



Portsmouth PMU specialise in the aseptic preparation of pharmaceuticals and parenteral nutrition, cytotoxics and patient-controlled analgesia in a variety of administration devices. With 2 aseptic rooms, 8 isolators, 2 preparation rooms and a checking and labelling area; an extensive environmental monitoring programme, incorporating both active and passive air sampling, is in place to ensure the environment is free from microbial contamination.

The environmental monitoring programme involves active and passive air monitoring as well as contact plates and is performed, at a minimum, weekly in all areas. Routine monitoring is performed in TSA and also monthly in SDA. Monitoring can involve in excess of 50 active air samples, and the need to sample 1000l of air at each location means high speed air samplers are essential to ensure monitoring is performed in a timely fashion and events can be reacted to whenever the need arises. Validation is often required in an unmanned state and therefore, work must be performed out of hours, having the SAS super 180 air samplers facilitates this. Isolator air samplers also enable the PMU to monitor sessions at their convenience without the risks involved in placing additional equipment into the isolator.

Cherwell provide Portsmouth PMU with a complete package; portable, high speed air samplers for general environmental monitoring, Redipor® prepared media for passive air sampling and specialist units for isolator monitoring. With over 35 years' experience, Cherwell's expertise within the pharmaceutical industry ensures appropriate advice and excellent levels of customer care.

Over 20 years of service supports environmental monitoring

Reliability, ease-of-use and sampling speed are all key considerations when selecting an active air sampler for an environmental monitoring programme. Having used Cherwell Laboratories' SAS air samplers for over 20 years, Portsmouth Pharmaceutical Manufacturing Unit (PMU) can continue their extensive environmental monitoring programme in confidence following the purchase of an additional SAS Super 180 air sampler.

History

Portsmouth PMU, formerly Queen Alexandra Hospital, have been using Cherwell's SAS air samplers and Redipor prepared microbiological media since the 1990's. Throughout this relationship both companies have experienced significant growth, regulatory changes and technological advances leading to changing requirements and the development of new solutions.

When Portsmouth first started looking for an air sampler for their environmental monitoring, the original SAS System offered the best solution on the market. With sampling speeds of 180 litres per minute, the SAS system was the fastest sampler available and unique in using a Contact plate as the consumable. These more readily available plates didn't tie the users to a bespoke and expensive consumable. Plus it offered portability for the user allowing them to easily conduct environmental monitoring in several locations.

However, compared to modern samplers, the units were heavy and were phased out by Cherwell following the development of the SAS Super range. Initially only available in a 90

litre per minute version, improved battery technology and product development soon enabled both 100 and 180 litre per minute models to suit different applications. The new easier-to-use and more portable SAS Super 180 continued to offer the high sampling speeds required by Portsmouth, and a unit was initially purchased in 2003, to use alongside the SAS System.

Current Order

Due to the high number of samples that need to be taken, Cherwell's SAS Super 180 continues to provide the ideal solution for Portsmouth PMU's general environmental monitoring.

With a sampling rate of 180 litres per minute, the unit completes a cubic metre in less than 6 minutes; reducing staff time and minimising disruption. An alternative sampler has previously been tried by Portsmouth, however this was considered too slow for their requirements and routine calibrations took too long, so when an additional unit was required in 2014, Cherwell were the obvious choice.

Julie Bowden, QA Releasing Officer, Portsmouth PMU commented

"When we were looking to buy a new unit, we didn't look at any other air samplers on the market. We only considered Cherwell due to our positive experience of the product and their excellent customer service. Cherwell are always very accommodating and deal with any queries straight away, we don't have to be passed on to someone else".

Reliable, Robust Air Sampling

Confidence in sampling results is imperative to any successful environmental monitoring programme, especially those involved in critical areas. Cherwell's SAS air samplers use the proven active sampling method of direct, multi point impaction where airborne particles are drawn through the sampling head and impacted onto the agar media surface of a standard, readily available Contact plate. Multi-point impaction ensures statistically sound results as they sample at a fixed rate and its suitability for general environmental monitoring was demonstrated by research work conducted at Porton Down.

The reliability and robustness of the SAS air sampling equipment, combined with Cherwell's technical expertise, were also key factors in Portsmouth's decision to continue using SAS units. Portsmouth PMU still use an SAS Super 180 unit 12 years after the initial purchase, confirming the lifetime value of the units. Based at Cherwell's facility in Bicester, UK, the engineering department offer a customer focused calibration service with a fast turnaround time. Calibrations can be arranged to fit in with customer requirements, minimising downtime and inconvenience.

"Cherwell make it easy for us to arrange recalibration at a time that suits us and the turnaround time is very quick" said Nicola Lightfoot, QC Technician, Portsmouth PMU. She added *"If any repairs are required, a quotation is always provided before the work is carried out and we are kept informed of progress"*.



**Nicola Lightfoot, QC Technician,
Portsmouth PMU**



Julie Bowden, QA Releasing Officer, Portsmouth PMU

Specialist Solutions

In 2008 Portsmouth PMU relocated from their hospital site to a purpose built modern manufacturing facility. This new facility incorporated an increased use of isolator technology and presented a new challenge for monitoring. Therefore, in addition to Cherwell's SAS Super 180 units, Portsmouth PMU use 2 specialist units with 8 sampling heads, for environmental monitoring within their isolators. Using the same principle as the Super 180, the SAS Super Isolator minimises contamination risk by reducing the need for intervention. Each stainless steel sampling head is located permanently inside the cabinet and connected to an external control unit; which can control multiple sampling heads. The external control unit ensures that dedicated monitoring programmes can be readily established and controlled.

When the SAS Super Isolator was first introduced to the market, Portsmouth were early adopters of the new technology and the process of integrating into new cabinets. Despite an unexpected problem encountered during installation, due to the wiring system of the isolator cabinet, everything was dealt with quickly and efficiently by Cherwell's in-house engineering department.

The Complete Solution

Cherwell have also been supplying Portsmouth with an ongoing, reliable and flexible solution for their prepared microbiological media requirements, with a regular delivery of Redipor Prepared media since 2006. Portsmouth's standing order ensures they receive scheduled deliveries with the added flexibility of being able to amend or cancel their order as required.

Julie Bowden commented

"All media we use is from Cherwell on standing order. If we need to cancel or amend our standing order for any reason, Cherwell are always very understanding and are fine with us doing this".

Currently TSA and SDA irradiated contacts and 90mm settle plates are used for routine sessional and environmental monitoring, with 90mm R2A used for routine water testing. A selection of single and double strength TSB is also used for routine operator and process validations. *"Although we do not currently use barrier pack plates in our isolators we are aware that you provide this option should we require it in the future."*

Conclusion

The relationship between Portsmouth PMU and Cherwell has been based on providing the most appropriate product to fit the required application, alongside a flexible and reliable service. Cherwell's focus on customer support, high quality products and technical advice is valued by Portsmouth PMU, who know their specific requests will be dealt with efficiently and effectively.

Through understanding the increasing regulatory requirements placed on pharmacy manufacturing units within the UK, Cherwell has been able to assist Portsmouth PMU in meeting these obligations. This has only been possible by having good knowledge of the industry sector and providing products that are fit for purpose.