL) also known as the Minimum Explosible Concentration (MEC) is defined as the lowest concentration of suspended dust capable of propagating flame. Therefore, when the amount of dispersed dust is below this concentration, an explosion cannot be propagated (Tasneem and Abbasi, 2006)

The LEL or MEC for many materials has been measured and is typically in the range of 10–500 g m^{-3} and is usually above 40 g m^{-3}. The effect of dust concentration on the explosibility of a dust cloud is shown in figure 2-4 (GSK TM 2003).

Above the LEL, the explosion violence of the dust cloud increases as the dust concentration increases, until an optimum concentration is reached giving the highest explosion violence; this concentration is usually well in excess of the amount of dust theoretically required to react with the available oxygen (Hassan, Khan, Amyotte, Ferdous, 2013).

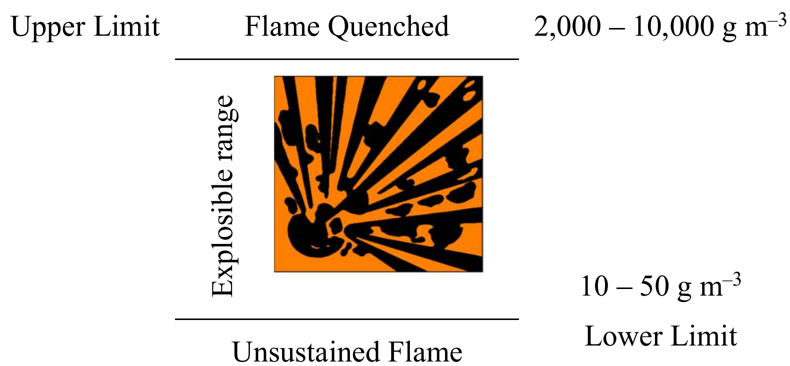


Figure 2-6 Effect of dust Concentration on the Explosibility

Source : (GSK TM 2003).

As per the GSK technical guidelines, safety is based on preventing the formation of a flammable atmosphere by keeping the concentration of dust below its LEL, it is normal to use a large safety factor because of the in-homogeneity of dust clouds. A figure of 25% of the LEL is normally used, i.e. for most dusts; the dust concentration should be kept below 10 g m^{-3}.

Although this may seem to be a very low concentration, it does have the appearance of a very dense fog with visibility in the region of 1 m. It should be appreciated that this concentration is also much higher than that associated with toxic hazards or nuisance problems.

2.5.1.6 Upper Explosive Limit

At high dust concentrations, significantly above the LEL, the explosion violence either decreases or stays roughly constant until a concentration is reached above which an explosion cannot be propagated the Upper Explosive Limit (UEL) (*GSK TM, 2003).*

The UEL for a dust is very difficult to determine and not well defined. These values, when measurement is attempted, are normally of academic interest only and in practice dust settles out from dense clouds under gravity and the dust concentration then enters the flammable range. For all practical considerations, dust concentrations considered to be above the UEL should be treated as potentially hazardous (*GSK TM, 2003).*

2.5.1.7 Limiting (Minimum) Oxygen Concentration

A dust cloud will explode only if the atmosphere in which it is dispersed contains sufficient oxygen (or other oxidant) to enable combustion to occur. The most violent explosions occur when the proportion of oxygen present is close to that required for complete combustion of the dust. As the oxygen concentration in the atmosphere containing the dispersed dust is reduced, the severity of the resulting explosion will decrease, until no explosion takes place.

The Limiting Oxygen Concentration (LOC) or Minimum Oxygen Concentration (MOC) required to support a dust explosion depends on the chemical nature, particle size and moisture content of the dust and the operating temperature of the process. Normally the values of Limiting (Minimum) Oxygen Concentration are between 3 and 15% v/v, though should be determined experimentally if inerting is to be used as the basis of safety. The test value must be corrected to allow for variations in temperature and pressure. The LOC should be reduced by 17% for every 100°C temperature increase above 0°C up to 200°C. Thereafter, the LOC should be reduced by a further 12% for every 100°C increase. The influence of pressure changes is unpredictable. Therefore, it is recommended that where possible the LOC should be established at operating temperature and pressure.

2.5.1.8 Powder Resistivity

The electrical resistivity of a powder determines the rate at which the powder, if charged, will lose its charge by conduction processes to any earthed (grounded) surface with which it is in contact. It tends to be high-resistivity powders that cause most electrostatic problems during processing. Resistivity is expressed in Ωm and its magnitude is generally assessed as follows:

$>10^9$Ωm	High-resistivity powders
10^6–10^9Ωm	Medium-resistivity powders
$<10^6$Ωm	Low-resistivity powders

Powders with a resistivity greater than 10^9Ωm are those likely to generate significant amounts of charge during handling, propagated (Tasneem and Abbasi, 2006) and have a long charge relaxation time. They are therefore more likely to produce electrostatic discharges and hold accumulated charge, with the risk present for some while, from several minutes to several days in the case of some highly insulating powders. A powder with a combination of high resistivity and low MIE can be particularly hazardous (Eckhoff, 2008).

The majority of powders handled in industry have a resistivity of greater than 10^8Ωm in the dry state. However, the resistivity can be significantly influenced by impurities that are normally absorbed on the surfaces of particles, especially moisture propagated (Tasneem and Abbasi, 2006).

In some instances an increase in moisture content of only a few percent can decrease the resistivity by an order of magnitude or more. This could be sufficient to produce a powder displaying conductive properties from one that would normally be of low conductivity in the dry state.

It is particularly important that good earthing (grounding) techniques are used to:

- Earth every conductor to prevent otherwise electrically isolated conducting parts accumulating charge;

- Assist with the dissipation of charge from a charged powder (*GSK Technical Manual 707-T1-102, 2003).*

2.5.1.9 Charge Relaxation Time

This is the time for the electrostatic charge on an object to relax by conduction to 1/*e*, or 0.37 of its initial value. Charge relaxation from a material in contact with an earthed (grounded) conductor takes place in an approximately exponential manner. The time is normally expressed in seconds but it should be appreciated that for some materials the relaxation time is appreciable and it is easier to express it in hours. Normally the longer the charge relaxation time the greater is the risk of generating electrostatic sparks.

The charge relaxation time measured for powders of various resistivity may range from several days or weeks in the case of insulating powders, such as plastics with resistivity 10^{14}–10^{16} Ωm, to milliseconds for conductive powders of resistivity less than 10^{6}Ωm.

The value for charge relaxation time can also be calculated from the material resistivity and dielectric constant (when known) using the following equation:

$$t_r = e_0 \, e_r s_v$$ where:

e_0 is the permittivity of free space

e_r is the dielectric constant

s_v is volume resistivity

(GSK TM, 2012)

2.5.2 Ignition Source

The most important requirement in either fire or explosion is ignition source. These ignition sources differ in terms of temperature, energy and power. Ignition sources, as an essential element of dust explosions, are divided into eight types: flame and direct heat, hot work, electrical sparks, static electricity, impact sparks, self-heating and smoldering, friction sparks, and hot surfaces (Tasneem and Abbasi, 2006).

2.5.3 Confinement of Dust Cloud

When the dust cloud is confined within a closed area, even as huge as a warehouse or factory, it can create required confinement to develop to a dust explosion. Dust particles can be spreaded in confined air for days, causing the increased dust particles to create high density dust cloud. When the dust cloud combusts, the confinement will cause powerful pressure to build and travel the explosion through every corner of the facility. Confined dust explosions have had the power to lift roofs from buildings or buckle solid concrete floors (OSHA-US).

Imperial Sugar dust explosion occurred at Port Wentworth, confined the push of explosion through tunnels and halls that led it to other confined dust clouds (CSB, 2008). This was happened due to the chain reaction of combustions, destroying the building and claiming several workers' lives.

2.5.4 Dispersion of Dust

Dispersion of dust is occurred when the accumulated dust is spread out over the air to create a dust cloud. Reason of dust dispersion may due to the daily activities such as sweeping, exhaust from machinery, or cleaning using compressed air. These activities may disturb accumulated dust and send it airborne to create the dispersion. Another cause of dust dispersion is due to the occurrence of small primary explosion and travel of shockwaves throughout the facility. These shockwaves can suspend the dust that had settled on rafters, pipes or HVAC ductwork and spread it throughout the air. Once this dust is dispersed, it can change from the initial fire to a huge explosion within a very short period.(GSK TM, 2003)

Controlling the dispersion of dust or preventing it suspended in air can stop the formation of explosion pentagon and this can simply be achieved through clean any accumulated dust to prevent it from having the possibility of becoming dispersed. A dust extraction system can be used to prevent large build ups of dust though these systems need to be properly cleaned and maintained to have necessary suction because the dust within these systems can ignites easily, and creates a fire that is difficult to control and extinguish.

Apart from the following the NFPA combustible dust protocols, maintaining the cleanliness of the facility in professional manner is much important as it helps to remove the fuel from the explosion pentagon and that would help to prevent the occurrence of man-made industrial disasters.*(NFPA guideline, 2008).*

2.6 Control, Prevention and Mitigation of Dust Explosions

Dust explosion can be announced as an industrial disaster. Any disaster situation in generally can be prevented in three ways: (i) inherent safety, (ii) engineered safety (passive and active), and (iii) procedural safety engineered.(Amyotte, Pegg and Khan, 2009)

2.6.1 Inherent Safety

Professor Trevor Kletz was announced as the father of process safety and inherent safety is a concept he proposed in the late 1970s in his Jubilee Lecture. This was first anounced as ”what you don't have, can't leak” one of his lectures done to the Society of Chemical Industry in Widnes, UK (Kletz, 1970). That concept of inherent safety pave the way to many safer designs in process industries. The subject inherently safer design was later used in many research publications and review papers in the subject area. Key principles that discussed under the inherent safety design can be summarized in,

2.6.1.1 Minimization

Reducing the occurrence of dust explosions can be achieved through following steps,

- Evading the formation of dust cloud.
- Maintaining the dust handling operation below the minimum explosible concentration if possible).
- preventing the deposit of dust layers (avoidance of dust layers). The effectiveness of good housekeeping for dust explosion minimization is discussed in detail by Frank. (Frank W, 2004)

2.6.1.2 Substitution

Substitution is the second best method to prevent the occurrence of dust explosions by replacing the high risk combustible materials with less risky ones. Some of the methods that can be applied are,

- Substituting the work procedures (e.g., instead of daily sweeping the process areas use of an explosion- proof vacuum cleaner to remove dust accumulations).
- Introducing dense-phase pneumatic transport systems to transfer the combustible powder instead of bucket elevators and other mechanical conveying systems.
- Substitution of static generating process hardware with less hazardous materials of construction (e.g., avoiding unnecessary use of insulating materials).
- Substitution of processing method which handled explosible powder (e.g., one of the ways this is been done is introducing of an inert powder that is a part of the final product).
- Substitution of the hazardous material (i.e., explosible powder itself). Feasibility of substituting explosive powder should be assessed in detail as the explosible powder is the desired product. *(Paul R. , 2009)*

2.6.1.3 Moderation

Moderation method of minimizing the occurrence of dust explosion is by altering the physical properties of particles or mixture. Some of the methods can be,

- Blending of solid inerts' to alter the composition of a dust.
- Increase of particle size would decrease the reactivity as well as the specific surface area and that would reduce the heat transfer through the powder.
- Avoiding the formation of hybrid mixtures of explosible dusts and flammable gases.
- maintaining the appropriate distance between the separate unit operations (Amyotte and Eckhoff, 2010)

2.6.1.4 Simplification

Simplification of the process through design, can achieved,

- Introducing the error tolerance design factors to process equipment to make them robust enough to withstand process deviations and other undesired events (e.g., shock-resistant design).
- Information on the hazardous properties should be simplified and make it clear for the employees who handled them. (Amyotte and Eckhoff, 2009)

2.6.2 Procedural Safety

Although there is a robust human component to the formerly explained parts in the hierarchy of controls, it is human beings who design, fabricate and install safety devices. The level of procedural safety is defined by the one in which the success or failure of a safe work practices or performance of factory employees. When the hierarchy of controls being considered, the procedural safety places the bottom most level as it associated with human error; this fact must be recognized and managed by comprehensive consideration of the human factors involved in performing a safety-oriented task (Amyotte and Eckhoff, 2009).

2.6.3 Active Engineered Safety

Active add-on devices are defined as the equipment which activated as a result of some degree of detection or activation of fire or smoke situation to perform their desired safety function. Reliability of these devices depends on the class of the device as well as the proper maintenance and testing to facilitate their reliable performance apart from the adequate design and manufacturing, these devices. Demand for active engineered procedures is purposefully intermittent, and there is thus a strong requirement to limit the probability for failure when they are needed. Examples here would include automatic dust explosion suppression systems and mechanical isolation valves, both of which employ detectors and actuators in addition to the actual safety device (suppressant-filled canister and metal plate, respectively). Depends on the method of application, inerting of powder is considered as the dust explosion prevention/ mitigation method that could be identified as either inherent or active engineered safety. As previously specified, inclution of an inert solid to an explosible dust so as to reduce the resulting mixture non-explosible, is an example of the inherent safety principle of moderation albeit through the procedural measure of adding the inert material (Amyotte and Eckhoff, 2010)

2.6.4 Passive Engineered Safety

Passive add-on devices, if adequately designed, manufactured and fitted for service, will accomplish their defined safety function merely by their presence. Passive device would not require any initiation or actuation (e.g., dust explosion overpressure) to fulfil its intended role. Explosion relief venting would fall in this category and, is designed with low strength material to relief or purposefully transfer the pressure through this vent in case of any event of explosion. (Amyotte, et al 2015).

2.7 Disaster Management Cycle Approach

Impacts of dust explosion is a disasters event which affect to health and safety of employees of a company, society and the business itself. As per Shaw, Pulhin and Pereira (2010), disaster is sudden, extreme and un-humane event to individual, animal and plant. Additionally, it is important to understand that catastrophe can be as a result of natural and also purpose by means of human movement. Dust explosion is a man-made disaster event that could control with adequate measures being taken.

