

FAQ – Microbial

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- What is microbial air sampling?

Microbial air sampling is the process by which air from controlled environments - i.e. cleanrooms and clean air devices, is characterized for microbiological contamination. Depending upon the application and regulatory requirements, a variety of sampling devices are used: active air impactor samplers, slit-to-agar samplers, settling plates, impingement devices, and contact plates.

- What sample air flow rate is best for my microbial sampler?

The regulations are not so prescriptive as to specify a particular minimum or maximum value for airflow rate through a microbial air sampler. This is true across the broad spectrum of regulations: EU GMP Annex 1: 2008, FDA Sterile GMP Guidelines, 2004, or ISO 14698-1 or -2.

The ISO 14698-1 document specifically requires all air samplers to be validated for both physical and biological collection efficiency because both recovery percentages are air flow rate and inlet geometry-dependent. Furthermore, ISO 14698-1 requires that the application be considered when choosing a sampler/flow rate. High flow rates may not be appropriate for aseptic batch monitoring because they sample too quickly to characterize the entire fill batch without risking drying out the culture medium, or they may risk damaging the viable particles of interest during the sampling process. Conversely, devices with very low flow rates may not be appropriate for sampling many locations in a large room because of the time that would be required to be allotted to the sampling.

- To use your equipment, do I have to validate a new media supplier, or can I utilize my existing media?

You should be able to use your existing media. Our microbial samplers have been specifically designed to accept media plates from multiple manufacturers by utilizing a spacer or adapter in order to maintain the proper air inlet slit to media plate distance for maximum validated recovery of micro-organisms. We have developed a library of petri plates and associated adapters that are supplied when the atria are ordered, as required. If your petri plate is not listed in our library, we will require a sample for evaluation.

- Can I sterilize and sanitize your equipment?

Yes, Particle Measuring Systems' equipment is easily sterilized and sanitized. The sample collection atria are manufactured from 316L stainless steel for maximum resistance to cleaning chemicals in common use throughout the life science industries, and are fully autoclavable. All sampler instrument cases are specifically designed to eliminate particle and microbe-trapping crevices and bends in materials for easy wipe-down and sanitization.

- In Grade A areas, do I have to monitor continuously for microbiological particles like I have to for non-viable particulates?

No, continuous monitoring for microbial contamination is not required; however, EU GMP Annex 1: 2008 mandates frequent monitoring of critical areas. While what constitutes frequent is open to interpretation, the intention of the regulation is that the entire fill process or batch is to be monitored by sampling air in short segments separated by pauses of sufficient length such that the total volume sampled is not so large as to desiccate the capture media. Further, as long as a minimum of 1 m³ is sampled over the course of the batch, the requirements are met.

- Can I use a hand-held device or portable sampler, or do you recommend fixed locations?

The choice of sampling method is application dependent, according to ISO 14698-1, and must take into consideration a number of factors. For example, appropriate flow rate and impact velocity, collection accuracy and efficiency, and the effect of the sampling method on the surrounding environment are just a few of the factors that must be considered.

For aseptic process monitoring, especially in critical areas, Particle Measuring Systems strongly recommends a fixed (dedicated) microbial sampling system. For monitoring of less critical areas or for spot-checking of microbial contamination, impactor air samplers and slit-to-agar samplers are recommended over settling plates and other methods.

- Where should I locate my microbial monitoring sample points?

According to the most recent revisions to key regulatory documents on aseptic processing (e.g. EU GMP Annex 1: 2008 and FDA September 2004 update to Pharmaceutical GMP), choice of monitoring locations should be based upon a documented risk assessment. A formally recognized risk assessment method (such as HACCP or FMEA) or other validated equivalent system should be employed to identify potential microbiological hazards to process or product and to identify risk zones where environmental conditions must be controlled to eliminate these hazards. Typically, non-viable particulate monitoring locations coincide with

microbiological monitoring locations; however, this choice must be documented by a formal risk assessment process or procedure.

- Why choose Particle Measuring Systems for my microbial air sampling needs?

Through the application of superior technology, quality, and services, Particle Measuring Systems has become the differentiated leader in microcontamination monitoring of clean manufacturing environments. Our track record clearly demonstrates that PMS understands that microcontamination monitoring in regulated industries is much more than just supplying high quality equipment. The long-standing commitment of our team of applications engineers and dedicated sales people to provide our customers with the right products for their needs, coupled with the 'we do it all' approach of our project management, systems installation team, and service personnel has made PMS the logical choice for contamination monitoring products for a majority of the leading pharmaceutical manufacturing and medical device manufacturing companies around the world. By selecting PMS for your microbial air sampling needs, you are choosing to work with a supplier that will work with you on every step of the way as your guide through the complex process of system design and/or sampling technology selection, implementation/installation, commissioning, validation, and training.

- Why does ISO 14698-1 require validation for both physical and biological collection efficiency?

Both physical and biological collection efficiencies are considered during the validation process because the impact velocity of the air hitting the media is a design compromise in each sampling device. Impact velocity must be sufficiently high enough to allow particles as small as 1 μm to be captured; however, the impact velocity must also be sufficiently low enough to ensure viability of microbiological particles by avoiding mechanical damage or break up of clumps of bacteria on impact. In other words, what is good for increasing physical collection efficiency is not good for high biological collection efficiency. Given the wide range of air flow rates seen amongst the many commercially available microbial samplers, it is the responsibility of manufacturers to evaluate their designs and flow geometries for both physical and biological collection efficiency.

- What is the difference between physical and biological collection efficiency?

Physical efficiency is the ability of the microbial air sampler to collect various sizes of particles, and is the same regardless of particle composition (i.e. whether the particle is a microorganism, carries a microorganism, or is just an inanimate particle.)

Biological efficiency is the efficiency of the sampler in collecting microbe-carrying, still-viable particles.