TRM Filter

Precise and reliable containment in the dedusting of toxic dusts with TRM Filter

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The question of how to treat toxic dusts in occupational hygiene is growing increasingly important. With dedusting filter systems in containment designs suppliers encounter a special need for protection. The detailed definition of these protection requirements at the highest level of design qualities encompasses far greater challenges than those more often to be overcome with regard to the improved protection of employees working with existing products in the pharmaceutical or any other process industry. In this technological atmosphere of new frontiers in an ethically relevant change it is the mission of the market leaders to discuss and accompany the development of a clear and appropriate deepening of a definition process, thus ensuring an effective design quality of containment systems. This specialist article searches for clarification, describes TRM Filter dedusting systems as standard containment solutions up to an OEL of 1 µg/m^3 and briefly describes a protective system for lower OELs of high potency active pharmaceutical ingredients (HPAPIs) that goes beyond standard systems.

The highest admissible dust load in the ambient air of a system, indicated in µg /m³, serves as a reference value for the containment design of systems – in our case: dedusting systems – in the pharmaceutical industry. This target value is referred to as Occupational Exposure Level (OEL). From the point of view of occupational hygiene, the range of 100 down to under 0.1 µg/m³ is considered to be relevant – a range of more than four powers of ten of leakage concentrations. Also, they were smoothly expressed in Occupational Exposure Bands (OEB) from 3 to 6, thus allowing for the indication of OELs under 1 µg /m³ (beyond OEB4) in a linear scale, which in a way was misleading. When it comes to especially low OELs, a keener precision in the process-related toxicological determination of requirements is very important. The same applies to rigorous process design through cross-lined quality analysis and in-depth validation.

Filter dusts as containment balance gaps

When considering dust that is released into the environment of a system as a total process material loss rate, process dedusting represents the largest flow of process materials loss apart from leakages in the feeding and removal of process materials. Therefore, operators of containment systems should keep a critical eye on dedusting. If a containment strategy is successfully implemented, almost all process failures, such as in solida formulation, are logically and mostly carried out via the dedusting filter system with temporarily fluctuating mass flows. In these cases, dedusting filter systems comprise at least two successive filter levels whose operation and maintenance must be carried out in a closed system owing to containment principles. The first filter level of a TRM filter system separates the dust load from the filtration air flow. With the Rotatronic technology of TRM Filter, the first level is cleaned in a matter of seconds, thanks to an intelligent differential pressure control. A collecting system captures the dust with appropriate exchangeable containment technologies. The first filter level of the air flow is followed by a second, not cleanable police filter. Both filters can be exchanged under containment in the Bag-in/Bag-out procedure (Picture 1: Bag-in/Bag-out).

PICTURE 1: **Bag-in/Bag-out**

Containment as an effective means of employee protection

In view of containment as a part of technological equipment design, the original consistent and ethical objective of providing comprehensive occupational hygiene and operator protection must not be neglected. For us and other competent market players, the conceivable scope of protection should not only be postulated as quality by design, but also consistently observed and systematically measured with regard to construction and manufacturing design. After all, these toxicologically relevant dust loads are invisible leakages. This means that the quality of a system cannot be judged from observations of human senses.

PICTURE 2: **Safe Bag**

With regard to mechanical structure, all containment dedusting systems include gas-tight housings, connection technology and the link between the core system and consumables (liners, bags, corresponding sealing materials) changing during operation. During manufacturing, the intactness of welding joints, the planarity of sealing surfaces and the tightness of the total structure are tested and documented. In collaboration with independent inspection institutes, samples of containment dedusting filters are inspected for their leakage rates when properly operated, including the exchange of dust collector and filter. There is a quantitative measurement of remaining leakage with the help of equipment developed by ISPE (International Society of Pharmaceutical Engineers) in a »Good practice guide« referred to as APCPPE (Assessing the Particulate Containment Performance of Pharmaceutical Equipment), in this context better known under the name of its predecessor SMEPAC (Standardized Measurement of Particulate Airborne Concentration). It is carried out under the conditions of a physical-technical test lab and involves several dozen trace analysis measurements of substitutes such as lactose. Finally, the achievement of the objectives of the individual designs of dedusting filter systems is mostly analysed during process validation of the operator in accordance with the FDA guidance ICH Q9.

PICTURE 3: **Continuous Liner**

Definite reliable containment standards with Practico and Optimo

TRM Filter produces ECH High Containment Dedusters as local dedusting filter systems for the formulation of solida for air flows of up to 1,000 m^3/h as well as ECR Total Pharma Dedusters, for instance for galenical conditioning processes with higher airflows of up to 21,000 m^3/h. With the described systematics in the containment functionality, TRM Filter developed staged designs for both product lines: Practico offers containment up to an OEL of 10 µg / m^3, Optimo up to 1 µg /m^3. For higher requirements exceeding the systematics specified here TRM Filter adapts designs and options of the Maximo to individual needs.

The ECH Practico was designed for semi-continuous operation with an OEL of up to 10 µg /m^3 (including OEB 3). For the Rotatronic cleaning of the primary filter within a few seconds a valve shuts at the raw gas inlet. The seal prevents the backflow of dust-laden cleaning air into the process. The filter dust is emptied into a safe bag (Picture 2: safe bag). As in all containment systems, the filter elements are exchanged via Bag-in/Bag-out ports.

For fully continuous operation up to an OEL of 1 µg /m^3 (including OEB 4), the ECH Optimo uses two parallel filter chambers. Only one of them is isolated from the process flow for a few seconds for filter cleaning. Once the filling level has been reached, the filter dust in the collection funnel is emptied into a continuous liner (Picture 3, continuous liner).

PICTURE 4: **ECH Maximo**

Containment of HPAPIs through competent case-specific adaptation of the Maximo

The design criteria specified above are not entirely valid for special dedusting filter systems for OELs under 1 µg /m³ (OEB5 and beyond). The TRM Filter product platform Maximo (Picture 4: ECH Maximo) is characterised by some specific and function-related design features and combines the fully continuous, cross-contamination protected configuration of two parallel filter chambers with the secondary protection of a glove box in addition to the dust collection in continuous liner. In addition, filter dusts are immobilised before the filter elements are replaced.

At the Achema 2018 (Hall 1.1, Stand E13), TRM Filter presents the precise and reliable containment dedusting systems Practico and Optimo in standard designs for OELs up to 1 µg /m³ (including OEB 4). Higher requirements (OEB5 and beyond) are met by TRM Filter on the basis of the Maximo system. TRM Filter complements the Maximo system to meet the exact HPAPI requirements accurately.

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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.