Disaster management is an integrated process of planning, organizing, coordinating and implementing measures that are needed for effectively dealing with its impact on people (Ho Oh, Deshmukh, & Hastak, 2010). The disaster management cycle illustrates the ongoing process by which various stakeholders in a society plan for and reduces the impact of disasters, react during and immediately following a disaster, and take steps to recover from the impact (Clerveaux, Spence, & Katada, 2010). The disaster management cycle is a comprehensive program which can be used to reduces the impact of disasters, react during and immediately following a disaster, and take steps to recover from the impact (Clerveaux et al., 2010). Figure 2-7 shows the disaster management cycle which broadly classifies disaster management efforts into pre-disaster risk reduction and post disaster recovery (Pathirage, Amarathunga, Senevirathna and Haigh, 2016)

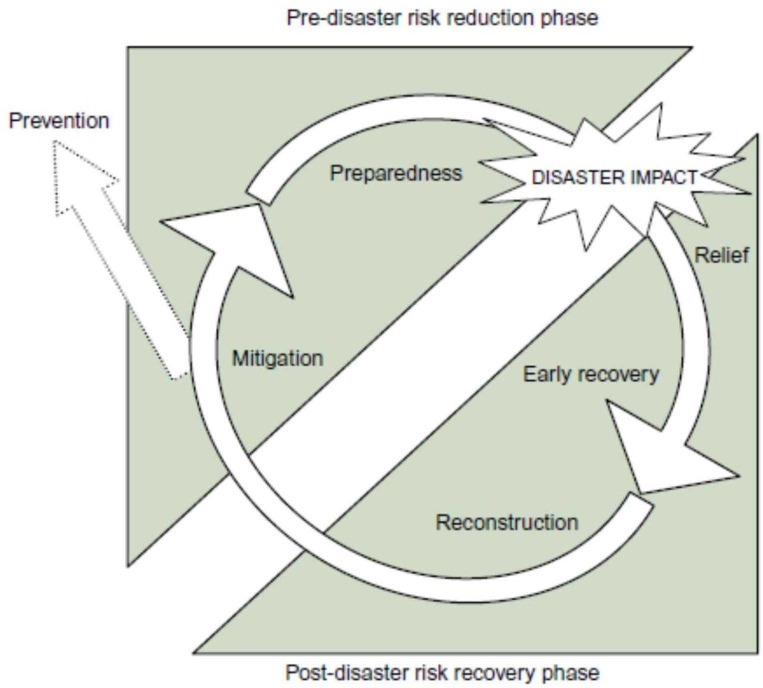


Figure 2-7 Disaster Management Cycle Approach

Source: Pathirage, Amarathunga, Senevirathna, and Haigh, 2016

2.7.1 Disaster Management Cycle Strategies

Disaster management cycle is a conceptual model which can be practiced as a pre-disaster risk reduction or as a post disaster recovery depends on the disaster type encounter. As per Amarathunga, et al (2016) key phases of disaster management are identified as mitigation, preparedness, relief and long-term reconstruction. Identification of comprehensive action plan for each element of the disaster management cycle can explain as disaster cycle strategies.

Mitigation strategy is developed for post disaster recovery though for the disasters which have not occurred yet, preventive strategies are used. One of the key strategies in the disaster cycle for prevent the occurrence of disaster can be explained under the preventive element. Dust explosion is a major industrial disaster that need to be prevented. The preventive actions introduced and implemented by industries to prevent the occurrence of dust explosions can be explained as preventive strategies.

Emergency preparedness plans developed to face a disasters situation is a preparedness strategy. This is equally important to minimize the impact of a disaster specially in catastrophic disasters like dust explosions. Predicting the possible disaster situations and prepare to face the disaster through pre-identified strategic plan is a preparedness strategy.

Response and recovery strategies are launched as post disaster activities to control the propagation of disaster and to quickly reinstate and recover from the disaster. Hence, this 4 disaster cycle strategies, prevention, preparedness, response and recovery elements were utilized to develop the conceptual model to minimize the impacts of dust explosions in pharmaceutical industry.

2.8 The Conceptual Model

The conceptual model shows the gaps and research problem to be fulfilled through this research in graphical manner by summarizing facts identified in the literature review. As per the historical cases by Tasneem and Abbasi (2006) and incident investigations by CSB (2008), dust explosion incidents can be categorized as a man made dsaster. Impacts of dust explosions described in section 2.4 can be minimized by correct identification of causes of dust explosions described in section 2.5. Identification of strategic plans for all the disaster cycle eliments of prevention, preparedness, response and recovery would benefit to pharamaceutical industries to prevent the dust explosion incidents and immediately recover incase of a disasters dust explosion event.

Figure 2-8 The Conceptual Model

The above conceptual model presented in Figure 2-8 will be used as the basis in empreical investigation in achieving aim of this study.

2.9 Summary

Recorded history of dust explosions goes back over 200 years, occurred in different industries. Chemical Safety Board – US has investigated large scale dust explosion incidents occurred around the world and explained their efforts to understand the causation, prevention and mitigation of dust explosions.*(CSB, Combustible Dust Hazard Study, 2006)*. While the 70 percent of powders handled in the industry is associated with explosion hazard, the risk of dust explosion is explained as the multiplication of likelihood and severity. Studies explained a number of important explosibility and ignitability parameters of dust clouds which influence the dust explosions. These include the,

(i) Maximum explosion pressure and maximum rate of explosion pressure rise in standardized closed-vessel tests
(ii) Minimum explosible dust concentration,
(iii) Minimum (limiting) oxygen concentration of the atmosphere for flame propagation,
(iv) Minimum ignition energy,
(v) Minimum dust cloud ignition temperature.

In addition, understanding the minimum ignition temperatures of dust types and dust deposits for numerous layer thicknesses and deposit volumes is significant to prevent open and smouldering dust fires. A dust explosion occurs due to the combination of five factors that is an **explosible, dust cloud** which act as the fuel, adequately mixed with **oxidant** in a **confined or partially confined environment** and ignited by a sufficiently energetic **ignition source**. This explosion may initiate as either primary or secondary event, and may generate hybrid mixture due to the co-presence of a flammable gas.

Dust explosion prevention and mitigation programs can be hierarchically prearranged from most effective to least effective in terms of measures related to: inherent safety (minimization, substitution, moderation and simplification), passive engineered safety, active engineered safety, and procedural safety. All the elements in control hierarchy should be grouped together for effective reduction of dust explosion risk. Further it is equally important to control the dust explosion incidents, is the key role played by senior management in ensuring a strong safety culture and an effective safety management system. Technical knowledge without the proportionate management commitment and program to ensure application of such knowledge is doomed to failure, hence the purpose of this thesis is to enhance the knowledge of the industries who seeks the technical competencies to prevent the dust explosions in those process industries.

CHAPTER 03

3.0 RESEARCH METHODOLOTY

3.1 Introduction

Research is an art of scientific investigation. The research methodology is the systematic process followed to achieve the aim and objectives of the research. The basic aim of developing this chapter is to give more outline view of the process that used in this research. Therefore, this chapter presented the methodological framework to achieve the research objectives identified in the first chapter. As such, the ultimate goal of the research is to develop a model to minimize dust explosion impacts in pharmaceutical industry.

3.2 Research Approach

The research approaches used to organize research including the collection of data in ways that are most likely to achieve research aim whereas it supported to organize the research activities to achieve research objectives (Tan, 2002; Easterby Smith et al, 2002). Research approaches can be categorized as qualitative approach and quantitative approach. According to Naoum (2012), the type of research approach depends on the purpose of study, type and availability of the information for the research. In the event of analysing this research problem, qualitative research approach was used.

Once the approach is defined, research strategy should be determined. The aim of this research is to develop a model to minimize dust explosions impacts in pharmaceutical industry by identifying causes and impacts of dust explosions and highlight the preventive, preparedness, response and recovery strategies to minimize the impacts of dust explosion. In-order to undertake the in-depth study regarding the research problem, multiple case study strategy was selected. According to Yin (2011), case study strategy attempts to illuminate a decision or set of decisions; why they were taken, how they were implemented and with what results. Hence, this research study used the case studies under qualitative research approach. For case studies, three major pharmaceutical plants in 3 countries, i.e. Sri Lanka, India and Bangladesh, belongs to one mother-company were taken in to study. Those plants are located in Mt. Lavinia plant in Sri Lanka, Nashik plant in India and Chittagong plant in Bangladesh.

3.3 Case Study Design

Once the research approach is designed, the focus should be made on to the case study design since this is the most critical part of the research design. A good case study design guides the investigator in the process of collecting, analyzing and interpreting findings in more logical manner to obtain ultimate output of research. The following five concepts illustrated the case study design.

3.3.1 Research Problem and Study Propositions

The research design is basically concentrated on the research questions. Mostly “what”, “how” and “why” questions provide an important clue to define research problem. The research question was “how to minimize the dust explosions impacts in pharmaceutical industry”. Thus, identify the causes and impacts of dust explosions and highlight the prevention, preparedness, response and recovery strategies to minimize the impacts of dust explosions in pharmaceutical industry.

Propositions directed attention to something that should be examined within the scope of the study. Additionally, propositions supported to identify the factors which contributed more to the research question and the propositions really capture what the researcher interested in answering through the research. Regarding the research problem, the researcher carried out background study on broader perspective to familiarize with the subject areas of dust explosion impacts in pharmaceutical companies. Thus, the comprehensive literature synthesis was undertaken to identify research issues in depth with relevance to causes of dust explosions, particle properties which impacts on dust explosions and the control measures to minimize its impacts. In developing literature synthesis, researcher referred books, journal articles, and unpublished dissertations to gather information.

3.3.2 Case Study Selection

Perry (1998) stated that the literature is rarely recommending the number of case studies to be used. According to Yin (2009), the number of cases in the case study can deviate from one to eight. As previously mentioned, with the aim of developing the framework, multiple case designs were used to attain more analytical conclusion. Due to the time constraints, three case studies were carried out with three pharmaceutical facilities in Sri Lanka, India and Bangladesh, which belongs to same mother company in United Kingdom.

3.4 Data Collection

In order to emphasize the research problem mentioned, appropriate data were collected. The prime consideration was given to the sources use to collect the accurate data to validate the research problem.

The data collection was done through site visits, observations, reviewing accident investigation reports and archival records and mainly by conducting interviews with the top level management of the above three manufacturing plants using an interview guideline. Data collection guideline was developed and used as it enables to include the necessary questions, clarify doubts, facilitate observations, guide documents to review and receive the most accurate answers while avoiding the misinterpretation between interviewer and interviewee. Further, interviews were focused to get the current controls, practices and documents related to dust explosion at three plants. Additionally, interviewer can grab the emotional facts from the respondent. Further, direct observations were conducted in order to emphasize and prove the research problem. Direct observations supported to get and validate the most accurate data from the organizations in order to illustrate the research problem. Also direct observations were taken as a supporting tool which verifies the information taken through interviews. Once the data was collected the data analysing phase conducted.

3.5 Data Analysis

The analysis of case study evidence is one of the least developed and difficult aspects of doing case studies (Yin, 2009). However, every case study should have a general analytic strategy to define what to analyse and why to analyse. According to Yin (2002), five specific techniques can be identified to analyse the case studies namely, pattern matching, explanation building, time series analysis, logic models and cross case synthesis. Among above techniques, pattern matching and explanation building were used to analyse the data since the researcher used multiple cases for data gathering. Thereafter, analyse the case content by using graphical analysis, logical analysis and constant comparison in order to aggregate most common causes, consequences and measures to minimize the impacts of dust explosions in pharmaceutical industry.

Dust explosion incidents and impacts minimization strategies practiced by each pharmaceutical manufacturing plant were obtained in details from plant environmental, health and safety managers and regional process safety engineers to strengthen the research findings. Further, past three year incidents data on incident behaviours, root causes, corrective and preventive actions taken were analysed for all three manufacturing plants.

3.6 Conclusion Drawing

Conclusion drawing are the final stage of the research process. According to the Patton and Appelbaum (2005) the ultimate goal of the research is to uncover the patterns, determine meaning, make conclusions and build theory. Thus, conclusions drawing are the important part in the study. According to Senarthne (2005) conclusions drawing support researcher to interpret the findings of the research. Therefore, it emphasizes the interrelationship of existing literature and the real practice in the industry. Further new research directions can also be recommended in this section of study.

3.7 Research Process

According to the Polonsky and Waller (2011), the research process should draft prior to conduct the research. Research process addresses the way of carrying out the research. Further, completed research process demonstrates the sequence of actions to achieve research objectives through reliable information (Kothari, 2004). The research process developed for this research study is given in Figure 3.1.

