SFHPHARM23

Check documentation and materials prior to the preparation of aseptic products

Overview

This standard covers the checking of documentation and materials prior to the preparation of aseptic products. It covers aseptic preparation for both dispensing and manufacturing.

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.

Performance criteria

You must be able to:

1. work within the relevant Standard Operating Procedures including the relevant health and safety procedures and within your own limits of competence
2. check that you have the correct documentation for the product
3. ensure that the starting materials have been collected correctly and are ready for the aseptic process
4. check that the transcriptions, calculations, batch numbers and expiry dates are all correct
5. check the allocated batch number and expiry date for the product
6. check that the documentation and labels generated are correct, complete, accurate, and legible
7. ensure the correct raw materials and equipment / consumables have been assembled for the product and are fit for purpose
8. quarantine product in accordance with organisational requirements
9. record and report any near misses or errors in line with organisational procedures
10. feedback any near misses or errors to colleagues to minimise potential future errors
11. act within the limits of your authority and refer any problems to an appropriate person
12. complete all relevant documentation and store appropriately in accordance with legal and organisational requirements

Knowledge and understanding

You 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. recognised guidelines for the aseptic process
10. the difference between preparation for individual patients and preparation for stock and how this is generally implemented in the workplace
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 environmentally controlled areas and when they should be used
14. the possible sources of contamination and appropriate methods of prevention
15. the various types of products
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 materials and equipment necessary for the preparation of aseptic products
19. aseptic techniques and when to use the different processes to minimise any associated risks

20. the importance of carrying out accuracy and quality checks
21. the reasons for safe systems of work including the quarantine requirements and the appropriate checking processes
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

External Links