

How can aseptic manufacturers prevent losses in the millions?



ACTIVE MICROBIAL air sampling at critical checkpoints in the aseptic processing of pharmaceuticals is used to demonstrate the effectiveness of operational control to ultimately support the release of aseptically manufactured products.

There are three crucial factors to consider when deciding on a microbiological monitoring instrument: does it fulfil the regulatory requirements, is it robust such that it is not itself a cause of failure and does it increase the safety of the product? Issues in an environmental monitoring programme can result in costly days of downtime and delays in release and availability of urgently needed drugs. MAS-100 Iso microbial air samplers from MBV AG are specifically designed for air monitoring in aseptic processing isolators. Every detail of each instrument has been perfected over the years together with established pharmaceutical companies and containment manufacturers.

Compliant with regulations

Microbial air sampling is a mandatory step to meet stringent regulatory requirements in aseptic production. The MAS-100 Iso microbial air samplers meet EU GMP Annex 1 requirements and are compliant with all regulations. MAS-100 Iso air samplers are developed according to good automated manufacturing practice (GAMP), fully validated according to ISO 14698 and EN 17141 biocontamination control standards and accurately documented, facilitating validation of environmental monitoring programmes. With MAS-100 Iso microbial air samplers there is no need to fear upcoming audits and inspections.

Maximum robustness

We aim to concern our customer as little as possible with active air sampling within complex aseptic production. Use of exclusively high-quality components in our Swiss production facility guarantees a durable product that is robust for routine operation. To maintain the instrument in highest condition and minimise downtime, MBV AG offers worldwide support through a global network of certified service engineers offering service, maintenance and calibration.

Best safety in isolators and RABS

Our constant motivation for perfecting our solutions is to help produce safe products for patients. MAS-100 Iso microbial air samplers thus benefit from the following features:


- a sampling head that takes up minimal space in the containment, allowing it to be located at the defined critical control point
- no moving, and potentially particle-forming, parts are located inside the containment
- highest collection efficiency with reproducible sampling results

- isokinetic sampling, which maintains the laminar air flow within the containment
- an easy to clean and disinfect sampling head made of high-quality stainless steel
- a sequentially switched valve system providing additional contamination protection
- the option to include a particle filter to protect operators from highly potent active pharmaceutical ingredients.

We translate your specific needs into high-end products

MBV AG has specialised exclusively in microbiological air monitoring for over 35 years. In addition to our standard products we offer customised end-to-end solutions. Together with you, we translate your specific needs into high-end products quickly and simply thanks to:

- our ability to listen and understand your needs
- our innovative development/R&D team with high expertise
- our capability for rapid prototyping
- solid and precise Swiss manufacturing.

We grow with your challenges. Test us. 

MAS-100 ISO. WINS OVER.

- Hygienic design and perfect workmanship
- Maximum protection for the product and environment
- 100% compliant with all regulations
- Durable and fail-safe in routine production
- Space-saving and suitable for all isolators and RABS



For further information about MBV, our products and services visit:

www.mbv.ch

I EXPECT
NOTHING.

Highest precision with microbial
air sampler MAS-100 Iso. So you
can focus on the essential.
www.mas100.com/isolators

MBV