独立行政法人
医薬品医療機器総合機構
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PMDA joins International program to rationalize GMP Inspections of API manufacturers

PMDA has been working to ensure the quality of drugs distributed in Japan through GMP inspections to confirm appropriate manufacturing management and quality control at manufacturing sites, including Active Pharmaceutical Ingredients (API) manufacturing sites, both in Japan and outside Japan.

In the situation that lots of APIs are manufactured in various countries, the "Program to rationalize international GMP inspections of active pharmaceutical ingredients/active substances manufacturers" has been implemented as an international cooperation among regulators in order to improve efficiency and effectiveness of GMP inspections.

PMDA has decided to join this program from 24 November 2016. The participation in the program allows PMDA, under confidential arrangements, to share information related to GMP inspections such as inspection plans and inspection results. By utilizing such information, PMDA will be able to effectively and reasonably conduct GMP inspection with higher quality. PMDA will also provide the similar information to the regulators participated in the program. Through the collaborative activities, PMDA will contribute to assurance of quality of drugs supplied all over the world.

The initiative aligns with the PMDA International Strategy 2015.

【Program to rationalize international GMP inspections of active pharmaceutical ingredients/active substances manufacturers】

Participants share information related to GMP inspections for API manufacturing sites outside of participated regions, which enables them to allocate inspection resource more appropriately. After the pilot phase, the program has been implemented since 2012. The current participants include EU, USA,

Australia, Canada and WHO. The details of the program are available in the following URL (Written in English) :
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/02/WC500123489.pdf