GHP

The QA and Technical Services Interest Group of the
Guild of Healthcare Pharmacists

Pharmaceutical Quality Assurance and Technical Services Symposium 2023

Thursday 28th and Friday 29th September 2023

International Convention Centre
Newport, Wales. NP18 1HQ

HPASG Specialist Pharmacy Service NHS NPPC unite

POSTER APPLICATION FORM

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Poster title	A Two Part study to investigate the Environmental (viable) and Physical impact on Pharmaceutical Cleanrooms when High Efficiency Particulate Air filtered supply is temporarily suspended.

Please submit details of abstract overleaf

Please note: all poster applications must be submitted by 18th August 2023

Please return your application to:

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marking the subject as "Symposium Posters"

ABSTRACT

A Two Part study to investigate the Environmental (viable) and Physical impact on Pharmaceutical Cleanrooms when High Efficiency Particulate Air filtered supply is temporarily suspended.

Focal Points

- *Research question(s)* - Is there a statistically significant impact on the physical and environmental parameters of pharmaceutical clean rooms following 12 hours of HVAC 'switch off' and are personnel the biggest source of contamination within our cleanrooms during HVAC 'switch off.'
- Results showed there was no significant impact on switching the HVAC off for 12 hours (out of working hours) and the presence of personnel within a cleanroom during clean air disruption, did provide the biggest source of viable and particulate contamination.
- The findings of this study, provides a validated method to enable the application of this novel HVAC control in other pharmaceutical aseptic units; through localised repeated sampling and risk analysis of the working conditions, products prepared and the fabric of the building; with the hope that this innovative study, gives the pharmaceutical manufacturing facilities the ability to implement new lean and sustainable ways of working.

Introduction

The manufacture of sterile pharmaceutical products must be conducted in dedicated cleanroom facilities, maintained and operated in line with EU GMP parameters (1). The Heating Ventilation and Air Conditioning (HVAC) system controls supply and extract of High-efficiency particulate (filtered) air, which is essential for maintaining regulatory requirements.

Approximately 50% of a pharmaceutical cleanrooms total energy is dedicated to continuously running a HVAC system (2); however, 78% of this systems operating time is for maintaining cleanroom parameters, when no operational activities are being undertaken.

This two part study was conducted to ascertain the risk and impact of switching off the HVAC system to the cleanroom environment, with the overall objective to enable safe implementation of HVAC switch off out of working hours, ultimately to reduce energy consumption.

Methods

Sampling was conducted within grade C and D cleanrooms, in line ISO14644-1 and ISO14644-3 (3).

Study 1

Disruption to clean air supply was implemented out of operational hours, with personnel access removed 1 hour prior to HVAC switch off and reinstated 1 hour post HVAC resupply. Sampling completed was the following:

- continuous measurements of temperature, humidity and differential pressure (environmental monitoring system)
- Pre and post supply 'switch off' and after resupply measurement of Air change rates (Hooded balometer), particle concentrations (MET1), viable active air sampling (TSA) and viable surface contact plates (TSA).

Study 2

This study was conducted in a grade D inner support room only, the following sampling methods were adopted:

I. Continuous particulate monitoring, center of the room.
II. Viable surface sampling using methods adopted in study 1.
III. Passive viable environmental monitoring using 90mm settle plates exposed for two hours.

Three different variable working conditions were adopted over a controlled two hour period.

1) Normal operating working parameters with 1 staff member working, no disruption to HVAC supply.
2) No staff members present, HVAC switched off for 1 hour with a 30minute clean-up period before and after.
3) Normal operating working parameters as set out in test 1, however HVAC supply disruption as set in test 2

Results

Study 1

All results for physical working parameters, particle concentrations and viable counts were well within EU GMP limits. Results obtained for the 0.5µm particles demonstrated no significant statistical variation. The 5µm data and viable active air sampling exhibited significant statistical variation; with less particles and viable growth measured following HVAC switch off and reinstatement. The results from contact plates however, showed a significant increase in viable growth recovered following reinstatement. At least 90% of the identified organisms were attributed to the human microbiome and conferred with a study conducted by Sandel in 2011 (4).

Study 2

All results for particle concentrations and viable counts within EU GMP limits. Significant variation was found for both 0.5µm and 5µm particle concentration when staff were working within the cleanroom and HVAC was switched off. Recovery rates for viable growth was low; however, significant variation found with viable growth detected between test 2 and test 3, direct correlation between the number of microorganisms recovered and concentration of 5 µm particles.

Conclusion

- There is no significant variation in the working parameters of the cleanroom following 12 hour HVAC system "switch off"
- Operators do significantly affect the environmental parameters of a cleanroom when a HVAC system is "switched off".
- Operators are the biggest risk to our cleanrooms and directly linked to significant variation in viable results.
- Removal of operators prior to HVAC "switch off" and restriction of re-entry post HVAC reinstatement, is key to ensuring surfaces are free from viable bioburden and minimal risk to pharmaceutical products.

References

[1] Medicines and Healthcare products Regulatory Agency (MHRA), 2022. Annex 1. 11th ed. London: Pharmaceutical Press.

[2]Tschudi, W. & Xu, T., 2001. Cleanroom Energy Benchmarking Results, California: University of California.

[3] NHS England, 2022. Delivering a 'Net Zero' National Health Service, London: NHS England and Improvement.

[4] Sandle, T., 2018. The human microbiome and the implications for cleanroom control. European Journal of Parenteral and Pharmaceutical Science, 23(3), pp. 89-98.