

Trending Data & Response Plans in the Cleanroom Setting





Executive summary

- Discover cleanroom best practices
- Great questions to ask cleaners at the RFP stage
- Explore two theoretical trending data scenarios and their solutions

Contamination within the cleanroom setting can lead to a variety of problems that can stretch all the way into the hands of your consumers and even leave your company out of compliance with the FDA. Depending on your industry, you might see products break down after their release due to above-normal particulate levels, or costly recalls due to contamination, or even injury to consumers due to contaminated products. The result? Consumer dissatisfaction, huge fines and penalties, forced work stoppages, lost profit from returned goods, or costly lawsuits from consumers who suffered due to compromised products. Being proactive and responsive to your environmental monitoring (EM) data can help head these problems off by ensuring a consistent state of control.

It's essential to establish precise standards for a cleaning routine to be carried out by a skilled and trained crew. If you're working with a vendor or contractor to do that work, it's vital that your company coordinate with the provider to respond quickly and effectively to any deviations from the norm or instances of contamination (assuming that your in-house team is consistently graphing levels of contamination, whether it be dust levels or microbe count). EM data recording is sometimes required for industry-specific compliance, such as giving oversight agencies like the FDA something to look at to prove control/prevention monitoring and satisfying regulatory requirements within critical production areas. Without tracking and trending, it's difficult to show that procedures for preventing and responding to contamination are effective.

In the cleanroom setting, one practice makes or breaks success more than any other: sanitation procedures. These procedures and standards must be spelled out clearly and followed to the letter. The supplement to that first practice is consistent measurement of microbes and particulate matter (depending on the industry, whether food and beverage, technology, pharma, etc.), setting alert limits, and drafting response plans to above-acceptable levels.



Deep expertise



Quality standards



Sustainable

So how can one identify whether their cleaning partner is following industry best practices? Discuss the following during the RFP stage:

1. What are your standards when hiring for skilled cleaning positions?
2. How are your skilled cleaners initially trained?
3. How will you pass on our skilled cleaning methods from SOP to individual cleaners?
4. Are your cleaners tested on their skills before being allowed on the job site?
5. Are your cleaners continuously trained?
6. How do you minimize turnover and maximize retention?
7. How will you work with us to mitigate deviations from the norm in terms of particulate counts, microbe levels, etc.?
8. What do you need from our company in order to make your efforts successful?
9. A vendor worth partnering with will have these questions already thought through and will be comfortable discussing the specifics with you.

So, what is an EM trend and how should you determine a response? A trend is derived from data measured over time which demonstrates deviations and conformance to established limits. Basically, a trend is a tendency or drift from the norm, such as consecutive readings greater than alert limits or multiple recoveries of the same organism. Acceptable limits should be defined in the company's EM policy.

Let's explore two scenarios where a trend occurred and coordinated response between client and vendor was needed in order to bring particulate/microbe levels back within the norms.

Scenario 1: A medical device manufacturer

Recently, customers of XYZ MedDevices have reported several instances of infection in patients whose treatment involved their newest device, a modified catheter. Upon further examination of the products, they all appear to have originated from the same facility, which started manufacturing the device three months ago. Even further investigation reveals that all the affected units originated from the same batch. Upon comparing the batch's "born on" date and particulate counts from the dates immediately before, there was a noticeable spike. Running through the facility's activities that day, XYZ MedDevices was able to determine that a delivery person's arrival coincided with the spike. In interviewing the internal team and the vendor cleaning team, it was confirmed that the delivery person went into the facility farther than they should have and breached aseptic protocols. This allowed for a raised level of contamination that ultimately led to compromised and nonsterile units being released on the market. In response, new protocols surrounding breaches of clean areas were established to prevent this happening again.



Scenario 2: A food packaging company

Food Company ABC keeps careful track of microbe levels within their facility so that an FDA audit never takes them by surprise or shuts them down. In coordination with their skilled cleaning vendor, they are usually far within safe norms. However, in the past two weeks, there has been an appreciable spike in microbe counts on Friday shifts. After coaching with the Friday crew, the spike in levels still happens on the third Friday. Upon further examination, the Thursday crew appears to be missing a step in the cleaning procedures, which is causing the spike on Friday. Once the Thursday crew is retrained, Friday levels return to normal by the fourth week.

Without thorough records of particulate levels, neither of these companies would have been able to determine the source of contamination and prevent the same manner of contamination from happening again. Simply having records is not enough to prevent contamination, either. Only the combination of proactive skilled cleaning methods, careful measurement of contaminant levels, along with creating response plans and measuring their success will suffice in keeping your critical environments clean and within acceptable levels.

Being served by well-managed people in the right jobs—feeling good about their contributions and growth opportunities—an ABM client will benefit in many ways from a “one team” culture:

- Higher quality work
- Increased productivity & reliability
- Ease of communication
- Reduced turnover, more familiar faces





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