Position Paper for better understanding on product registration framework for Medical Device between Japan and Taiwan

15 Oct. 2021

Under the Arrangement between the Interchange Association and the Association of East Asian Relations for the Establishment of the Framework of the Cooperation on the Medical Product Regulation (hereinafter, "Framework") signed 5 November 2013, the Ministry of Health, Labour and Welfare (MHLW) / Pharmaceuticals and Medical Devices Agency (PMDA) and the Taiwan Food and Drug Administration (TFDA) of the Ministry of Health and Welfare have continuously collaborated information sharing on medical device product registration. This activity is to lead better understanding of regulations and product registration process in Taiwan and Japan. MHLW/PMDA and TFDA confirmed mutual position regarding these achievements as follows:

1. The purpose of this position paper is to enhance better understanding of recent regulations in Japan and Taiwan, and to reduce the gap during product registration for industry through Question and Answer (Q&A) for product registration process documents. The Q&A document is confirmed by both sides respectively.

2. This work is conducted by Product Registration Working Group between MHLW/PMDA and TFDA. Further collaboration on this issue may be discussed under the Framework.

3. Any publication which is generated under this activity needs the confirmation by both MHLW/PMDA and TFDA.

4. This document is not intended to create any legally binding obligations.

5. Any difference arising from the interpretation or implementation of this position paper will be resolved through the consultations under the Framework.

6. This position paper may be amended in the future, when it would be confirmed jointly.

This position paper was jointly prepared by

MHLW/PMDA and TFDA,

and will be opened to stakeholders in Japan and Taiwan.