Australian Government

Assessment Requirements for HLTPHA014 Conduct small-scale compounding and labelling of pharmaceutical products

Release: 1

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Modification History

Not applicable.

Performance Evidence

Evidence of the ability to complete tasks outlined in elements and performance criteria of this unit in the context of the job role, and:

- follow workplace procedures and industry codes to correctly and safely compound and label at least 5 different batches of pharmaceutical products listed in the Australian Pharmaceutical Formulary and Handbook (APF)
- interpret standard pharmaceutical references
- identify issues outside scope of own practice and refer to an authorised person
- perform the activities outlined in the performance criteria of this unit during a period of at least 240 hours of work related to hospital or health services pharmacy support in a clinical workplace environment. These 240 hours may be applied collectively across all units of competency that include the requirement for workplace hours for the purposes of assessment.

Knowledge Evidence

Demonstrated knowledge required to complete the tasks outlined in elements and performance criteria of this unit:

- National, State or Territory legal and ethical requirements for pharmacy work, and how these are applied in organisations, including:
  - codes of conduct
  - personal protection equipment (PPE)
  - duty of care and implications of negligence
  - privacy, confidentiality and disclosure
  - records management
  - rights and responsibilities of workers, employers and patients
  - specific legislation:
    - medication and their use
    - the practice of pharmacy
    - different schedules of medication and pharmaceutical products
  - work role boundaries including responsibilities and limitations in compounding products
  - work health and safety

- key information in standard pharmaceutical references and their use in compounding, including:
  - Australian Pharmaceutical Formulary Handbook (APF)
  - Monthly Index of Medical Specialities (MIMS) or AusDI Advanced
  - Australian Medicines Handbook (AMH)
  - Micromedex
- rationale for, and key features of:
  - The Society of Hospital Pharmacists (SHPA) Guidelines for Medicines Prepared in Australian Hospital Pharmacy Departments
  - Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments
- product identification and handling, including those for:
  - formulary medication and non-formulary medication
  - products with the required integrity as well as those whose integrity has been compromised
  - routine of handling products and products requiring special handling
- nature and use of different dosage forms including:
  - oral
  - parenteral products
  - topical
- infection control requirements for small scale compounding of pharmaceutical products, including:
  - correct disposal of sharps and residues
  - cleaning and disinfection processes
  - personal hygiene
  - sources and types of contamination and required responses including microbial, cross-chemical, physical, environmental and corrective strategies
- compounding processes relating to small scale compounding, including:
  - nature and use of oral and topical dosage forms
  - chemical and physical properties of raw materials in relation to formulation and compounding
  - types of equipment, their key features and use
  - compounding of a product according to a work sheet
  - principles and procedures of formulae calculations, weights and measures
  - processes for dilution, suspension, incorporation and reconstitution
- risk considerations and procedures for pharmaceutical compounding:
  - product security
  - handling and storage of hazardous materials
  - quarantine periods
- requirements for formulated compounding documentation

  - different documentation types, their scope and purpose
  - worksheet processes
  - information quality requirements including clarity, logic and completeness
- labelling requirements for compounded products, including:
  - adherence to legislative requirements
  - name, form and strength of product
  - ancillary labels as part of label details
  - hazard warnings
  - spacing for entry of batch numbers and expiry dates
- packaging methods, container materials and principles for selection
- storage and transport requirements and rationale for different types of product including:
  - hazardous materials
  - special storage considerations:
    - humidity
    - isolation
    - light
    - temperature
    - ventilation
- features and use of pharmacy systems used for small scale compounding.

Assessment Conditions

Skills must be demonstrated in the workplace with the addition of simulations and scenarios where the full range of contexts and situations have not been provided in the workplace.

Assessment must ensure access to:

- use of suitable facilities, equipment and resources, including:
  - weighing and measuring equipment
  - utensils
  - raw materials
  - pharmaceutical references
- modelling of industry operating conditions, including presence of time constraints for activities
- authorised person with whom to consult.

Assessors must satisfy the Standards for Registered Training Organisations' requirements for assessors.

Links

Companion Volume implementation guides are found in VETNet - https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=ced1390f-48d9-4ab0-bd50-b015e5485705