

Table 7 Outsourced Activities Standards

- 7.1 Principle: Any activity covered by the GDP regulations that is outsourced should be correctly defined, agreed and controlled in order to avoid misunderstandings which could affect the integrity of the product. There must be a written Contract between the Contract Giver and the Contract Acceptor which clearly establishes the rights, obligations and duties of each party.
- 7.2 Contract Giver:
- 7.2.1 The Contract Giver is responsible for the activities contracted out.
- 7.2.2 The Contract Giver is responsible for assessing the competence of the Contract Acceptor to successfully carry out the work required and for ensuring by means of the contract and through audits that the principles and guidelines of the regulations are followed. An audit of the Contract Acceptor should be performed before commencement of, and whenever there has been a change to, the outsourced activities. The requirement for audit and frequency should be defined based on risk depending on the nature of the outsourced activities. Audits should be permitted at any time.
- 7.2.3 The Contract Giver should provide the Contract Acceptor with all the information necessary to carry out the contracted operations in accordance with the specific product requirements and any other relevant requirements.
- 7.3 Contract Acceptor:
- 7.3.1 The Contract Acceptor is responsible for the activities covered by the regulations and delegated by the Contract Giver.
- 7.3.2 The Contract Acceptor should have adequate premises and equipment, procedures, knowledge and experience, and competent personnel to carry out the work ordered by the Contract Giver.
- 7.3.3 The Contract Acceptor should not pass to a third party any of the work entrusted to him under the contract without the Contract Giver's prior evaluation and approval of the arrangements and an audit of the third party by the Contract Giver or the Contract Acceptor. Arrangements made between the Contract Acceptor and any third party should ensure that the wholesale distribution information is made available in the same way as between the original Contract Giver and Contract Acceptor.
- 7.3.4 The Contract Acceptor should refrain from any activity which may adversely affect the quality of the medicinal product(s) handled for the Contract Giver.
- 7.3.5 The Contract Acceptor must forward any information that can influence the quality of the medicinal product(s) to the Contract Giver in accordance with the requirement of the contract.