Overview

October 4, 2016

São Paulo, Brazil

Takao Yamori, Ph. D
Executive Director

1. Regulatory cooperation: ANVISA and MHLW/PMDA

- **Signing of Confidential Arrangement**
  （Manaus, November 2012)

- Decision of holding Joint Seminar
  (Brasilia, February 2014)

- 1st Brazil-Japan Seminar
  （São Paulo, August 2014)

- **2nd Brazil-Japan Seminar**
  （Tokyo, September 2015)
  Memorandum of Cooperation (MOC) was signed.

- Informal bilateral meeting
  （Brasilia, November 2015)

2. Role of PMDA (Pharmaceuticals and Medical Devices Agency)

Headquarter

Established in 2004

Kansai Branch

Launched on Oct. 1, 2013

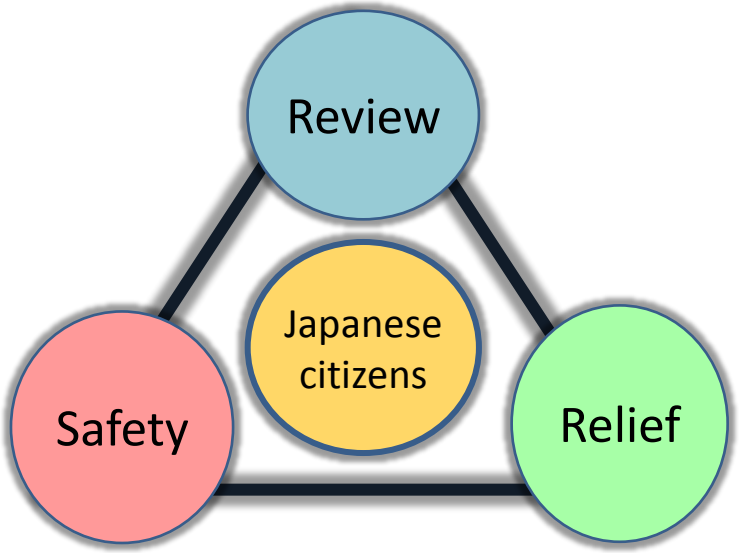
Hokuriku Branch

Launched on June 9, 2016

Major Services

- Scientific Review for Drugs & Medical Devices
- GCP, GMP Inspection
- Scientific Advice on Clinical Trials
- Safety Measures
- Relief Services

Unique Three-pillar System Securing Nation's Safety



3. Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs

- Managed by Office of International Cooperation (established in April 2016)
- 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

Training Seminars held in FY2016

- Pharmaceuticals Review Seminar (July 25-29, 2016)
- Pharmaceuticals Review Seminar in Bangkok, Thailand (Sep. 26-29)
- Medical Devices Seminar (Nov. 7-11)
- GMP Inspection Seminar* (Dec. 5-9) * co-hosted with PIC/S
- APEC MRCT/GCP (Jan - Mar, 2017)
- APEC Pharmacovigilance (Jan - Mar, 2017)

Thank you very much for your attention.