Regulations for Medicament Contract Manufacture and Analysis

(Amended Date:2013-08-02)

1. Full text of 16 Articles adopted and issued per 22 October 2004 Department of Health Order No. Wei-Shu-Yao-0930333509; for implementation from the date of issuance
2. Articles 8 and 12 amended and issued per 2 August 2013 Ministry of Health and Welfare Order No. Bu-Shou-Shi-1021101814

Chapter 1: General Principles

Article 1 These Regulations are adopted pursuant to Article 42, paragraph 2 of the Pharmaceutical Affairs Act ("the Act").

Article 2 Contract manufacturing and analysis of drug (medicinal) products shall be conducted in accordance with these Regulations; matters for which these Regulations make no provision shall be governed by other relevant laws and regulations.

Article 3 "Contract manufacturing," as used in these Regulations, means the contract of another firm to perform manufacturing during any stage, successive stages, or the entire process of the manufacturing of a drug.

Article 4 "Contract analysis," as used in these Regulations, means the contract of another firm or a relevant agency to carry out research and development in the technical aspects of medicinal products, control of production, quality control and stability testing for active pharmaceutical ingredients, semi-finished products, and end products.

Article 5 An application shall be submitted to and approved by the central competent health authority prior to any contracted manufacturing or analysis of medicinal products.
Only a pharmaceutical firm that currently holds a drug license or has applied for registration and market approval for a given medicinal product may make an application for contract manufacturing and analysis of medicinal products.

Article 6 Except where otherwise provided by law or regulation, when a medicinal product has been approved for contract manufacturing or analysis, related product liability is borne by the contract party.

Article 7 When the effective term of a contract for manufacturing or analysis expires and the contract is not renewed, or the contract is rescinded for any reason during its effective term, or the items to be manufactured or inspected are changed, the contract party shall first find another contract manufacturer or relevant agency and newly apply for contract manufacturing or analysis in accordance with regulations.

Chapter 2: Contract manufacturing of medicinal products

Article 8 A contract manufacturer shall be a medicinal product factory in compliance with the Regulations Governing Good Manufacturing Practices for Medicinal Products.

Article 9 The contract party shall firstly find a contract manufacturer, then fill in an application and attach

the contract for manufacturing signed by the two parties and related documents, and apply to the central competent health authority for approval.

Article 10 The labeling and packaging of a drug (medicinal) product that has been approved for contract manufacturing shall conform with the Act and related laws and regulations, and in addition, shall include the name and address of the contract party and the contract manufacturer. With the approval of the competent central health authority, however, the name of the country where the contract manufacturer is located may be used in lieu of the contract manufacturer's name and address.
The usage instructions for the drug (medicinal) product of the preceding paragraph shall conform to the Act and related laws and regulations, and in addition, the contract party and the contract manufacturer shall be respectively indicated, including the names and addresses of each.

Article 11 Extension of the effective term of the license for a drug (medicinal) product that has been approved for contract manufacturing shall be carried out by the holder of the license in accordance with the provisions of the Act, related laws and regulations.

Chapter 3: Contract analysis of medicinal products

Article 12 An entity that conforms with any of the following descriptions may accept a contract for analysis of drug (medicinal) products:
1. A medicinal product factory that is in compliance with the Regulations Governing Good Manufacturing Practices for Medicinal Products.
2. A domestic or foreign academic research

institute that meets the requirements of good laboratory practices for non-clinical laboratory studies.
3. An analysis institution or laboratory that meets the certification requirements under Article 104-4 of the Act.
4. Other entity approved on an ad-hoc basis by the competent central health authority.

Article 13 The contract party and the contract inspector shall enter into a contract analysis agreement, which shall include matters related to the scope of contract analysis, an operation plan, and the standard operating procedures.

Article 14 The contract party shall firstly find a party, willing to undertake the contract analysis, then fill in an application form and attach the contract analysis agreement, related documentation and apply to the central competent health authority for the approval. The central competent health authority may carry out an on-site analysis of the contract inspector as it deems necessary in accordance with the actual conditions.

Article 15 When the approval has been obtained for contract analysis, the number of subject items to be inspected that the contract party submits to the contract inspector shall be two or more times the number needed for analysis; any subject items remaining after analysis with their packaging intact shall be sealed and returned to the contract party by the contractor.

Chapter 4: Supplementary Provisions

Article 16 These Regulations shall be implemented from the

date of issuance.