International Activities

Cooperating with APEC Activities: Regulatory Harmonization Steering Committee

About RHSC

RHSC (Regulatory Harmonization Steering Committee) is a committee established to promote regulatory convergence of pharmaceuticals and medical devices in the APEC (Asia-Pacific Economic Cooperation) region. Currently, the activities are chaired by the Food and Drug Administration of the United States, and PMDA is serving as a vice-chair.

RHSC sets the priority work areas (PWAs) for regulatory convergence, and for each PWA, human resource development and regulatory cooperation among regulatory authorities are promoted by utilizing existing international guidelines and standards. Regulatory authorities and academic institutions with excellent knowledge and experience in the region are designated as Centers of Excellence (CoEs), and CoEs provide training seminars for

regulatory authorities and others. Ministry of Health, Labour and Welfare (MHLW)/PMDA is serving as a champion economy for several PWAs.

APEC-RHSC Public Website

RHSC's PWAs and their champion economies (As of May 2025)

- MRCT/GCP inspection: Japan, Thailand
- Pharmacovigilance: Republic of Korea
- Advanced Therapy-Biotherapeutic Products: the United States, Singapore
  Sub-champion: Biotechnological Innovation Organization (BIO)
- Good Registration Management: Chinese Taipei, Japan
- Global Supply Chain Integrity: the United States
- Medical Device: Japan, the United States, Republic of Korea
  Sub-champions: Japan Medical Imaging and Radiological Systems Industries Association (JIRA),
  Advanced Medical Technology Association (AdvaMed)
- Pharmaceutical Quality: the United States
  Sub-champion: Pharmaceutical Research and Manufacturers of America (PhRMA)
- Electronic Data Standards: the United States

Center of Excellences (CoEs) in Japan

PMDA was endorsed to become formal CoEs for 3 PWAs (Note), providing training seminars for regulators through Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC)

(Note) “MRCT/GCP inspection” PWA and “Pharmacovigilance” PWA in 2017, and “Medical Device” PWA in 2020

Furthermore, Kobe University provides workshop for "Biotherapeutics" PWA with support from MHLW. In 2020, it became the first academic institution in Japan to be designated as CoE.

Press releases regarding PMDA recognized as formal CoEs.

- "MRCT/GCP inspection PWA" and "Pharmacovigilance PWA" (Endorsement for becoming formal CoEs) (Vietnam in Feb. 2017) (Only Japanese)
- "Medical Device PWA" (Endorsement for becoming formal CoE) (web meeting June, 2020) (Only Japanese)