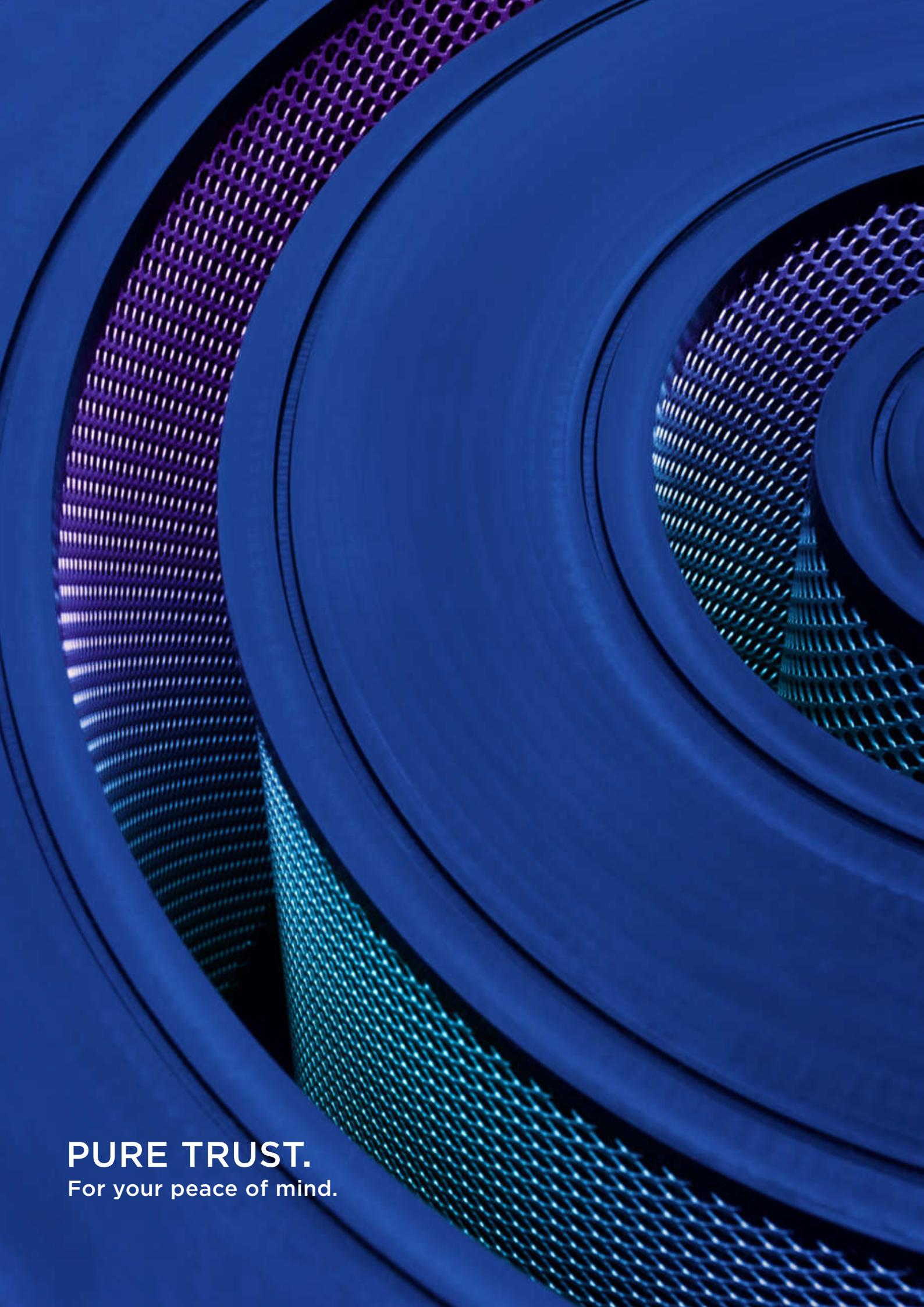
TRM Filter®

TOTAL AIR FILTRATION SOLUTIONS

for Pharmaceutical Industry


PURE TRUST.
For your peace of mind.

Our journey

TRM Filter was **established in 1982** as a small family business manufacturing filter cartridges for various applications. Having seen firsthand the challenges faced by the industry, we began designing and manufacturing our air filtration systems in 1998.

We have made tremendous progress over the last two decades and now work with renowned partners in the pharmaceutical industry around the world, with **over 1000 air filtration systems installed** worldwide.

Having the privilege of working with, listening to, and learning from our partners, our excellence and desire to innovate has led us to many advanced solutions that we now incorporate into our product portfolio. Recognizing the importance of continuous improvement, we never settle and always seek to challenge ourselves to become even better.

With **our mission** to **give our clients peace of mind**, we strive to make our products and services reliable and seamlessly integrated into processes and operations, with minimum input required by the end user.

Peter Tomšič
CEO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Role of reliable air filtration in the pharmaceutical industry

Introduction

In the pharmaceutical industry, maintaining a safe and controlled environment is paramount to ensuring personnel, environmental and product safety. Air filtration plays a critical role in achieving these goals. In addition, air filtration is critical to meeting the industry's stringent quality and regulatory standards.

Environmental protection

Environmental responsibility is a critical aspect of pharmaceutical manufacturing. By capturing and eliminating harmful particles from the air stream, air filtration systems and solutions help to reduce the risk of environmental contamination. This is also essential to demonstrate compliance with environmental regulations and to obtain or maintain a license to operate.

Health and safety

Pharmaceutical manufacturing involves the handling of various chemicals and biological materials that can pose health risks. As the health and safety of personnel is non-negotiable, a properly designed and capable air filtration system is a must to ensure a safe working environment with efficient removal of airborne hazards. This reduces exposure to harmful substances, limiting the risk of occupational illness and improving overall workplace safety.

Quality assurance

Airborne contaminants can compromise the integrity of pharmaceutical products, leading to potential deviations and recalls. Effective air filtration systems are essential to prevent contamination from dust and other particles. This commitment to air quality not only supports compliance with Good Manufacturing Practices (GMP) and ISO standards but also enhances the overall reliability and reputation of pharmaceutical operations.

Energy efficiency

With energy costs accounting for up to 70% of the product lifecycle cost of air filtration, solutions must be designed and selected with energy efficiency in mind. Such approaches not only reduce operating costs but also contribute to sustainability goals.

