WHITEPAPER

THE IMPORTANCE OF EFFECTIVE DUST & SOLVENT CONTROL AND CONTAINMENT IN THE PHARMACEUTICAL WORKPLACE

In many instances, pharmaceutical and chemical manufacturing involves the handling and processing of powder or granular ingredients, many of which have exposure or explosion risks attached when in dust form. A comprehensive risk assessment of each and every application is essential before evaluating the appropriate dust control solution.

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THE IMPORTANCE OF EFFECTIVE DUST CONTROL AND CONTAINMENT IN THE WORKPLACE

There is a growing trend for pharmaceutical ingredients, particularly Active Pharmaceutical Ingredients (API's), to consist of smaller molecules to provide faster reactions and greater potency. Solvents are often used in the processing phases. Whilst providing significant benefits in terms of drug delivery and performance, it creates a number of challenges for pharma manufacturers and their production processes. The API's create very fine dusts and often high solvent concentrations during the product handling and manufacturing processes. The finer the dust, the greater explosive potential due to increased surface area and greater concentration. Dust collector manufacturers are having to contend with higher Pmax & Kst values on dusts , as well as a greater number of applications involving hybrid dust and gas mixtures. All this can have significant cost implications therefore, even more vigilance is required to ensure the correct safety devices are specified for the dust collector and EX-rated items of supply. The fine dusts also pose the greatest risk to the worker's health, with harmful particles being retained in the lungs, effective filtration is required combined with containment solutions to ensure the dust doesn't escape during normal operation as well as during routine maintenance (filter changes, waste dust disposal etc).

The questions that need answering when analysing the potential risks associated with dusts generated in the workplace include the following:

1. Are the dusts potentially hazardous to human health and the environment?
2. Do they have the potential to cause explosions or fires?
3. Do they have the potential to interfere with moving parts of machinery and electrical components?
4. Is there the potential for cross-contamination of products?
5. The effective control of dusts, particularly when the finer particles become airborne, is an essential part of the manufacturing process. In this article we will identify the key components of an effective dust control system, the legal requirements that must be met and the ancillary equipment available for optimum protection and system energy efficiency. It can be a complex and considerable capital purchase so there is a real need to get it right, first time.

Before even considering the dust control system, the first step is to fully understand the ingredients that are being used in production. The MSDS (Material Safety Data Sheet) is a good start, providing basic details relating to toxicity, handling requirements etc. but more specific information is required:

Dust particle size analysis – the greater the percentage of sub- micron particles then typically, the greater the explosive potential and potential harm to human health, the environment and machinery. This information will help in choosing the dust control equipment required for effective dust capture, transport and filtration. There are companies that provide dust particle analysis and some dust control companies have their own laboratory and analysis facilities.

Dust collector designed specifically for pharmaceutical and hazardous dust.

Dust explosive characteristics – there are certain values that need to be determined so the correct explosion protection and explosion venting measures can be specified as part of the dust control system. The first of these is the Kst value which measures the rate at which a dust explodes. The second is the Pmax which is the maximum pressure produced when the dust explodes in a sealed vessel. The third is the minimum ignition energy (MIE). For many standard materials, these figures are already known and a dust control company will help to verify them. However if they aren't known or there is some doubt, there are companies who can undertake the explosion testing to obtain these values.

Explosive atmospheres in the workplace can be caused by the presence of combustible dusts, flammable gases, mists and vapours, a mixture of some or all of these. Contain an explosive atmosphere in a sealed environment (such as a dust collector) with an ignition source and you have all the necessary constituent parts for an explosion to occur. In pharmaceutical manufacturing, it is common for a dust collector to be extracting air mixed with highly explosive dusts and gases. It is therefore critical for the manufacturer to know the explosive potential of the dusts, gases and dust/gas mixtures they are handling. It is relatively inexpensive to get the dusts tested to determine the required information as described below:

Kst – the normalized maximum rate of explosion pressure rise (measured in bar m/s). The dusts can then be categorized as follows to help with the protective equipment selection.

