CAPS® Sterile Compounding Review:
Gaining Cleanroom Control through Tracking and Trending

The Cleanroom Certification Trending Issue | NOV 2020

Cleanroom Scenario

Mary, a pharmacy director at a mid-sized hospital, was forced to quickly adjust her sterile compounding production after she suddenly learned from her certifier that the air changes in her ante-room had dropped to 39 air changes per hour (ACPH), below her pharmacy's requirement to have at least 40 ACHP in that room.

Wondering if she could have identified and prevented a problem earlier, Mary decided to take a second look at some older reports.

Before falling to 39 in the failed certification report, two prior reports revealed 46 and 45 ACPH. In Mary's opinion, the difference between 46 and 45 did not demonstrate a significant trend. She decided to look further into the reports at some of the other test data. She started by examining the amount of air that was supplied through each HEPA filter located in the ante-room's ceiling.

What she found was truly eye-opening...

Are You Tracking Your Data?

Our hypothetical story is probably not that uncommon. On most days, it is likely that pharmacists spend more time scrutinizing labels than they do tracking quality records. After all, comparing drug names and concentrations against the prescriber order is essential to ensure patient safety.

However, sterile compounding pharmacists must also be cognizant of, and have confidence in, all the information that assesses the quality of their compounded drugs. In addition to the drug names listed on the label, the quality control data contained in gloved fingertip testing, viable sampling, and airflow testing can be viewed as some of the other "active ingredients" that comprise a sterile preparation.

Instead of being concerned that it will take time away from drug monitoring, pharmacists should recognize that tracking, trending, and scoring items like air quality can be equally relevant to patient safety. The environment in which a sterile drug is compounded has the potential to affect a substantial number of orders that is filled by the pharmacy.

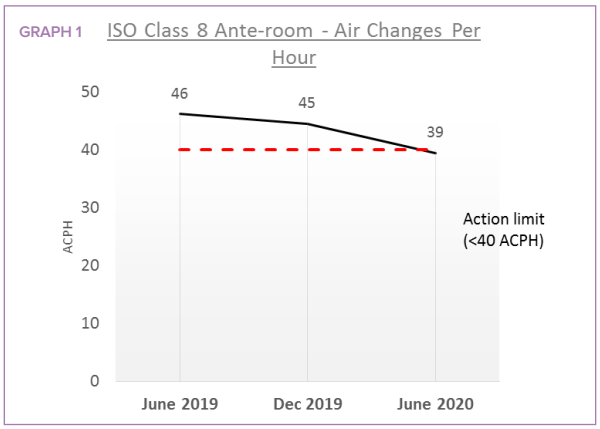
Trending quality control can help pharmacy managers identify potential problems before they impact or even overwhelm their sterile compounding programs.

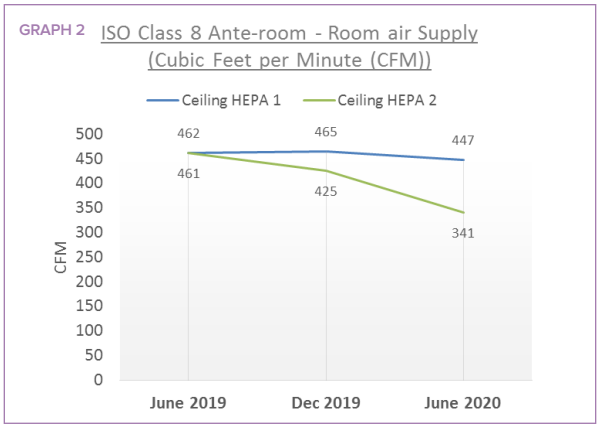
What Mary Learned—and How it Helps

Before starting her investigation, Mary refreshed her knowledge on some important concepts about cleanroom airflow. With proper design, when clean air is introduced into a cleanroom, it enters through HEPA filters in the ceiling and travels downward to eventually exit the room through returns located low on the walls. To reduce contamination created from people and activity, newly filtered air from above must continuously replace the older air in the work area.

To keep pace with each cleanroom's unique level of activity, pharmacies should require a high enough number of air changes per hour instead of relying on the minimum standard. For example, to control the level of skin particles released during their garbing process, Mary's pharmacy required at least 40 ACPH in their ISO-class 8 ante-room.

Before falling to 39 in the certification report that failed, two prior certification reports showed 46 and 45 ACPH in the ante-room (Graph 1). Pharmacies that only review data as a snapshot in time—without trending—would simply note the passing ACPH numbers in December of 2019.





Trending graphs provide a clearer perspective, however. When she looked at the two HEPA filters in the ante-room, it was evident that the air supply from Ceiling HEPA-2 was in decline (Graph 2). This directly correlated with, and shined a spotlight on, the corresponding decline in ACPH visualized in Graph 1. Taken together, both graphs could have alerted Mary to take a closer look at that HEPA filter six months before the eventual ACPH failure.

A Critical Lesson

Tracking and trending is valuable because it allows pharmacies to act before a negative event occurs. Instead of taking sudden and costly actions—like decreasing beyond-use dates or stopping production—pharmacists can be alerted sooner and schedule a measured response while they are still in control.

We recommend using alert levels to call attention to quality control measurements before action levels are exceeded. An alert level warns you that a result is not yet failing, but it is close to the edge. In Mary's scenario, it would have given her time to take corrective action before her certification failure.

The corrective action can be simple, such as adjusting fan speed when air supply drops to an alert level. Or it may require something more involved like replacing a HEPA filter. In any case, early notification allows the director to schedule maintenance, recertification, and cleaning during times that better suit the operation and leads to better outcomes where work is not lost, time is saved, and sterile preparations are labeled with greater confidence.

You can minimize the possibility of this hypothetical scenario becoming reality

Our team is ready to assist you with evaluating quality control tracking and suggest improvements for monitoring and assessing your data.

Call or e-mail if you'd like to put our expertise to work.

Success Requires Creative Solutions

CAPS Consulting℠ is a team of pharmacy experts who are proficient in sterile compounding. We perform USP <797>, USP <800>, and 503B outsourcing compliance tests each and every day, year round, at 22 regional 503A pharmacies and three 503B outsourcing facilities across the United States. Our consulting team is ready to share this expertise with you.

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