CMC Strategy Forum Japan 2017
Welcome and Introductory Comments

Takao Yamori
Executive Director / Director of Center for Product Evaluation
Pharmaceuticals and Medical Devices Agency (PMDA)
PMDA’s International Strategic Plan 2015

International Pharmaceutical Regulatory Harmonization Strategy

MHLW

Pharmaceuticals and Medical Devices Agency
Current International Activities

ICH: International Conference on Harmonisation
PDG: Pharmacopeial Discussion Group
IMDRF: International Medical Device Regulators Forum
IGDRP: International Generic Drug Regulators Pilot
ICCR: International Cooperation on Cosmetics Regulation
APEC LSIF RHSC: APEC Life Science Innovation Forum Regulatory Harmonization Steering Committee
OECD MAD: OECD Mutual Acceptance of Data
HBD: Harmonization By Doing

ICDRA: International Conference of Drug Regulatory Authorities
ICMRA: International Coalition of Medicines Regulatory Authorities
Bilateral Cooperation b/t MHLW/PMDA and other Authorities

As of 28 Jun. 2017


Confidentiality Arrangement signed
Joint symposium held

PMDA staff stationed at the agency

Cooperative Arrangement signed
Cooperative Arrangement on cooperation of pharmacopoeia signed

1: Cooperative Arrangement has been signed between the Interchange Association of Japan and East Asia Relations of Taiwan
December 4
(09:00-12:00, 13:45-15:00)
1. Recent Trends in the Regulation of Biopharmaceutical Products

(15:30 – 17:45)
2. ICH Q12 Update

December 5
(09:00 – 12:00)
3. Challenges in Global Development of Drug Device Combination Products

(13:15 – 17:00)
4. Use of Prior Knowledge to Support CMC Development in Conventional and Expedited Settings
Enjoy!

http://www.pmda.go.jp/

PMDA