Reliable protection against toxic dusts and full explosion safety with TRM Filter dedusting systems

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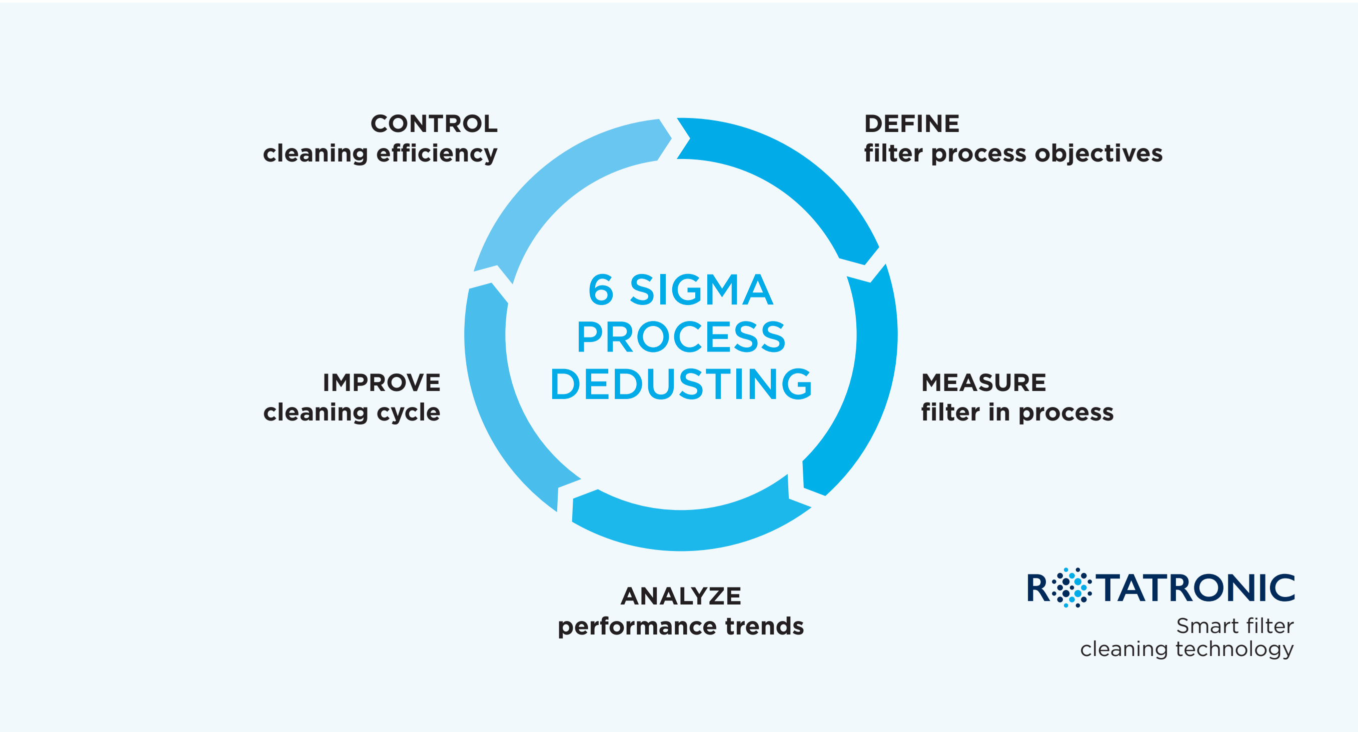
The dedusting of plants and processes in the pharmaceutical industry has particularly exacting requirements: Maximum filtration performance protects against dust residue, and filter systems and their handling are usually subject to dust-tight containment. Even if explosions occur during processes, environment, staff and process landscapes are systematically protected against process material leakage. This is achieved using tested and expert-approved, effective design solutions for explosion protection which enable reliable dedusting, even of highly-potent active ingredients (HPAPIs).

PICTURE 1: Rotatronic filter cleaning in the filter cartridge

Smart filtration as the basis for intelligent containment and superior explosion protection

Whichever way you look at it, when processing solids in the pharmaceutical industry you want to avoid losing valuable material as dust waste or having to separate, handle or dispose of dust residue. Intelligent designs with carefully devised protection strategies are based on premium filtration performance through surface filtration followed by HEPA or ULPA filters, and on maximising the life cycle of cleanable filters. TRM Filter relies on Rotatronic as its proprietary filter cleaning system. Here, rotating nozzles move closely over the filter surface, cleaning as they go (Picture 1). Intelligent systems monitor the filter behaviour to determine the the point in time at which cleaning takes place (Picture 2). This makes the filter elements last up to six times longer than standard systems, as a filter system whose filters do not require frequent replacement is less susceptible to opening or leakage.



