# The 2nd Thailand-Japan Symposium

**- New Drug Review, GMP Inspection, Pharmacovigilance -**

September 1st, 2014
(Updated on December 10th, 2014)

Pharmaceuticals and Medical Devices Agency

**Purpose:**

Globalization of research and development, manufacturing and marketing of pharmaceutical drugs has progressed, and cooperation in regulatory activities amongst pharmaceutical regulatory agencies has become a necessity. Nowadays, Asian countries have become significant in the area of clinical development and manufacturing of pharmaceuticals, and therefore, PMDA strives to strengthen the collaborative relationship with the Asian regulatory agencies.

This symposium is cohosted by ThaiFDA, the regulatory agency of Thailand, and PMDA, the regulatory agency of Japan, as in the 1st Symposium held in 2013. The aim of this symposium is to continue to strengthen Thailand and Japan's mutual relationship and cooperative framework for pharmaceutical regulation and promote thorough understanding of regulatory systems of the two host countries amongst the pharmaceutical industries.

**Host**：

Thai Food and Drug Administration (ThaiFDA), Pharmaceuticals and Medical Devices Agency (PMDA)

## 1. Date [ The Symposium was already held ]

October 15th (Wed) - 16th (Thu), 2014

## 2. Venue

**The Four Wings Hotel Bangkok**
**Address**： 40 Sukhumvit Road 26, Klongtoey, Bangkok 10110 Thailand
**Tel:** +66-2-260-2100
**URL:** http://www.fourwingshotel.com/

## 3. Agenda

**Day 1 (October 15th)**

**Opening Remarks** (10:30-11:00)

(1) Dr. Kazuhiro Shigetoh (Executive Director, PMDA)
(2) Mr. Akihiko Uchikawa (Minister of Economics, Embassy of Japan in Thailand)
(3) Dr. Boonchai Somboonsook (Secretary-General, ThaiFDA)

**Session 1: New Drug Review and Pharmaceutical Affairs Act** (11:00-16:00 )

(1) **New Drug Review System of ThaiFDA**
Dr. Tharnkamol Chanprapaph (Bureau of Drug Control, ThaiFDA)

(2) Recent Update of Medical Product Regulation in Japan
Mr. Kaoru Misawa (International Coordination Officer for Pharmaceuticals, PMDA)

(3) New Drug Application (NDA) Review of Anticancer Drugs in Japan
Dr. Takahiro Nonaka (Review Director, Office of New Drug V, PMDA)

**Day 2 (October 16th)**

**Session 2: GMP Inspection** (9:30-12:00)

(1) **ThaiFDA and PIC/S Membership**
Ms. Thitiporn Tanratanawongs (Director of Bureau of Drug Control, ThaiFDA)

(2) Participation in PICS
Mr. Ichiro Tsunoi (Director, Office of Manufacturing/Quality Compliance, PMDA)

**Session 3: Pharmacovigilance** (13:30-16:30)

(1) **Data Management and Utilization of Pharmacovigilance**
1. Mrs. Wimon Suwankesawong
(Head of Health Product Vigilance Center, ThaiFDA)
2. Ms. Sareeya Wechwithan
(Health Product Vigilance Center, ThaiFDA)

(2) Present and Future of Drug Safety Measures in Japan
Ms. Kaori Yamada (Division of Epidemiology, Office of Safety I, PMDA)

**Closing Remarks** (16:30-17:00)

(1) Dr. Pathom Sawanpanyalert (Deputy Secretary-General, ThaiFDA)
(2) Dr. Mayumi Shikano (Associate Center Director for Advanced Review with Electronic Data Promotion and Science Board, PMDA)