

How clean is your cleanroom?



TIM RUSSELL, BUSINESS DIRECTOR-CONTROLLED ENVIRONMENTS AT TSI INCORPORATED IN CONJUNCTION WITH PMT (GB) EXPLAINS THE CASE FOR A FACILITY MONITORING SYSTEM IN A CLEANROOM ENVIRONMENT.

Many facilities choose to install facility monitoring systems to monitor particle counts and other environmental parameters. There are multiple benefits associated with use, and it makes great business sense, however, the advantages to a business are not always fully understood.

These benefits include:

- Reduced waste
- Improved yield
- Improved quality
- Increased profits

While there are some organisations that choose to install a facility monitoring system just because regulatory guidance states one should be installed and used, many, given the choice, would choose not to. Initial capital and ongoing maintenance costs seem expensive, the mountains of data that will require analysis seems daunting, and alert and action level excursions often leads to time consuming root cause investigations. Plus, there are also necessary considerations around the maintenance, calibration and validation overhead involved.

WHY DO REGULATIONS EXPECT A MONITORING SYSTEM TO BE INSTALLED?

1. Risk reduction

A facility monitoring system improves probability of hazard detection, leading to a reduction in risk. Product quality is impacted if too many airborne particles find their way into the product, compromising patient safety. Only when deploying and correctly positioning monitoring probes to frequently collect data, is there a chance of detecting particles. If there are no particle monitoring probes installed close to critical processing locations, the probability of detecting particles entering the process is zero.

Turning critical data into information is key. This can be conducted through real-time data presentation, reports and alarm notifications. The ability to do this results in increased knowledge

and a better understanding of the manufacturing process. This increased knowledge leads to recognising when the process is drifting out of control before it's too late and means a less segregated product, less product waste and fewer interruptions during manufacturing without compromising patient safety.

2. Monitoring makes great business sense

Today, monitoring systems are already being used to support energy saving initiatives. There are significant energy savings to be made when setting back air change rates and air velocities whilst being safe in the knowledge that environmental conditions have not been compromised.

Continuous particle monitoring in a facility means the exact time of a particle excursion is known and immediately notified to end users. This supports timely root cause investigations and minimises how much of the batch is segregated – saving a significant amount of money.

The availability of Alternative Microbiological Methods (AMMs), such as continuous laser induced fluorescence particle counting, means there is also an option for immediate understanding of the microbiological quality of the air surrounding the process. This could possibly lead to intervention free manufacturing and supports Real Time Release Testing (RTRT).

Smart factories of the future will have fully interoperable systems where data is seamlessly exchanged between multiple platforms. Sharing and centralising facility monitoring system data transforms it into holistic information that aids decision making. This holistic information could predict that an excursion is likely, enabling proactive steps to be taken to positively impact yield and significantly save on manufacturing costs.



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