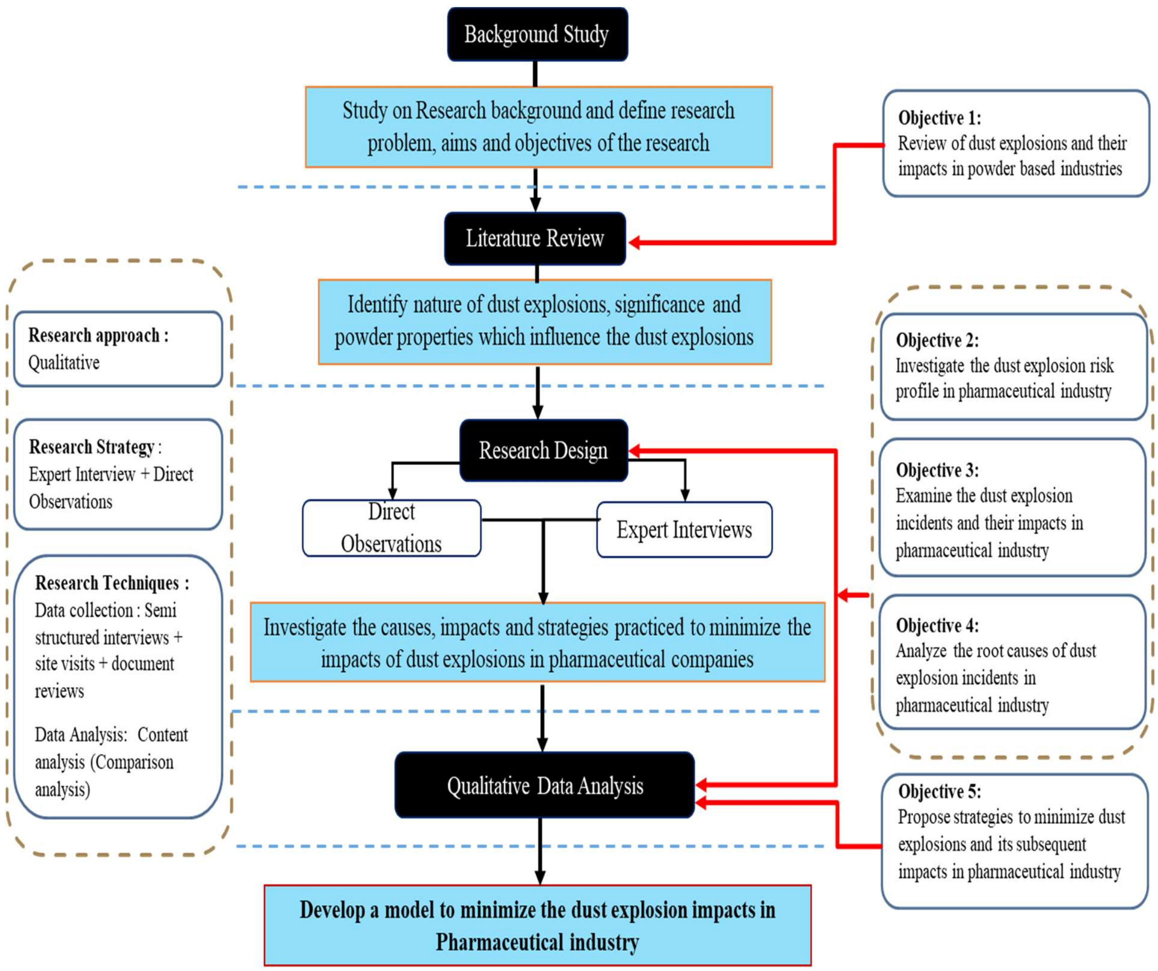


Figure 3-1 The Research Process

Source: Developed by Researcher

3.8 Summary

This chapter discussed the methodology of research including research design, research process and research techniques. Qualitative approach was selected as the best way to conduct the research and case study research methodology was chosen to conduct the nature of study. Due to the time constrain only three cases were taken in to analyse. Finally, a model was developed based on the findings to minimize the impacts of dust explosions in pharmaceutical industry.

CHAPTER 04

4.0 ANALYSIS AND FINDINGS

4.1 Introduction

Chapter 3 elaborated the research methodology used for this research whereas, the purpose of this chapter is to explain the research analysis and findings of the study in detailed manner. Three major pharmaceutical factories belong to same mother company was selected for this research study. All three manufacturing plants produce pharmaceutical products using different categories of raw materials including combustible powders. By analysing the manufacturing processes, there are some processes, operations and activities but not all, has high risk of dust explosions. In this chapter, research findings of the realistic incident investigations are explained. The data collection was done through multiple case studies.

Section 4.2 of this chapter presented the general description about the three selected cases and Section 4.3 discussed the cross case analysis. Under Section 4.3, subsections identified the processes, activities which associated with dust explosion risk and strategies they practice to minimize the impacts of dust explosions.

4.2 Profile of the Case Study Plants

The research applied case study method under qualitative approach for empirical investigation. The study investigated three pharmaceutical manufacturing plants under one mother company located in Sri Lanka, India and Bangladesh for indepth investigation. Profiles of the three pharmaceutical plants were analysed in Table 4.1 to summarize the basic information of plants including, country, geographical location, scale of the business, year of the establishment, categories of products where each plant manufactures, production capacity, work force and governing health safety and environmental standard.

Table 4-1 Plant Profile analysis of 3 pharmaceutical manufacturing plants

Criteria	**Plant A**	**Plant B**	**Plant C**
Country	Sri Lanka	India	Bangladesh
Geographical Location	Mount Lavinia	Nashik	Chittagong
Scale of business	Medium	Large	Large
Year of establishment	1948	1956	1972
Production categories	Pharmaceutical Tablets and Liquids	Pharmaceutical Tablets	Pharmaceutical Tablets and Liquids
Production capacity	125 Tons/ month	350 Tons/ month	280 Tons/ month
Working force	350 employees	750 employees	550 employees
Safety Health and Environmental Management Systems	Company owned management system	Company owned management system	Company owned management system
Data collection tools used	Interviews Document review Plant observations	Interviews Document review Plant Observations During Official visits	Interviews Document review Plant Observations During Official visits

4.2.1 Plant A

Plant A is a medium scale pharmaceutical manufacturing plant established in 1948. It manufactures pharmaceutical tablets and verities of liquids with average manufacturing capacities of 125 Tons/month. Plant A operates with 350 employees and Environmental Health and Safety System is governed through company owned management system. EHS Department governs the environmental health and safety of the plant and department comprises with six members that is Senior EHS Manager, EHS Manager, Occupational Hygienist, EHS Executive, Occupational Health Physician and Occupational Nurse. The company owned management system is driven by morally and responsibly on environment, health and safety aspect through zero harm to environment and safety of all the stakeholders including neighbours.

4.2.2 Plant B

Plant B is the largest pharmaceutical manufacturing plant in the Indian subcontinent region, established in 1956. It manufactures pharmaceutical for intestinal and stomach ulcers with ranitidine hydrochloride tablets and verities of pain relief tablets with average manufacturing capacities of 350 Tons/month. Nashik plant operates with 750 employees. Environmental Health and Safety department comprises with 11 members and General Manager EHS is the department head of Health Safety and Environmental department. EHS system is governed through company owned management system and it contains sixty numbers of EHS internal standards.

4.2.3 Plant C

Chittagong site is the latest pharmaceutical manufacturing plant introduced in to the Indian subcontinent region, established in 1972. It manufactures pharmaceutical for intestinal and pain relief categories with magnesium stearate tablets and pain relief tablets with average manufacturing capacities of 280 Tons/month. Chittagong plant operates with 550 employees. Environmental Health and Safety department is comprises with 8 members and Senior Manager EHS is the department head of Health Safety and Environmental department. EHS system is governed through company owned management system and it contains sixty numbers of EHS internal standards.

4.3 Cross Case Analysis

The cross case analysis was the technique which was used to analyses data of three identified cases to explain the strategies practiced by pharmaceutical companies in minimizing the impacts of dust explosions. Further, it identifies the similarities and differences across three cases under three broad elements; (a) investigate the dust explosion incidents and their impacts in pharmaceutical industry, (b) causes of dust explosions in pharmaceutical industry and (c) procedures and strategies practiced by pharmaceutical companies to minimize the impacts of dust explosions.

4.3.1 Plant Profile Analysis

When analyzing the profile of three plants in Figure 4.1, two plants are categorized under large scale and one is a medium scale based on the capacity of manufacturing and number of employees work in each plant. Plant B in comparison with Plants A and C having large number of employees and as a result of that number of EHS professionals in Plant B is higher than other two plants. Further position of the EHS department head in plant B is two levels above the position of Plants A and C due to the same fact (GM EHS vs Senior Manager EHS). But in comparison to number of employees per EHS professional, Plant A is better than other 2 plants as it has the lowest number of employees to look after by an individual EHS professional.

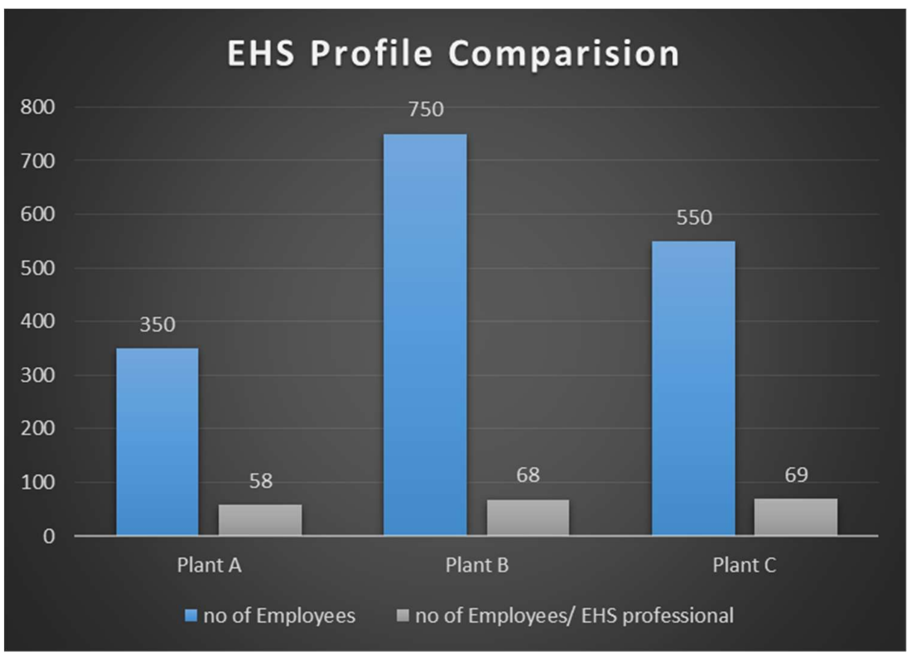


Figure 4-1 EHS Profile Comparison of Three Plants

4.3.2 Dust Explosion Risk Profile Analysis

Identifying the dust explosion risk profile of a plant is utmost important to identify the necessary controls that need to be introduced. Dust explosion risk of a pharmaceutical manufacturing plant depends on the products they manufactured using high dust explosion risk raw materials, quantity of those materials stored at plant and the controls that plant implemented to prevent the occurrence of a dust explosion.

4.3.2.1 Product Wise Risk Profile

Table 4.2 presents the product wise risk profile. Risk profile of all three plants have been analysed based on the number of powdered raw materials, which has high dust explosion risk. Dust explosion risk of powders being assessed based on the minimum ignition energy of that material.

Table used the following colour code to mark the risk levels according to the analysis given in the table, Plant A has one product with high risk explosive raw material, Plant B has one high risk material with two medium risk materials and Plant C has two high risk materials with one medium risk materials. By comparing the explosive risk profile of plants based on their products, Plant C Operates with the highest risk. But when compare number of combustible powders, both plants B and C are in high risk than Plant A. By analyzing Table 4.2, Plant A has one powdered raw material with high dust explosion risk and one with low dust explosion risk, though Plant B has one high dust explosion risk powder with two medium dust explosion risk powders. Plant C on the other hand is in the highest risk profile due to the availability of two powdered raw materials with high dust explosion risk and one medium dust explosion risk powder.

Table 4-2 Comparison of Risk Profile by products

Plant	Number of products with powdered raw materials	Powdered Raw Material	Associated Risk	Related Physical Property
Plant A	**2**	Paracetamol Powder	Strong Explosion Eco Toxic	MIE* – 6 to 7mJ EC50 – 134mg/L
		Sodium Carbonate	Eye Irritation	Not Applicable
		Citric Acid	Eye Irritation	Not Applicable
		Orange flavor powder	Minor explosion	MIE - > 500mJ
Plant B	**4**	Magnesium Stearate	Medium Explosion	MIE – 13 to 16 mJ
		Ranitadine Hydrochloride	Strong Explosion	MIE - < 2mJ
		Chloropheniramine maleate	Inhalation Toxic	LD50 – 306 to 351 mg/kg
		Eye Irritation	Eye Irritation	Not Applicable
		Sodium benzoate	Minor Explosion	MIE – 60 to 70 mJ
		Sodium citrate	No significant Risk	Not Applicable
Plant C	**3**	Paracetamol Powder	Strong Explosion Eco Toxic	MIE* – 6 to 7mJ EC50 – 134mg/L
		Methyl Parabens	Strong Explosion	MIE - < 2mJ
		Sodium Benzoate	Minor Explosion	MIE – 60 to 70 mJ
		Chloropheniramine maleate	Inhalation Toxic	LD50 – 306 to 351 mg/kg

Powders with high dust explosion risk
Powders with medium dust explosion risk
Powders with low dust explosion risk

Source: GSK MSDS web portal. * MIE – minimum ignition energy

4.3.2.2 Location and Quantity Wise Risk Profile

After shortlisting all the high and medium risk powders, which are prone to dust explosions, an assessment was done to identify the locations within the plants where these high dust explosion risk powders are used. As per the experience of the researcher and the observations made during the site visits, it was identified that the storage warehouse, weighing section and manufacturing are the locations where these powdered materials are largely used. Quantities stored at each location depends on three factors, i.e. (i) quantity used of that chemical for a batch, (ii) size of the batch and (iii) lead time of material delivery.

Comparing the amount of combustible powders used in different locations it is clearly visible that all plants having the largest number of combustible powders handled in warehouse. But when analyzing in detail, none of the plants are opening these bulk raw material bags in storage warehouses due to the quality assurance reasons, hence there is no tendency to create a dust cloud, which is the most significant requirement of dust explosion to happen. But, if there is an emergency situation such as combustible powder bag falling when handling, warehouse is the most vulnerable location for dust explosion to happen.

The amount of combustible dust used in weighing section and production floor is basically depends on the batch size each plant manufactures. When comparing the details given in Table 4.3, all three plants are using high explosive risk materials, that is Plant A Paracetamol powder, Plant B Ranitidine Hydrochloride powder and Plant C again Paracetamol powder in considerably large quantities in all their weighing and manufacturing sections.

