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PHARM20.2016 Prepare documentation and materials for the manufacture and assembly of medicinal products

OVERVIEW

This standard covers the preparation of documentation and collection of raw materials, components and other consumables necessary to prepare medicinal products for manufacture and assembly. 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. the recognised guidelines relating to manufacture of medicinal products

11. the importance of maintaining a clean working environment
12. the importance of personal hygiene and the correct use of protective / clean room clothing
13. the different types of environmental areas and when they should be used
14. the possible sources of contamination and appropriate methods of prevention
15. the principles of formulae calculations, weights and measures
16. the importance of environmental parameters, how to carry out their monitoring and the referral procedures if they are outside the set limits
17. the various types of products
18. chemical and physical properties of ingredients relevant to formulation and compounding, including any interactions between raw materials and components
19. the materials, consumables and equipment necessary for the preparation of medicinal products and the processes to minimise any associated risks
20. labelling and packaging requirements and conventions
21. the procedures for cleaning, decontamination, and preparing the environment and equipment
22. the importance of using approved documentation
23. how to identify near misses and errors
24. the causes and consequences of near misses and errors
25. local and/or national error reporting procedures and communication channels
26. 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. put on the appropriate clothing relevant to the area of work, following the correct procedure
3. clean the appropriate environmental area(s) using the correct equipment and materials
4. ensure that the area of work is always clean and tidy
5. monitor relevant environmental parameters and ensure that where appropriate they are within the set limits
6. generate the relevant documentation according to local guidelines and protocols
7. confirm you have the correct documentation for the product, completing any calculations as appropriate
8. allocate the batch number and expiry date for the product
9. generate the labels and ensure that all labels produced are accounted for and complete, accurate and legible
10. select the correct starting materials, equipment and packaging for the product, recording the relevant information on the correct documentation
11. confirm the starting materials and equipment are fit for purpose
12. make clear and accurate entries on all the relevant documentation
13. ensure that the appropriate in-process checks have been carried out by the relevant person

14. record and report any near misses or errors in line with organisational procedures
15. feedback any near misses or errors to colleagues to minimise potential future errors
16. sanitise the materials and equipment for transfer into the work area
17. act within the limits of your authority and refer any problems to an appropriate person
18. 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 PHARM22.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