Proprietary filter cartridge by TRM Filter

At TRM Filter we understand these and other air filtration challenges faced by the pharmaceutical industry. Our air filtration systems are designed in partnership with our customers to deliver superior performance, reliability, and efficiency, ensuring that world-changing industries such as the pharmaceutical industry can operate at their best.

Filtration standards

The air filtration industry is strictly governed by a series of standards that evaluate the performance characteristics of air filters and classify them into appropriate classes. This makes the industry regulated and highly transparent to the end user.

The following two standards are considered gold standards of high-efficient air filtration:

- ISO 29463-1 High-efficiency filters and filter media for the removal of particles from air,
- EN 1822-1 High-efficiency air filters (EPA, HEPA, and ULPA).

ISO 29463 is a newer standard with its roots in EN 1822 and was introduced primarily to provide clarity in the air filtration standard maze. It recognizes EPA, HEPA, and ULPA filter classes commonly found in industrial applications, which are summarised in the comparison table below. All filter classes are defined based on the Most Penetrating Particle Size (MPPS), which is the worst-case scenario for a given air filter.

Filter group	Filter class as per EN 1822	Filter class as per ISO 29463	Efficiency – integral [%]	Penetration – integral [%]
EPA	E10		≥ 85	≤ 15
	E11	ISO 15 E	≥ 95	≤ 5
		ISO 20 E	≥ 99	≤ 1
	E12	ISO 25 E	≥ 99.5	≤ 0.5
		ISO 30 E	≥ 99.9	≤ 0.1
HEPA	H13	ISO 35 H	≥ 99.95	≤ 0.05
		ISO 40 H	≥ 99.99	≤ 0.01
	H14	ISO 45 H	≥ 99.995	≤ 0.005
		ISO 50 U	≥ 99.999	≤ 0.001
ULPA	U15	ISO 55 U	≥ 99.9995	≤ 0.0005
		ISO 60 U	≥ 99.9999	≤ 0.0001
	U16	ISO 65 U	≥ 99.99995	≤ 0.00005
		ISO 70 U	≥ 99.99999	≤ 0.00001
	U17	ISO 75 U	≥ 99.999995	≤ 0.000005

Classification of filter elements as per ISO 29463 and EN 1822

Pleated filter media

In-house filter element engineering & manufacturing

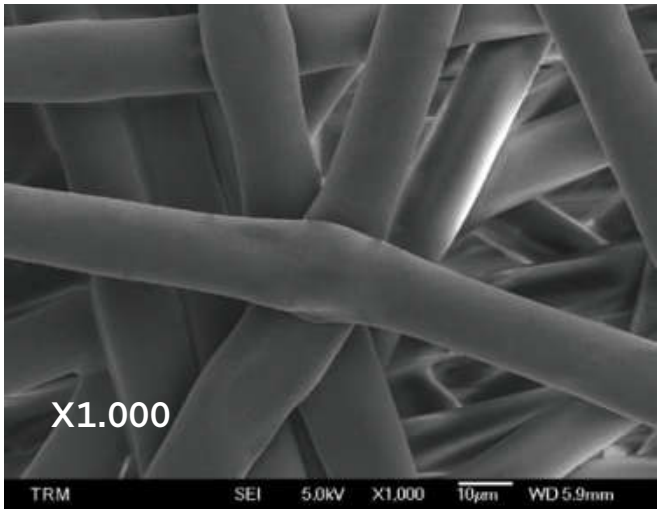
To meet the challenges and stringent requirements of the pharmaceutical industry, at TRM Filter, we design and manufacture our own filter elements. This enables us to ensure high-quality design, performance optimization, and continuous improvement of our filter elements, whilst maintaining stringent quality assurance requirements.

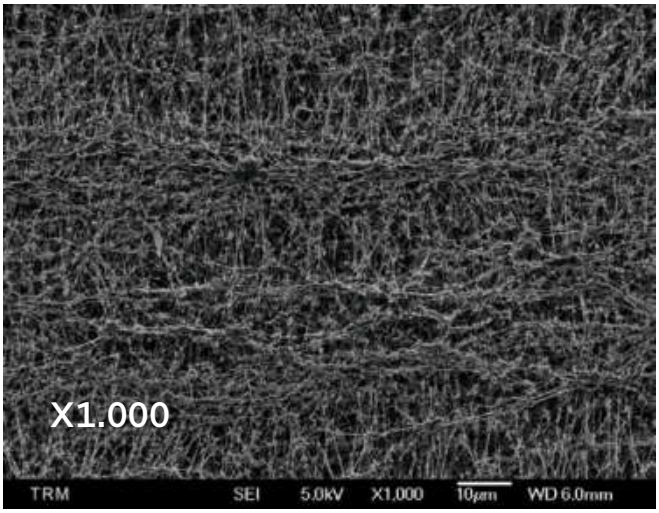
With our current production capabilities, we can manufacture and test proprietary filters with efficiencies up to HEPA H13 (ISO 35 H according to ISO 29463). This is done using surface filters with ePTFE membranes as shown in the pictures below.

Such ePTFE membrane filters, in combination with our proprietary ROTATRONIC filter cleaning system, ensure:

- High filtration performance,
- Optimized pressure drop (energy savings),
- Improved cleanability and extended filter life,
- Adaptability and development of special filter types based on customer requirements.

Polyester filter media without (left) and with (right) ePTFE membrane, with same resolution (10 µm)





