# MEMORANDUM OF COOPERATION (MOC)
# IN THE FIELD OF PHARMACOPOEIAS
# BETWEEN
# THE UNITED STATES PHARMACOPEIAL CONVENTION (USP)
# AND
# THE MINISTRY OF HEALTH, LABOUR AND WELFARE (MHLW)
# OF JAPAN

The United States Pharmacopeial Convention (USP) and the Ministry of Health, Labour and Welfare (MHLW) of Japan, hereinafter referred to as “Participants”, and individually as “Participant”, shared their views to expedite cooperation of the Pharmacopoeias under the following framework.

## 1. Principle

The purpose of this Memorandum of Cooperation (hereinafter referred to as “this MOC”) is to strengthen relations and to promote cooperation on standard setting of pharmacopoeia.

This MOC is not intended to create any legally binding obligations under national or international laws.

## 2. Institutions and Contact Points

The Participants are the institutions responsible for the management of this MOC. The Participants hereby designate the following contact points in order to communicate with each other and exchange information on the framework:

a. For the United States Pharmacopeial Convention Side:
   Global External Affairs,

United States Pharmacopeial Convention - USP

b. For the Japanese Side:
Pharmaceutical Evaluation Division,
Pharmaceutical Safety and Environmental Health Bureau,
Ministry of Health, Labour and Welfare - MHLW
and
Division of Pharmacopoeia and Standards for Drugs,
Office of Standards and Guidelines Development,
Pharmaceuticals and Medical Devices Agency - PMDA

**3. Means of Cooperation**

The Participants will organize a face-to-face bilateral meeting once a year in principle, and collaborate on workshops and personnel exchanges to share experiences and information on development of monographs and methods of testing under the terms of this MOC.

Within the framework of this MOC, the collaboration covers all products under the scope of both Participants and their relevant activities, including, but not limited to:

A. Active Pharmaceutical Ingredient (API)
B. Excipients
C. Finished Products
D. Monographs, general chapters, methods, tests, and assays
E. Chemical Medicines
F. Herbal products
G. Biological medicines
H. Reference Standards
I. Laboratory tests

The Participants may, by mutual consent, add to, or delete items from the list specified herein.

**4. Technical Working Group**

The Participants will organize, when necessary, an ad hoc Technical Working Group with staff members of the institutes and relevant experts, as part of the cooperation under this MOC.

**5. Minutes**

The minutes of annual bilateral meetings and ad hoc Technical Working Group meetings will be drawn up in English after each meeting.

**6. Financial Arrangements**

Each of the Participants will bear its own costs in relation to the implementation of the cooperation under this MOC.

**7. Confidentiality**

The participants share the view to develop a document for the exchange of confidential information within one year after the signing of this MOC.

**8. Miscellaneous**

The cooperation under this MOC will commence on the date of its signature, and will continue for a period of five (5) years. It will be automatically renewed for successive periods of five (5) years, unless one of the Participants issues a written notice to the other Participant of its intention to terminate the cooperation under this MOC ninety (90) days before the current expiration date.
This MOC may be modified with the mutual written consent of the Participants.

Signed in Tokyo, on the 15th of September, 2016, in duplicate in the Japanese and English languages, each text having equal value. In case of any divergence of interpretation, the English text will prevail.

**For the United States Pharmacopeial Convention**

Jaap Venema
Chief Science Officer
The United States Pharmacopeial Convention

**For the Ministry of Health, Labour and Welfare of Japan**

Toshihiko Takeda
Director General
Pharmaceutical Safety and Environmental Health Bureau
Ministry of Health, Labour and Welfare