PICTURE 2: Rotatronic 6 σ cleaning process control

Easy when you know how: ATEX protection against ignition sources, structural explosion protection against process risks

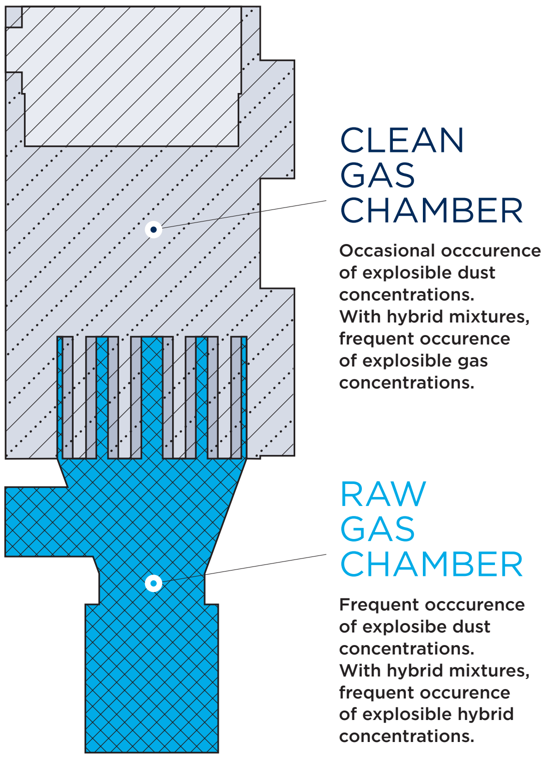
Explosion protection deals with the risks posed by the systems and components of a process plant governed by the ATEX (ATmosphères EXplosibles) Equipment Directive 2014/34/EU, and by the process governed by the ATEX Workplace Directive 1999/92/EC. In the manufacture of chemical active ingredients especially, where many pharmaceutical manufacturers started out, it seems natural to look at the inherent explosion risks arising from process control, for instance in connection with high pressures, high temperatures or the enormous chemical potential of the components. However, in process environments where less rigorous process controls and a lower degree of process monitoring technology are required, there are few points of contact with the ATEX Workplace Directive 1999/92/EC.

On the other hand, the set of rules which makes up the ATEX Equipment Directive 2014/34/EU originated from another quest for legal regulation: the standardisation of machinery and components within the European Community for the purpose of ensuring free movement of goods. The Directive defines the scope of measures for the protection against explosions caused by ignition sources arising from components and machinery as defined by the Machinery Directive 2006/42/EC insofar as the machinery is fitted with or intended to be fitted with moving parts. According to the ATEX 2014/34/EU Guidelines (second edition of December 2017), machinery is subject to the ATEX Directive 2014/34/EU if it is operated internally and/or externally in an explosive atmosphere and has its own protected ignition sources that must be classified according to the degree of protection they require. Under section 243, paragraph 1 of the Guidelines, the ATEX Directive does not apply to the filters mentioned in this article since they do not have their own sources of ignition. Instead, the Guidelines refer to the Machinery Directive 2006/42/EC and specifically to the risks of electrostatic charging to be covered in accordance with the standard EN 13463-1 Non-electrical equipment for use in potentially explosive atmospheres – Part 1: Basic method and requirements. Furthermore, it requires complementary risk control in accordance with the ATEX Workplace Directive 1999/92/EC. ATEX markings according to the Equipment Directive are a familiar sight, but sometimes erroneously applied to filters.

There is an overwhelming desire among operating companies, insurers and consulting entities to find simple, summarising descriptions for explosion protection levels of dedusting systems which norms and guidelines do not suggest. In certification documentation, it is possible to confirm the application of norms including the applicable principles of the ATEX equipment directive. Where a system is not placed in an external hazardous area, it is customary and legal to state this by identifying a dedusting filter's permissible internal zoning with suitable markings. It should be stressed that such marking can be **falsely** interpreted to include the correct conclusion to an overall process risk assessment and control. This ultimate objective is fulfilled only by an ATEX workplace risk assessment that enters into the intended use statement for the dedusting filter system. Furthermore, such compromise markings cannot be aggregated into a single marking, where systems are simultaneously placed in an exterior hazardous area.