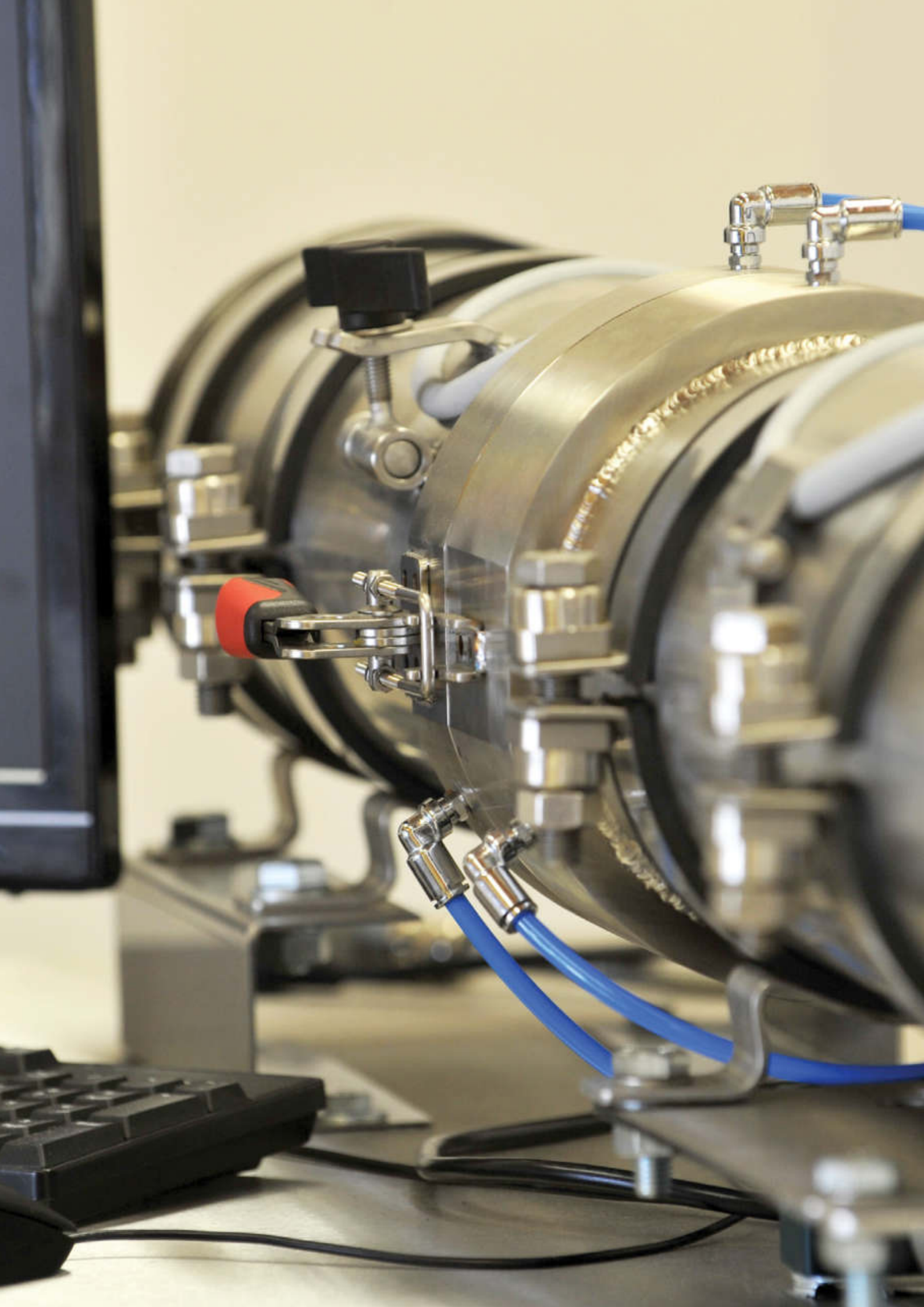
Filter integrity testing

Filter integrity testing is the final barrier to protect against potential releases of hazardous substances to the environment, as part of commissioning and qualification, and periodically during the lifetime of the filter. The **ISO 16170** standard specifies in-situ test methods for high-efficiency particulate air filters used to limit releases to the environment during the lifetime of the filters.

The standard specifies the method of measuring the particle concentration before and after the filter using a challenge aerosol (e.g. DEHS). By counting the number of particles before and after the filter, the difference in particle number is defined, from which the filter efficiency can be calculated and evaluated according to the ISO 29463 standard introduced above.

At TRM Filter, we integrate the ISO 16170 measurement setup into our equipment, allowing the end customer to reliably evaluate filter performance at any point during operation and address potential challenges in a timely manner.

Example of filter integrity test ports with Tri-Clamp connection points as per DIN 32676

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Total solutions.
With you in focus...

Developing with and for our customers, we are highly user-focused and pay attention to every detail that matters to our users.

In addition to **reliable filtration**, which is the cornerstone of our business, we are committed to the health and safety of our end users. That is why reliable, **user-focused containment** and **integrated explosion protection** are at the heart of all our solutions. To give our customers peace of mind, we strive to provide **turnkey solutions** based on specific customer requirements, including **engineering**, **equipment supply**, **installation**, **commissioning**, and **lifetime support** of the equipment.

From the concept design stage, we are experienced in challenging the design with critical issues and providing solutions to meet your needs. Using in-house knowledge, our test equipment, and in conjunction with our partner laboratories, we can provide **on-site assessment and analysis** of process conditions (e.g. particle concentration, dust type, combustibility assessments, etc.). Based on this, we can advise on the most appropriate process and safety approaches to air filtration for specific applications, including filter media selection, explosion protection concepts, etc.

With our **in-house design and manufacturing** capabilities, we are then able to ensure **flexibility** in the final solutions, including challenging process conditions (e.g. high-temperature applications) or layout constraints. In addition, with our proprietary ROTATRONIC software, we can fully integrate our system into the customer's process equipment or BMS.

Due to the stringent GxP requirements, we are also trained and able to carry out the **full range of qualifications (IQ, OQ, PQ)** including the supply of GDP-compliant documentation packages.

< On-site example of ECR-3P2

On-site example of ECR-10-4 filter system with central dust collection

...and positive impact on the environment and the community

Recognizing the great opportunities and working with major companies, we have joined ever-increasing community of companies that cherish sustainability. We are working tirelessly to reduce the environmental impact of our equipment throughout its lifecycle, as well as supporting positive change in the community.

By setting clear sustainability targets and being **independently assessed by EcoVadis and Avetta**, we can demonstrate our commitment and help our partners achieve their sustainability goals.

We have started to develop our solutions using **recycled or partially recycled materials** to reduce our carbon footprint without compromising quality.

