

International Symposium for Asia Regulatory Coordination
~ Memoriam for Establishment of PMDA Asia Office ~

Date: 29th August 2024

Time: 9:00 – 16: 30 (Thailand time, GMT+7)

Venue: The Okura Prestige Bangkok, 3rd floor, Grand ball room

(57, Park Ventures Ecoplex 57 Witthayu Rd, Lumpini, Pathum Wan, Bangkok, Thailand)

[Morning session] MC: Ms. TAKEMURA Yuriko, PMDA

Time	Contents
9:00 – 9:15 (15 min)	Opening Remarks H.E.Prof. TAKEMI Keizo, Minister, Ministry of Health, Labour and Welfare, Japan
9:15 - 9:25 (10 min)	Purpose of establishing PMDA Asia Office Dr. FUJIWARA Yasuhiro, MD, Ph.D, Chief Executive, Pharmaceuticals and Medical Devices Agency, Japan
9:25 - 9:35 (10 min)	Direction of PMDA Asia Office Dr. KITAHARA Jun, Head, Pharmaceuticals and Medical Devices Agency Asia Office, Japan
9:35 - 9:40 (5 min)	Welcome Remarks Dr. Narong Aphikulvanich, Secretary General, Thai Food and Drug Administration, Thailand
9:40 - 9:45 (5 min)	FDA's expectation to PMDA Asia Office (Pre-recorded) Dr. Theresa Mullin, Associate Center Director (Strategic Initiatives) Center for Drug Evaluation and Research, Food and Drug Administration, US
9:45 - 9:50 (5 min)	EMA message for the Opening of PMDA Asia Office (Pre-recorded) Mr. Martin Harvey Allchurch, Head of International Affairs, European Medicines Agency
9:50 - 10:00 (10 min)	Collaboration with PMDA Asia Office - from the cancer clinical trial – Dr. SETO Yasuyuki, MD, Ph.D, Director, National Cancer Center Hospital, Japan
10:00 - 10:10 (10 min)	Collaboration with PMDA Asia Office - from the infectious disease clinical trial – Dr. MIYAZAKI Hideyo, MD, Ph.D, Director, National Center for Global health and Medicine, Japan
10:10-10:15 (5 min)	The Role and Contribution of JPMA in Asia Dr. UENO Hiroaki, Representative Director, Japan Pharmaceutical Manufacturers Association

10:15 - 10:30 (15 min)	Photo Session/ Break
Session 1: Changes in the Regulatory Environment Surrounding the Asian Region and Responses -Collaboration with PMDA-	
10:30 - 12:00 (90 min)	<p><u>Moderator</u></p> <ul style="list-style-type: none"> ✧ Dr. KITAHARA Jun, Head, Pharmaceuticals and Medical Devices Agency Asia Office, Japan ✧ Dr. Azizah Ab Ghan, Head of Biologics Section, Centre of Product and Cosmetics Evaluation NPRA, Malaysia <p><u>Speakers</u></p> <ul style="list-style-type: none"> ✧ Mr. YASUDA Naoyuki, Associate Executive Director (International Programs), Pharmaceuticals and Medical Devices Agency, Japan (15 min) ✧ A/Prof. Cheng Leng Chan, Group Director, Health Products Regulation Group, Health Sciences Authority, Singapore (15 min) ✧ Ms. Worasuda YOONGTHONG, Director of Medicines Regulation Division, Thai Food and Drug Administration (15 min) <p><u>Panel Discussion</u> (45 min) (Speaker+ below)</p> <ul style="list-style-type: none"> ✧ Ms. Siti Naasirah Hj Aji, Head of Drug Registration Unit, Ministry of Health, Brunei Darussalam ✧ Dr. Azizah Ab Ghan, Head of Biologics Section, Centre of Product and Cosmetics Evaluation NPRA, Malaysia ✧ Dr. Bounxou KEOHAVONG, Director General, Food and Drug Department, Ministry of Health, Lao P.D.R.
12:00 - 13:00 (60 min)	Lunch Break

