

**MEMORANDUM OF COOPERATION
BETWEEN
THE HEALTH SCIENCES AUTHORITY OF REPUBLIC OF SINGAPORE
AND
THE MINISTRY OF HEALTH, LABOUR AND WELFARE OF JAPAN
TO
STRENGTHEN REGULATORY COOPERATION**

The Health Sciences Authority of Republic of Singapore (HSA), and The Ministry of Health, Labour and Welfare of Japan (MHLW) (hereinafter referred to collectively as “the Participants” and individually as a “Participant”),

INTENDING to promote and strengthen mutually beneficial cooperation in accordance with the applicable laws and regulations of the respective countries,

ENHANCING mutual understanding through existing collaboration scheme,

HAVE REACHED the following recognition:

1. Purpose

1. The purpose of this Memorandum of Cooperation (hereinafter referred to as “this MOC”) is to establish and facilitate a constructive regulatory cooperation between HSA and MHLW.
2. This MOC is not intended to create any legally binding obligations between the Participants under national or international law.

2. Areas of Cooperation

1. The Participants will promote mutually beneficial cooperation on reliance and exchange of information, as well as on the relevant administrative and regulatory matters within the jurisdictions of the Participants.
2. The Participants will especially encourage to conduct regulatory cooperation in the fields of:
 - a. Exploring regulatory collaboration, in areas of interest to the Participants across the region and throughout product lifecycle, including regulatory reliance and regulatory innovation;
 - b. Good Manufacturing Practice (hereinafter “GMP”) Inspection Reliance;

- c. Cutting-edge Information exchange based on both interests; and
 - d. Collaboration in international and regional programs and scientific initiatives.
3. Any other areas of regulatory cooperation will be mutually decided upon subsequently by the Participants in writing.

3. Means of Cooperation

1. The Participants may hold meetings, as necessary, to discuss major topics related to the areas of regulatory cooperation and evaluate progress, where relevant. GMP Inspection Reliance will be one of the major topics discussed among the Participants' GMP experts.
2. The meetings may be considered on an in- person basis, including at the margin of international meetings, or through other mechanisms including virtual way as mutually decided upon by the Participants.
3. English will be used as a common language for the meetings.

4. Working Group

1. A Working group (hereinafter referred to as "the WG") will be established at the meeting based on the Participants' mutual interests.
2. The WG may consider the holding of related meetings and training workshops in association with the meeting, based on the Participants' mutual decisions.
3. The Participants may jointly decide to invite representatives from the relevant industries and academia to participate in the WG, depending on the agenda of the meeting.

5. Minutes

The minutes of the meetings will be drawn up in English by the Participants after each meeting, where applicable.

6. Contact Points

The Participants will designate the following respective contact points for the implementation of this MOC:

- a. For HSA: Director or Deputy Director, HSA International Cooperation at hsa_intl_office@hsa.gov.sg
- b. For MHLW: Director, Office of International Regulatory Affairs, Pharmaceutical Safety Bureau

7. Financial Matters

1. Each Participant will bear its own costs in relation to the implementation of the cooperative activities under this MOC.
2. When deemed necessary and by mutual consent, the Participants may invite funds from any third party to support the activities under this MOC.

8. Resolution of Differences

Any differences arising from the interpretation and/or implementation of this MOC will be resolved amicably through consultations between the Participants.

9 . Confidentiality of Information

1. The Participants will use the information and documents exchanged between them only within the scope of the decided purposes; and each Participant will not disclose any exchanged information under this MOC to a third party without the written consent of the Participant which is the source of it.
2. The Participants confirm that this clause will continue to be applied between Participants notwithstanding the discontinuation of this MOC.

10. Commencement, Modification and Discontinuation

1. The cooperation under this MOC will commence on the date of its signature and will continue for a period of five (5) years.
2. This MOC will be automatically renewed for another successive period of five (5) years, unless a written notice is given by either Participant of its intention

to discontinue this MOC to the other Participant at least ninety (90) days before the intended date of discontinuation.

3. This MOC may be modified with the mutual written consent of the Participants and will be an integral part of this MOC.
4. The discontinuation of this MOC will not affect the duration or implementation of on-going cooperation, project or other activities which have been confirmed upon before the date of the discontinuation of this MOC, unless the Participants decide otherwise.

SIGNED in duplicate in Tokyo on April 20, 2026, in Japanese, and English languages, all texts having equal value. In case of any divergence of interpretation of the texts, the English text will prevail.

For
Health Sciences Authority
The Republic of Singapore

For
The Ministry of Health, Labour and Welfare
of Japan

Adj Prof (Dr) Raymond Chua
Chief Executive Officer
Health Sciences Authority

Naoki Miyamoto
Director General
Pharmaceutical Safety Bureau
Ministry of Health, Labour and Welfare