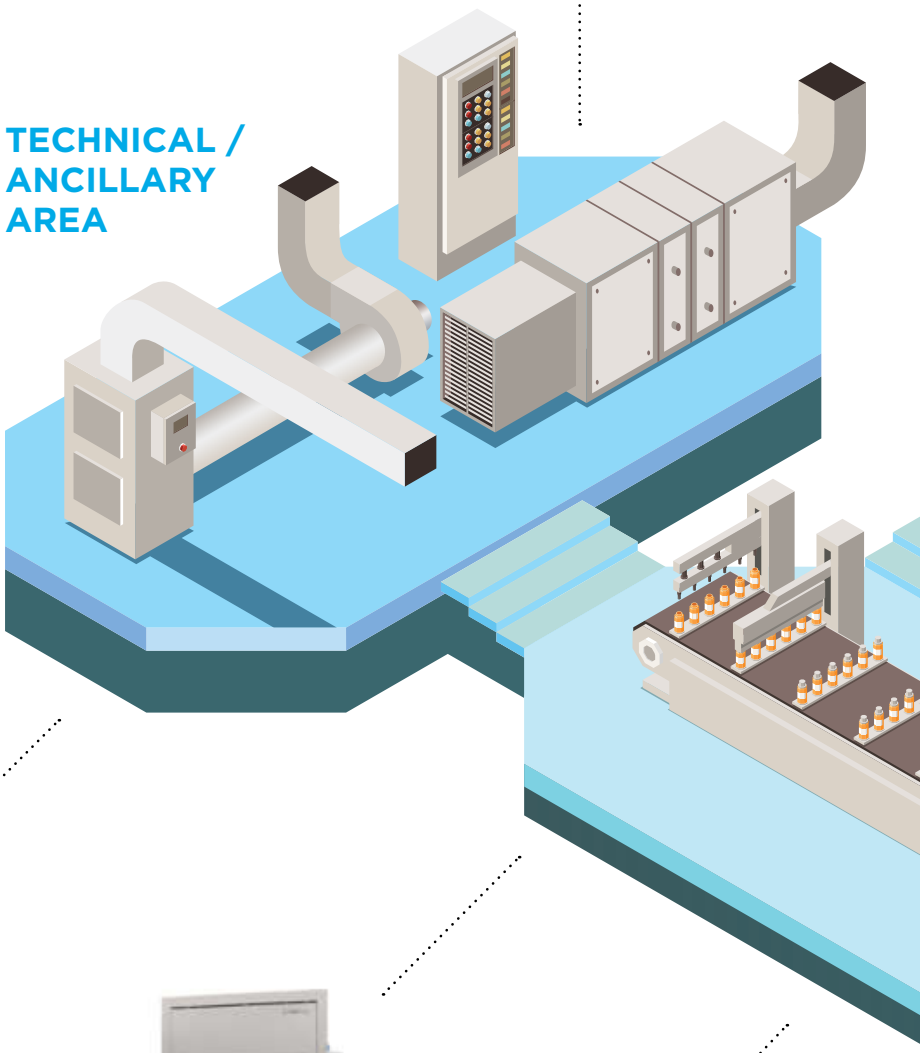
In addition, we have also worked hand in hand with our major customers on projects where we have set and achieved significant **reductions in CO_2 emissions**, demonstrating that with the right mindset and approach, there are always opportunities to contribute to the environment.

With all our work and commitment to sustainability, we have been **recognized by the government** as a major potential SME for circular economy and sustainable transformation, for which we have also **received EU funding** and support to drive these changes forward.

Products & solutions

Designed with the needs of the pharmaceutical industry in mind, our air filtration solutions cover all applications within the industry, including **process equipment filtration**, **local exhaust ventilation**, **central dust collection**, and **room filtration**. All these systems can be installed and used in **clean rooms**, **R&D or QC labs** as well as **ancillary/technical areas**.

ECR-10-5 with CDC

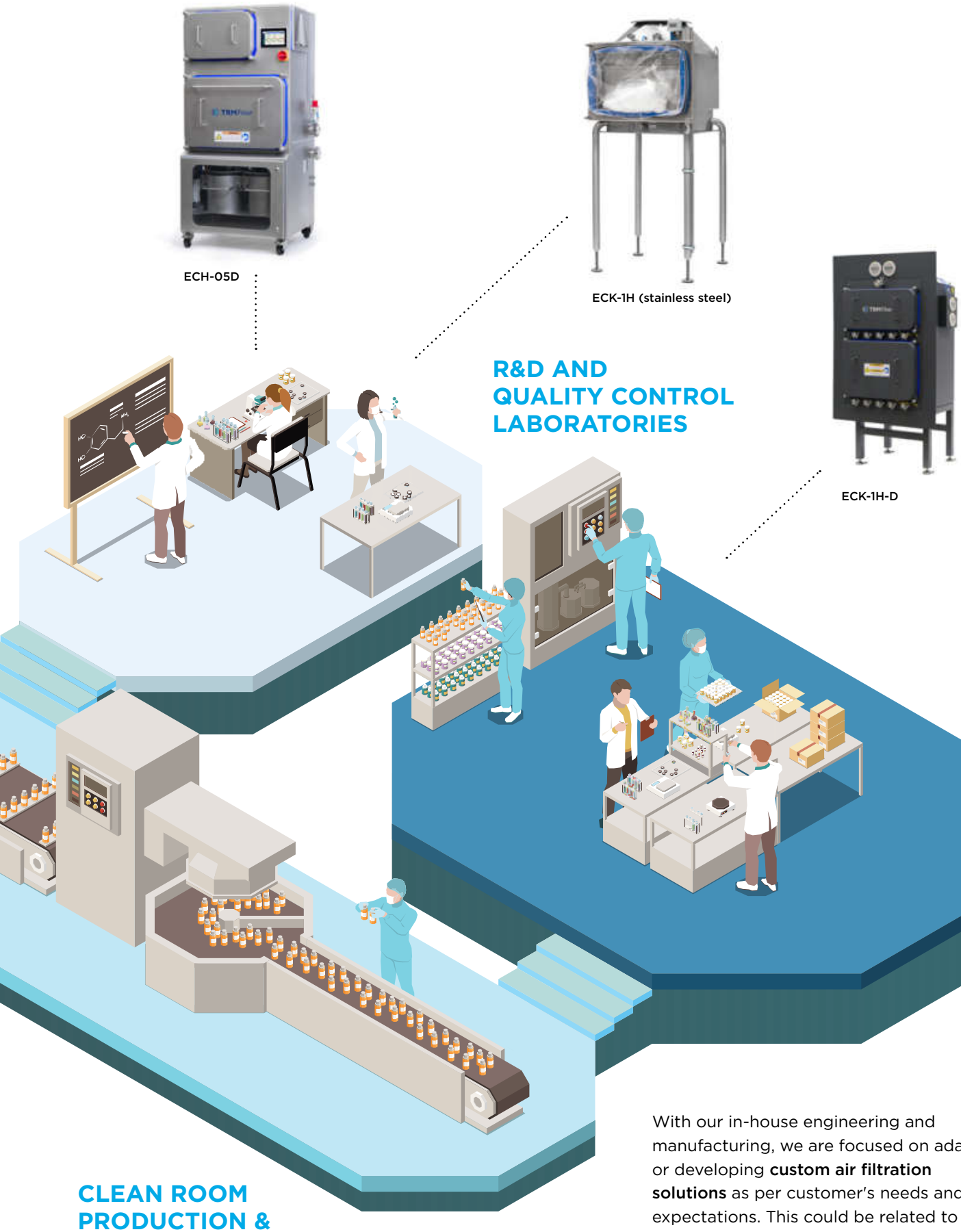


ECB-2P1

ECK-1H

ECK-W

ECH



ECH-05D

ECK-1H (stainless steel)

