SFHPHARM16
Assist in the manufacture and assembly of medicinal products

Overview

This standard covers the processes and procedures for assisting in the assembly of batch medicinal products including preparing the environment and self. It also covers the breaking down of large containers of medicinal products and repacking them into sizes that are convenient to use. This is known as `assembly' and is often referred to as `pre-packing'. Your practice will be consistent with your occupational role and carried out under the regulatory and ethical frameworks established in the context of current legislation. You will work at all times within Standard Operating Procedures that relate to the way in which a pharmacy service is provided in your place of work. 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 work within the relevant Standard Operating Procedures including the relevant health and safety and Control of Substances Hazardous to Health procedures and within own limits of responsibility
- P2 before you start the preparation confirm that the correct worksheet, labels, raw materials, equipment and consumables are available and ready for use
- P3 assisting in undertaking relevant environmental monitoring checking that the parameters, where appropriate, are within the set limits:
  - P3.1 prior to preparation
  - P3.2 during preparation
  - P3.3 following completion of preparation
- P4 inform the appropriate person if the environmental parameters are outside the set limits
- P5 put on the appropriate clean room clothing following correct gowning procedure
- P6 assist with cleaning and preparing the environmental areas using the correct materials
- P7 assist with preparation of products in accordance with the batch sheet using the correct process and equipment and undertaking all process checks at the relevant stages
- P8 label product, pack and if necessary label into any secondary packaging and take quality control samples as appropriate
- P9 assist with completion of all necessary reconciliation calculations correctly and accurately for the product and the labels
- P10 complete all documentation clearly and accurately, ready for checking
- P11 quarantine product following the final check by the appropriate person
- P12 clean and decontaminate all environmental areas using the correct cleaning method
- P13 ensure that all equipment is dismantled, cleaned, decontaminated and correctly stored or disposed of correctly
- P14 report any defects to an appropriate person
- P15 report in accordance with Standard Operating Procedures any out of specification results/unusual events where appropriate
- P16 take appropriate action following an unusual event, within the limits of your authority

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Knowledge and understanding

You need to know and understand:

K1 the basic principles of quality assurance relating to manufacture of medicinal products
K2 the principles of current good manufacturing practice
K3 the difference between preparation for individuals and preparation for stock and how this is generally implemented in the workplace
K4 current health and safety legislation and how it applies to the working environment, including Control of Substances Hazardous to Health
K5 the principles of Standard Operating Procedures and why it is important to work within these procedures
K6 the limits of your own role and the referral procedures
K7 basic hygiene and the importance of maintaining a clean working environment
K8 personal hygiene and the use of protective / clean room clothing
K9 the possible sources of contamination
K10 environmental parameters, their importance and how to carry out their monitoring
K11 the principles of weights and measures
K12 the preparation, assembly and maintenance of equipment
K13 principles and procedure of different processes in manufacturing medicinal products and when to use them
K14 labelling and packaging requirements
K15 the reasons for and importance of carrying out in-process checks, end product quality checks and quarantine requirements
K16 the disposal of waste materials and cleaning material
K17 dismantling, cleaning, decontaminating and storing equipment
K18 cleaning and decontamination of preparation area
K19 the importance of recording information clearly, accurately and in a systematic, timely manner and of the storing of this information

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Additional Information

External links

1. This standard links with the following dimension within the NHS Knowledge and Skills Framework (October 2004):
2.
3. Dimension: HWB10 Products to meet health and wellbeing needs

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