Active Air Samplers

4 Considerations when buying an Active Air Sampler

cherwell

an analytichem company

1. Introduction

When purchasing an active air sampler to meet the regulatory requirements of GMP Annex 1, it is important to consider several key factors.

Here are four essential considerations:

1.1 FUNCTIONALITY

Sample Volume: Ensure that the air sampler can accommodate the required sample volume based on the graded area. Grade A and B areas typically necessitate a 1000L sample, while lower graded areas like C and D may require alternative sample volumes, depending on the associated risk.

Flow Rate: The air sampler should have a sufficient flow rate to enable quick sampling. A flow rate of 180L/min, for example, allows for a rapid assessment of the environment, collecting 1000L of air in under 6 minutes.

Battery Life: Evaluate the number of samples that can be taken on a single charge. Longer battery life extends the sampling time without requiring frequent recharging. Additionally, ensure that the battery provides consistent power to maintain the correct airflow as the battery's energy diminishes.

1.2 COMPLIANCE

Physical Efficiency: The air sampler should be capable of capturing particles smaller than 2µm onto the agar plate without causing mechanical damage to microorganisms.

Biological Efficiency: Look for an air sampler that consistently provides 100% expected growth with particles of the desired size. Smaller particle sizes are preferable for accurate assessment of the environment.

Data Retrieval: Compliance with GMP Annex 1 and EN/ISO regulations may necessitate the ability to retrieve instrument data, including operator information, sampling location, sample volume and date, to ensure data integrity.

1.3 CLEANING AND MAINTENANCE

Lowering contamination within any cleanroom is fundamental to maintaining a process. Part of this is the appropriate selection of an air sampler that is compatible with and resistant to the cleaning detergents and methods employed in the facility's cleaning regime. It should withstand disinfectants such as vaporized hydrogen peroxide (VHP), IPA, and others.

Any air sampler should be easy to maintain, with straightforward checks like ensuring clear sampling holes, and should have a quick charging capability for efficient sampling.

1.4 ADAPTABILITY AND SUITABILITY

Environmental monitoring programs are based on risk assessment. The nature of the product being manufactured, and the design of the facility will influence and determine the locations for sampling. For instance, in a filling line, multiple heads may be required for sampling. Determine if the air sampler can accommodate such requirements, either through single/multiple units or integration with an isolator system.

Plate Compatibility: Understand how the plate of choice used in the air sampler, can affect the sampling efficiency and have an impact on your data accuracy.

1.5 ADDITIONAL CONSIDERATIONS

Service and Calibration: Evaluate if the supplier offers additional servicing and calibration. Understand the specific checks performed during servicing and enquire about the turnaround time for servicing a unit. Determine if calibration can be done on-site or off-site to minimize downtime and enquire about the provision of calibration documentation.

Support: Ensure that the supplier possesses a comprehensive understanding of the air sampler range and can provide guidance, expert knowledge, and support for developing an environmental monitoring program related to active air sampling.

Petri Dish or Contact Plate: Does the air sampler offer the option of using Petri dishes or contact plates; and if so, which do you choose? The answer is either, as there is no difference in the performance of impaction between either the contact configuration or the petri configuration of an air sampler unit. The choice between contact and petri, depends on the plates you currently use and personal preference, but it is worth bearing in mind before you purchase.

By carefully considering these four main factors along with the additional considerations, you can make an informed decision when purchasing an active air sampler to meet the regulatory requirements of GMP Annex 1.

cherwell

an analytichem company

7 & 8 Launton Business Centre,
Murdock Road, Bicester, OX26 4XB,
United Kingdom.

T: +44 (0)1869 355500
W: www.cherwell-labs.co.uk
E: sales@cherwell-labs.co.uk