ECK-1H-D

R&D AND QUALITY CONTROL LABORATORIES

CLEAN ROOM PRODUCTION & PACKAGING

With our in-house engineering and manufacturing, we are focused on adapting or developing **custom air filtration solutions** as per customer's needs and expectations. This could be related to layout restrictions, demanding process conditions (e.g. high-temperature filtration) or specific application requirements.


ROTATRONIC®
Smart filter
cleaning technology
ROTATRONIC

ROTATRONIC
Smart filter cleaning & control

With Industry 5.0 and the importance of digitalization, we have joined forces and combined our knowledge and expertise in mechanical filter systems with powerful software to make another leap in air filtration performance. By doing so, we have developed ROTATRONIC, a **unique filter cleaning system** with **powerful software functions and integration** capabilities.

ROTATRONIC Smart filter cleaning

With our in-house design and production of filter elements, we have been able to introduce a special filter cleaning system using **rotating cleaning nozzles** that circulate inside the filter element itself. During the filter cleaning cycle, these nozzles rotate closely to the filter surface, directing compressed air over a short distance onto the filter media, enhancing the cleaning effect at reduced air pressure.

Rotating filter cleaning nozzles

The design of the special cleaning nozzles in our dust collectors has been carefully considered to minimize the number of components, reduce internal pressure loss, and ensure effective cleaning of the entire surface of the filter cartridge.

With all the above, ROTATRONIC **extends the life of the filter element** and reduces the mechanical stress on the filter, which contributes to the overall performance of the filter. At the same time, a longer filter life **reduces the total cost of ownership** in terms of OPEX and energy required to maintain the filtration system.

ROTATRONIC Control

None of the major benefits of ROTATRONIC would be possible without the **proprietary control software** that is the brain of our air filtration systems. It consists of an **intelligent filter cleaning algorithm**, based on Six Sigma process optimization, which continuously monitors the performance and clogging tendency of the filter media during operation. Based on this data, the filter is cleaned to the ideal level, extending its life and reducing aging.

ROTATRONIC Control - HMI screen

The software does more than just control the filter cleaning cycles. It also provides **comprehensive monitoring and control** of all aspects of the filtration process through a **user-friendly graphical interface (HMI)** that can display key data, logs, and parameters. It also offers:

- Full integration with process equipment or building management systems (SCADA, BMS).
- Connection of additional sensors to monitor and record parameters such as filter outlet emissions, humidity, temperature, or airflow.
- Other control connections as required by the customer.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Containment

Containment is the cornerstone of any pharmaceutical operation to prevent cross-contamination, environmental release, or worker exposure to increasingly hazardous Active Pharmaceutical Ingredients (APIs) and other substances. Air filtration systems are critical as they are often the **last barrier**, hidden behind the wall, where such substances accumulate in larger quantities. In addition, the air filtration system cleans and often recirculates contaminated air back into the cleanroom, which must be done with unquestionable reliability.

Containment strategy

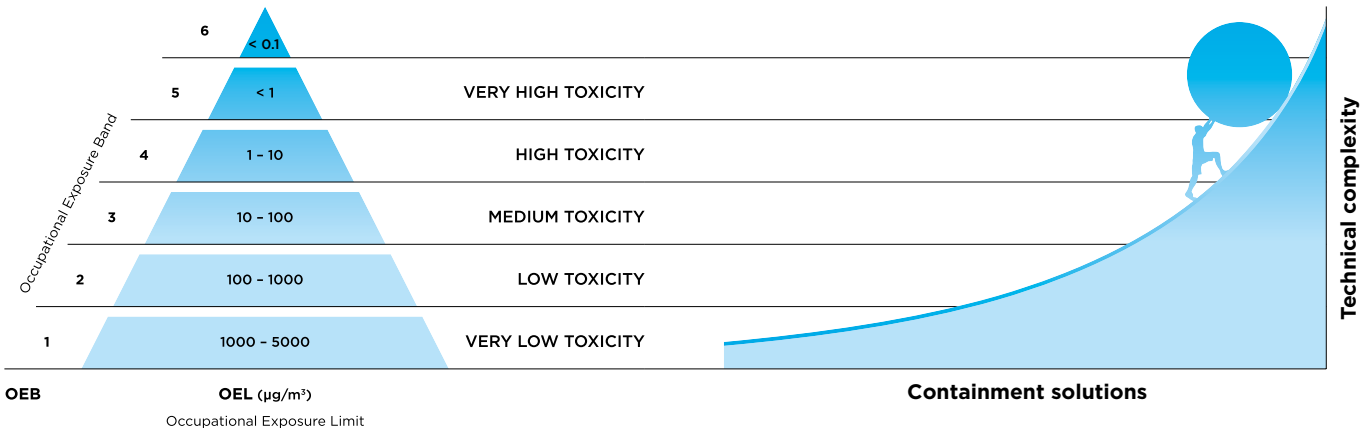
The pace of pharmaceutical development is accelerating, with new compounds being discovered and marketed every day. Even if these new molecules have undergone rigorous research and pre-clinical/clinical trials, there are still **many unknowns, including their toxicological potential**. As such risks can have a significant impact on human life or the environment, compromise is not an option.

With all the above in mind, more than ever, **air filtration should be seen as an integral part of the containment strategy** in pharmaceutical production, **requiring in-depth expertise** on the part of the manufacturer to support the approaches and needs of the end customer. As there is no one-size-fits-all solution, such approaches require collaboration and alignment between multiple stakeholders to achieve successful project completion.

