Article Content

Title： Regulations Governing Contract Manufacturing of Medical Devices CH

Announced Date： 2021-04-15

Category： Ministry of Health and Welfare（衛生福利部）

Article 1 The Regulations are stipulated in accordance with Paragraph 3, Article 23 of the Medical Devices Act (hereinafter referred to as “the Act”).

Article 2 The term “contract manufacturing” as used in the Regulations refers to a domestic medical device firm to commission other medical device manufacturers to be in charge of the manufacturing processes, including manufacturing, packaging, labeling, sterilization, and final inspection and release of a medical device (herein after referred to as “all manufacturing processes”) in Subparagraph 1 of Article 10 of the Act, or the manufacturing and sterilization procedures.

Article 3 A domestic medical device firm applies for contract manufacturing shall submit an application form to the central competent authority with the following documents and information, and pay the fees:
1. The business permits of the contract party and the contract manufacturer if the contract manufacturer is a domestic medical device manufacturer.
2. The business permit of the contract party if the contract manufacturer is a foreign medical device manufacturer.
3. The medical device manufacturing license of the contract manufacturer. However, if the medical devices to be manufactured through contract manufacturing are product items that do not need to obtain a manufacturing license in accordance with the provisions of Paragraph 2 of Article 22 of the Act, then medical device manufacturing license is not required.
4. The contract manufacturing agreement made between the contract party and the contract manufacturer.
The application for contract manufacturing set forth in the preceding paragraph may be submitted via the electronic or other means designated by the central competent authority.

Article 4 The contract manufacturing agreement referred to in Subparagraph 4, Paragraph 1 of the preceding article shall state the followings:
1. Names and addresses of the contract party and the contract manufacturer.
2. The mutual agreement to engage in contract manufacturing.
3. Categorization, risk classification and items of medical device(s) to be manufactured through contract manufacturing.
4. Process(es) of the contract manufacturing.

5. Rights and responsibilities of the contract party and the contract manufacturer.

Article 5 The approval of the application for contract manufacturing of medical device in accordance with the provisions of Article 23 of the Act, registration shall be carried out by the central competent authority with the following information:
1. Name and address of the contract party.
2. Name and address of the contract manufacturer.
3. Medical device item(s) of the contract manufacturing.
4. Process(es) of the contract manufacturing.

Article 6 The applicant shall be notified of the registration information of preceding article. When that there are any change made in the information registered, within 30 days from the date of occurrence of the change, the firm shall apply for change of registration by submitting the application form to the central competent authority with the document(s) and information set forth in Article 3, and shall pay the fees.
The application for change of registration set forth in the preceding paragraph may be submitted via the electronic or other means designated by the central competent authority.

Article 7 In the event that products manufactured through contract manufacturing approved in accordance with the Regulations violate the Act, the contract party shall be held responsible. However, this shall not apply if it is otherwise provided in other laws.

Article 8 For medical devices manufactured all manufacturing processes through contract manufacturing approved in accordance with the Regulations, the names and addresses of the contract party and the contract manufacturer shall be indicated on the labels, package inserts or packaging of the product. However, if such information has been indicated in the registration and market approval or the listing system, the information of the contract manufacturer can be replaced with the firm's country, region or administrative area.

Article 9 The central competent authority, under any of the following circumstances, shall revoke or cancel the approval and registration of contract manufacturing of the medical device:
1. The business permit of the contract party or the contract manufacturer has been revoked or canceled.
2. The manufacturing license of the contract manufacturer has been revoked or canceled.
3. The contract party or the contract manufacturer states that the contract manufacturing relationship has been discontinued.

Article 10 The Regulations shall be implemented on May 1st, 2021.