Beyond Compliance: Using Cleanroom Certification Reports to Strengthen Your Quality Program

Most sterile compounding organizations recognize cleanroom certification as a regulatory requirement. Every six months, certifiers evaluate primary and secondary engineering controls, perform testing, issue a report, and the documentation is filed until the next certification cycle.

While certification is essential for demonstrating compliance with USP <797>, many organizations miss an opportunity to use these reports as valuable quality management tools.

A cleanroom certification report contains much more than a pass/fail determination. It provides important information about the current state of the facility and can help pharmacy leaders identify trends, evaluate risks, and support ongoing quality improvement efforts.

One of the most important aspects of a certification report is verification that engineering controls are functioning as designed. Airflow velocity measurements, HEPA filter integrity testing, room pressurization, smoke pattern evaluations, and particle count data provide insight into whether the facility is capable of maintaining the environmental conditions necessary for sterile compounding.

When reviewed carefully, these results can highlight subtle changes that may warrant further

investigation. For example, airflow measurements that remain within acceptable limits but demonstrate a gradual decline over time can provide an early indication of equipment degradation or filter loading.

Certification reports can also be valuable when investigating viable sampling excursions. If viable air sampling, surface sampling, or total particle monitoring identifies unexpected results, certification data may help determine whether facility conditions contributed to the event. Reviewing airflow patterns, pressure relationships, and equipment performance can provide important context during an investigation.

Another area often overlooked is the identification of recurring findings. Organizations sometimes focus exclusively on correcting individual deficiencies without evaluating whether the same observations appear repeatedly across multiple certification reports. Repeated findings may indicate larger issues related to facility design, maintenance practices, operational procedures, or staff training. Trending certification observations over time can help uncover these underlying causes and support more effective corrective actions.

Certification reports should also be reviewed collaboratively. While designated persons and quality leaders typically receive the reports, involving pharmacy managers, compounding supervisors, facilities personnel, and environmental monitoring personnel can improve understanding of the findings and encourage a proactive approach to risk management. These discussions often lead to process improvements and a stronger overall quality culture.

Perhaps most importantly, certification should not be viewed as an isolated activity. The most effective quality programs integrate certification results with environmental monitoring data, personnel competency evaluations, media fill testing, and routine quality assessments. Looking at these data sources together provides a more complete picture of the facility's state of control and helps organizations identify emerging risks before they affect product quality.

Cleanroom certification is certainly a compliance requirement, but it can also be much more. When certification reports are reviewed, trended, and incorporated into broader quality discussions, they become powerful tools for continuous improvement. Organizations that move beyond a simple pass/fail mindset often gain valuable insights that strengthen their contamination control strategy, improve operational reliability, and ultimately support the safety of the patients they serve.

As organizations focus on maintaining a state of control, it's also important to recognize the professionals who help make that possible. National Controlled Environment Certifier Day, observed on November 5th, is an opportunity to acknowledge the cleanroom certifiers who evaluate engineering controls, verify environmental performance, and help identify potential risks before they impact operations. Consider taking a moment to thank your certifier, share positive feedback about their services, or highlight their contributions within your organization. Strong partnerships between pharmacies and certifiers support more than compliance; they contribute to a culture of quality and ultimately help protect patient safety.

Parasol Tip: After each certification, schedule a dedicated quality review meeting to discuss trends, observations, and opportunities for improvement. Treat the report as a quality management resource, not just a compliance document.