Table 4-3 Comparison of Risk Profile by Location and Quantity Stored at Plant

Plant	**Combustible Powder**	**Quantity Available in Warehouse (kg)**	**Quantity Available in Weighing (kg)**	**Quantity Available in Manufacturing (kg)**	**Quantity Available in Other Locations (kg)**
A	Paracetamol Powder	100,000	600	2,400	Not available
B	Magnesium Stearate	150,000	100	500	Not available
	Ranitidine Hydrochloride	15,000	200	100	Not available
	Sodium benzoate	12,000	15	15	Not available
C	Paracetamol Powder	200,000	600	5,000	Not available
	Methyl Parabens	1,000	20	10	Not available
	Sodium Benzoate	15,000	15	30	Not available

When compared with total volume of combustible powders handled at weighing and manufacturing sections, risk profiles of Plants A, B and C can be mapped in to a risk profile chart as in Figure 4.2.

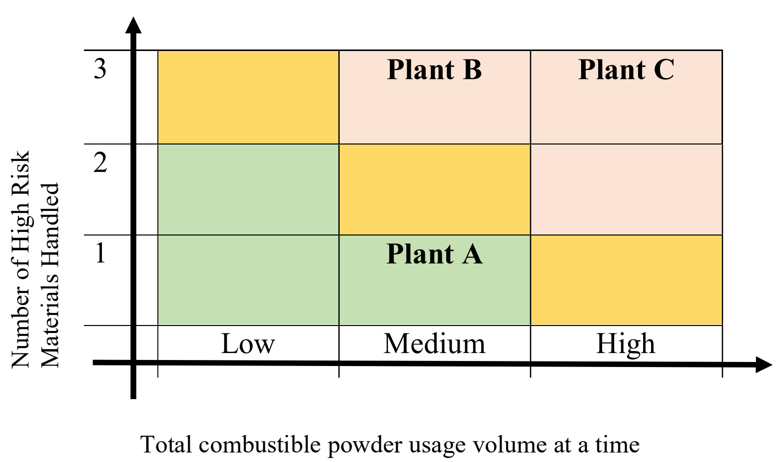


Figure 4-2 Risk Profile Comparison

Figure 4.2 is plotted to map the plants based on their combustible powder usage volume at a time and number of high risk materials handled. As per the chart, higher the total combustible powder usage volume and higher the number of high risk materials in plant, the plant becomes higher risk profile plant. Based on this chart, Plant C can be classified as a plant with highest dust explosion risk and Plant A as the plant with least dust explosion risk. Plant B is a plant with highest dust explosion risk but it is less risky than plant C. If the plants map based on their dust explosion risk in to an equation, it can be explain as,

$$\boldsymbol{Plant\ A < Plant\ B < Plant\ C}$$

During the interviews done with experts, it was identified all 3 plants have been captured the dust explosion risk in their process safety risk assessment HAZID (Hazard Identification) mandated by the corporate. This is a basic qualitative assessment to identify the dust explosion risk in the plants, but Plant A in addition to above has done a HAC (Hazard Area Classification) or risk zoning, a quantitative risk assessment approach based on the amount of explosive materials used at different locations. Based on that assessment, the plants have zone the areas as high, medium and low risk zones and engineering controls have been introduced based on those zoning classification. On that aspect, Plant A has taken a clear picture of their risk profile and controlled risk reduction compared to Plants B and C.

4.3.2.3 Activity Wise Risk Profile

Risk scoring is a rating given by all three pharmaceutical plants in their general risk assessment to identify the risk level of activities they do. It is been calculated based on a risk matrix for likelihood and severity with 1 to 5 scale given in Annexure iii by multiplying both likelihood and severity (likelihood x Severity). Reference to Table 4.4 ,sampling, dispensing, sieving, dust extraction, powder transferring and tablet compression are common processes for all three pharmaceutical manufacturing plants though, risk scoring given by three teams differ due to various factors. The frequency of the process, time duration process runs and date to the last incident defines the likelihood scoring and number of employees involved and how sever the outcome of the incident would defines the severity scoring. Analysing the risk scores given by three plants it is visible that all three plants have assigned severity score as 4 or 5 for all the combustible dust handling operations irrespective of its scale. Likelihood, on the other hand depends on the frequency of the process, time where process runs. Hence, it is visible that dust explosion risk is always has the outcomes of either catastrophic or major. As per the risk assessments, Plant A has three red risks, Plant B has two red risks and Plant C has 1 red risk.

When it comes to ignition sources, all three plants have sparks from electrical equipment, electrostatic discharges, heat or spark from mechanical friction, hot surfaces and naked flames. But only Plant C has exothermic reaction, which may create ignition sources due to high heat.

Table 4-4 Risk Profile Analysis by Process

Processes & Activities	**Availability of processes and risk score defined by the plant**						**Ignition sources Available**	**Plant A**	**Plant B**	**Plant C**
	Plant A		Plant B		Plant C					
	A	R	A	R	A	R				
Sampling	√	2x4	√	2x5	√	1x4	Spark from electrical equipment	√	√	√
Dispensing	√	2x4	√	2x4	√	2x4	Electrostatic Discharge	√	√	√
Sieving	√	3x5	√	2x4	√	2x5	Heat or Spark from mechanical friction	√	√	√
Dust Explosion	√	2x4	√	3x4	√	2x5	Hot surfaces	√	√	√
Powder Transferring	√	2x5	√	3x5	√	2x4	Naked flames	√	√	√
Compression	√	3x5	√	2x4	√	3x5	Combustion or Exothermic reactions	NA	NA	√
Granulation	NA		√	2x4	√	2x4				
Powder milling	√	3x5	√	3x5	NA					
Powder blending	NA		√	2x5	NA					
Fluidized Bed Drying	NA		NA		√	3x4				

A – Availability; R- Risk Score ; NA – Not Available

- Very High Risk Activity
- High Risk Activity
- Medium Risk Activity
- Low Risk Activity

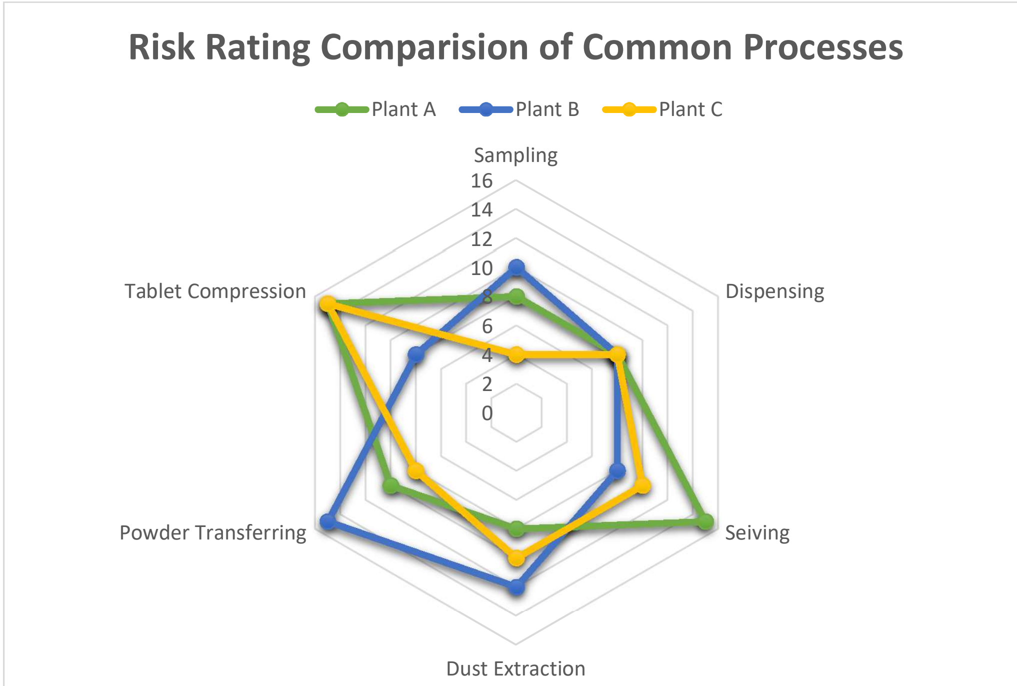


Figure 4-3 Risk Rating Comparison of Common Processes in Three Plants

According to Figure 4.3, among the common processes of all three manufacturing plants, dispensing is the only process where risk score does not depends on the scale or size of the plant. All three plants have equally rated the dispensing activity on their risk assessments because only limited number of powdered material amount is being taken in to dispensing room for quality purposes. Tablet compression is a very high dust explosion risk process in both Plants A and C, and it is a medium risk for plant B due to the risk rating of 8. When analysing the differentiations visible in tablet compression, powder transferring, dust extraction and sieving processes, main factors affecting this change of risk score are:

- Batch size of the process (risk score increases with batch size)
- Whether this material subjected to this unit operation is high dust explosion risk powder or medium dust explosion powder
- Number of peoples affect if there is an incident
- Frequency of the operation (number of batches manufactured in a month)

By comparing the process wise dust explosion risk profiles of all three plants, it is visible that Plant A has 3 very high risks, 1 high risk and 3 medium risks, Plant B has 2 very high risks, 3 high risks and 2 medium risks and Plant C has 1 very high risk, 3 high risk, 3 medium risks and 1 low risk. Higher the number of very high and high risks, position the plants in high risk zones under the dust explosion risk. Hence, the process wise dust explosion risk can be expressed in below relation.

Plant B > Plant A > Plant C

4.3.3 Investigation of Dust Explosion Incidents

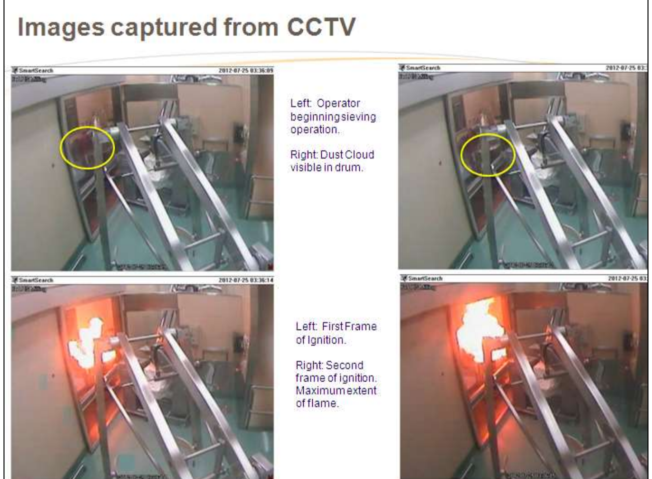
Incident details and investigations of realistic information of dust explosion incidents happened in all three manufacturing plants have been explained in Tables 4.5, 4.6 and 4.7. Following sections further detailed dust explosion incidents with the root cause analysis of those incidents done using the five why analysis tool.

4.3.3.1 Plant A

The summery of dust explosion incidents reported in Plant A is given in Table 4.5.

Table 4-5 Dust Explosion Incident Details in Plant A

a.	Date of the dust explosion incident	25th July 2012
b.	Incident description	At approximately 03:36 on the morning of Wednesday the 25th of July 2012 there was a powder ignition incident at Plant A An operator was manually sieving paracetamol powder into a stainless steel Muller drum with a stainless steel sieve. During the sieving process the paracetamol powder additions formed a dust cloud which subsequently ignited. The fire event lasted 15 seconds. The operator received superficial burns to the left cheek and ear lobe and was taken to the local hospital
c.	Powder type responsible for dust explosion	Paracetamol Powder

d.	Ignition Source	Static Electricity
e.	Section that the incident happened	Tablet manufacturing section
f.	Activity/ Process incident occurred	Sieving Process
g.	Injuries encounter	Fatal – None Medical treatment – 01 First Aids – None
h.	CCTV footages	

Based on the interview findings, plant visit details and by looking at the CCTV footages, researcher has used five-why analysis tool to investigate the incident for easy identification of immediate, underline and root causes. Dust explosion occurred during the sieving of paracetamol powder and first why gives the immediate cause of the incident which is "ignition of combustible paracetamol powder". Manual sieving operation has created the dust cloud and required ignition source from the static discharge. Underline causes for the incident was "inadequate earthing" and "accumulation of dust layers on top of the machine". These underline causes result the root causes that are "inadequate risk assessment" and "inadequate housekeeping".

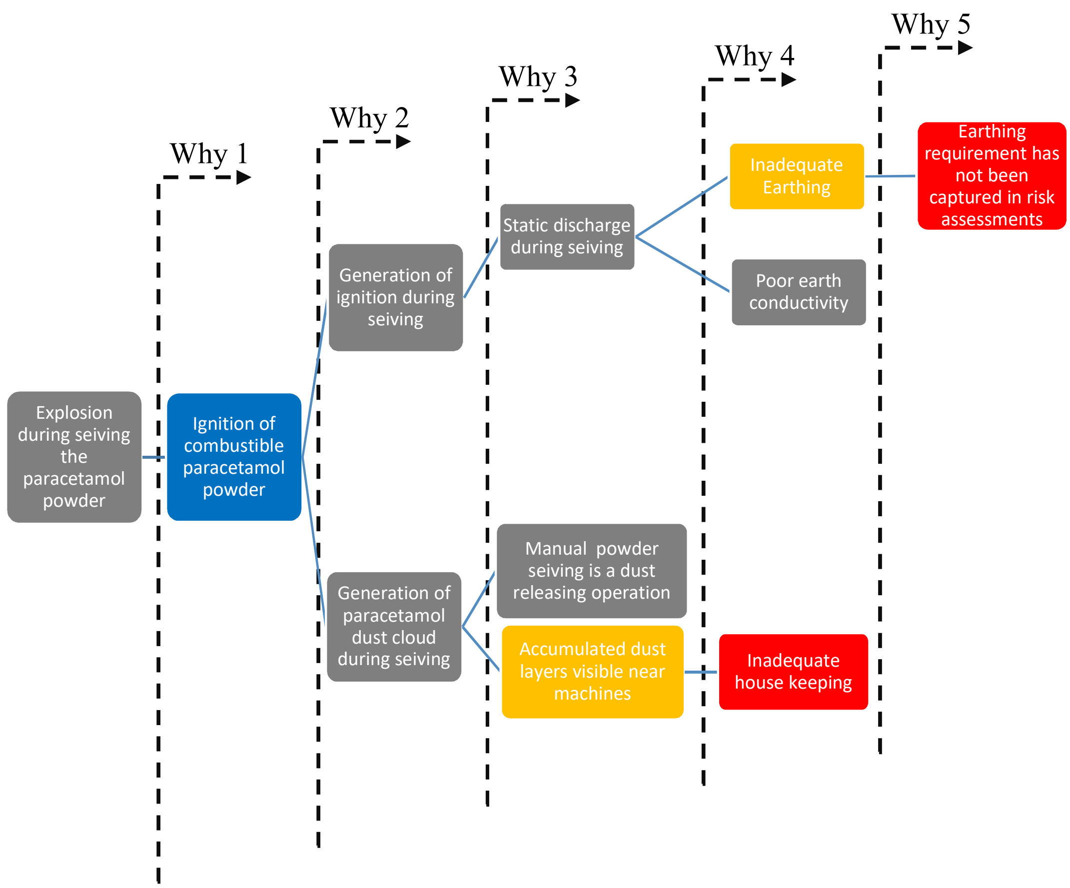


Figure 4-4 Five-why Analysis of Plant A Dust Explosion Incident

4.3.3.2 Plant B

The summery of dust explosion incident reported in Plant B is displayed in Table 4.6, which was ended up with 2 fatal injuries.