When assessing risks according to the ATEX Workplace Directive 1999/92/EC for the pharmaceutical industry (in particular with regard to the conditioning of active ingredients and the handling of powdery active ingredients and delivery forms), we sometimes have to deal with environments that pose explosion risks. Explosions can be caused by ordinary oxygen/air dusts as well as hybrid mixtures of air, dust and solvents that go beyond the usual sources of ignition associated with the machinery and components used and are created by interactions between process and process materials.

The assessment of these risks and measures for appropriate protection are explained in VDI guideline 2263 published by the Association of German Engineers (VDI). Parts 6 and 6.1 of the guideline are specifically dedicated to dedusting filters. However, the risks identified there are no more reflected in the ATEX marking according to the ATEX Equipment Directive 2014/34/EU than in the protective measures taken, since the scope of the two regulations differs. At least with the ATEX system for marking devices and systems, it is possible to add an (-X) to indicate that further explanation in the documentation should be followed. The system documentation of the dedusting filter provides binding information about whether reference to further explosion protection measures was provided or not, as the documentation allows for operation as intended. The intended operation determines the admissible substance categories based on their explosion parameters by indicating the admissible limiting physical conditions.



PICTURE 3: **Frequency of occurrence of explosive concentrations in the chambers of dedusting filters**

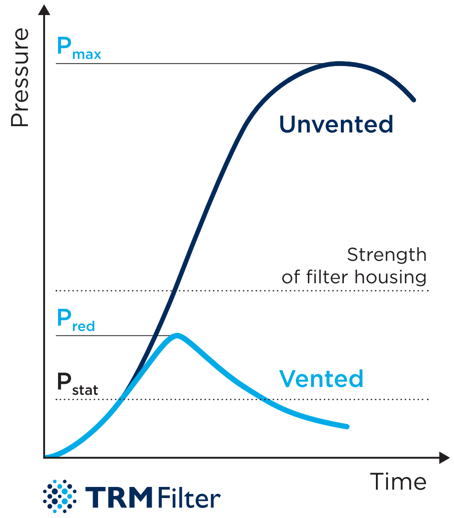
PICTURE 4: **ECO explosion-proof deduster**

The ATEX protection requirements of the Equipment Directive are categorised by means of a simple system of zones. The corresponding requirements with regard to the explosion risks of the procedure are also determined by risk assessment in accordance with VDI 2263. As with the ATEX zones, this involves assessing the frequency with which a certain mixture occurs. Furthermore, the probability of a specific mixture within a system exploding during process steps and the force of the explosion are explained and assessed so that necessary measures can be defined. This rather complicated approach takes into account the increasingly complex world of processing as well as the incompleteness of relevant data regarding the behaviour of substance mixtures under the physical conditions of a process state. This means that the operator is responsible for carrying out a reasonable assessment. However, when drawing up specifications between operators and manufacturers of machinery and process devices, the internal process areas can be worded in simpler terms – analogous to the ATEX zones – to make them more comprehensible. One could say, for instance, that the crude gas chamber of a dedusting filter is »analogous to a zone 21+1« (Picture 3).

Well-balanced concepts and responsible solutions from experts

Getting to grips with the residual risk of the explosion of organic dusts and hybrid mixtures in the dedusting filter is a task that can be reliably mastered. If further system components are decoupled to prevent explosions spreading **from** as well as **into** the filter from upstream process steps, neither explosion pressure nor flames can cause an explosion consisting of flame front and compression wave in any of the subsequent four ways of execution.

The obvious approach is to provide dedusting filters with a pressure-resistant design to withstand maximum explosion pressure. Even with the most explosive mixtures, the maximum explosion pressure remains below 12 bar. TRM Filter's *ECO type explosion-resistant dust collector* is a good example of this construction. Its round design offers maximum protection against explosions, whilst its extreme strength means it can withstand explosion pressures of up to 14 bar. Furthermore, this type of dedusting filter system is decoupled from the process on the crude and clean gas side, for instance by fast-acting slide valves or passive explosion isolation VENTEX valves. (Picture 4: *ECO explosion-resistant dust collector*). This construction type enables TRM Filter to produce compact dedusting filter systems with an extraordinarily small footprint that are



PICTURE 5: **Explosion pressure curve**

PICTURE 6: **Dedusting filter with explosion vents**

suitable for high airstream volumes and at the same time prevent product from escaping in the event of an explosion. Owing to their pressure-resistant construction, these compact designs are slightly more expensive than other designs.

