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

PASG Specialist Pharmacy Service NHS NPPC unite

POSTER APPLICATION FORM

Name(s)	Sarah Ward
Hospital / Organisation	Arrowe Park Hospital
NHS Trust / Health Board	Wirral University Teaching Hospital NHS Foundation Trust
Contact address	Wirral Aseptic Services, Wirral University Teaching Hospitals NHS Foundations Trust, Arrowe Park Road, Upton, Wirral. CH49 5PE
Telephone No.	0151 604 7251
E-mail address	Sarah.ward82@nhs.net

Poster title	Contamination Control in Cleanrooms

Please submit details of abstract overleaf

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

Please return your application to:

admin@pasg.co.uk
marking the subject as "Symposium Posters"

ABSTRACT

Contamination Control in Cleanrooms

- How effective are current cleaning regimes in controlling contamination in an ageing unit? What impact does production workload have on this?
- Increased workload does not necessarily correlate with increased out-of-specification environmental monitoring in an ageing aseptic unit
- Good cleaning processes can compensate for an ageing aseptic unit and production can be increased without compromising contamination control (to an extent)

Introduction

The controlled aseptic cleanroom environment must maintain stringent levels of cleanliness to prevent contamination of final medicinal products. The production of sterile pharmaceuticals in hospital aseptic units can only be performed safely if the cleanroom environment is scrupulously maintained. Examples of the consequences of contamination in parenteral products have been well documented.

In this work, environmental monitoring data were analysed from a six-year period to assess the level of control of the cleanroom environment and the efficacy of procedures to minimise contamination against seasonal variation, production increase and an ageing unit. Changes in practice were also studied and their impact on the microbiology landscape in the cleanroom was analysed to establish a set of recommendations for future monitoring of the cleanroom environment.

Methods

Environmental monitoring data was collected from January 2017-December 2022 and assessed against EU GMP limits. Data from finger dabs, settle and contact plates were included from Grade A and B sessional, weekly and quarterly monitoring.

Results

Almost all of the months analysed had less than 1% of all plates showing out-of-specification results, showing good contamination control. Across the same time period, production levels and the number of plates sampled increased dramatically. We were also able to rule out any particular cleanroom production environment contributing disproportionately to out-of-specification results.

Conclusions

With good practice, it is possible to compensate for an ageing unit and to increase workload in a controlled manner. In the future, there is likely to be increased demand on aseptic units and a thorough understanding of each unit is crucial.