Mobile operation and process qualification in production

Extraction and filtration systems for cleanrooms and clean-room areas

Continuously rising quality requirements, increasing component and product miniaturization as well as increasingly sophisticated manufacturing processes have promoted the development of cleanroom technology. Cleanrooms and associated clean-room areas do therefore increasingly form the basis for development of high-quality products as to be found for example in pharmaceutical industry, PCB technology, laser and glassfibre technology, micro electronics, precision mechanics, food industry and packaging technology.

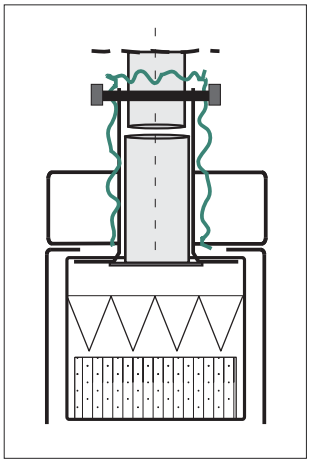

Figure 1: Filter cartridge with extraction pipe and integrated protection tube

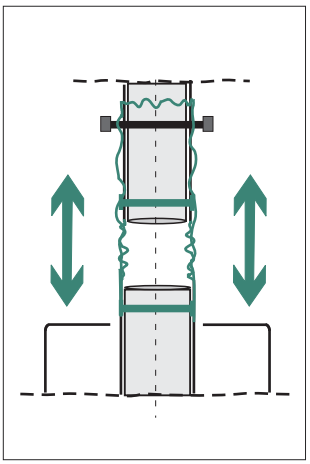

Figure 2: Filter cartridge with extraction pipe and extendable flexible protection tube

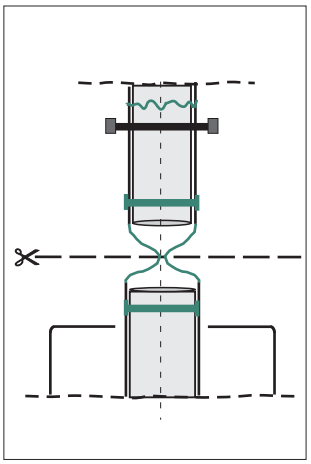

Figure 3: Sealing of the protection tube

Even minimal contamination during the manufacturing process might lead to a loss of functionality or other important product quality factors. Hence, cleanroom technology deals with the following problems:

- How to protect staff and workplace from airborne particles and micro-contamination (hygiene)
- Deciding which contamination sources have to be taken into consideration
- Examining the influence of these contamination sources on the production process, each separately and altogether
- Controlling the individual contamination sources
- Identifying contaminations analytically, with respect to the measuring methods' sensitivity

Usage of cleanroom technology, however, does not always mean production conditions as for example in micro-electronics, where personnel wear protective clothing and work in particle-free rooms. These conditions are usually associated with high costs.

For production processes in food industry or pharmaceutical industry, cleanroom technology is being reduced to the basics. Cleanrooms are realized as separated areas whose quality is provided by the supply of clean air and overpressure. This way, great effects can be achieved at minimum costs.

cleanroom classes and effective norms

Cleanroom technology is nowadays defined by so-called cleanroom classes. These cleanroom classes clearly define the maximum concentration of particles and germs or CFM (colony forming units). Controlling these classes has been rendered possible by standardising measuring methods. This has made air quality a standardised size controlling the effects of measures that aim at accordance to air quality in manufacturing facilities. The old US Federal Standard 209 classified cleanroom based on particle concentration. This standard has in the meantime been replaced by the new ISO 14644-1 and ISO 14644-2. These classify cleanrooms in EC-GMP by germs (CFM). A comparison of these directives is shown in table 1.

Accordance to cleanroom classes (contamination classes) is determined by the following parameters and has to be taken into consideration already during the planning phase of a cleanroom/clean-room area:

- definition of the right cleanroom class
- air purity, air exchange rate, air quantity
- clothing in cleanrooms
- required air filters, filter classes
- planning of locks and entrance areas
- air flow
- choice of suitable equipment
- possibility of equipment qualification

Mobile extraction and filtration systems for contamination-free rooms and areas

As the leading manufacturer of mobile extraction and filtration devices, the TBH GmbH, located in Straubenhardt, Germany, has also been occupied with the subject of cleanrooms and clean-room areas. With the help of end-users, this has led to the creation of a new, practice-oriented device series, TBH CR (image 1), featuring