Table 4-6 Plant B Dust Explosion Incident Details

a.	Date of the Dust Explosion Incident	18^{th} Aug 2014
b.	Incident description	At approximately 19:36 evening Monday the 18^{th} of Aug there was a powder ignition incident at Plant B When Ranitidine hydrochloride powder transferred to granulation process through powder transferring system, the dust cloud generated

		inside the powder transferring system has ignited. Explosion has initiated inside the powder transferring unit has exploded the entire powder transferring system. Fire event has lasted for about 30 minutes period at the time it was extinguished by ERT. Two operators working at granulation unit has experienced noise induced hearing loss for one ear and first degree burning of left side of their body.
c.	Powder type responsible for dust explosion	Ranitidine Hydrochloride Powder
d.	Ignition Source	Static charge
e.	Section that the incident happened	Powder granulation section
f.	Activity/ Process incident occurred	Powder transferring Process
g.	Injuries encounter	Fatal - 02 Medical treatment - None First Aids – None

Based on the interview details, plant visit observations to the incident location and by analysing the CCTV footages, researcher has used five-why analysis tool to investigate the dust explosion incident happened in Plant B. The incident was due to the explosion inside the powder transferring system and immediate cause for the incident came as the first why of the analysis is ignition ranitidine hydrochloride powder while transferring. Appearance of ignition source inside the powder transferring system has form the dust explosion pentagon, which necessary to initiate dust explosion. The underline causes for the incident was “lack of awareness about the combustible nature of ranitidine powder” and “no proper process safety risk assessment done during the design stage”. These underline causes resulted “inadequate training” and “inadequate risk assessment” as the root causes of the incident.

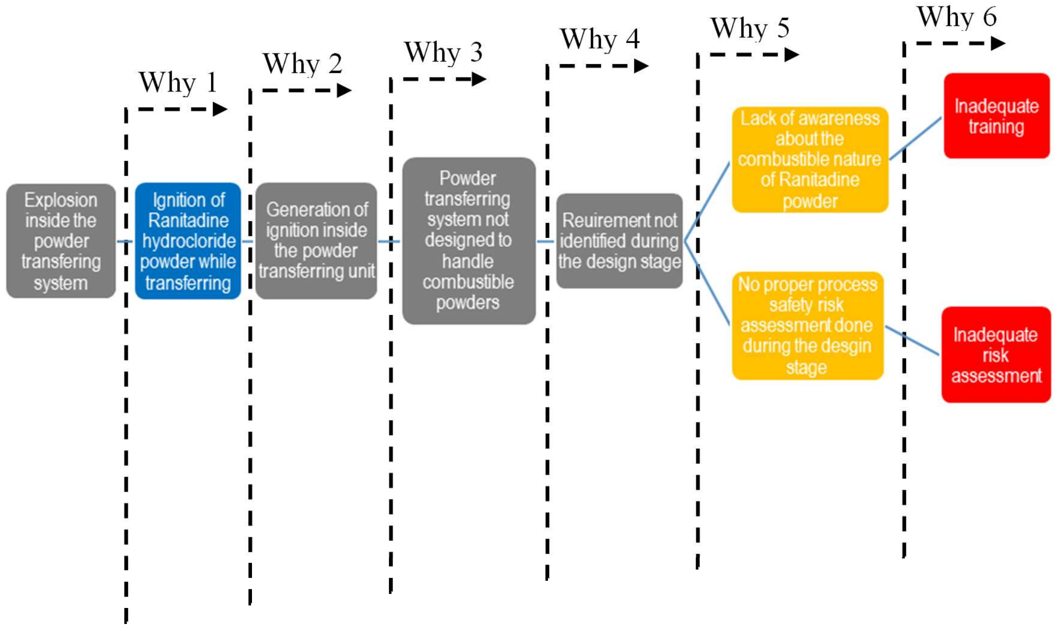


Figure 4-5 Five-why Analysis of Plant B Dust Explosion Incident

4.3.3.3 Plant C

The summery of dust explosion incident reported in Plant C is presented in Table 4.7.

Table 4-7 Plant C Dust Explosion Incident Details

a.	Date of the Dust Explosion Incident	17th Nov 2015
b.	Incident description	At approximately 06:46 on the morning of Tuesday the 17th of November there was a powder ignition incident at Plant C. An operator was manually transferring waste paracetamol powder in the dust extractor collection drum into a stainless steel intermediate

		container which normally is a dust forming activity. During transferring he has tried to switch on the light near to the area due to the dark condition of the environment. When he switch on the electrical spark generated from switch has ignite the Panadol dust cloud created due to waste powder transferring activity. A small explosion has happened followed by a fire event which lasted about 40 seconds. The explosion event has thrown the operator for about 2m away and he has experienced broken bone injury to his left arm, due to hit with nearby steel part.
c.	Powder type responsible for dust explosion	Paracetamol Powder
d.	Ignition Source	Electrical spark
e.	Section that the incident happened	Tablet manufacturing section
f.	Activity/ Process incident occurred	Dust powder cleaning process at dust extractor system
g.	Injuries encounter	Fatal – None Medical treatment - 01 First Aids - None

Based on the interview findings, plant visit observation and by analysing the root cause analysis done by plant team, researcher has used five-why analysis tool for the dust explosion incident reported in Plant C. The incident was happened due to the transferring of waste powder in to the intermediate container. Immediate cause was identified as "explosion of paracetamol dust". Generation of ignition energy when switching on has created the dust explosion pentagon at the waste powder handling area. Underline cause was identified as the "non-rated electrical appliances in classified zones" reason for this deviation is due to the root cause of "deficiencies in Change Management system". Change management is an important aspects in health and safety management system where any change which impacts to health and safety should be assessed in detail prior to implement the change. Change which was done in explosion classified zone was not assessed prior to implement was the main reason for this incident.

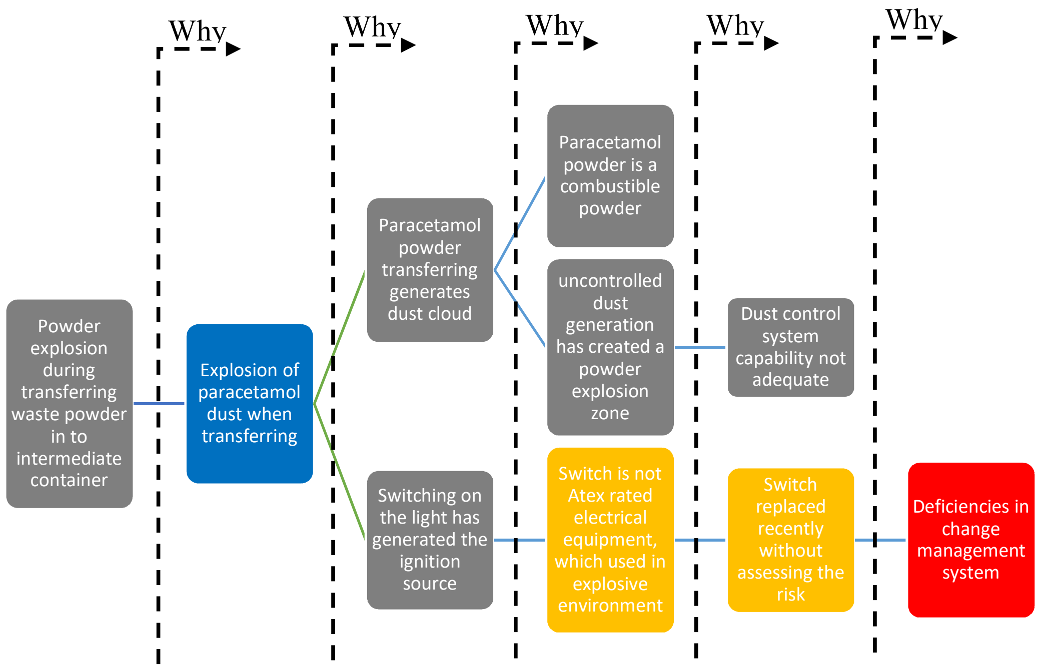


Figure 4-6 : Five-Why Analysis of Plant B Dust Explosion Incident

4.3.4 Analysis of Causes Related to Dust Explosions

Analysing the causes related to dust explosions is important to control and prevent the recurrence. Three cause categories "immediate cause", that is the most immediate reason for the incident, the "underline cause" is the unsafe condition or act come as a result of root cause and the ultimate managerial reason resulted the accident is named the "root cause". The summary of findings is given in Table 4.8.

Table 4-8 Causes of Dust Explosion

Plant	Cause Type		
	Immediate Causes	**Underline Causes**	**Root Causes**
Plant A	▪ *Ignition of combustible paracetamol dust when sieving*	▪ *Inadequate earthing created the static electricity when sieving.*	▪ *Earthing requirement has not been captured in the risk assessment cause*

	(**pentagon elements responsible for the cause:** creation of **dust cloud** while sieving and static charge appeared as the **ignition source**)	▪ *Accumulation of combustible dust on process areas*	*inadequate risk assessment.* ▪ *Inadequate house keeping*
Plant B	▪ *Ignition of combustible Ranitidine hydrochloride powder inside the powder transferring system* (**pentagon element responsible for the cause:** spark generated from machine has created the **ignition source**)	▪ *Uncontrolled spark erupted with in the powder transferring unit* ▪ *Lack of awareness about the combustible powders handle at the manufacturing floor*	▪ *Neither process safety risk captured in a general risk assessment or any special explosion risk assessment cause inadequate risk assessment.* ▪ *Inadequate trainings for the people involve with combustible powders*
Plant C	▪ *Generation of spark in an explosive dust handling area* (**pentagon elements responsible for the cause:** spark generated from electrical switch has created the **ignition source**)	▪ *Use of Non rated electrical equipment in dust explosion zone classified areas*	▪ *Deficiencies in the change management system or area incompatible electrical appliance has been installed to explosive dust handling area without assessing the risk*

Table 4-8 causes of dust explosions has summarize the immediate, underline and root causes of the three dust explosion incidents reported in three pharmaceutical manufacturing plants and every immediate cause is linked with dust explosion pentagon element that is mostly responsible to form the explosion pentagon, highlighted in the table, to initiate the dust explosion. In order to identify the root causes for any incident, all three plants uses common approach named "Six Step Root Cause Analysis Method" (Refer Appendix i). This is a comprehensive root cause analysis methodology which includes three investigation tools to identify immediate cause, underline cause root cause and derive relevant corrective and preventive actions to prevent it happen again, that is,

1. Five "W" one "H" approach (who, when, where, what, which, how)
2. Gap analysis through should happen and did happen approach

3. Fishbone approach

Based on the Five-why analysis done, all three incidents have highlighted the immediate (blue boxes), underline (orange boxes) and root causes (red Boxes) for the incidents and identified causes were tabulated in Table 4.9.

Analyzing the above three incidents, Plants A and B has concluded the incident analysis with two root causes including one common root cause of inadequate risk assessment. This is one of the common root cause for many incidents where proper risk assessment not been done in the initial stage of a project to identify the dust explosion risk when handling the combustible dusts. Further, specific risk assessment tools should be practiced to identify dust explosion risk and control measures to prevent dust explosion incidents. Other root causes of Plants A and B are inadequate housekeeping and inadequate trainings respectively. Inadequate housekeeping creates the stagnation of combustible dust particles around the process area, allows to create combustible dust cloud in any sudden vibration or shake. In such a situation, if an ignition source erupted in a combustible dust cloud that can easily create the dust explosion pentagon. Lack of awareness on combustible dust and dust explosion incidents by operators handle the combustible dust always becomes a risk to the company and that has appeared in plant B incident.

Root cause of Plant C has converge the investigation for deficiencies in change management system. Any change done in combustible powder handling zones should be critically assessed prior to proceed the change, because any of the control measure is detached from the system due to the change that would lead to an incident as in Plant C.

4.3.5 Actions Taken to Address the Identified Causes

Identification of root cause of an incident is utmost important to prevent the recurrence of such incidents. All three plants have identified action plans to address the identified causes and effectiveness of those actions taken depends on the ability of those actions to address all the causes. Hence, it is important that good blend of corrective and preventive actions should be available to mitigate the similar incidents happen again.

Table 4.9 collated all the actions taken by all 3 plants to address the dust explosion incidents happened in those plants.