- ST1 Dust – Kst 0 bar m/s up to 199 bar m/s
- ST2 Dust – Kst 200 up to 299
- ST3 Dust – Kst 300 +

Pmax – the maximum explosion pressure of a dust cloud (measured in bar). This is a standard test and not to be confused with the actual pressure that can occur in a vessel.

MIE – The Minimum Ignition Energy (mJ) of a dust cloud by electrical and electrostatic discharges.

Once these values are realised, the internal and external ATEX Zones for the dust collector can be determined by undertaking thorough risk assessments of the process to which the dust collector is applied as well as the area in which the dust collector is installed. The dust collector can then be de- signed with all the appropriate safety systems installed, based on ATEX zone identification and ATEX Category shown below:

Dust EN 61241-10	Gas EN 60079-10	Details
Zone 20	Zone 0	A place in which an explosive atmosphere is continually or frequently present (more than 1000 hrs p.a).
Zone 21	Zone 1	A place in which an explosive atmosphere is likely to occur occasionally in normal operation (more than 10 hrs but less than 1000 hrs p.a).
Zone 22	Zone 2	A place in which an explosive atmosphere is not likely to occur in normal operation, but if it does it only occurs for short periods (more than 0.1 hrs but less than 10 hrs p.a). Alternatively if an explosive atmosphere can occur in case of a failure (e.g. if a cover opens or a bag is dropped).

ATEX Category	Typical Zone Suitability
1G (Gas), 1D (Dust)	Equipment suitable for all gas and dust zones that is safe in normal operation, in case of malfunction as well as in a rare malfunction.
2G, 2D	Equipment suitable for zone 1, 2 and 21, 22 that is safe in normal operation and in case of a malfunction.
3G, 3D	Equipment suitable for zone 2, 22 that is safe in normal operation.

This information will help in the correct specification of the safety features that need to be applied to the dust collector which include the following:

A reputable and knowledgeable dust collection company can provide advice on how compliance can be achieved, either through the retrofitting of the safety devices or the supply of new equipment. Despite the fact that the ATEX directives have been around now for well over a decade, there are a number of common myths that still prevail and need dispelling. These include the following:

1. **'There has never been an explosion previously so it must be safe'.**
   This has been a common excuse used after an explosion has occurred and they do happen also in pharmaceutical plants . A full risk assessment should be undertaken for each application involving a dust collector. If the dusts are explosive, if there are flammable gases present, then ATEX safety measures need to be installed on the dust collector.

2. **'The dusts being generated in our production processes are not explosive'.**
   Have the dusts been tested by an independent testing facility? These tests range in price from €1000 to €1500, which is not a big investment when you consider the potential cost of an actual explosion. If the test results show that a lower class of safety device is required then there will be some significant cost savings. Ask a dust collection expert to provide you with details of a recommended test facility.

3. **'We have eliminated all ignition sources so there is no possibility for an explosion to occur'.**
   It is always better to look at explosion prevention measures rather than explosion protection. However, it is very difficult to eliminate the potential for human error. No matter how well controlled a manufacturing process is, there is always some human involvement required, particularly during breakdown, servicing or routine maintenance. Statistic shows clearly that this is the case.

4. **'The dust concentrations are so low an explosive atmosphere isn't possible'.**
   The dust concentrations may be low in the extract airflow, but as the filters are being automatically cleaned inside the collector then a much higher concentration of dust will be present. It is necessary to look at the accumulated dust and the regeneration.

Once it has been established that the dust is explosive you have to start a process where you evaluate the different solutions to create a safe system. Here you have to work around the framework given by the dust properties as well as the health and environmental aspects of the processed material.

Antistatic Features/Earthing – Antistatic filter cartridges and dust collector earthing ensure that any static charge that builds up can be dissipated, preventing the possibility of a spark as an ignition source. In cases with ignition sensitive dusts and gases extra care needs to be taken such as using antistatic paint, antistatic containment bags and antistatic secondary filters.

