AIR SAMPLER

pharma update

Air sampling in controlled manufacturing environments

Manufacturers of pharmaceuticals and medical devices are required to demonstrate that their products do not present a microbiological risk to the consumer or recipient. Part of this process involves environmental monitoring, in order to ensure that risks from microbiological contaminants are kept to an absolute minimum.

Like many regulated companies, Vascutek is using the new Oxoid Air Sampler to meet their active air sampling requirements and to demonstrate that standards within their 'clean room' environments are being maintained.

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Quality assurance

Based in custom-built facilities in Inchinnan, near Glasgow, Vascutek is one of the world's leading designers and manufacturers of specialised products used in the treatment of cardiovascular disease. Their vascular prosthetic grafts (artificial arteries) are used by surgeons all over the world, and so they need to be able to trust that the products are of the highest quality and pose no additional threat to already seriously ill patients.

As a result, these grafts are manufactured under Class 10,000 clean room conditions. Such categorisation requires active air sampling to be performed at least once a month in each clean area to ensure that levels of micro-organisms in the air fall within acceptable limits. Responsibility for this task lies with the Microbiology section of the company's Quality Assurance Department.

Company Microbiologist, Barbara Blackett, explains, "Active air sampling is an important part of our overall environmental monitoring programme. Until last year we used a single air sampler (the Oxoid M.A.Q.S. II) but our business expanded a lot and we had to look into buying a second sampler. This enabled us to monitor a larger area at one time and also, because we can stagger their annual calibration, it means we are never without a functioning air sampler."

Ease of use

The compact and robust Oxoid Air Sampler is designed to monitor microbiological air quality in controlled environments, using proven impaction technology that has been used reliably in quality assurance applications for many years.

The system is easy to use, with a simple keypad and an easily navigated menu (in a choice of languages) that leads the user through a variety of preset or user-defined functions, including flexible sampling volumes, delayed start, multiple run and variable interval options.

"We looked at several different models," Barbara continues, "but we felt that the new Oxoid Air Sampler best meets our needs. Some systems were too big and bulky - not easy to carry. Others were very complicated. We found the new Oxoid sampler, on the other hand, to be more practical and much more user friendly. It's very simple to operate and is more compact - easier to carry. Effective air sampling is not an option for us - it's a requirement, and so we must be able to rely on the system we use. The ease of use and simplicity of the new Oxoid Air Sampler gives us confidence in using it and we've been very happy with its performance so far. So happy, in fact, that we intend to purchase a third sampler this year."

"Our business is continuing to expand and so we have even more clean rooms to monitor," Barbara explains. "We knew we needed another air sampler, so we looked around again, just to check on the efficiency, simplicity and price of what was available. The Oxoid Air Sampler came out on top for us again."

The Oxoid Air Sampler has been shown to be efficient and reliable, with validation studies demonstrating a physical efficiency of 100% for particles 0.8 to 19.0 microns in size (ISO 14698:2003 Annex B). Once activated, the unit automatically samples air at a fixed rate of 100 litres per minute. Air is drawn through small holes in the sample head and directed onto the surface of an agar plate. A flashing LED shows that sampling is in progress and an audible signal indicates the end of the sampling period. At this point the agar plate is removed and incubated in order to assess levels of contamination.

"We particularly like the time display, which counts down during the sampling time, "adds Barbara. "It can be helpful to know how long it has to go."

The details of up to 98 consecutive runs are stored within the unit. This information is easily accessed and visualised on the alpha-numeric display or can be printed via a standard printer cable. Alternatively, the Oxoid Air Sampler Software allows data to be downloaded to a computer for reporting and trend analysis.

Flexibility

The Oxoid Air Sampler can accommodate 55mm and 90mm plate formats.

"We liked that we were able to use our own plates in the sampler," Barbara comments. "Some systems require you to use their own specialised agar products, but with the new Oxoid Air Sampler you have the flexibility of choice. We used to prepare our own culture plates for air sampling but in the last year, as we've become busier, we've been using Oxoid prepared media. We've found this to be a really convenient and time-saving option."

Oxoid provides a full range of suitable pre-poured culture plates for use with the Oxoid Air Sampler, including Tryptone Soya Agar and Sabouraud Dextrose Agar in 90mm and 55mm contact plate formats. These can be supplied irradiated and/or triple wrapped, as required.

Support

The Oxoid Air Sampler is supplied fully calibrated with a traceable calibration certificate. Furthermore, the sample head can be changed, or removed for cleaning, quickly and easily - without the need for recalibration. Recalibration at the required intervals, advice and support is provided by the fully trained Oxoid Technical Support Team.

"The service we've received from Oxoid has been excellent," concludes Barbara. "It's a great comfort to know that Oxoid microbiologists are on hand to answer any questions and to help with any problems."

For further information about the new Oxoid Air Sampler, Oxoid Prepared Media and other products available for environmental monitoring please speak to your local Oxoid representative or visit www.oxoid.com

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