

Cleanroom solutions

Applications:

Bio-pharmaceutical

Loads:



Processes:

Isolation

Contamination control



Fedegari Group has engineered a set of products specially designed for clean room applications and aseptic manufacturing:

Powered by

Thema4

FMF – Unidirectional Flow Fan Filters Modules

FMF is a modular unit which creates a vertical unidirectional airflow in Class ISO 5 according to ISO 14644-1 ("Grade A" EU GMP), protecting the critical area. The airflow maintains the clean room under a higher pressure than the surrounding environment, thus avoiding any contamination risk.

FMF modules can be combined together to create a tailor-made solution to assure the most cost-effective protection to critical areas inside pharmaceutical production sites.

Design and technical features

- AISI 304 stainless steel casing
- Suitable for different assembling solutions (suspended, fitted on false ceiling grids or on supporting legs)
- G3/G4 efficiency disposable synthetic fibre pre-filters (according to EN 779) and H14 efficiency filters

Key benefits

Grade A air supply

FMF modular units: customizable shape to assure safety on critical areas

Integrable systems to satisfy all needs related to clean rooms operations

FCP new design & engineering: -40% of total cost of ownership

Safety & contamination control: operator, product & environment

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FCP – Down Flow Booth (down cross workstation)

FCP – Down Flow Booth is a unidirectional vertical airflow unit, ISO 5 air cleanliness classification according to ISO 14644-1 (Grade A air supply and Class C according to EU GMP) designed to contain any kind of pharmaceutical powders or chemicals during sampling and dispensing operation. FCP has been designed according to the ISPE Good Practice Guide: “Assessing the Particulate Containment Performance of Pharmaceutical Equipment”.

The booth design addresses operation of sampling and dispensing and assures total protection of the operator, of the environment and of the product.

Fedegari has redesigned the workstation to reduce the electric power required to run the process by:

- lowering by 50% HEPA filters’ pressure drop
- resizing prefilter area: 50% extra capacity
- installing more efficient fans
- installing individual adjustable airflows

Thanks to this design and engineering improvement, FCP Down Flow Booth has lowered its total cost of ownership by 40%.

Design & technical features

- Compact ceiling and rear plenum optimize usable work area while minimizing floor space
- Three-stage filtration, G4, F9 and H14 can be accommodated (Bag-in, Bag- out pre-filter replacement upon request)
- Energy-efficient LED light fittings minimize airflow disruption
- Removable bulkhead panels enable access to fans, cooling coil and fine dust filter for maintenance