Table 4-9 Actions to Address the Causes

Plant	Action Items	Action type	Type of cause addresses
Plant A	Assemble fire and explosion data for all materials sieved at site	Preventive	Immediate
	List out every sieving operation that involves explosive dust	Corrective, Preventive	Immediate
	Conduct a gap analysis for all the sieves at plant to identify the adequacy of earthing and correct the findings	Corrective, Preventive	Underline
	Include earthing checks using an appropriate combination of visual inspection and or resistance measurement prior to start sieving operation	Corrective, Preventive	Underline
	Introduce cleaning schedule for dust handling areas to prevent the stagnation of dust	Corrective, Preventive	Underline, Root cause
	Re-look the risk assessments of combustible dust handling operations to check the adequacy of those assessments	Preventive	Root cause
	Provide awareness to all the employees who handle combustible dust about their explosion characteristics and dust explosion incidents	Preventive	Immediate, Underline, Root cause
Plant B	Identify all the fire and explosion properties of powder materials at plant to identify the combustible dust at plant	Preventive	Immediate
	Conduct a gap analysis for all the electrical appliances at plant which are handled in combustible dust handling areas to check whether they are rated electrical equipment to be used in dust explosion zones and replace all with rated equipment	Corrective, Preventive	Underline
	Go through all the risk assessments of combustible dust handling operations to check the adequacy of those assessments with the regional experts	Preventive	Root Cause

	Involve operators and technicians when conducting dust explosion risk assessment to improve the awareness of them on the subject	Preventive	Immediate, Underline, Root cause
	Provide awareness to all the employees who handle combustible dust about their explosion characteristics and dust explosion incidents	Preventive	Immediate, Underline, Root cause
	Display signs , posters to improve the awareness and as reminders	Preventive	Underline, Root cause
Plant C	(HAC) Hazard Area Classification zones drawings should be displayed at each locations where combustible dust are handled	Corrective	Underline
	Conduct an assessment at all the combustible dust handling locations to check whether electrical appliances used in those locations are rated equipment	Corrective, Preventive	Underline
	Strengthen the change management process by introducing a forum to assess the risk of all the changes to be done prior to complete the task	Preventive	Root Cause
	Improve the awareness of all the technicians, operators and relevant personal about the dust explosion incidents, rated electrical appliances, importance of using them in those areas	Preventive	Immediate, Underline, Root cause
	Awareness to be given for procurement team about Atex rated equipment	Preventive	Underline
	Prestart-up check sheet should be introduced to all the combustible dust handling areas to assess the risk prior to start the job	Preventive	Underline, Root cause

Effective identification of control measures to address the incidents happened is utmost important to control of dust explosion incidents and to prevent the recurrences. By analysing the actions taken by plants, it is visible that all three plants have identified good blend of corrective and preventive actions to address all types of causes that is immediate, underline and root causes. Plant A has identified seven actions, where three of them are preventive type and rest of the four actions act as both corrective and preventive types. Out of those seven actions, three actions to address the immediate cause, four actions to address underline cause and three actions to address root cause. Compared to Plant B and Plant C, Plant A has the best blend of corrective and preventive actions to effectively control the dust explosions. When it comes to addressing of all types of causes, all three plants have equally focused to address all three immediate, underline and root causes identified from the investigation.

In all three action plans, there are two common action items which act as both corrective and preventive types, that is; "conduct an assessment to identify the gaps in actual and standard requirements and fill the identified gaps" in Plant A, "identify the gaps in earthing" in Plants B and "identify the gaps in using explosion proof electrical appliances used in explosive dust handling zones" in Plant C. Conducting initial risk assessments and hazard area classification studies, it is highly important on processes where combustible dust is handled. Outcome of those assessments elaborates the areas needed to be classified as dust explosion zones and in to what level, types of electrical appliances that need to be installed on those areas (Atex rated), earthing requirement that needed to be fulfilled to prevent static charges. Once initial risk assessment is conducted, a gap assessment should be done on an identified frequency to verify what was installed after initial risk assessment, is maintained as expected.

Other common action item that enforced by all three plants is, providing awareness to different levels of employees, to enhance the knowledge on dust explosions, combustible dust, hazard area classifications, rated electrical appliances used in hazardous zones and significance of maintaining the control measures of during operation. These awareness programs and time to time refresher trainings provide platforms to bridge the knowledge gap and addresses all spectrum of causes as well.

4.3.6 Impacts of Dust Explosions

Impacts of dust explosions in pharmaceutical industry is much more catastrophic compared to food or other industries due to the handling of various chemicals with different risk profiles. Although the incidents reported in all three plants were considerably minor, quotes of safety managers in all three pharmaceutical plants evident that they are well aware of criticality of dust explosion incidents in pharmaceutical industry and interviews done with them revealed the impacts of dust explosions in pharmaceutical industry.

EHS Manager of Plant A explained "*we were very lucky that the incident happened at our plant was an insignificant case compared to the incidents happened due to the dust explosions due to the high severity of the impacts"*. GM EHS in Plant B explained "*dust explosion incidents can be explained as incidents which has high severity and low probability. Further he explained this can lead to serious safety health & environmental implications and we experienced a fatal incident four years before*." Senior EHS Manager EHS in Plant C explained "*dust explosion happened in pharmaceutical industry would be more serious compared to other industries due to lot of chemicals we handle"*. When analysing the impacts of dust explosions in pharmaceutical industry, that can be categorized in to health and safety of people, environment and the business. Impacts identified during the interviews have tabulated in Table 4.10.

Table 4-10 : Impacts of Dust Explosions in Pharmaceutical Industry

Category of Impact	Impacts on Dust Explosions
Safety and Health	1. Death can be happened to large group of people who are within the impact zone. a. Once the explosion happened sudden release of pressure waves may cause blasting of internal organ of people resulting sudden death b. Sudden release of heat waves may cause burning resulting second degree and third degree buns causing death. c. Collapsing of buildings where explosion happen may cause death of people 2. Permanent irreversible disabilities a. Broken bones and multiple injuries due to collapse of buildings b. Eye blindness due to exposure to high temperatures c. First degree and second degree burns of skin 3. Permanent deaf - Noise induced hearing loss due to exposure to sudden release of high noise

	4. Respiratory issues due to inhalation of dust particles propagate from the collapse of building 5. Respiratory issues due to inhalation of toxic gases generates from burning of pharmaceutical material 6. Blood poisoning due to the inhalation of toxic gases generates from burning of pharmaceutical material
Environment	1. Release of high pressure waves, thermal energy causing the damage to flora and fauna around the blast. 2. Release of dust particles to environment would settle around the area may cause social issues due to the disturbance happen for the lifestyle of inhabitants. 3. Release of dust particles would settle on water bodies may deteriorate the water quality around the area 4. Release of toxic gases due to the burning of pharmaceutical powders. 5. Release of toxic gases captured by clouds may return to floor through rains
Business	1. Direct Impacts a. Fines and imprisonment due to loss of human lives b. Financial loss due to the extreme damage happen to the machinery, buildings and property. c. Fines in the criminal court for not preventing an accident. d. Loss of business due to stoppage of production e. Loss of customers f. Loss of shareholders 2. Indirect Impacts a. Loss of employee moral b. Loss of business reputation c. Extra cost to be incurred on remedial actions, investigations and legal d. Cost of rehabilitation

Impacts of dust explosions in pharmaceutical industry can be classified in to three aspects (i) impacts on health and safety, (ii) impacts on environment and (iii) impacts on business.

When analysing the dust explosion related impacts on health and safety, almost all the impacts are either fatal or irreversible due to the catastrophic nature of the dust explosions. Death, permanent deaf, blood poisoning due to pharmaceutical smoke inhalation might be obvious repercussions of a large dust explosion in pharmaceutical industry. Impacts on environment due to the dust explosion incidents are mainly related to release of dust and toxic gases to environment. These will badly affect the surrounding community and eco systems. Business impacts of dust explosions in pharmaceutical industry is as common as any major accident happened in any business because it directly and indirectly affects to the business. Fines and imprisonment of business owner, seal the business by the government are the legal enforcements which would discontinue the operation or business. By analysing both direct and indirect impacts of dust explosions, indirect impacts heavily affect the business as it links with rehabilitation of employee morale, rehabilitation of business and the reputation, as these factors can permanently close the business from its survival.

4.3.7 Analysis of Dust Explosion Impact Minimization

All the incidents discussed on above Sections evident that all three plants have experienced dust explosion incidents with in last five years period. As a result of those incidents mother company belongs to all these three plants have come-up with master project named Process Safety. Senior EHS manager of plant A explained that "*Process safety is one of the key blue chip projects mandated by Corporate in the year of 2012 and dust explosion is one of the important phenomenon discussed under process safety*". This implies all these three plants have mandated the process safety implementation project in all plants as a preventive measure for series of process safety incidents happened in other plants belongs to this mother company. As per the Senior EHS Manager this project has seven milestones as described in Annexure iv.

Controls implemented by Plants A, B and C to prevent the occurrence of dust explosions can be analysed using control hierarchy approach, that is, Elimination, Substitution, Engineering Controls, Admin Controls and PPE. All the control measures implemented by three pharmaceutical plants were further identified under the disaster cycle elements with the support of experts interviewed.

Table 4-11 Control Measures Implemented by Each Plant to Minimize Dust Explosions

Control measures Implemented	**Disaster cycle element**	**Plant A**	**Plant B**	**Plant C**
Elimination				
Eliminate the use of combustible dust	Preventive	X		
Conduct hazard area classification study to understand the explosive zones and introduce zone relevant controls to eliminate explosive atmosphere	Preventive	X	X	X
Conducting general and specific risk assessments on dust explosions	Preventive	X	X	X
Control the entry of ignition sources in to HAC zones through work permits	Preventive	X		
In Change management, any material, methods, process, safety device or operator related to combustible dust should be critically assessed prior to do the change	Preventive	X	X	X
Hazard, Risk and vulnerability assessments	Preparedness	X	X	X
Substitution				
Replace the combustible dust by an alternative which is not explosible or is less explosible	Preventive			X
Modify the characteristics of explosive powders by increasing the particle size, water content etc.	Preventive		X	
Engineering Controls				
Specifying mechanical and electrical equipment which is suitable for the explosive zones, as determined by the HAC study to eliminate the sparks from mechanical and electrical equipment	Preventive	X	X	X
Eliminate the static electricity using effective earthing	Preventive	X	X	X
Schedule adherence to preventive maintenance program for equipment/ processes with dust explosion risk	Preventive	X	X	X
Develop clear communication channels for effectively manage the emergency information	Preparedness	X		X
Introduce early warning systems like smoke detectors, dust detectors etc.	Preparedness	X	X	X
Develop clear and accurate information channels to transfer information during emergency situation. (public addressing system, walky talky, etc.)	Response	X		X

Administrative Controls				
Collate all the explosive information of combustible dust handle at site	Preventive		X	
Provide awareness to different levels of employees, on dust explosions, combustible dust, hazard area classifications, rated electrical appliances used in hazardous zones etc.	Preventive	X	X	X
Emergency preparedness and disaster preparedness plans	Preparedness	X	X	X
Coordination among the team with clear responsibilities of Emergency Controller, Incident Controller, Fire Team leader, Fire team members.	Preparedness	X	X	X
Education, training, awareness and conduct mock drills for internal and external stakeholders to prepare them for emergency situation	Preparedness		X	
Develop decentralized responsibility and authority framework to act upon any dust explosion emergency at each section	Response	X	X	X
Maintain clear coordination with outside resources like fire brigade and Ambulance	Response	X	X	X
Establish logistic and supply arrangement during emergency	Response	X	X	X
Launch identified business continuity plan procedures for quickly recover from the disaster	Recovery	X	X	X
Assess the resources, information and human impacts from the disaster	Recovery	X	X	
Develop teams to recover critical elements under resources, information and employee morale to reconstruct and rehabilitate the processes	Recovery	X	X	
Personal Protective Equipment				
Maintain additional resources of firefighting and disaster response toolkits to be used during the emergency	Response	X	X	X

4.3.7.1 Control Through Elimination

Analysing the controls implemented by all three plants to minimize the impacts of dust explosions, it is visible that eliminative controls enforced by all three plants are almost similar except two points, eliminate the use of combustible dust and control the entry of ignition sources through work permit system.

In the year of 2016 with the initiation of process safety diagnostic and initial dust explosion risk assessments conducted under the blue chip project, Plant A has identified one of their products uses Ranitidine hydrochloride, a highly explosive powder as a raw material. By analysing the risk and available control measures management of plant A has decided to discontinue that particular product as a control measure. Further compared to Plants B and C, Plant A has introduce another control to control the entry of ignition sources in to classified zones through work permit system named “hot work permit”. If any of the activity, tool uses to perform a task emits sparks those activities are prohibited to entered in to classified zones. If it is an important requirement, in doing hot work inside the classified zone, that is being done by complete stoppage or isolation of combustible powder handling operations.

4.3.7.2 Control Through Substitution

Analysing the substitution controls implemented, there are very few controls have imposed as in pharmaceutical industry it is very rare in changing the chemicals used as it comes through research and development and through clinical trials. On this aspect Plant C has substitute one of highly explosive powder named “Dextromethorphan Hydrobromide” with non-combustible powder named “Chloropheniramine Maleate” for their mouth wash product as a result of process safety project.

Plant B had done a physical characteristic change for sugar powder which they use pharmaceutical manufacturing by increasing the particle size of the sugar powder. Sugar powder is considered as a medium grade combustible powder which has the minimum ignition energy of less than 30 mJ if it is in fine powder grade, but if the particle size increases the explosive nature of sugar powder reduces.

4.3.7.3 Control Through Engineering Controls

Introducing engineering controls play a vital role in dust explosion control. After conducting the initial risk assessments and zone classifications, replacement of mechanical and electrical equipment which is suitable for the explosive zones must be done to control the dust insertion in to appliances and spark proof type to generate sparks in explosive environments. Effective earthing of equipment to prevent static charge generation and schedule adherence to preventive maintenance of equipment which are used in explosive dust handling areas are key engineering controls that need to be practiced in controlling dust explosions.

Under the engineering controls Plant B has not installed entire site wide public addressing system to effectively communicate a message among all the employees at a time. This would become a barrier to communicate clear message during an emergency situation. During a disasters situation maintaining the communication channel is highly important as to update the current situation during responding to the situation.

4.3.7.4 Control Through Administrative Controls

Most of the controls implemented by all three plants are administrative type and those administrative actions link to all for elements in the disaster cycle. Providing awareness to different levels of employees on dust explosion related topics and developing emergency preparedness plans which include all type of emergencies that can happen in plant are common elements where all three plants are practicing in common. Developing plant level emergency preparedness plan and business continuity plan are two mandatory requirements by the corporate to address the disasters situations, including dust explosions that can happen in plants.

