ACTIVE Particle Control Technology and USP 800 Pharmaceutical Compounding

A White Paper
Prepared by SecureAire
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Introduction

Hospital-acquired infections (HAI) occur in 1.7 million patients in the United States each year and are linked to 75,000 deaths.[1,2] The annual cost of HAIs to the healthcare system exceeds $20 billion.[1,2] More recently, cases of increased infection from airborne contamination sources have developed. Forced-air warming devices and heater-cooler units utilized in operating rooms have been shown to harbor pathogens that have been traced to HAIs.[3,4] Many hospitalized patients are immuno-compromised making them at even greater risk for infection. **Another potential source of airborne HAIs stems from the contamination of medications within the sterile compounding pharmacy zones.**

Traditional methods of filtration do not trap the majority of airborne pathogens (most of which are smaller than 2.5 microns) and none of them kill the pathogens. Even if they are trapped, airborne pathogens continue to be viable unless killed by additional means. These methods include drying, freezing, and sulfuric acid baths which will kill many microorganisms. All of these methods are cumbersome, costly, and significantly disrupt the laboratory or pharmacy workflow.

Compounding Pharmacy Sterile Zones – Regulations for Medication Safety

The United States Pharmacopeia (USP) recently released new requirements for handling medications in healthcare settings, USP 800. Titled, "The Handling of Hazardous Drugs in Healthcare Settings," the regulations identify the requirements for receipt, storage, mixing, preparing, compounding, dispensing and the administration of hazardous drugs to protect the patient, healthcare personnel and the environment. These requirements go into effect on December 1, 2019.

USP 800 requirements include the following:

1. Elimination of the current allowance in 797 for facilities that prepare a low volume of hazardous drugs that permits placement of a BSC (biological safety cabinet) or CACI (compounding aseptic containment isolator) in a non-negative pressure room. All hazardous drug compounding shall be done in a separate area designated for hazardous drug compounding and will be maintained at a "negative" pressure in order to protect healthcare personnel.

2. An allowance for a Containment Segregated Compounding Area (C-SCA), a separate, negative pressure room with at least 12 air changes per hour (ACPH) for use with compounding hazardous drugs. Low- and medium-risk hazardous drug CSP (compound sterile preparations) may be prepared in a BSC located in a C-SCA, provided the beyond-use date of the CSP does not exceed 12 hours. A CACI that meets the requirements in 797 may be used for hazardous drug compounding if it is placed within a C-SCA.

3. An increase in emphasis on the "Monitoring of Air Quality for Nonviable and Viable Airborne Particles" and the "Monitoring of Surfaces for Viable Particles".

While the above requirements are only a subset of the new standard requirements, the increased oversight by regulatory authorities to include monitoring of nonviable and viable particles is a clear transition to cleanroom practices within pharmacies. Table 1 provides a reference to the adopted ISO 14644-1 Cleanroom Standard which dictates the number of allowable particles by referenced ISO Class.

ISO Class	Particle Count/m^3 (> 0.5 µm)	FED STD 209E Equivalent
3	35.2	Class 1
4	352	Class 10
5	3,520	Class 100
6	35,200	Class 1000
7	352,000	Class 10,000
8	3,520,000	Class 100,000

Table 1. ISO Cleanroom Standards with FED STD 209E Equivalents for Airborne Particles

The requirement for dynamic (real time) testing now exists within the Pharmacy environment. This begins first with initial commissioning and then continues, based upon specific ISO Class, on a monthly (Viable Particles) or bi-annual (Nonviable Particles) schedule. As sufficient data now exists to support the direct correlation between Nonviable and Viable Particle counts within the healthcare environment[5], it is expected that the adoption of USP 800 will produce improved results.

Technology Built for Health and Medication Safety

SecureAire has developed a technology platform to address the critical issue of Indoor air contamination within the healthcare environment. The technology optimizes both ionization and polarization to effectively collect small particles, viruses, bacteria, TVOCs and gases. The system conditions contaminants to adhere to the media material or other particles, which subsequently get captured. Utilizing and optimizing electric fields and charge to ionize/polarize contaminants, as well as polarizing the internal media material in the system, resulting in a significant reduction in airborne contamination. The following compounding pharmacy room study demonstrates the effectiveness of ACTIVE Particle Control Technology and its ability to capture and kill pathogens in sterile pharmacy zones.

Case Study: Mid-Size Hospital, Major Metropolitan Area

A mid-sized hospital in a major metropolitan area discovered an increase in infections related to its compounding pharmacy. While uncovering this situation, they also documented a significant increase in bacterial contamination within in the pharmacy causing it to be out of compliance and thus forced to operate at a significantly reduced capacity. The purpose of this study is to document the effectiveness of a SecureAire ACS Air Purification System in reducing bacterial colony-forming units (CFUs) and airborne particulate counts within the sterile compounding pharmacy zones.

Methods

Airborne particle counts and bacterial CFUs were measured before and after a SecureAire ACS Air Purifier was deployed in the chemotherapy room of a sterile compounding pharmacy. Particles were measured from six different sample ports prior to and after the intervention. CFUs were determined after culture from 20 individual samples taken within the compounding pharmacy before and after the SecureAire intervention.