Explosion Venting – A vent panel can be installed on a dust collector to safely dissipate an explosion pressure and flame. The vent panel will be sized according to the volume of the dust collector, the Kst and Pmax values. During an explosion, the vent panel will rupture and the explosion pressure wave and flame sent into a pre-determined safe area, horizontally or vertically using vent ducts reinforced to the same level as the dust collector. It is vital that the dust collector has been tested and verified to withstand the pressure and not leak flames uncontrolled (EN 14460). This solution is not suitable for toxic dust as large quantities will be ejected in case of an explosion.

Flameless Venting – These devices use the similar sizing criteria as the vent panels. They safely vent the explosion pressure and have the added benefit of stopping the flame propagation but they cannot vent into a zoned area and they do require a safety zone around the device. They are typically designed for indoor installations to reduce the risk to workers. There are limitations to their selection which your dust collector supplier will be able to determine. Also this solution means that dust will be ejected and in this case in a confined area.

Designed to be the “weak” link of the vessel, explosion vents open when pre- determined pressures are reached inside the dust extractor allowing the over- pressure and flame fronts to exit to a safe area. Explosion vents minimize damage to the dust extractor caused by overpressure created by a deflagration.

Designed to install over a standard explosion vent, the flameless venting extinguishes the flame front exiting the vented area, preventing it from exiting the device. This allows conventional venting to be accomplished indoors where it could otherwise endanger personnel. They cannot vent into another zoned area (risk of secondary ignition).

Suppression – These systems are designed to detect and chemically extinguish an explosion before it can propagate. Although these are typically more expensive systems to install, they are suitable for internal dust collector installations, low range ST3 dusts and also ensure the containment of toxic dusts.

Safety Valves/Dampers – There are a wide range of valves designed for ducting with a variety of names including non-return valves or isolation dampers, which basically perform the same function. They are designed to prevent any flame front from an explosion travelling down the dirty air ducting and causing secondary explosions in the production facility. Each device will have specific requirements relating to its positioning and connecting ductwork specification. Active valves are often combined with suppression as they reduce contamination of the production.

The ATEX directives apply to new equipment as well as existing equipment, including those items installed prior to the introduction of the directives. There are a large number of dust collectors currently in operation that do not have the necessary safety features and therefore do not comply.

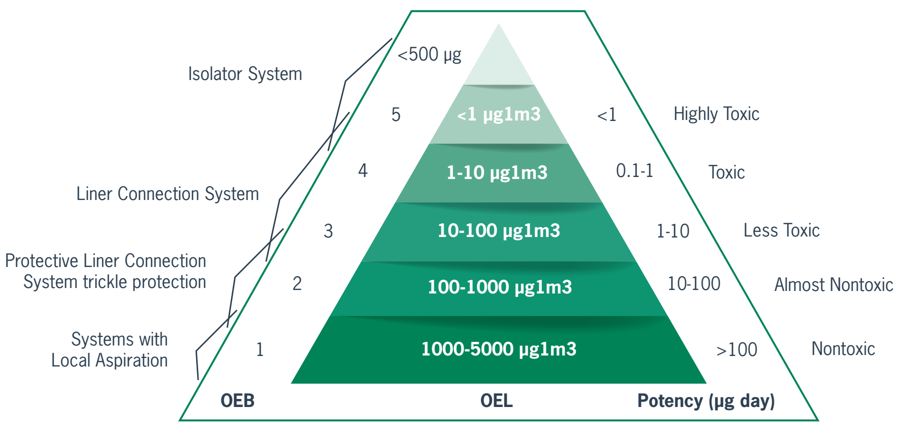
EUROPEAN DIRECTIVES

1. Directive 99/92/EC (also known as ATEX 137 or the ATEX Workplace Directive) on minimum requirements for improving the health and safety protection of workers potentially at risk from explosive atmospheres.
2. 2014/34/EU (also known as ATEX Equipment Directive) on the approximation of the laws of Members States concerning equipment and protective systems intended for use in potentially explosive atmospheres. The dust collector must comply with this directive if it is located in an ATEX Zone and/or it is collecting potentially explosive dust. Compliance is achieved by incorporating the necessary safety features determined by the explosive potential of the dust.

