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HOW TO CHOOSE CLEANROOM MONITORING INSTRUMENTS

Lighthouse Worldwide Solutions

Overview

Your cleanroom monitoring tools are what keeps your cleanroom in compliance. They are a critical component of your contamination control strategy. Choosing one can be overwhelming, but there are questions you can ask which make it much simpler.

Choosing Your Cleanroom Monitoring Tools

Lighthouse Worldwide Solutions has been manufacturing portable and remote cleanroom and outdoor air monitoring equipment since 1982. With that depth of knowledge, we have gained tremendous industry expertise we use to assist with any cleanroom monitoring requirements. In this paper, we will focus on selecting a portable particle counter and air sampler for cleanroom certification applications.

One of the biggest challenges in any cleanroom is setting up a suitable environmental monitoring program (EMP). Which instruments are used for sampling? How frequently should samples be taken? How much sampling is required? What guidelines do you need to follow? Excellent cleanroom design takes each of these factors, and more, into account. You need a firm understanding of the different technologies capturing cleanroom air samples portable particle counters and portable air samplers, as well as a firm grasp on cGMP and regulatory guidelines.

This paper explores the parameters and questions to ask when selecting cleanroom monitoring equipment. We will look at the technologies used to capture air samples in the cleanroom for viable and non-viable airborne contamination.

Selecting the Right Particle Counter

Like most tools you use, there are numerous options when you conduct a Google search for "airborne particle counters" and "portable air samplers". There so many choices it becomes overwhelming.

Your airborne particle counter selection criteria should be based on the specifications of the instrument, the resolution of its smallest detectable particle size, flowrate, usability, and several other noteworthy features. 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 21501-4:2018 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, optic parts replacements, and 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.

Top 10 Questions To Consider When Purchasing Particle Counters

1. **Can the particle counter be calibrated to meet the ISO 21501-4:2018 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 touchscreen and is it intuitive to use and sample?**
4. **What is the flow rate, i.e. how fast can it sample a 1m³ volume of air?**
5. **How many particle channels does the unit support? Are the sizes right for your 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 the Right Air Sampler

Like an airborne particle counter, there are many options available for air samplers. ISO 14698 is an excellent guide to assist in the selection of an air sampler.

Cleanroom managers commonly use impaction air samplers. One of the most critical factors is 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. This is also known as the cut-off point and is considered the resolution of the air sampler. ISO 14698 expects the d50 to be as low as 1µm.

The d50 is what ensures your air sampler will meet your measurement needs, but another important criteria is the HEPA exhaust. Not many impaction air samplers on the market actually meet this criteria or even have HEPA exhaust filters.

When it comes to air samplers, you should consider the best resolution and for the air sampler to be compatible with ISO 14698.

Top 10 Questions To Consider When Purchasing Air Samplers

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 touchscreen and is it intuitive to use?**
5. **What is the flow rate, i.e. how fast can you 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?**

In Conclusion

There is a wide variety of cleanroom monitoring instruments on the market. When selecting either a particle counter or an air sampler, you should keep in mind your specific application and adherence to cGMP, as the products you manufacture will require cGMP to be followed.

We recommend verifying the instrument you choose is easy to clean, small, lightweight, and has at least a 2-year warranty. It should be serviced on-site to keep down-time to a minimum. You should also consider logistics questions, such as:

- **How easy will it be to train your team on using this equipment?**
- **How many sample records can it keep?**
- **Is there a 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 demos, so you can do comparisons of each instrument. We highly recommend using them before committing to purchase to make the best decision for your EMP.

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