SFHPHARM55
Final release of compounded parenteral anti-cancer therapy products for clinical use

Overview

This standard relates to the release of relevant anti-cancer therapy products for clinical use. It requires compliance with the relevant legislation. 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 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 work within the legislative framework and guidelines in your place of work including Standard Operating Procedures

P2 check that the manufactured product(s) meets defined specifications

P3 take corrective action in the event that the defined specifications are not met

P4 ensure that the equipment and facilities meet required standards during manufacture, and take corrective action if required

P5 ensure that raw materials and finished products have been stored correctly and are within their valid shelf life

P6 adhere to the relevant Standard Operating Procedures and assess the importance of deviations, taking corrective action if required

P7 assess the importance of changes to planned production

P8 ensure that the product meets the requirements of the original order or prescription

P9 ensure that the label on the product is correct

P10 approve release of the product

P11 complete relevant records in accordance with Standard Operating Procedures

P12 seek clarification or advice from an appropriate person if required

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Knowledge and understanding

You need to know and understand:

K1 the principles of Current Good Manufacturing Practice, Good Dispensing Practice and Standard Operating Procedures and their application

K2 approved local and national requirements for release for clinical use of anti-cancer therapy products, including recording and reporting mechanisms for non-conforming products

K3 the implications of not adhering to legislation and guidance

K4 safety protection guidelines and their application

K5 approved product specification

K6 storage requirements for raw materials and finished products

K7 the differing responsibilities associated with professional and technical release

K8 your level of personal responsibility and accountability

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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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