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PHARM17.2016 Manufacture and assemble medicinal products

OVERVIEW

This standard covers the processes and procedures for the manufacture, packing and over-labelling 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 appropriate for 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, professional and ethical frameworks established in the context of current legislation. You will need to take a reflective approach to your work.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. A caring and compassionate approach should be adopted in line with current healthcare guidance.Users of this standard will need to ensure that practice reflects up to date information and policies.Version No 2

KNOWLEDGE AND UNDERSTANDING

You will need to know and understand:

1. the Standard Operating Procedures and the importance of adhering to them at all times
2. the importance of working within the limits of your competence and authority, when to seek agreement or permission from others and when to refer on to an appropriate person
3. current health and safety legislation and how it applies to the working environment
4. legal, organisational and policy requirements relevant to your role, the role of others in your organisation and the activities being carried out
5. the relevant national and local guidelines, policies and procedures that are available and how and when they should be accessed
6. the importance of adhering to information governance policies and maintaining confidentiality when sharing information about individuals with others
7. the duty to report any acts or omissions that could be detrimental to individuals, yourself, colleagues or your employer
8. the principles of good manufacturing practice, including pharmaceutical quality systems and your role within that
9. the difference between preparation for individual patients and preparation for stock and how this is generally implemented in the workplace

10. guidelines relating to manufacture of medicinal products
11. the importance of using approved documentation
12. the importance of maintaining a clean working environment
13. personal hygiene and the use of protective / clean room clothing
14. the possible sources of contamination and the appropriate methods of prevention
15. the importance of environmental parameters, how to carry out their monitoring and the referral procedures if they are outside the set limits
16. chemical and physical properties of ingredients relevant to formulation and compounding, including any interactions between raw materials and components
17. the principles of formulae calculations, weights and measures
18. the preparation, assembly and maintenance of equipment
19. the principles, properties and uses of different types of containers and when to use the various types
20. the nature and use of different product forms
21. the preparation and use of environmentally controlled conditions
22. principles and procedures for preparing medicinal products
23. reconciliation of materials, labelling and packaging requirements
24. the reasons for safe systems of work including the quarantine requirements and the appropriate checking processes
25. how to identify near misses and errors
26. the causes and consequences of near misses and errors
27. local and/or national error reporting procedures and communication channels
28. principles and procedures for the sterilisation of products
29. the safe disposal of waste materials and cleaning materials
30. how to dismantle, clean, decontaminate and store equipment correctly
31. how to clean and decontaminate the preparation area
32. the importance of recording, storing and retrieving information in accordance with organisational procedures

PERFORMANCE CRITERIA

You must be able to do the following:

1. work within the relevant Standard Operating Procedures including the relevant health and safety procedures and within your own limits of competence
2. ensure that equipment is checked as calibrated and validated before use
3. before you start the preparation, confirm that the correct documentation, raw materials, equipment and consumables are available and ready for use
4. monitor relevant environmental parameters and ensure that where appropriate they are within the set limits
5. take appropriate action if the environmental parameters are outside the set limits
6. put on the appropriate clothing relevant to the area of work, following the correct procedure
7. ensure the environmental areas are clean and prepared using the correct materials
8. prepare products in accordance with the documentation using the correct process and equipment and undertaking all process checks at the relevant stages
9. complete any necessary sterilisation/sanitisation processes to meet the quality assurance requirements

10. label product, pack and if necessary label into any secondary packaging and prepare quality control samples as appropriate
11. complete all necessary reconciliation and calculations correctly and accurately for the product, packaging and labels
12. complete all documentation clearly and accurately, ready for checking
13. quarantine product in accordance with organisational requirements
14. ensure that the environmental areas are cleaned and decontaminated using the appropriate method and equipment
15. ensure that all equipment is dismantled, cleaned, decontaminated and correctly stored or disposed of correctly in accordance with Standard Operating Procedures
16. report any out of specification results, unusual events or defects to an appropriate person in accordance with Standard Operating Procedures
17. record and report any near misses or errors in line with organisational procedures
18. feedback any near misses or errors to colleagues to minimise potential future errors
19. take appropriate action following an unusual event, within the limits of your authority
20. complete all relevant documentation and store appropriately in accordance with legal and organisational requirements

ADDITIONAL INFORMATION

This National Occupational Standard was developed by Skills for Health. This standard has been merged with PHARM16.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