Further strategies for controlling explosion pressure aim to make the reduced explosion pressure (P_{red}) occurring in the filter inferior to the pressure resistance of the dedusting filter (Picture 5: explosion pressure curve). An easy way to achieve this is to equip the dedusting filter with explosion vents or flameless venting devices. Explosion pressure develops at a rate that can be calculated with the constants K_{St} for dusts, K_G for gases and P_{max}. When the static opening pressure (P_{stat}) of an explosion vent is exceeded, the vent opens and releases the explosion pressure with a discharge speed determined by its effective venting area. The total pressure inside the filter equals the sum of both curves and reaches its maximal value in the P_{red}. These types of filter systems are decoupled in the same fashion as explosion-proof dedusting filters. Designs for indoor applications either use flameless pressure relief systems or the explosion discharge is conveyed to the outside through a vent duct. This design allows this construction of dedusting filter systems to be used in large airflows. It is a cost-efficient, low-maintenance solution, especially where, in the event of an explosion, dusts are conveyed safely to the outside through short ducts. Calculating the effective venting area is relatively straightforward. However, the installation of this design generally requires substantial planning efforts (Picture 6).

The majority of relevant dedusting filter systems in the pharmaceutical industry exclude the leakage of dust from the system in case of an explosion. It is common practice to control explosion pressure through chemical explosion suppression (Picture 7). A pressure sensor with a reaction pressure that is equivalent to the P_{stat} of a pressure relief system electronically triggers the injection of an extinguishing agent. This extinguishing agent reduces the explosion pressure with its total speed (depending on its spread from the place of injection and its extinguishing speed) analogous to pressure relief, thus restoring maximum P_{red}. As described above, these filter systems are also decoupled – for instance, by sensor-activated, fast-acting slide valves. This combination allows for medium-sized dedusting filter systems that provide reliable protection against the escape of toxic dusts or hybrids. The installation process can easily be planned. Owing to their rigorous control requirements, these explosion suppression systems are in the medium price segment. In addition, they require commissioning by experts, yearly maintenance and the exchange of the extinguishing agent after several years.

Knowledge of the minimum ignition energy (MIE), explosion speed factor K_{ST} for dusts or K for hybrid mixtures and maximum explosion pressure P_{max} is needed for the evaluation and design of the explosion protection strategies mentioned so far.

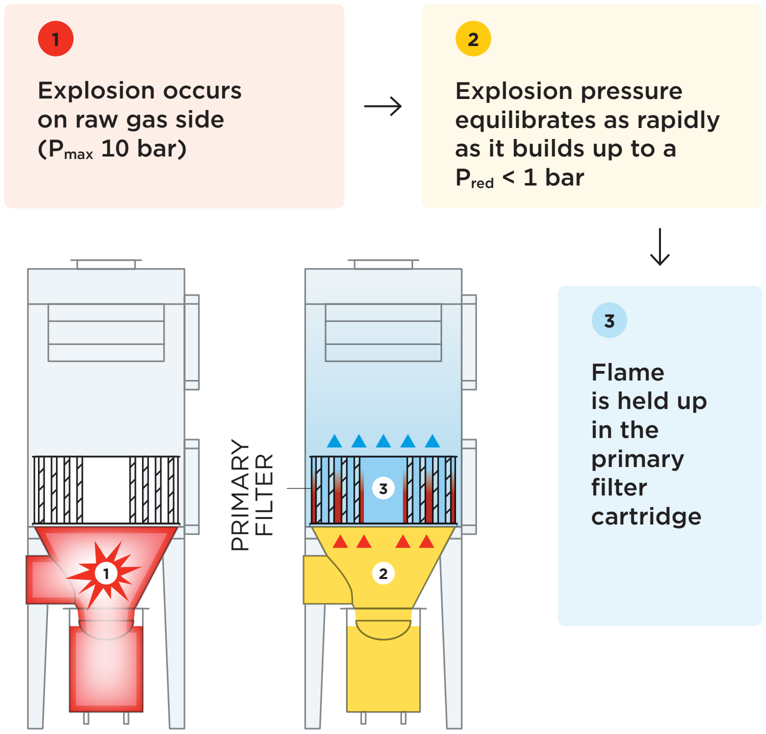
Simple design and comprehensive explosion protection through internal pressure relief of explosion pressure-resistant ECR and ECH dedusting filter systems