[Afternoon session] MC: PMDA secretariat

Session 2: Challenges for Capacity Building of Asian Regulatory Authorities - Utilization of PMDA-ATC for the Asian Region -	
13:00 - 14:30 (90 min)	<p><u>Moderator</u></p> <ul style="list-style-type: none"> ✧ Ms. ENDO Ayumi, Office Director, Office of Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs, PMDA ✧ Ms. Jesusa Joyce N. Cirunay, OIC, Deputy Director General, Field Regulatory Operations Office, Food And Drug Administration Philippines <p><u>Speakers</u></p> <ul style="list-style-type: none"> ✧ Ms. Jesusa Joyce N. Cirunay, OIC, Deputy Director General, Field Regulatory Operations Office, Food And Drug Administration Philippines (15 min) ✧ Dr. Rita Endang, Apt, M.Kes, Deputy Chairperson, Indonesian FDA (15 min)

	<ul style="list-style-type: none"> ✧ Dr. KITAHARA Jun, Head, PMDA Asia Office, PMDA (15 min) <p>Panel Discussion (45 min) (Speaker+ below)</p> <ul style="list-style-type: none"> ✧ Ms. Nguyen Linh Chi, Officer, Drug Registration Division, Drug Administration of Vietnam ✧ Mrs.Chhay Roatheany, Deputy director of drug and food, Drug and Food Ministry of Health, Cambodia ✧ Mrs. Syamsidar Thamrin, Head of Center for Human Resources Development of Food and Drugs Control, Indonesian FDA
14:30 – 14:45 (15min)	Break
Session 3: Asia Clinical Trials and Collaboration with Asian Regulatory Authorities - Collaboration to Improve Clinical Trial Capacity in Asia -	
14:45 - 16:25 (100 min)	<p>Moderator</p> <ul style="list-style-type: none"> ✧ Dr. NAKAMURA Kenichi, MD Ph D, Director, Department of International Clinical Development, National Cancer Center, JAPAN ✧ Dr. Virote Sriuranpong, MD Ph D, Director, Chulalongkorn University, Thailand <p>Speakers</p> <ul style="list-style-type: none"> ✧ Dr. TERADA Mitsumi, MD Ph D, General Manager, Asian Partnerships Office, Department of International Clinical Development, National Cancer Center (15 min) ✧ Dr. Suvimol Niyomnaitham, Vice Director, Siriraj Hospital, Thailand (15 min) ✧ Dr. Akhmal Yusof, Chief Executive Officer, Clinical Research Malaysia, Malaysia (15 min) ✧ Dr. TOKITA Daisuke, MD Ph D, Director, Asian Partnerships Office, Department of International Clinical Development, National Center for Global health and Medicine, Japan (10min) <p>Panel Discussion (45 min) (Speaker+ below)</p> <ul style="list-style-type: none"> ✧ Mr. TOMOTSUGU Naoki, Head of Executive Management, Department Of International Trials, Executive Manager Of Thailand Collaborating Office, National Center for Global health and Medicine, Japan ✧ Mr. NAKAJI Shigeru, Chairman, Drug Evaluation Committee, Japan Pharmaceutical Manufacturers Association, Japan ✧ Dr. KITAHARA Jun, Head, PMDA Asia Office, PMDA, Japan ✧ Ms. Akanid WAPEEWUTTIKORN, Pharmacist (Senior Professional Level), Medicines Regulation Division, Thai Food and Drug Administration, Thailand
16:25 - 16:30 (5min)	<p>Closing Remarks</p> <p>Dr. SATO Daisaku, Councilor for Pharmaceutical Affairs, Ministry of Health, Labour and Welfare Japan</p>

Reception Party

Date: 29th August 2024

Time: 16:45 – 19:00 PM (Thailand time, GMT+7)

Venue: The Okura Prestige Bangkok, 3rd floor, Sora Room

(57, Park Ventures Ecoplex 57 Witthayu Rd, Lumpini, Pathum Wan, Bangkok, Thailand)

MC: Ms. ENDO Ayumi, PMDA

16:30 -	Registration
16:45 -16:50	Welcome Remarks H.E.Prof TAKEMI Keizo, Minister, Ministry of Health, Labour and Welfare, Japan
16:50-16:55	Welcome Remarks Dr. Suwit Wibulpolprasert, Advisor for Minister of Public Health, Thailand
16:55 - 17:00	Toast Dr FUJIWARA Yasuhiro, MD Ph D, Chief Executive, Pharmaceuticals and Medical Devices Agency, Japan
17:00 - 18:55	Free to engage in conversation
18:55 - 19:00	Closing Remarks Dr KITAHARA Jun, Head, Pharmaceuticals and Medical Devices Agency Asia Office, Japan