There have been changes to the ATEX Equipment Directive (changing from 94/9/EC to 2014/34/ EU) to try and create a more level playing field for suppliers of EX-rated equipment. There has been a lack of trust in the CE marking and also concerns regarding the different practices and quality of the notified bodies issuing the certifications. There will also be increased surveillance of the protective equipment market to help uncover those not reaching the required standards or deliberately flouting the laws. This is welcomed in the dust collection industry by reputable manufacturers because there has been a worrying trend for the production and promotion of sub-standard equipment, with price levels rather than safety levels being the main focus.

Exposure limits – the more potent the dust the lower the exposure limits set for personnel coming into contact with the materials. It is the employers' responsibility to know and understand the exposure limits for each product they are using, and take the necessary steps to ensure the limits are not exceeded. The information regarding exposure limits is country specific. Using the UK as an example, the information is available via the HSE website: http://www.hse.gov.uk/coshh/basics/exposurelimits.htm

An industry descriptive graphic is illustrated below



The next stage is to determine where in the process the dust is being generated. It is important to extract the dust from source to ensure that it does not escape into the workplace. A reputable dust control company will have the necessary qualified and experienced personnel to design the correct dust control system, specific to the application. The main constituent parts of a typical system are as follows:

Capture Hoods – there are a wide range of capture hood designs to choose from. A dust control company should be able to specify the most appropriate design for each and every extract point. Well-designed capture hoods with the required airflow face velocity will ensure any airborne dust is extracted. This will help to negate the four main risks outlined at the start of this whitepaper.

Example of an installation of a typical dust extraction/ collection system.

Ducting – the circular ducting transports the dust to the dust collector unit where it is filtered. Selecting the correct diameter of ducting at every branch of the ducting system requires an experienced and qualified engineer. They will calculate the airflow velocity requirements to effectively transport the dust through the ducting layout, ensuring the system is well balanced. If the dust is moved too quickly then it may affect the filters in the dust collector. If the dust is moved too slowly then it may collect in the ducting system causing a significant hygiene, fire and explosion risk. To fast can cause problems with high energy consumption and even impact sparks.

Dust Collector Unit – the dust collector unit is essentially a self-cleaning filter housing with a fan that moves the contaminated air out of the workplace, filters the dust and fume particles and dis- charges them into a bin or similar receptacle. The choice of filter material is critical and dependent on the dust characteristics, size, shape, charge and also the application conditions including temperature, humidity, pH etc. The area of filter material required is also important so that the dust collector is sized appropriately to handle the airflow and dust concentration as effectively and efficiently as possible. For particularly potent dusts or those with a higher percentage of sub-micron dust particles, it may be necessary to incorporate a secondary set of filters, HEPA or absolute filters, to ensure the very finest of dust particles are captured. Any gases present in an application will also be extracted so these must also be taken into account when assessing the potential risks.

Fan - The choice of fan and associated motor is also critical to the overall effectiveness of the dust control system. The fan has to achieve the required airflow and pressure to match to design criteria established by the dust control engineer. A good rule of thumb is that the fan should have an efficiency of 80% or higher, other technical requirements can limit the efficiency but it’s a reasonable target and more important than the motor efficiency.

Dust collector units with pulse-jet, compressed air cleaning are designed to run continuously and facilitate 24/7 production. With energy costs rising, the energy efficiency of the system is an important consideration when specifying the chosen system supplier. It is possible to evaluate the total cost of ownership of the dust control unit, taking into account each aspect of the system operation.

The fan may be running continuously so the most efficient motor should be installed to keep the power consumption as low as possible. Variable Speed Drives (VSD's) can be installed where appropriate to regulate the system airflow and also help to reduce the energy consumption. The fan should be sized to work at its optimum level; under-sizing or oversizing will impact both the system performance and energy efficiency.

