

The critical role of active viable air sampling for Annex 1 compliance

The EU GMP Annex 1, effective from 25 August 2023, requires the implementation of a contamination control strategy (CCS), among other provisions. Consequently, it is imperative to meet microbial and particulate limits within a controlled environment.

ANNEX 1-COMPLIANT viable air sampling products such as MAS-100 Iso NT and MAS-100 Iso MH are indispensable in executing a monitoring strategy. In combination with settle plates for passive monitoring, existing MAS-100 Iso users already fulfil all the Annex 1 requirements with regard to environmental monitoring and CCS.

Environmental monitoring with MAS-100 ISO

Manufacturers must ensure a systematic and routine assessment of their manufacturing environment by monitoring air quality, surface contamination, and other relevant parameters within cleanrooms and critical zones. Chapter 9 gives guidance on such routine monitoring, including alert and action levels, as well as data handling. The following are key requirements and they can already be met with MAS-100 Iso viable air samplers:

- **Identification to species level** (§9.31): The MAS-100 Iso takes a representative sample at an isokinetic flow rate of 100 litres/minute at each critical control point, collected on an agar plate. Agar-based methods permit germ identification, which is imperative for root cause analysis and ongoing process improvement.
- **Continuous viable air monitoring in grade A** (§9.24) and combination of methods (§9.22): By combining active air sampling with MAS-100 Iso, and continuous monitoring with a traditional settle plate, both requirements are met.
- **No growth in Grade A** (§ 9.30): Active air sampling delivers a quantitative volumetric snapshot sample taken with an ideal combination of biological and physical sampling efficiency. It complements other monitoring methods to prevent unwanted product contamination.
- **Supporting data for recovery efficiency** (§ 9.29): MBV customers benefit from consistent, high-quality equipment, accompanied by detailed documentation



on performance, and physical and biological recovery efficiency. Traceability of data to international standards is assured by calibration tools calibrated in MBV's own ISO 17025-accredited laboratory.

- **Consider rapid methods** (§ 9.28): MBV collaborated with Rapid Micro Biosystems to create a solution for active viable air sampling that enables customers to use rapid methods with their Growth Direct® plates.

The importance of isokinetic sampling

The subject of isokinetic sampling of particles is – although vital in connection with the usually relatively large viable particles – barely mentioned in Annex 1. However, the representative collection of particles from the air over a defined time and area, without disturbing the air path, must be the objective.

MAS-100 Iso is designed to sample air at a flow rate of 100 litres per minute. This is achieved isokinetically – ie, within the surrounding air flow and without any histogram shift of the sampled particles that may over- or under-sample microbe-carrying particles.

Embrace Annex 1 with confidence

Far-sighted suppliers such as MBV already offer solutions so that their customers can embrace Annex 1 with confidence. Not only do the MAS-100 Iso products themselves comply with

the regulations, but in combination with a settle plate, they also enable compliant continuous air monitoring during operation and airborne germ analysis in aseptic production.

MBV controls the entire value chain from design and manufacturing, through to distribution and after-sales service. It works directly with quality containment producers, so MBV can support clients in customising their equipment, and has already automated active microbial air sampling for several of its customers. ☺



Miriam Schönenberger, PhD

Product Manager at MBV AG

Expert in viable air monitoring and science enthusiast with a passion for microbiology and cancer research.



AIR. NOTHING ELSE.

For further information, visit:

www.mbv.ch/en