With the *ECR-Total Pharma Dedusting Filter* (Picture 8) and *ECH-Occupational Hygiene Dedusting Filters*, TRM Filter has opted for a simpler, more elegant solution to planning and device equipment: both dedusting filters are explosion-resistant, since they discharge explosion pressure within the filter system and hold back explosion flames. With TRM Filter design, additional decoupling measures beyond integrated butterfly valves are only required in exceptional cases.

Only an ignitable mixture of explosive substances can explode. Consequently, in cleanable dedusting filters, ignitable dust concentrations occur only during the cleaning of the filter in the crude gas chamber (Picture 9). Therefore, TRM Filter's *ECR Total Pharma Dust Collector* and *ECH High Containment Dust Collector* seal the crude gas chamber on the suction side during filter cleaning by means of a valve. Continuous operation is guaranteed through parallel filter chambers. Few exceptional process conditions can be found, wherein explosions evolve from different ignitions. They can occur when e.g. extraordinarily high dust concentrations are aspirated and therefore brought into the filter from the upstream process interface. Such exceptional conditions require additional explosion isolation. This is an important process issue, however, and not a filter matter, and should therefore be discussed elsewhere. Also, where hybrid mixture occurs, solvent residues that are not retained on the filter will pass through the clean gas chamber. In any event, should an explosion occur in the crude gas chamber, it will be discharged via the dissipative filter cartridge into the clean gas chamber. Crude and clean gas chambers Crude and clean gas chambers physically communicate and divert the explosion pressure to a P_{red} below the pressure resistance

PICTURE 7: **Dedusting filter with suppression system**

PICTURE 8: **ECR Total Pharma Deduster**



PICTURE 9: **Internal pressure diversion with ECH and ECR Dust Collectors**

of the dedusting filter housing. The dissipative filter cartridge (a type-tested explosion protection component) holds the explosion flame back. Due to its dissipative design, it also prevents the ignition of solvents in the filter passage. Solvents passing through the cleanable filter do not come into contact with any other ignition sources in the clean gas chamber or downstream flow paths. These filter systems do not require decoupling on the pure gas side, as per the dedusting filter system's scope.

By operating suitable modules in parallel, this construction type allows for the design of large dedusting filter systems which remain sealed even in the event of an explosion. Planning is simple in regards of both installation and explosion protection technology. In addition, the systems are very compact and quite cost-efficient – compared to massive filter systems such as the *ECO explosion pressure-resistant dedusting filters*. Relatively low cost of commissioning, maintenance and replacement provisions are incurred.

Trouble-free dedusting solutions with the security of explosion pressure-resistant and user-friendly containment dedusting filters

TRM Filter's ECR Total Pharma Dust Collectors and *ECH High Containment Dust Collectors* are safely protected against the effects of explosions. Rigorous explosion protection tests carried out by the Research Establishment for Applied System Safety and Health (FSA) have proven that these systems meet all such pharmaceutical industry requirements in a clear cut – design. Both systems work according to the toxicological requirements for pharmaceutical processes at five tried and tested containment levels. These dedusting filter systems can be upgraded to higher containment levels throughout their operational lifetime. Upgrading options comprise all levels from the Enduro design, without containment measures, up to the Optimo design, for OELs of up to 1 µg/m³ (including OEB 4). Furthermore, the Maximo configuration offers a design platform for OELs below 1 µg/m³ (OEB 5 and higher). Both new developments of TRM Filter are fully compliant with all the requirements for state-of-the-art pharmaceutical dedusting filter systems. The complete systems open up new horizons for reliable filter solutions that have long been appreciated by leading pharmaceutical manufacturers. They offer safety in attractive, tested and proven design quality.

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Established in 1982, TRM Filter is based in Ljubljana, Slovenia. The company focuses on the development and production of innovative pharmaceutical dust removal systems in the domains of pharmacy, chemistry and food industry. Rotatronic Technology developed by TRM Filter meets the high requirements for explosion-protected High Containment filter systems, offering the best filter performance while also being low-maintenance. TRM Filter's solutions are implemented by leading pharmaceutical companies. The company is run by Peter Tomšič.