

Table 2 Organization and Personnel Standards

- 2.1 Principle: There must be sufficient competent personnel to carry out all the tasks for which the wholesale dealer is responsible. Individual responsibilities should be clearly understood by the staff and be recorded.
- 2.2 General:
- 2.2.1 There should be an adequate number of competent personnel involved in all stages of the distribution activities of medicinal products. The number of personnel required will depend on the volume and scope of activities.
- 2.2.2 The Personnel organizational structure of the wholesale dealer should be set out in an organization chart. The role, responsibilities, and interrelationships of all personnel should be clearly indicated.
- 2.2.3 The role and responsibilities of employees working in key positions of distribution activities should be set out in written job descriptions, along with any arrangements for deputising.
- 2.3 Designation of responsibilities:
- 2.3.1 The wholesale dealer must designate personnel responsible for GDP compliance. Relevant personnel of distribution activities should have appropriate competence and experience as well as knowledge of and training in GDP regulations.
- 2.3.2 Wholesale dealer should nominate personnel for out of hours contact (e.g. emergencies and recall). Designated responsible person(s) may delegate duties but not responsibilities.
- 2.3.3 Written job descriptions for designated responsible person(s) should define their authority to take decisions with regard to their responsibilities. The wholesale dealer should give the designated responsible person(s) the defined authority, adequate resources and responsibility needed to fulfil their duties.
- 2.3.4 Designated responsible person(s) should carry out their duties in such a way as to ensure that the wholesale dealer can demonstrate GDP and that public service obligations are met.
- 2.3.5 The responsibilities of the designated responsible person(s) include:
- (1) Ensuring that a quality management system is implemented and maintained.
 - (2) Focusing on the management of authorised activities and the accuracy and quality of records.
 - (3) Ensuring that initial and continuous training programmes are implemented and maintained.
 - (4) Coordinating and promptly performing any recall operations for

medicinal products.

- (5) Ensuring that relevant customer complaints are dealt with effectively.
- (6) Ensuring that suppliers and customers are approved..
- (7) Approving any subcontracted activities which may impact on the regulations.
- (8) Ensuring that self-inspections are performed at appropriate regular intervals following a prearranged programme and necessary corrective measures are put in place.
- (9) Keeping appropriate records of any delegated duties.
- (10) Deciding on the final disposition of returned, rejected, recalled or falsified products.
- (11) Approving any returns to saleable stock.
- (12) Ensuring that any additional requirements imposed on certain medicinal products by national legislation are adhered to.
- (13) Other distribution activities.

2.4 Training:

- 2.4.1 All personnel involved in distribution activities should be trained on the requirements of GDP regulations. They should have the appropriate competence and experience prior to commencing their tasks.
- 2.4.2 Personnel should receive initial and continuing training relevant to their role, based on written procedures and in accordance with a written training programme. Designated responsible person(s) should also maintain their competence in GDP through regular training.
- 2.4.3 Training should include identification of medicinal products and prevent falsified medicines from entering the supply chain.
- 2.4.4 Personnel dealing with any medicinal products which require more stringent handling conditions should receive specific training. Examples of such medicinal products include hazardous medicinal products, radioactive materials, controlled drugs, and temperature-sensitive medicinal products.
- 2.4.5 A record of all training should be kept, and the effectiveness of training should be periodically assessed and documented.

2.5 Hygiene: Appropriate procedures relating to personnel hygiene, relevant to the activities being carried out, should be established and observed. Such procedures should cover health, hygiene and clothing.