Emergency preparedness plan developed for dust explosion emergency have identified all the locations where dust explosions can happen in the plant and have developed procedures for each identified case explaining how to act. Further it explains the relevant employees who have responsibilities under each situation and those people have been trained through planned emergency mock drills.

Business continuity plan is a document that have been developed to explain quick recover of business from an emergency. When a dust explosion happened in plant it has identified the maximum possible area where the explosion can impact and identify all the resources that can destroy due to the impact. By collating all the relevant documents, information, specifications and suppliers relevant to those impacting resources in a one document with the procedures defined how to acquire them within a short period of time, company can recover the damage in very short period of time.

Under the admin controls except Plant B, the other two plants have not conducted emergency preparedness mock drills with the involvement of outside community including neighbour’s, fire brigade and police. Hence on that aspect Plant B is ahead of Plants A and C.

4.4 Data Analysis Summary

Analysed data has been summarized in Table 4.12 for easy management and development of model to minimize the dust explosion incidents in pharmaceutical industry.

Table 4-12 Data Analysis Summary

#	Topic	Collated summary of the answers
01	Processes and Activities related to dust explosions in pharmaceutical industry	a. Dust extraction b. Powder transferring c. Powder dispensing d. Granulation process e. Fluidize bed drying process f. Powder compression process g. Powder milling h. Powder sieving i. Powder sampling
02	Identified Ignition sources in pharmaceutical Industry	a. Spark from electrical equipment b. Electrostatic Discharge c. Heat or Spark from mechanical friction d. Hot surfaces e. Naked flames f. Combustion or Exothermic reactions
03	Causes related to dust explosions	**Immediate Causes** - Ignition of combustible pharmaceutical dust. - generation of spark in an explosive dust handling area **Underline Causes –** - Lack of awareness about the explosion characteristics of the powder materials handled. - Uncontrolled ignition sources - Inadequate earthing - Accumulation of combustible dust on process areas - Use of Non rated electrical equipment in dust explosion zone classified areas **c. Root Causes** - Earthing requirement has not been captured in the risk assessment cause inadequate risk assessment. - Inadequate house keeping - Neither process safety risk captured in a general risk assessment or any special

		explosion risk assessment cause inadequate risk assessment. - Inadequate trainings for the people involve with combustible powders - Deficiencies in the change management system due to area incompatible electrical appliance has been installed to explosive dust handling area without assessing the risk
04	Impacts of Dust Explosion in pharmaceutical industry	**Safety and Health Impacts** 1. Death can be happened to large group of people who are within the impact zone. a. Once the explosion happened sudden release of pressure waves may cause blasting of internal organ of people resulting sudden death b. Sudden release of heat waves may cause burning resulting second degree and third degree buns causing death. c. Collapsing of buildings where explosion happen may cause death of people 2. Permanent irreversible disabilities a. Broken bones and multiple injuries due to collapse of buildings b. Eye blindness due to exposure to high temperatures c. First degree and second degree burns of skin 3. Permanent deaf – Noise induced hearing loss due to exposure to sudden release of high noise 4. Respiratory issues due to inhalation of dust particles propagate from the collapse of building 5. Respiratory issues due to inhalation of toxic gases generates from burning of pharmaceutical material 6. Blood poisoning due to the inhalation of toxic gases generates from burning of pharmaceutical material **Environmental Impacts** 1. Release of high pressure waves, thermal energy causing the damage to flora and fauna around the blast. 2. Release of dust particles to environment would settle around the area may cause social issues due to the disturbance happen for the lifestyle of inhabitants.

		3. Release of dust particles would settle on water bodies may deteriorate the water quality around the area 4. Release of toxic gases due to the burning of pharmaceutical powders. 5. Release of toxic gases captured by clouds may return to floor through rains **Business Impacts** Direct Impacts a. Fines and imprisonment due to loss of human lives b. Financial loss due to the extreme damage happen to the machinery, buildings and property. c. Fines in the criminal court for not preventing an accident. d. Loss of business due to stoppage of production e. Loss of customers f. Loss of shareholders Indirect Impacts a. Loss of employee moral b. Loss of business reputation c. Extra cost to be incurred on remedial actions, investigations and legal d. Cost of rehabilitation
05	Dust Explosion Impact minimization strategies in pharmaceutical industry	Preventive Strategies a. Eliminate the use of combustible dust b. Conduct hazard area classification study to understand the explosive zones and introduce zone relevant controls to eliminate explosive atmosphere c. Control the entry of ignition sources in to HAC zones through work permits d. Conducting general and specific risk assessments on dust explosions e. In Change management, any material, methods, process, safety device or operator related to combustible dust should be critically assessed prior to do the change f. Replace the combustible dust by an alternative which is not explosible or is less explosible g. Modify the characteristics of explosive powders by increasing the particle size, water content etc. h. Specifying mechanical and electrical equipment which is suitable for the explosive zones, as determined by the HAC study to eliminate the sparks from mechanical and electrical equipment

		i. Eliminate the static electricity using effective earthing j. Schedule adherence to preventive maintenance program for equipment/ processes with dust explosion risk k. Collate all the explosive information of combustible dust handle at site l. Provide awareness to different levels of employees, on dust explosions, combustible dust, hazard area classifications, rated electrical appliances used in hazardous zones etc. <u>Preparedness Strategies</u> a. Hazard, Risk and vulnerability assessments b. Develop clear communication channels for effectively manage the emergency information c. Introduce early warning systems like smoke detectors, dust detectors etc. d. Emergency preparedness and disaster preparedness plans e. Coordination among the team with clear responsibilities of Emergency Controller, Incident Controller, Fire Team leader, Fire team members. <u>Response Strategies</u> a. Develop clear and accurate information channels to transfer information during emergency situation. (public addressing system, walky talky, etc.) b. Develop decentralized responsibility and authority framework to act upon any dust explosion emergency at each section c. Maintain clear coordination with outside resources like fire brigade and Ambulance d. Maintain additional resources of firefighting and disaster response toolkits to be used during the emergency <u>Recovery Strategies</u> a. Launch identified business continuity plan procedures for quickly recover from the disaster b. Assess the resources, information and human impacts from the disaster c. Develop teams to recover critical elements under resources, information and employee morale to reconstruct and rehabilitate the processes

4.5 Dust Explosions Impacts Minimization Model

By collating all the information gathered through the expert interviews, site visits, document reviews and analysed data, were mapped in to the disaster cycle elements of preparedness, preventive, response and recovery to develop a model to minimize the dust explosions in pharmaceutical industry.

Leaning from the mistakes is well known approach to minimize the accidents or incidents. Dust explosion incidents reported in three multinational pharmaceutical manufacturing plants were taken in to considerations to identify the causes and impacts of dust explosions. Proactive and reactive controls those plants were introduced on dust explosion impact minimization was analysed in details under the preventive, preparedness, response and recovery pillars of disaster cycle.

Dust explosion preventive strategies are based on the initial risk assessment conduct on dust handling areas. Once the combustible dust used at plant are identified, as an outcome of the initial risk assessment, HAC study is used to identify the types of controls need to be introduced to prevent the occurrences of dust explosions.

Initial preparation to confront a dust explosions incident by identifying areas in the plant with dust explosion risk is important if the incident happened by by-passing the controls in preventive strategies. Response and recovery strategies were identified that is practiced in pharmaceutical companies to quick recover and reinstate from the disasters dust explosion incident that can happen.

Refer the attached figure

Figure 4-7 Dust Explosion Impact Minimization Model

CHAPTER 05

5.0 CONCLUSIONS AND RECOMMENDATIONS

5.1 Introduction

This chapter presents conclusions of the research which were derived from the findings of this research. Furthermore, the chapter presents recommendations for the pharmaceutical industry to minimize the impacts of dust explosions through disaster cycle approach. In addition, this research was carried out based on many limitations and those were stated in this section. Finally, further research areas have been identified as a direction in this research area.

5.2 Conclusions

The aim of this research is to develop a model to minimize dust explosions and its subsequent impacts in pharmaceutical industry. Through the literature survey, facts and information related to the subject was gathered and enhanced the theoretical knowledge related to the identified topic. Then at the analysis and findings, research aim and objectives were attained through interviews, document reviews and plant observation of three plants which was selected as cases.

The phenomenon of dust explosion, dust types which can create explosions and factors required for dust explosion to be happened were discussed in details through the literature survey to review the dust explosions. Through the statistical records of dust explosions, powder types and powder based industries that is in the risk of dust explosions were identified. Historical landmark cases of dust explosions identified through literature survey to explain the impacts of dust explosions in powder based industries.

In-order to fulfil the second objective, researcher used interviews with experts in the pharmaceutical plants and direct observations were made by doing the plant visits to confirm the information provided by interviewed experts. In Section 4.3.2, risk profile has been analysed based on three aspects, that is (i) product wise risk profile in Section

4.3.2.1, (ii) location and quantity wise risk profile in Section 4.3.2.2 and finally (iii) activity wise risk profile in section 4.3.2.3.

Through the expert interviews and reviewing the documented information in plants, all the powdered raw materials used in all plants were listed out and filtered them based on their physical properties to identify the high, medium and low dust explosion risk powdered raw materials to verify the product wise dust explosion risk profile. High and medium dust explosion risk powders were then short listed and details related to volume of those powders maintained at each plant in location wise were taken from the interviews, to identify the location wise risk profile. Finally, the risk associated with different unit operations were analysed based on the risk assessments done by all plants and the owners of those processes to identify the activity wise risk profile.

Third objective of this research was achieved through interview and analyzing the realistic incidents happened at each plant. Gathered information was included in to five-why analysis tool to investigate the immediate, underline and root causes of incidents. Inadequate risk assessment was a common root causes in two cases and inadequate, training, inadequate housekeeping and poor change management was identified as rest of the root causes for dust explosion incidents happened in those identified cases. Impacts of dust explosion was identified by interviewing the health and safety professionals in all three pharmaceutical plants and partly by literature reviews.

Causes of dust explosions were identified through the investigation of incidents happened at plants. Causes were categorized in to three aspects named immediate, underline and root causes. As described in above inadequate risk assessment came as a common case for two incidents. Inadequate earthing, lack of awareness, accumulation of combustible dust and use of non-rated electrical appliances were identified as the underline causes of investigate dust explosions. Further to above, literature survey used to identify the factors which can influence the dust explosions in pharmaceutical industry.

The final objective of this research was achieved by developing a model to minimize the dust explosions and its subsequent impacts in pharmaceutical industry. This model was developed based on the research findings, literature survey and sequential gathering of information from the analysed data. Causes of dust explosions were identified through the accident investigations done for realistic incidents. Causes were segregated in to immediate, underline and root causes and that would help to develop action plans to effective control of dust explosions. Impacts of dust explosions were collated based on the interviews done with experts in the industry. Impacts of dust explosions in pharmaceutical industry is significant compared to other industries due to the seriousness of impacts. Fatal and irreversible injuries or illnesses are the main health and safety related impacts. Effect of dust explosions to business is critical as it would lead to permanent discontinuation of business due to the direct and indirect impacts.

The disaster cycle was a world proven approach to address the disasters. By analysing the information in Section 4.3.5, it is evident the dust explosion is a disasters event in industrial scale. Hence, disaster cycle approach was considered to control the impacts of dust explosions. Preventive, preparedness, response and recovery strategies developed by all three pharmaceutical plants to minimize the impacts of dust explosions were closely analysed through the direct observations and documented evidence observed during the site visit was taken in to consideration when developing the model to minimize the dust explosion impacts.

5.3 Recommendations

As the outcome of this research, it emphasizes the means of minimizing the dust explosion impacts in pharmaceutical companies. Conducting prior risk assessments by analysing the physical properties of powdered materials to identify the powders with dust explosion risk is an important activity that need to be initiated prior to start any process in pharmaceutical industry. This risk assessment includes hazard area classification study (HAC) to identify the area of concern due to the dust spreading. Controls needed to be implemented should be identified prior to initiate the operation in those identified zones.

Providing awareness to all levels of employees is a vital task to control the dust explosions. This should not be limited only to operators in those dust handling areas, but for the cleaning staff of the plants. Training and awareness about dust explosions, explosive powders handled in the plants, hazardous zones and rated electrical appliances need to be used in those identified zones should be educated to all employees to effective prevention of dust explosions.

Last but the most important factor is predicting the dust explosion incidents at plants and developing emergency preparedness, response and recovery strategies help organization to minimize the impact of dust explosion and quickly reinstate to original state. Developing a comprehensive plan including all those strategies and provide necessary trainings for relevant stakeholders to on their responsibilities in dust explosion recovery plan.

5.4 Limitations of the Research

This research was carried out in three pharmaceutical manufacturing plants belongs to one mother company due to the lack of pharmaceutical manufacturing companies which produce tablet products in Sri Lanka. Further remaining local companies not aware about the dust explosion incidents and no any records found in industry for large scale dust explosions happened. Hence, the data collection becomes more difficult. Researcher had to spend long time to collect data as he had to visit the pharmaceutical plants belongs to other countries under the official travels.

5.5 Areas for Further Research

As a guidance for researchers regarding this subject matter, some further research areas can be identified in order to improve the knowledge of dust explosions for industry professional.