<
High-containment though-the-wall dust collector for clean room areas

Containment performance

The **Occupational Exposure Limit (OEL)** is the key information we need to understand to plan the correct containment approaches. From the OEL values, the customer should develop a **Containment Performance Target (CPT)** applicable to equipment and systems used. This may be equal to the OEL or may include safety factor, making the CPT even more stringent and technically challenging. With **now even OEB 6 (OEL < 0.1 µg/m3)** becoming present in the industry, the topic is becoming super challenging and needs to be addressed correctly.



TRM Filter has long experience and proven performance in containment. We have **validated our solutions in-house** using tests as per Assessing the Particulate Containment Performance of Pharmaceutical Equipment (APCPPE) guidance from the ISPE. In addition, we have carried out **numerous on-site containment performance tests** with our customers in real-time conditions to prove that our containment performance is reliable and safe.

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In-house APCPPE testing

Explosion protection

In pharmaceutical production, almost all dusts are organic and therefore combustible. In addition, organic flammable solvents and gases are also used, creating additional risks. According to the current ATEX Workplace Directive 1999/92/EC and NFPA regulations, the use and handling of combustible dust or flammable liquids/gases requires special attention due to the risk of explosion.

Historically, **air filtration systems have unfortunately been involved in many explosions**, some with serious consequences and loss of life. This is mostly due to the remoteness of such systems, poor understanding of the risk, limited maintenance, and the unfortunate physiochemical properties of dust with very small particle sizes.

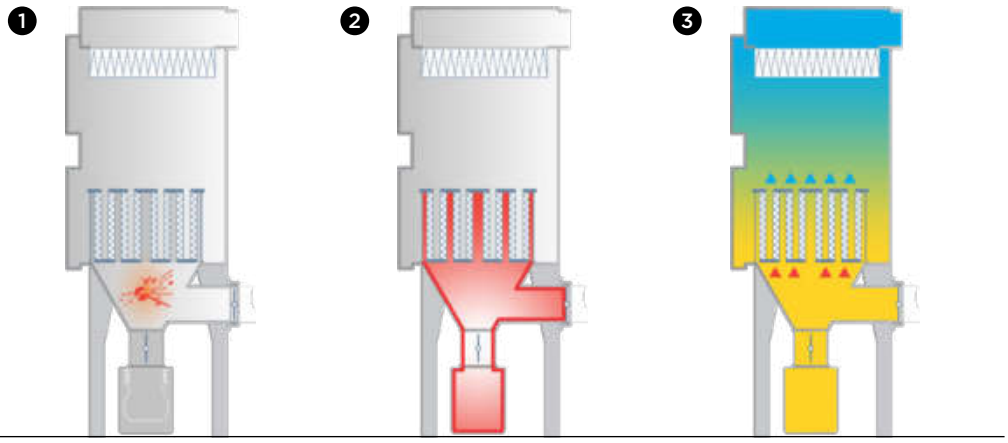
For this reason, **appropriate explosion protection for air filtration systems is essential**. This can be based solely on the **elimination of ignition sources** if the minimum ignition energies (MIE) are higher than 10 mJ and minimum ignition temperatures (MIT) are higher than 300 °C, hence not sensitive to ignition. For all other dust and hybrid mixtures, systems should be provided with **explosion mitigation and isolation** measures.

There are many traditional explosion protection solutions on the market, including explosion venting, explosion suppression, etc. These systems can be effective but have several drawbacks, such as additional space required for installation, release of hazardous materials in the event of an explosion, etc.