- modular construction for easy, contamina tion-free filter change
- the possibility of process qualification of the complete unit after filter change and during the unit's operation
- cleanroom-suitable, low-contamination materials (abrasion resistant, easily cleanable, low
- possibility for deposit of micro particles) DIN EN ISO 14644-1 certified device construction, as confirmed by CCI (Contamination Control Instruments) in Stuttgart, Germany

Contamination-free filter removal

The modular device construction makes it easy to realize contamination-free filter removal. The filter cartridge's construction contains the extraction pipe as well as an extendable flexible protection tube (figure 1). Once the extraction pipe is disconnected, the protection tube will extend and cover the disconnection point (figure 2). Thereby, the protection tube can be sealed over the open air inlet (figure 3), providing for dust-proof shielding against the environment. Filter removal is done by sealing the plastic protection film, ensuring contamination-free removal.

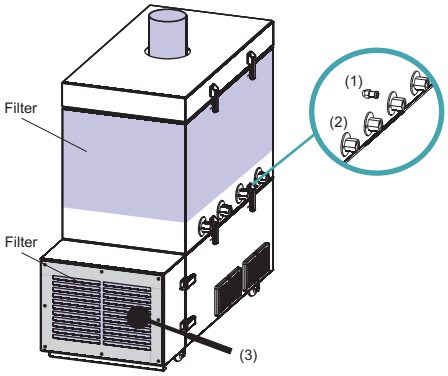

Figure 4: Integrated produt features for qualification of the device in the production area (1: overpressure measuring on tightness; 2: qualification measurement behind the main filter)

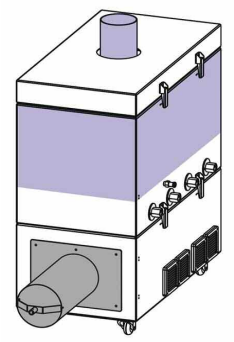

Figure 5: Optional measuring module for intake of measuring probe (3: qualification measurement of the enture device in the air outlet area)

Device qualification in the production area

CR series extraction and filtration devices are, depending on their configuration, equipped with tools for easily qualifying the device in the production area (figure 4). The filter cartridge basically is mounted upon a so-called seal-seat testing frame that renders possible testing the filter cartridge – base case junction on leak tightness – overpressure measuring (1). Furthermore, the device can optionally be equipped with four measuring rods that will be positioned beneath the filter cartridge. This provides particle measurement directly behind the filter cartridge – qualification measurement. Additionally, the device can be equipped with a measuring module inside the air outlet area, rendering possible the qualification of the entire device – qualification measurement (3).

DIN EN ISO 14644 certified device construction

The extraction and filtration device's construction has been tested and confirmed by CCI (Contamination Control Instruments) in Stuttgart, Germany. Thereby, the CR series is, depending on the equipment level, suitable for usage in cleanrooms of ISO classes 3, 5, 7 or 9. Air throughput of the CR series devices varies between 280, 330 and 440 m³/h. Due to the extraction devices' modular construction, filter equipment is freely selectable. For extraction of microparticles, the Z-filter package is available, consisting of a Z-line pre-filter (F5) and a downstream-connected HEPA filter (H14). These filter packages are offered in stainless steel or MDF cases (MDF = medium density fibreboard, incinerable).

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Tabelle 1. Normen der Reinraumklassifizierung

DIN EN ISO 14644-1							EG-GMP		US Federal Standard 209E SI	
Room-classification	Cn = max. count of particles per cubic meter and particle diameter						Room-classification	Colony composing units KBE/m³	English SI-Unit ft³	Metric SI-Unit m³
	0,1 µm/³	0,2 µm/³	0,3 µm/³	0,5 µm/³	1,0 µm/³	5,0 µm/³				
ISO 1	10	2								
ISO 2	100	24	10	4						
ISO 3	1.000	237	102	35	8				1	M1,5
ISO 4	10.000	2.370	1.020	352	83				10	M2,5
ISO 5	100.000	23.700	10.200	3.520	832	29	A/B	< 1	100	M3,5
ISO 6	1.000.000	237.000	102.000	35.200	8.320	293	(B)	10	1.000	M4,5
ISO 7				352.000	83.200	2.930	C	100	10.000	M5,5
ISO 8				3.520.000	832.000	29.300	(C)/D/E/F	200	100.000	M6,5
ISO 9				35.200.000	8.320.000	293.000	inc. employees			