PMDA Town Hall

International Strategy and International Contribution of PMDA

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Today regulators face • • •

Capacity Building  Work-sharing
PMDA International Strategic Plan 2015
VISION 1: To contribute to the world through regulatory innovation

VISION 2: To maximize the common health benefits to other countries/regions

VISION 3: To share the wisdom with other countries/regions
Today’s Topic: Capacity Building and Asia

- “Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC)”
- APEC LSIF Regulatory Harmonization Steering Committee (RHSC)
- Symposium and bilateral meeting in Asia

APEC: Asia Pacific Economic Cooperation  LSIF: Life Science Innovation Forum
RHSC: Regulatory Harmonization Steering Committee
WHAT WE DO at PMDA Asia Training Center (ATC)

- Organize Training programs held at PMDA and overseas
- Exchange staff members for on-the-job training
- Training themes:
  - Best Regulatory Practices in Product Review, Safety Info Analysis, etc.
  - ICH, IMDRF, IGDRP, ICCR, PIC/S Guidelines
  - Specific topics per request by partner country
Asia Training Center

Center Director
Mr Haruo Akagawa

Vice Director
Dr Toshi Tominaga

Office of International Cooperation
Director
Dr Junko Sato

Coordinates all the activities

Project Team
Project Team
Project Team
Project Team
Project Teams for Training Seminars

Pharmaceuticals Review Seminar (July 25 - 29)
Medical Devices Seminar (Sept - Feb)
Pharmaceuticals Review Seminar (Oct - Dec)
GMP Inspection Seminar* (Dec) * co-hosted with PIC/S
APEC MRCT/GCP (Jan - Mar, 2017)
APEC Pharmacovigilance (Jan - Mar, 2017)
APEC LSIF
Regulatory Harmonization Steering Committee (RHSC)

RHSC’s GOAL:
“Regulatory Convergence” in APEC Economies by 2020

RHSC Member Economies:
Canada, China, Chinese Taipei, Indonesia, Japan, Korea, Malaysia, Mexico, Peru, Philippines, Russia, Singapore, Thailand, U.S.

APEC: Asia Pacific Economic Cooperation
LSIF: Life Science Innovation Forum
RHSC: Regulatory Harmonization Steering Committee
“Regulatory Convergence” in APEC Economies by 2020

Pharmacovigilance

Biotherapeutics

Cell and Tissue Based Therapeutic Products

MRCT / GCP Inspection

Good Registration Management

Global Supply Chain Integrity
MHLW/PMDA’s activities at APEC LSIF RHSC

- Co-chairing APEC-LSIF-RHSC
- Champion to lead
  - MRCT/GCP inspection
  - Good Review Management
- Training Center of Excellence (CoE) for
  - MRCT/GCP inspection
  - Pharmacovigilance

CoE: APEC Training Centers of Excellence for Regulatory Science
Symposiums and Bilateral Meetings
PMDA’s Capacity Building Activities in Asia

PMDA-ATC activities
- Bilateral Meeting
- APEC CoE
- Symposium, Trainings
Thank You

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