Example of a dust collector unit showing various safety features, specified according to the particular dust and gas characteristics found in an application.

The compressed air supply for the pulse-jet cleaning is also an aspect of the system with associated energy costs. The correct set-up of the dust collector unit during commissioning is therefore necessary to ensure the filter cleaning regime is operating as per the manufacturers' instructions. It is worthwhile monitoring the compressed air usage as any reductions can equate to significant energy cost savings.

A well designed, balanced system will be both effective in terms of performance as well as energy efficient. When replacing older dust control systems with new ones, the return on investment can be very quick when the energy cost implications are realised.

The dust collector and ducting will incorporate a number of safety systems depending on the risks associated with the application. The comprehensive risk assessment will help to identify these and the level of protection required. Many of these will be legal or safety requirements under directives such as ATEX 2014/34/EC directive concerning equipment and protective systems intended for use in potentially explosive atmospheres (for EU Member States), NFPA for USA . As outlined the protective systems include safe explosion venting solutions, dust collector reinforcement, antistatic and earthing features, spark minimising fans, explosion suppression systems and various forms of ducting safety valves.

Another critical consideration and one which is often overlooked, involves effective containment of potent dusts. Once the airborne dust is captured at source, it needs to be contained at every stage of the extraction process. This is a major consideration when preventing cross contamination of products. It will help to satisfy authorities such as the Food and Drug Administration (FDA) ,European Medicines Agency (EMA) ,Medicines and Healthcare Regulatory Agency (MHRA) and others when assessing any Good Manufacturing Practice (euGMP) compliance across all production processes. Therefore, tight seals on the ducting joints, dust collector and any ancillary equipment, such as the protective systems, are imperative. Surrogate testing of the system once installed is recommended as this will give greater reassurance that all potent dusts are being contained.

Containment is also essential during maintenance of the dust collector unit. The filters will need replacing when they have reached the end of their service life, usually indicated by a constant rise in the differential pressure across the primary or HEPA filters. This filter change will either be carried out by a maintenance team or by a third-party contractor. For potent dusts there should be a specific and integral safe change operation for both the dust discharge system (for safe disposal of the collected dust) and the filter change-out. The better the design of these operations, the easier it is to facilitate a safe change and so prevent any release of harmful dust, up to the point of safe disposal.

The safe change , Bag in Bag Out (BIBO) performance of equipment on filter changes and discharge systems can and should be validated or surrogate tested in accordance with the guideline “ISPE Good Practice - Assessing the particulate containment performance of pharmaceutical equipment” - Second Edition - 2012, drawn up by the SMEPAC committee and published by ISPE or similar guide lines for the device .

SUMMARY

To summarise, when evaluating an existing dust control system for its suit- ability or designing a new installation, there are a number of key steps which will help towards a successful system installation.

1. Employ a specialist dust control company or specifier who will have the required experience and know-ledge to assist at every stage of the project. This will prevent any costly mistakes and ensure the system specified and installed is fit for purpose with all the necessary levels of protection to satisfy the legal requirements. Look for evidence in terms of case studies of similar projects successfully completed, focusing on the system performance, system safety functions (including explosion prevention, safe explosion venting and safe-change operations) and energy efficiency information.
2. Understand the ingredients/products being used and in particular, their characteristics and potential hazards when in dust form. If there is any doubt, or if there is some critical information missing, then get the dust tested. Determine the exposure limits for each material and the relevant Personal Protection Equipment (PPE) if required.
3. Undertake a full risk assessment of the existing or proposed production processes to determine the potential hazards. Identify where any dust will be generated, whether the workforce will be ex-posed to it, whether there will be fire and/or explosion potential or interference with machine moving parts/ electrical componentry.
4. Choose and install the system which is the best solution to satisfy the specific requirements identified. Establish a maintenance schedule to monitor the system to maintain optimum performance and help identify further energy cost savings.

REFERENCES

1. HSE Website (UK) www.hse.gov.uk
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