

SFHPHARM52

Prepare and maintain the working environment for aseptic manufacture and dispensing of medicinal products in cleanrooms



Overview

This standard relates to the preparation, maintenance and monitoring of the controlled environment used for manufacture and dispensing of medicinal products in cleanrooms. It includes maintenance of and compliance with the Principles of Good Manufacturing Practice and associated guidance. Your practice will be consistent with your role and be carried out under the relevant regulatory and ethical frameworks. You will work at all times within local Standard Operating Procedures.

Users of this standard will need to ensure that practice reflects up to date information and policies.

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Performance criteria

You must be able to:

- P1 ensure that the work area is safe for use
- P2 ensure availability of relevant documentation for procedures to be undertaken and work in accordance with them
- P3 carry out routine environmental monitoring as specified by Standard Operating Procedures
- P4 check that equipment is performing correctly and safe to use
- P5 identify, record and report non-compliance with relevant standards or deviation from approved procedures
- P6 where relevant, take appropriate corrective action in response to such issues

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Knowledge and understanding

You need to know and understand:

- K1 the Principles of Good Manufacturing Practice and associated guidelines and standards
- K2 the relevant Standard Operating Procedures
- K3 the classification of cleanrooms and the importance of environmental monitoring and the specified testing frequency
- K4 methods & tests for physical and biological environmental monitoring & their purpose
- K5 the nature of possible contaminants and the implications of contamination
- K6 the range of measures designed to exclude or prevent contamination
- K7 expected performance and limitations of equipment
- K8 your personal responsibilities and accountabilities

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Additional Information

External Links

This standard links with the following dimension within the NHS Knowledge and Skills Framework (October 2004):

Dimension: HWB10 Products to meet health and wellbeing needs

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