Invitation to the 2024 APEC GRM CoE Workshop (Good Registration Management Center of Excellence Workshop), 3rd- 5th September, Chinese Taipei

Dear Colleagues,

On behalf of TFDA, PMDA, and APAC, we cordially invite representatives from APEC member economies to participate in the "2024 APEC Good Registration Management (GRM) Center of Excellence Workshop" which will be scheduled for September 3rd to September 5th. The latest workshop draft program is attached for your reference.

This workshop is a part of an activity of the APEC Roadmap to Promote Good Registration Management, co-championed by Chinese Taipei and Japan, under the Regulatory Harmonization Steering Committee (RHSC). The objectives of this roadmap are to promote the concept of GRM and enhance mutual trust for regulatory convergence among the APEC member economies. To establish a sustainable platform for promoting regulatory convergence, capacity and cooperation in areas of medical products, RHSC has been promoting the model of Center of Excellence for each priority work area since 2015. TFDA was formally regarded as an APEC LSIF Training Center of Excellence for Regulatory Science (CoE) in July 2017 in the field of GRM. Since then, TFDA holds the GRM training events annually.

In order to assist in promoting regulatory science of GRM in APEC, the workshop devoted to optimize the GRM application to entire product life cycle. The workshop will bring together APEC economies and key stakeholders to discuss the best practices and regulatory science. It's meaningful to the progress of health care and regulatory harmonization. The grand meeting will be a great opportunity for experience sharing. Full of knowledge, practice, and fun, it will be our great honor to have your join.

We are pleased to invite participants who are: 1) regulatory professionals from regulatory authority or industry, 2) with hands-on experience in the management of regulatory reviews or regulatory submissions, 3) academia who are interested in understanding guidelines such as Good Review Practice or Good Submission Practice, and 4) professional bodies who are actively involved in training.

There is no registration fee for this workshop. We would like to request nomination of representatives from regulatory authorities and/or from industries. The representatives from Health authority or APAC associations respectively are encouraged to complete the on-line registration form on the webpage (https://www.apecgrmcoe.tw/2024CoE/) of this workshop before **6/28**. For more details, please refer to the latest version of agenda. Should you have any inquiries, please feel free to contact the Workshop Secretariat at GRMCOE@gmail.com. We will be glad to provide you with more detailed information.

We look forward to your participation in the 2024 APEC Good Registration Management Center of Excellence Workshop.

Sincerely,

Shou-Mei Wu, PhD
Director-General
Food and Drug Administration
Ministry of Health and Welfare
Chinese Taipei

SUZUKI Hiroshi
Executive Director
Pharmaceuticals and Medical Devices Agency
Japan