TECHNICAL PAPER

Selecting the Right Monitoring Instruments for Cleanroom Classification and Routine Reclassification Following current cGMP

by Jason Kelly

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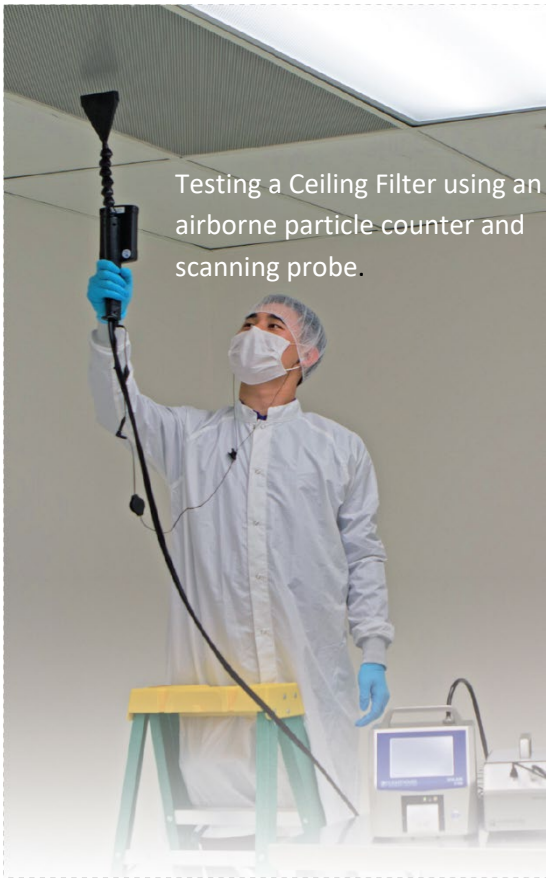
Lighthouse Worldwide Solutions has been manufacturing portable and remote cleanroom and outdoor air monitoring equipment since 1982. We have over 35 years of experience providing monitoring solutions to the Cleanroom Industry. With that knowledge, we have gained tremendous Industry expertise and experts on-hand to assist with any Cleanroom Monitoring requirements. In this paper, we will focus on portable particle counter and air samplers selection when used for cleanroom certification applications.



Testing a Ceiling Filter using an airborne particle counter and scanning probe.

One of the biggest challenges in any cleanroom is setting up a suitable environmental monitoring (EM) program. Which instruments are used for sampling, how frequent samples should be, how much sampling is required, what guidelines do I need to follow? All of these questions need a firm understanding of the different technologies capturing cleanroom air samples in portable particle counters and portable air samplers, as well as a firm grasp on cGMP and regulatory guidelines.

In order to understand these different aspects in setting up an EM program or if you are a Cleanroom certification company and you need to choose the right technology, then this article explores the parameters and questions to ask when selecting cleanroom monitoring equipment. Let's look at the technologies used to capture air samples in the cleanroom for viable and non-viable airborne contamination.

Selecting the right particle counter and air sampler

Like most tools we use, when it comes to choosing the right ones there are many options when you conduct a Google search for "airborne particle counters" and "portable air samplers". There so many choices it becomes overwhelming.

Selecting a Particle Counter

An airborne particle counter selection criteria should be based on the specifications of the instrument, the resolution of its smallest detectable particle size, flowrate, how easy it is to use and several other factors that are worthy of consideration. Particle counters are a major investment, with some companies purchasing a few hundred at a time, so doing your homework and looking at the supplier, their track record and their service abilities as well as the particle counter itself are all crucial factors in the decision-making process.

A particle counter requires an annual calibration. The ISO 21501:2007 calibration standard must be used for particle counter calibrations according to ISO 14644-1:2015. Depending on usage and how well the instrument is maintained, it may also require sensor cleaning, and optic parts replacing as well as a general service. Particle Counter lasers have become more reliable and longer lasting but there still is wear and tear over time and laser replacements after several years should be expected.

Setting up an Airborne Particle Counter and isokinetic sample probe for Cleanroom Classification.

Below are the top 10 questions to consider when purchasing a portable particle counter.

1. Can the particle counter be calibrated to meet the ISO 21501:2007 standard and can the supplier calibrate the unit on-site, is there a service level agreement contract?
2. How easy is the user interface to program and run ISO or GMP reports?
3. Does it have a color touchscreen and is it intuitive to use and sample?
4. What is the flow rate how fast can I sample a 1m³ volume of air?
5. How many particle channels does the unit support are the sizes right for my application?
6. Is the enclosure compatible for disinfection and wipe down?
7. Is the enclosure free from particle traps and easy to wipe down?
8. How heavy is the unit do I need a trolley to cart it around is it truly portable?
9. What size is the unit could it go into an isolator or LAF cabinet easily?
10. How long does the battery last and what is the charge time?

Selecting an Air Sampler

Like an airborne particle counter, there are many options available. ISO 14698 is an excellent guide to assist in the selection of an air sampler. Impaction air samplers are most commonly used and a critical factor known as the d50, which is the particle diameter at 50% where 50% of this particle size will impact on the media, and 50% will be influenced by the air sampler air path. Also known as the cut-off point, the d50 as well as the air sampler having a HEPA exhaust are two major factors to consider when selecting an appropriate unit for your application. ISO 14698 expects the d50 to be as low as 1µm. Not many impaction air samplers on the market actually meet this criteria or even have HEPA exhaust filters. The d50 is also considered to be the resolution of the air sampler. When it comes to air samplers it is best to choose the best resolution and for the air sampler to be compatible with ISO 14698.

Portable Air sampler with d50=1µm and HEPA exhaust filter inside LAF cabinet Grade A zone

Below are the top 10 questions to consider when purchasing a portable air sampler.

1. Can the supplier calibrate the unit on-site, is there a service level agreement contract?
2. How easy is the user interface to program and setup samples?
3. Can the unit load different media plates from different suppliers easily?
4. Does it have a color touchscreen and is it intuitive to use?
5. What is the flow rate how fast can I sample a $1m^3$ volume of air?
6. What is the resolution of the air sampler what is the d50 cut-off point?
7. Is there a HEPA exhaust filter to prevent recirculation of the sample back into the cleanroom?
8. Is the enclosure free from particle traps and easy to wipe down?
9. How easy is it to load the 90mm media plate and is the base easily detachable for sterilization?
10. How long does the battery last and what is the charge time?

Summary

Cleanroom Monitoring instruments have varying specifications and models available in the market. When selecting either a particle counter or an air sampler keep in mind your specific application and adherence to cGMP as the products you manufacture will require cGMP to be followed.

Verify the instrument you choose is easy to clean, is small, lightweight has at least a 2 year warranty and can be serviced on-site to keep down-time to a minimum. How easy will it be to train your team on using this equipment, how many sample records can it keep, is there a color touchscreen, is the unit programming intuitive, is it using the latest laser and sensor technology? You should ask yourself these questions to protect your investment and plan on this equipment lasting long into the future. Do your research talk to multiple vendors request demo's do comparisons of each instrument use them before committing to purchase and you will make better decisions for your EM program.

References:

- ISO 14644-1:2015
- PICs GMP Guide Annexes PE 009-13
- ISO 14698:2003
- ISO 21501:2007