

NHS PQAC Advice Note

High Microbial Counts and Shedders



With apologies to "Shulz"

Introduction

High microbial counts need to be investigated and it is important that during root cause investigation data should be analysed to determine whether results are person specific.

If the high results are attributed to particular staff they are colloquially known as shedders.

An average person sheds 0.7kg of skin flakes per year which corresponds to about 600,000 particles every hour. Large quantities of skin flakes observed when cleaning a changing room can indicate a member of staff may be suffering from eczema or similar skin complaints.

Definition

A shedder is a person that raises the 'in use' microbial count to values beyond the classification of the room even when wearing appropriate garments* and good technique has been demonstrated / assured. Establishing a clear pattern linking the person to higher counts over time is important.

*according to EU GMP annex 1 sections 19 and 43. ^{Reference 1}

This is a rare problem, and great care is needed to establish if an individual is a significant shedder or merely guilty of poor technique. In particular review the following data

- Finger dab results (Repeated high results are a common first indicator)
- The above usually / frequently linked to higher plate count in rooms

Note: Everyone sheds, it is a matter of degree and environmental impact as to whether an individual is classified as a "shedder"

Action

Close monitoring is vital; trending analysis will establish if a member of staff is a shedder.

Treatment and/or the rigorous application of correct gowning may be sufficient to prevent the condition affecting the clean room.

In taking appropriate action, it is recommended that the following check list be followed and findings documented. The report should be depersonalised as far as possible as there may be some important learning for other members of staff.

- 1 Discuss the results with the member of staff paying particular attention to EU GMP Annex 1 sections 39, 40 and 41 ^{Reference 1} If the subject suffers from a common skin complaint such as eczema, greater problems may be seen in winter when the air is dry or if the clean room is dehumidified.
- 2 Personal Hygiene: Recommend a daily bath or shower. In addition, the application of a simple, aqueous, unscented, preserved body moisturiser or lotion immediately after bathing could be advised.
- 3 Test garments before and after donning as indicated in NHS PQAC Guidance (Yellow Cover Document 2006) ^{Reference 2}
- 4 Additional garments could be worn. This could be a second mask, a second pair of gloves or additional overshoes.
- 5 Different garments e.g. better fitting coat or coverall or for a higher grade environment garment.
- 6 Moving the staff to work in a lower risk area.

Further Comment: In some individuals, nervousness, anxiety and excessive perspiration may exacerbate these issues and should be considered when action is taken.

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NHS Pharmaceutical Micro Protocols Group

Tim Sizer; John C Rhodes; Sarah Hiom; Linda Musker; Janet Shaw; Mark Oldcorne; Bernie Sanders

References

1. (EU GMP) Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2007: See Annex 1 sections 19, 39, 40, 42 and 43
2. Munton T et al "Clean Room Garment Monitoring" Feb 2006 NHS Pharmaceutical Quality Assurance Committee