
Case Study: EMS, AUSTAR & PMS Working Together to Deliver a Contamination Control Solution for an Isolator

Overview

Learn how an isolator manufacturer (AUSTAR) partnered with a local supplier (EMS) to provide and install Particle Measuring Systems (PMS) instruments to meet their customer contamination monitoring requirements.

About AUSTAR

AUSTAR AUSTAR Group is a leading technology-based pharmaceutical engineering solution provider with comprehensive knowledge and experience in life-science process technology, applications, industry regulatory rules and practices. AUSTAR can help clients address issues in quality, compliance and operations excellence. They are dedicated to providing equipment-engineering-service-consumables turnkey solutions that promote industry advancement and create value. [Learn more.](#)



About Environmental Particle Solutions (EMS)



EMS Particle Solutions is an industry leader in Cleanroom Technology, providing our clients with a full range of solutions in cleanroom monitoring and particle detectors. EMS additionally provides a purpose-built Calibration Laboratory to include repairs to manufacturer's specification. Our Company provides end to end service in the provision of designing systems, project managing systems, full maintenance and complete validation package. EMS is a full-service distributor of Particle Measuring Systems (PMS) equipment. [Learn more.](#)

Which PMS contamination control instruments did EMS & AUSTAR use to satisfy customer specifications?

Following technical discussions with EMS, AUSTAR chose PMS viable microbial monitoring instruments and non-viable particle counters to monitor and ensure the classified Sterility Test Isolator environment is not compromised during the sterility testing process. AUSTAR purchased a Lasair® III particle counter for monitoring the non-viable particles, and for the viable particles they purchased as MiniCapt® Mobile Active Air Sampler with a Biocapt® Impactor head. To complete the package, they purchased an isokinetic probe and all necessary tubing.

Their selections included:

Non-viable

- Lasair® III remote or portable particle counter

Viable

- MiniCapt® Mobile Active Air Sampler
- BioCapt® Impactor

Why AUSTAR chose PMS instruments and how EMS supported their needs

In this project, PMS equipment was specified by AUSTAR's client because they currently have PMS equipment on site and are familiar with how to use it. Per AUSTAR UK Director, Paul Hudson: "This request was not a problem to fulfill because EMS and AUSTAR have a long-standing relationship. AUSTAR had the full confidence to move forward to fulfill our client's (PMS) requirements with the knowledge that EMS would be able to provide the technical support AUSTAR & their client required."



EMS and AUSTAR mutually wanted to ensure that their customers' equipment fully met GMP contamination control regulations such as ISO 14644-1 & 2 and EU GMP Annex 1, and Data Integrity standards such as 21 CFR Part 11, which is accomplished with PMS equipment. Additionally, sourcing their PMS equipment through EMS is a benefit to AUSTAR because they could source complete contamination control solutions from a single provider with the application expertise to get the job done.

What type of technical support was required from EMS by AUSTAR?



Tim Blank, Product Development engineer at AUSTAR, noted that since the Sterility Test Isolator is internally decontaminated with vaporized hydrogen peroxide (VHP) the lines leading to the components used to monitor this environment must also be VHP decontaminated. EMS had the technical know-how and experience to assist AUSTAR in installing a VHP loop to draw the VHP through the lines to a local exhaust point, thereby decontaminating the system while protecting the PMS instrumentation. Additionally, EMS provided AUSTAR with step-by-step validation documentation for the PMS equipment enabling AUSTAR to validate the Sterility Test Isolator system, including the contamination control instrumentation.

Conclusion

The EMS/AUSTAR/PMS partnership allowed the end customer to receive a validated, turn-key solution to their contamination control monitored Sterility Test Isolator. By utilizing EMS for their know-how and hands-on experience with PMS instruments and real-world applications, AUSTAR was able to save resources on researching, evaluating, purchasing and integrating contamination monitors on their own and were able to deliver a fully validated system that met their customer specifications.

About Particle Measuring Systems



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Particle Measuring Systems Inc. (PMS), a subsidiary of Spectris plc, is a global technology leader and expert in contamination monitoring, the inventor of laser particle counting, and now is the leading provider of solutions for monitoring and controlling many forms of contamination that impact companies that manufacture in ultra-clean environments. For more information visit pmeasuring.com.