- Identification of dust explosions impacts in food industry
- Research studies to identify the powdered materials which can create dust explosions.
- Analysis of flammable chemical fires in industry

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ANNEXURE I : HISTORICAL CASES OF DUST EXPLOSIONS

Source: Dust Explosions – Cases, Causes, Consequences and Control (Tasneem and Abbasi, 2006)

Year	Location	Dust Type	Equipment	Deaths	Injuries
1785	Turin, Italy	Wheat flour	Bakery	0	2
1807	Leiden, Netherland	Black powder	Ship	151	2000
1911	Liverpool, UK	****	****	37	100
1911	Manchester, UK	****	****	3	5
1913	Manchester, UK	****	****	3	5
1916	Duluth, MN	Grain	Steel bin	****	****
1919	Cedar Rapids, IA	Corn starch	Starch plant	43	****
1924	Peking, IL	Corn starch	Starch plant	42	****
1924	USA	Sulphide dust	****	1	6
1924	USA	Sulphide dust	****	1	1
1924	USA	Sulphide dust	****	2	1
1926	USA	Sulphide dust	****	3	1
1930	Liverpool, UK	****	****	11	32
1944	Kansas City, KS	Grain dust	****	****	****
1949	Port Colbourne, CA	Grain	Steel bin	****	****
1952	Bound Brook, NJ	Phenolic resin dust	Hammer mill	5	21
1952	Saskatchewan	Grain dust	Shipping bin	6	14
1955	Waynesboro, GA	Grain dust	Feed plant	3	13
1956	South Chicago	Grain	dust Elevator	****	****
1958	Kansas City	Grain	dust Elevator	****	****
1960	Canada	Sulphide dust	****	2	****
1960	Albern, Vienna	Grain dust	****	****	****

1962	St. Louis, MO	Grain dust	Feed plant	3	13
1964	Paisley, UK	Grain dust	****	2	34
1965	London, UK	Flour	Flour mil	4	37
1969	Sweden	Sulphide dust	****	2	1
1970	Kiel, FRG	Grain dust	Grain silo	6	18
1970	Germany	Grain dust	shipping canal	6	17
1970	Norway	Wheat grain	dust Silo	****	****
1971	New Orleans	****	Bushel Elevator	****	****
1972	Norway	Silicon	Milling section	5	4
1973	Norway	Aluminum	Mixing vessel	5	2
1974	Canada	Sulphide dust	Fox mines	****	****
1974	Preska, South Africa	Sulphide dust	dust Mines	1	1
1975	Norway	Fish meal	grinding plant	****	****
1976	Norway	Barley/oats	dust Silo	****	****
1976	Oslo Norway	Malted barley	dust Silo	****	****
1977	Galvesto, TX	Grain dust	Grain silo	15	****
1977	Westwego, Louisiana	Grain dust	Grain silo	36	10
1979	Lerida, Spain	Grain dust	Grain silo	7	
1979	Canada	Sulphide dust	Ruttan mine	****	****
1980	Germany	Coal Dust	Cement factory	****	****
1980	Iowa, USA	Corn dust	Bucket elevator	****	****
1980	Minnesota, USA	Grain dust	Bucket elevator	****	13
1980	Naples, Italy	Grain dust	Grain silo	****	8

1980	Ohama, NE, USA	Grain dust	Head house	****	****
1980	St. Joseph, MO, USA	Grain dust	Shipping bin	1	1
1981	Canada	Sulphide dust	Mattabi mines	****	****
1981	Corpus Christi, TX	Grain dust	Bucket elevator	9	30
1981	Bellwood, NE, USA	Grain dust	Bucket elevator	****	****
1981	Germany	Coal Dust	burner plant	****	****
1982	British Columbia, Canada	Coal Dust	Coal Silo	****	****
1983	Anglesey, UK	Aluminum powder	Aluminum powder production		2
1984	USA	Coal Dust	Coal Silo	****	****
1985	Australia	Sulphide dust	Elura mines	****	****
1985	Canada	Sulphide dust	Lynn lake	****	****
1985	Germany	Coal Dust	Coal Silo	****	1
1985	Norway	seed flour	Brunswick mines	****	****
1986	Canada	Sulphide dust	Langsele mines	****	****
1986	Sweden	Sulphide dust	****	****	****
1986	Canada	Sulphide dust	****	****	****
1986	Australia	Sulphide dust	****	****	****
1987	Canada	Sulphide dust	****	****	****
1987	China	Textile dust	Dust collection system	58	177

1987	Oslo, Norway	Malted barley	dust Silo	****	****
1988	Norway	Grain dust	dust Silo	****	****
1988	Sweden	Coal Dust	Coal Silo	****	****
1989	Sweden	wheat flour	bran Silo	****	****
1990	Japan	Benzoyl peroxide	Storage	9	17
1992	Moriya, Japan	Potassiumchlorate andaluminumdust	Mixing operation	3	58
1994	Okaharu, Japan	Cotton waste	Textile mil	****	****
1994	Tokyo, Japan	Rubber waste	Shoe factory	5	22
1997	Japan	Tantalum dust	****	1	1
1997	Blaye, France	Grain dust	Grain Storage	11	****
1999	Michigan	Coal Dust	Powerhouse	6	14
1999	Massachusetts	Resin	Oven	3	12
2000	Japan	Mg–Al alloy dust	****	1	1
2000	California	Aluminum dust	****	****	****
2002	Mississippi	Rubber	Recycling plant	5	****
2003	Kentucky	Resin	Production line	7	****
2003	Kinston, NC	Polyethylene	Pharmaceutic al plant	6	38
2004	Avon, OH	Lacquer dust	****	****	****

ANNEXURE II – COVERING LETTER

P. S. Buddika,
MSc. in Occupational Safety & Health Management,
Department of Building Economics,
University of Moratuwa.

……/ ……. / 2018

………………………..
………………………..
………………………..

Dear Sir/ Madam,

Interview Guideline For Thesis on A Model to Minimize Dust Explosion Impacts In Pharmaceutical Industry

I'm P. S. Buddika, postgraduate student reading for Masters in Occupational Safety and Health Management at Department of Building Economics, University of Moratuwa. My research aims to develop a Model to Minimize Dust Explosions Impacts in Pharmaceutical Industry. The research is carried out under the supervision of Dr. Yasanika Sandanayake, Senior Lecturer in the Department of Building Economics, University of Moratuwa.

An Interview guideline is attached here with. In order to collect data from subject matter experts in powder based pharmaceutical industry, this interview is done using a structured questionnaire . Interview will be taken place for maximum of 60 minutes time and in order to collect data more accurately, notes taking and voice recording (with interviewees permission) will be done.

I assure that information collected during this interview will only be used for research purpose, whereas the confidentially of the data collected is maintained at all times. The information shared and time dedicated despite of the busy schedule is highly appreciated.

Thank you,
Yours faithfully,
…………………..
Samith Buddika (samith06@gmail.com)

ANNEXURE III – INTERVIEW GUIDELINE

Section 1 – **Background Information**

1.1 Details of the Organization
  a. Name of the Organization (Optional) - …………………………………........
  b. No of Employees Work - ……………………………………
  c. Production Capacity (in Powder Section)- ……………………………………

1.2 Details of Respondent
  a. Name (Optional) - ……………………………………
  b. Designation - ……………………………………
  c. Work Experience (in years) - ……………………………………
  d. Job Role in Brief -
  ……………………………………………………………………………
  ……………………………………………………………………………
  ……………………………………………………………………………

Section 2 – **Introduction to the Production Plant**

2.1 What are the main Sections/ Divisions comes under pharmaceutical manufacturing?
  ……………………………………………………………………………

2.2 What are the pharmaceutical products produced in those Sections/ Divisions and how many employees are deployed in those Sections?

#	Manufacturing Section	Products Manufactured	No of Employees Deployed

2.3 How many shifts do you operate ? and how many hours they work per shift?
  ……………………………………………………………………………

2.4 Can you explain what are the,
  a. Powdered raw materials you use for each product?
  b. Physical properties of that material?
  c. Associated risk in those raw materials?

#	Product	Powdered Raw Materials	Physical Properties	Associated Risk	Related Physical Property

2.5 What are the combustible powders you used as raw materials and how you can justify your answer?

………………………………………………………………………………………
………………………………………………………………………………………
………………………………………………………………………………………

2.6 Can you elaborate the average quantity of those combustible powders available at each section of your factory? (average stock maintain at a time)

#	Combustible powder	Quantity available in warehouse (kg)	Quantity available in weighing section (kg)	Quantity available at production floor (kg)	Any other location if available please specify (kg)

Section 3 – **Dust Explosions Risk in Powder Based Industries**

3.1 What methodologies you used to assess the risk in your organization?

………………………………………………………………………………………
………………………………………………………………………………………

3.2 Have you captured "Dust Explosion" risk in any of those risk assessments?

Yes ☐ No ☐

If yes, in what methodology?

………………………………………………………………………………………
………………………………………………………………………………………

If No, Why?

………………………………………………………………………………………
………………………………………………………………………………………

3.3 Do you use any specific types of risk assessing tools to assess the risk of dust explosion?

Yes ☐ No ☐

If yes, what are those?

……………………………………………………………………………………

……………………………………………………………………………………

If No, Why?

……………………………………………………………………………………

…………………………………………………………………………………...

3.4 Can you explain how this special risk assessment tool is used till the risk is controlled?

……………………………………………………………………………………

3.5 Can you explain, (fill the table in next page)

a. Processes and Activities where dust explosion risk is associated at different sections that you identified in Q 2.6
b. Give reasons for your above answer
c. What are the ignition sources available at those sections
d. What is the risk score that you have given for that particular activity or process

Section	**(a) Processes and Activities**	**(b) Reasons for above Answer**	**(c) Ignition Sources Available**	**(d) Relevant Risk Score for the Process or Activity**
Warehouse				
Weighing				
Production floor				
Any Other				

3.6 Can you indicate the most probable location where the dust can be exploded and why?

……………………………………………………………………………………

Section 4 – **Investigate the Dust Explosion Incidents**

4.1 Have you ever experienced any dust explosion incident at your facility in history?

Yes ☐ No ☐

If yes, please provide below details,

a. Date of the incident ? ………………………………………………………….
b. Incident description ? ………………………………………………………….
c. Powder type responsible for dust explosion ? …………………………………
d. Section that the incident happened ? ………………………………………….
e. Activity/ Process incident occurred ? …………………………………………
f. Injuries encounter,
   - Fatal –
   - Medical treatment –
   - First Aids –
g. What methodology you used for root cause analysis ? ……………………….
h. What was the immediate cause for the incident ? …………………………….
i. What was the underline cause of the incident ? ………………………………
j. What was the root cause of the incident ? ……………………………………
k. What was the ignition source for that explosion ? ……………………………
l. What were the immediate & long term remedial actions taken ? …………….
m. What were the preventive actions taken ? ……………………………………

If No, Please provide below details

a. What kind of approach you practice to identify near miss incidents ? ……….
b. Have you encounted any dust explosion near miss incidents ? ……………….
c. Near miss Incident description ?..
d. What were the contributing factors for those near miss incident ?..................
e. What was the immediate cause for the near miss incident
f. What was the underline cause of the incident
g. What were the root causes for the near miss incident
h. What were the immediate & long term remedial actions taken to prevent it happen again ?

Section 5 – Effects of Dust Explosions in Pharmaceutical Industry

5.1 What are the effects of dust explosion for the,

a. Safety of People
b. Health of People
c. Environment
d. Company

Safety of People	Health of People	Environment	Company

5.2 If happened how it can impact to your business?

a.	Legal Impact	
b.	Financial Impact	
c.	Social Impact	
d.	Reputation of the business	
e.	Employee Moral	
f.	Any Other	

Section 6 – **Control measures to prevent the dust explosion**

6.1 How you involve in risk assessing programs, what is your procedure on risk assessment?

………………………………………………………………………………………

6.2 What is your approach if you come across high risk index value for dust explosion risk as a result of above risk assessment?

……………………………………………………………………………………..

6.3 Are you practicing any systems, approaches to eliminate the dust explosion risk from your organization? If yes, what are those?

………………………………………………………………………………………

6.4 What are the Engineering controls you have in your organization to prevent dust explosions?

………………………………………………………………………………………

6.5 What are the administrative controls you have in your organization to prevent dust explosions?

………………………………………………………………………………………

………………………………………………………………………………………

6.6 What are the preparedness programs you have identified to face for dust explosions?

………………………………………………………………………………………

6.7 In the event of a dust explosion what is your response plan to minimize the impact?

………………………………………………………………………………

6.8 What is you plan to quickly reinstate the operation back to normal or to effectively recover from dust explosions

………………………………………………………………………………………

……………………………………………………………………………………

ANNEXURE IV – RISK RATING CRITERIA

Likelihood scale

Scale	Description	
5	Almost Certain	
4	Likely	
3	Possible	
2	Rare	
1	Unlikely	

Severity Scale

Scale	Description
5	Catastrophic
4	Major
3	Moderate
2	Minor
1	Insignificant

Risk Rating = Likelihood Score X Severity Score

Severity Score						
	Catastrophic Score 5	5 (Medium Risk)	10 (High Risk)	15 (Very High Risk)	20 (Very High Risk)	25 (Very High Risk)
	Major Score 4	4 (Medium Risk)	8 (Medium Risk)	12 (High Risk)	16 (Very High Risk)	20 (Very High Risk)
	Moderate Score 3	3 (Low Risk)	6 (Medium Risk)	9 (Medium Risk)	12 (High Risk)	15 (Very High Risk)
	Minor Score 2	2 (Low Risk)	4 (Low Risk)	6 (Medium Risk)	8 (Medium Risk)	10 (High Risk)
	Insignificant Score 1	1 (Low Risk)	2 (Low Risk)	3 (Low Risk)	4 (Medium Risk)	5 (Medium Risk)
		Unlikely Score 1	**Rare** Score 2	**Possible** Score 3	**Likely** Score 4	**Certain** Score 5
		Likelihood Score				

ANNEXURE V – PROCESS SAFETY MILESTONES

Milestone	Scope
E1	Complete Initial web based trainings for relevant team members and Plan a date for initial kick-off.
E2	Process Safety Expert on sites identified. Fire/explosion data collated for materials handled and plan developed to generate any missing data
E3	Identification of Process safety risks through PHIRA and Hazard Area Classification studies for top 5 unit operations
E4	All process safety trainings complete for all the groups in plant
E5	Process safety Red and Amber risks identified from the E3 to be mitigated
E6	Develop basis of Safety procedures to educate operators working in those locations about the critical parameters for top 5 unit operations
E7	Develop basis of safety procedures for remaining unit operations