PARTICLES....PHARMACY’S NEW ENEMY
AN ORGANIZATION'S RESPONSE TO REGULATORY COMPOUNDING STANDARDS

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Introduction
The introduction of compounding standards from the National Association of Pharmacy Regulatory Authorities (NAPRA) and enforcement of provincial regulatory standards in Ontario for hospital pharmacy has mandated the need for an environmental monitoring program for sterile compounding areas. Compounding of sterile products is an integral part of the practice of pharmacy and ensuring these standards are consistently met is best practice to ensure all sterile compounding preparations are free from contaminants and safe for patient use.

Different areas of a sterile preparation area have different requirements for air cleanliness. ISO Standard 14644-1 outlines the allowable concentration of airborne particles for a given ISO Class Number. Figure 1 highlights the different ISO air classification levels allowable in a primary engineering control, cleanroom and anteroom.

Primary Objective: To implement an environmental monitoring program in the cleanroom facilities at the Juravinski Cancer Centre to test for viable and non-viable particle counts levels to comply with the new provincial legislative requirements and NAPRA sterile compounding standards.

Design
Pharmacy in collaboration with Health Safety Wellness first developed policies and procedures outlining key principles for environmental testing of particle counts within the Juravinski Cancer Center’s cleanroom facilities. Sampling and action plans were then developed (Figure 4) and testing began at the Juravinski Cancer Center in August 2014 at an interval of every 6 months. The sampling plan included testing inside the biological safety cabinets, countertops, passthroughs, doorways and around the cleanroom and anteroom.

Results

Development of the program involved collaboration with Health, Safety and Wellness and was important in planning and managing particle count excursions. The following graphs outline particle count trends over two years of semi-annual monitoring of cleanroom facilities.

Discussion
Analysis of Value
A collaborative team approach was instrumental to the successful development of this program. After each round of sampling, a meeting with Health Safety Wellness was scheduled to review results and action plans and discuss trends in excursions. The value of this program was demonstrated in several instances and has highlighted areas of deficiencies within the new cleanroom facilities such as facility design flaws and provided areas of focus for cleaning practice for both pharmacy and housekeeping staff. The inclusion of Environmental Services to our committee after the program began also educated and improved compliance with cleaning procedures from housekeeping staff. Measurement of particle counts have increased pharmacy staff awareness and adherence to standard operating procedures. We continue to expand our environmental monitoring program with the addition of surface sampling in 2017.

Benefits
➢ Increased staff awareness for adherence to cleaning standard operating procedure
➢ Validates facility renovation design
➢ Highlights problem areas with cleaning

Conclusion
The implementation of an environmental monitoring program has proven to be a valuable outcome measure for adherence to sterile compounding standards and highlighted the importance of standard operating procedures and proper facility design.

References

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