Assist in the preparation of documentation, materials and other items for manufacture and assembly of medicinal products



Overview

This standard covers assisting in the preparation of documentation and collection of raw materials, components and other consumables necessary to prepare medicinal products. 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 `prepacking'. 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.

Assist in the preparation of documentation, materials and other items for manufacture and assembly of medicinal products

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 ensure that appropriate clothing is worn at all times
- P3 clean the appropriate environmental area(s) using the correct materials
- P4 confirm you have the correct worksheet and labels for the product
- P5 select the correct raw materials and equipment / consumables, for the product, recording the relevant information on the worksheet
- P6 confirm the raw materials and equipment / consumables are fit for purpose
- P7 make clear and accurate entries on all the relevant documentation
- P8 ensure the `first check' is carried out by an appropriate person
- P9 disinfect the raw materials, consumables into the clean room if appropriate
- P10 report any problems outside your area of responsibility to an appropriate person

Assist in the preparation of documentation, materials and other items for manufacture and assembly of medicinal products

Knowledge and understanding

You need to know and understand:

- K1 the basic principles of quality assurance including current good manufacturing practice
- K2 the difference between preparation for individual patients and preparation for stock and how this is generally implemented in the workplace
- K3 your responsibilities under Control of Substances Hazardous to Health and current health and safety legislation and how it applies to the working environment
- K4 the importance of Standard Operating Procedures and why you must always work within these procedures
- K5 the importance of working within the limits of your own role
- K6 basic hygiene and the importance of maintaining a clean working environment including conducting a weekly and monthly clean
- K7 the importance of personal hygiene and the correct use of protective / clean room clothing
- K8 the different types of environmental areas and when they should be used
- K9 the possible sources of contamination
- K10 the materials, consumables and equipment necessary for the preparation of medicinal products
- K11 the principles of formulae calculations, weights and measures
- K12 the procedures for cleaning, decontamination, and preparing the environment and equipment
- K13 labelling and packaging requirements and conventions
- K14 the importance of recording information clearly, accurately and in a systematic, timely manner and of the storing of this information

Assist in the preparation of documentation, materials and other items for manufacture and assembly of medicinal products

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

Assist in the preparation of documentation, materials and other items for manufacture and assembly of medicinal products

Developed by	Skills for Health
Version number	1
Date approved	June 2010
Indicative review date	June 2012
Validity	Current
Status	Original
Originating organisation	Skills for Health
Original URN	PHARM22
Relevant occupations	Health and Social Care; Healthcare and Related Personal Services
Suite	Pharmacy
Key words	Sterile production, non-sterile production, manufacturing, pre-packing, pharmaceutical manufacturing, chemotherapy manufacturing, cytotoxic drugs, pharmacy, production.