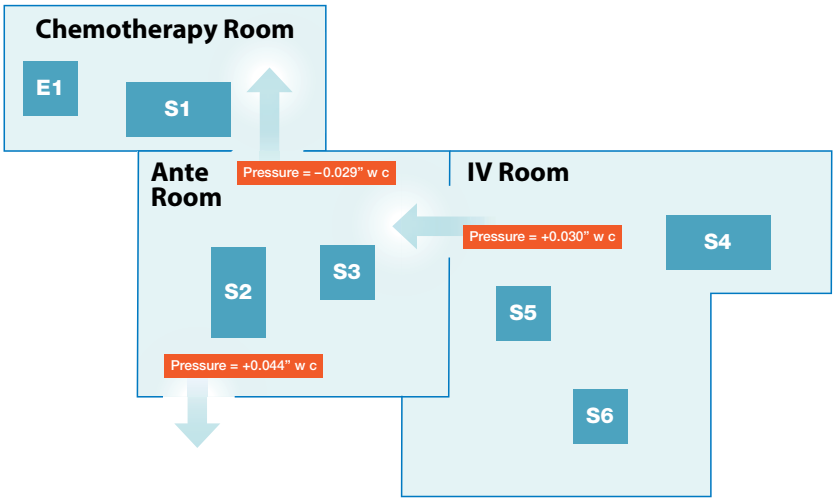

Figure 1. Compounding Pharmacy Layout with Supply and Exhaust Air Vents and Pressure Relationships

Results

The results from the deployment of SecureAire's ACTIVE Particle Control Technology are shown in Figures 2 and 3 below. The particle count chart shows a significant decrease in airborne particle contamination levels within the chemotherapy compounding pharmacy. However, more importantly, the intervention also significantly reduced the number of CFUs which enabled the pharmacy to resume operation at full capacity.

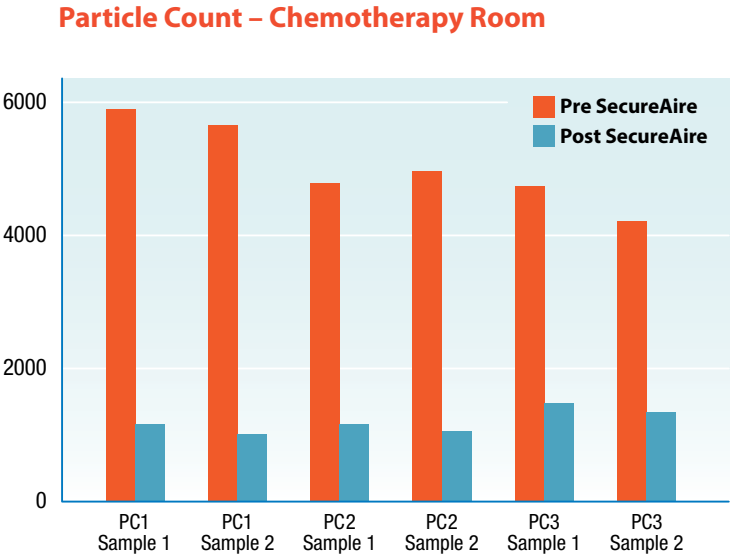

Figure 2. Particle Counts at 0.5 microns/ft³

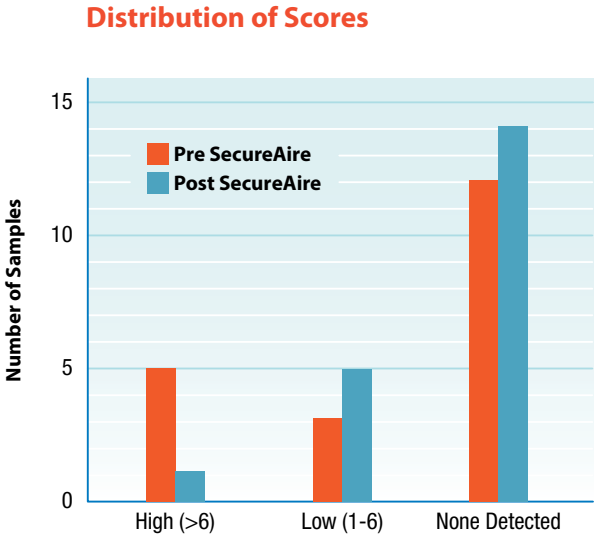

Figure 3. Samples showing CFU Count Reductions

Conclusions

The introduction of SecureAire's ACTIVE Particle Control process which includes particle conditioning, capture, and kill technology significantly reduced the airborne particle (and pathogen) load and significantly reduced the CFUs cultured in the chemotherapy compounding pharmacy. The effectiveness of the technology enabled the hospital to re-certify the cleanliness levels and to re-establish the full use of their compounding pharmacy. Prior to that, the pharmacy was operating at a reduced level of productivity which created significant operational inefficiencies that required them to find alternatives to distribute and administer medications to patients in need.

The link between airborne particulate exposure and HAIs is clear. Traditional filtration methods do not have the ability to transfer critically-small contaminants for capture within the environment; however, ACTIVE Particle Control Technology provides measurable and clearly very valuable results.

This clinical study demonstrates that SecureAire's ACTIVE Particle Control Technology, available in easily deployable configurations, reduced particulate counts and CFUs in a sterile compounding pharmacy.

The ability to deploy ACTIVE Particle Control and Pathogen Inactivation Technology exists today and could improve clinical outcomes and reduce the greater-than-$20+ Billion annual cost of Hospital Acquired Infections and reduce inflammatory and degenerative diseases.

References

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8. *www.youtube.com/watch?v=YZ41aLoHrhQ*

About SecureAire

SecureAire is headquartered in Dunedin, Florida. The Company is the industry leader in **Particle Control Technology**, which is based upon technologies developed and employed in semiconductor cleanrooms. SecureAire has advanced and developed highly sophisticated air purification technologies that makes "air flow the dominant transport mechanism for airborne contamination."

For more information please visit us at our website **www.secureaire.com.**

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