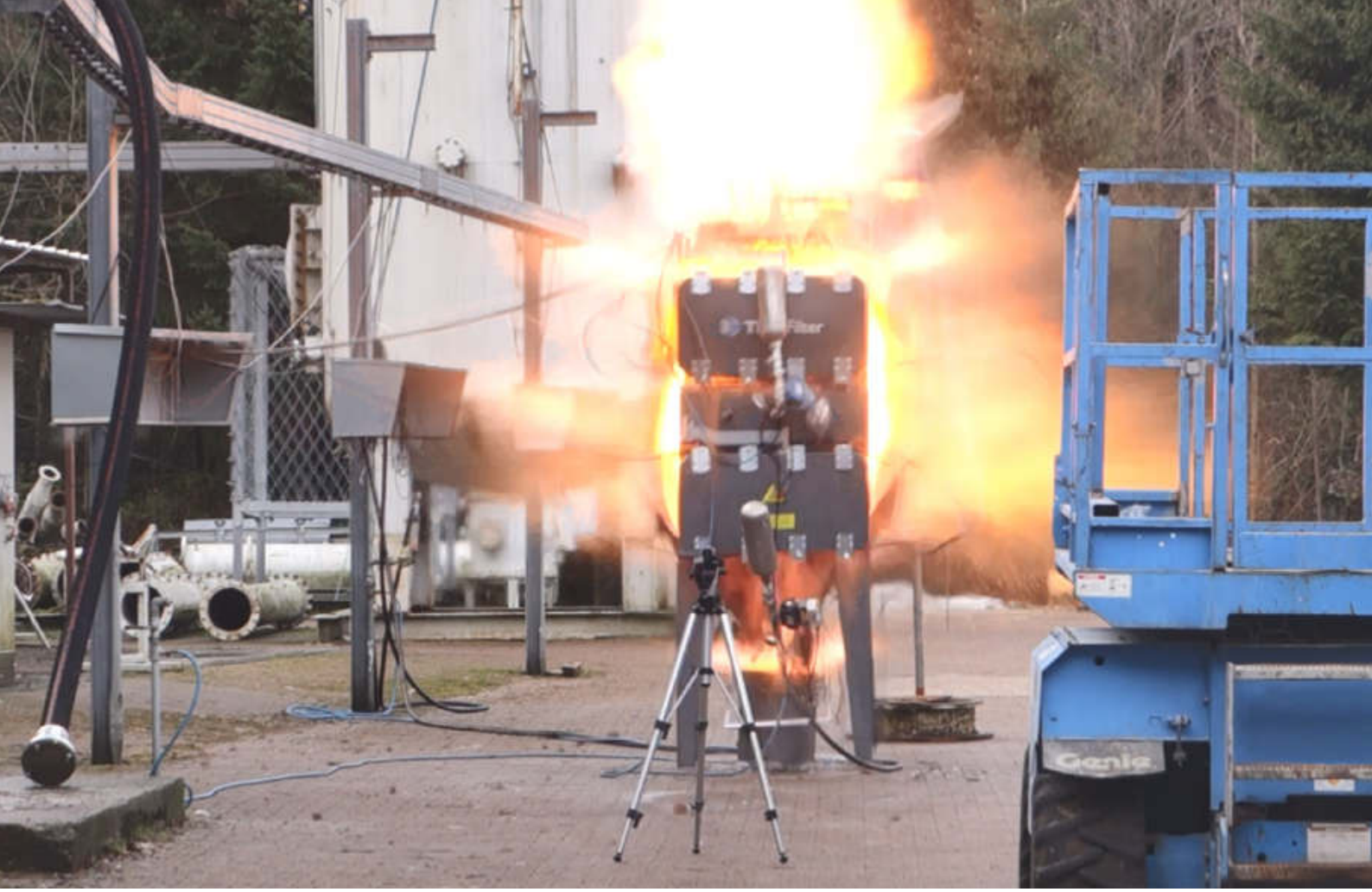
Inherent explosion protection

TRM Filter has developed and independently tested an inherent explosion protection concept, where the **filter element acts as a flame barrier** and keeps the flame/pressure contained within the filter housing. An **inlet butterfly valve is used for explosion isolation**, further reducing the reliance on additional stand-alone systems.

The core principles of inherent explosion protection:



1. Ignition occurs on the “raw gas” side of the air filtration system (ECR unit is used as an example).
2. Pressure and temperature increase due to combustion. A specially designed geometry ensures that only a limited explosion pressure is developed, well below the burst pressure of the dust collector housing. To prevent the explosion from spreading to upstream equipment, the dust collector is isolated using a flame-resistant inlet shut-off valve.
3. The explosion pressure is vented through the primary filter element to the “clean gas side” of the filter. Due to the special design of the filter element, the filter element acts as a flame barrier, extinguishing the flame completely.



Live explosion testing of TRM Filter systems at FSA GmbH, Germany

This innovative design has enabled us to achieve the following benefits:

- Explosion protection with zero emission of hazardous substances to the external environment.
- Consistently compact unit size without compromising filtration performance.
- Seamless integration of explosion protection into the design, with minimal additional maintenance.

Our design has been successfully **validated at FSA GmbH in Germany**, where our systems were subjected to 'live' explosion tests. With several test batches, we have demonstrated that our systems can operate safely with:

- **Dry organic or metallic combustible dust** with Pmax up to 10 bar and KST up to 640 bar-m/s.
- **Hybrid mixtures** with Pmax up to 10 bar and K-value up to 505 bar-m/s.

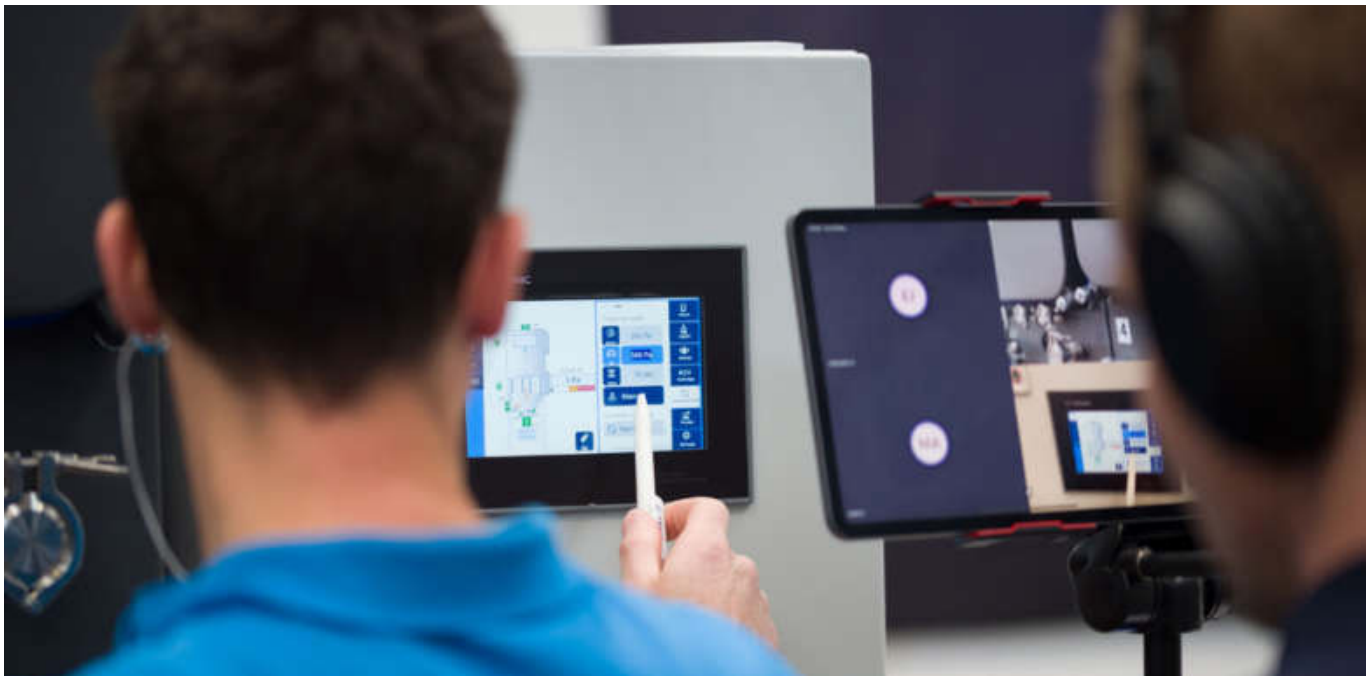
Alternative approaches to explosion protection

In addition to our flagship inherent explosion protection, TRM Filter can design and incorporate other traditional explosion protection systems if required by the application or the customer.

We are also able to assist with any queries and provide explosion protection advice to ensure optimum design and successful project implementation.

GxP qualification, validation & documentation

At TRM Filter, we understand the critical importance of equipment qualification and validation in the pharmaceutical industry. Our rigorous process ensures that our equipment operates reliably and consistently, meeting the highest standards of quality and regulatory compliance. Partnering with us offers peace of mind, knowing that all necessary validation documentation is meticulously prepared and maintained.



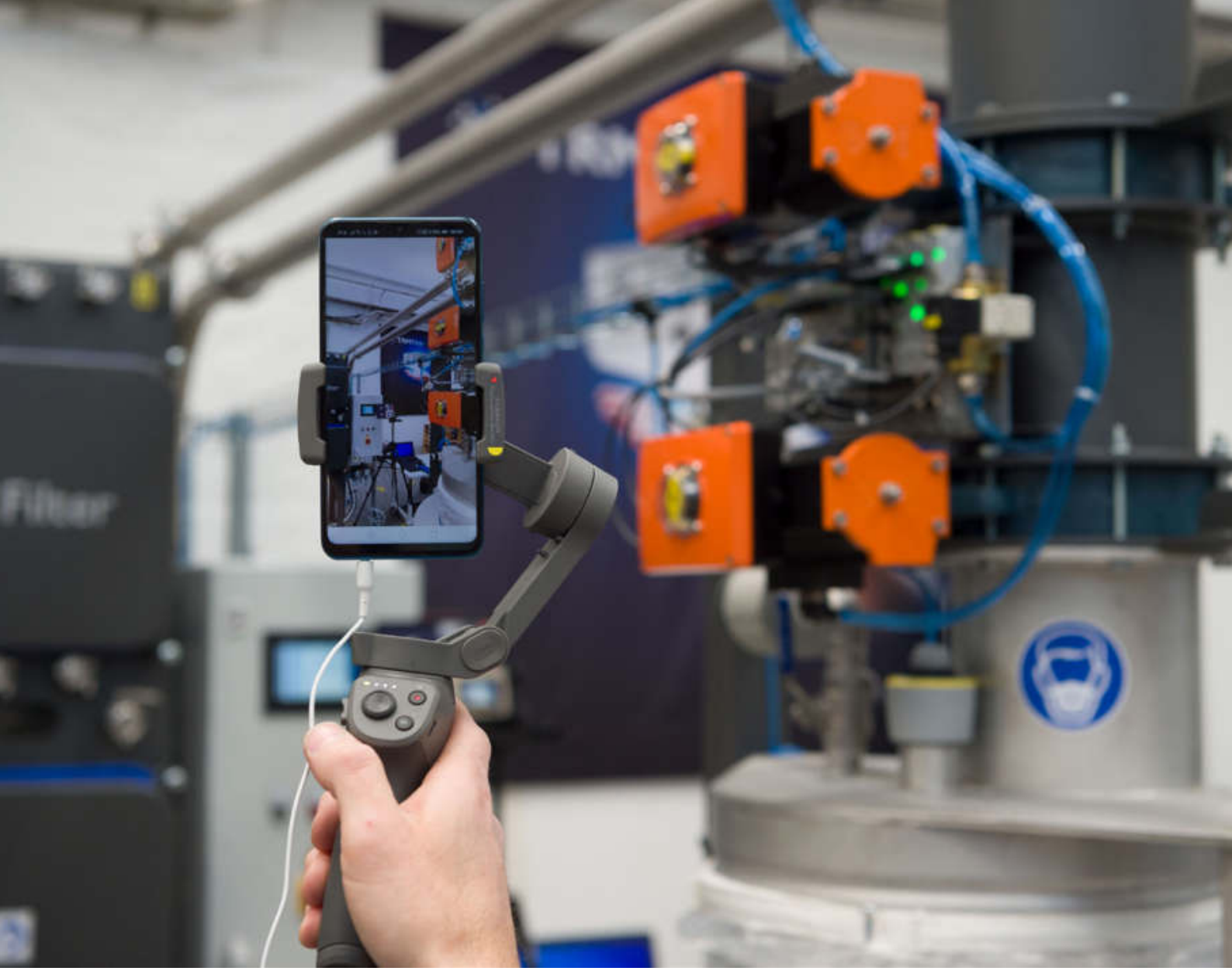
Equipment qualifications

We start with a thorough understanding of the customer's specific requirements. Our **Design Qualification (DQ)** process ensures that the equipment design is perfectly aligned with the operational needs.

Once installed, the **Installation Qualification (IQ)** process verifies that every component of the equipment has been installed correctly and to both manufacturer and regulatory specifications. We document every detail, from equipment identification to utility connections, to ensure that all installation steps are performed with precision.

The next stage is **Operational Qualification (OQ)**, which rigorously tests the equipment to ensure it operates within specified parameters. By thoroughly testing control systems and safety features, we confirm that the equipment is ready for reliable operation.

The final phase, **Performance Qualification (PQ)**, validates that the equipment will perform consistently during actual production operations.



Acceptance testing

Providing the full range of qualification and validation protocols, we are also able to support and provide the full scope of **Factory Acceptance Testing (FAT)** as well as **Site Acceptance Testing (SAT)** based on the end customer's requirements and needs.

Comprehensive documentation

Our qualification and validation process is supported by detailed documentation at every stage, all done by **Good Documentation Practice (GDP)**. We provide all necessary documentation to ensure full regulatory compliance and to facilitate seamless audits and inspections.

Expert support

Our team of experts is dedicated to supporting our customers throughout the validation process. From initial design to performance testing, we tend to collaborate closely to overcome any challenges and ensure the success of the device validation.

Commitment to long-term support

At TRM Filter, we prioritize a customer-focused culture and continually enhance our products and services to meet the evolving needs of our customers. To ensure that we can effectively support our growing customer base, we have developed comprehensive equipment lifecycle services that focus on:

- Reliable stocking and rapid delivery of spare and wear parts,
- On-site equipment inspection and maintenance,
- Engineering and implementation of change and modification requests.

Spare and wear parts

With our in-house manufacturing and warehousing capabilities, we can guarantee fast turnaround times for spares and consumables. In addition, we offer special arrangements upon request, such as expedited parts delivery or safety stock options, to ensure minimal downtime for our customers.

Equipment inspection and maintenance

Our team of trained service technicians performs thorough on-site preventive inspections to ensure our air filtration systems are operating efficiently and safely. We also provide a rapid response for curative maintenance, addressing any urgent issues promptly. Our expertise also extends to the inspection and maintenance of integrated components from external partners, such as explosion protection systems.

Change requests

We recognize that change is a constant in the industry. Our engineering team is equipped to handle modifications and adaptations to air filtration systems throughout their lifecycle. We ensure that these changes are implemented quickly and effectively, without compromising performance or warranty coverage.

We are always just a phone call or email away, ready to assist in any way we can.


TRMFilter

TRM Filter designs and manufactures advanced air filtration solutions for world changing industries.

We have earned the trust of the world's leading pharmaceutical companies and OEMs by providing reliable and safe solutions that give our customers peace of mind.

TRM Filter®

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