First Thailand-Japan Symposium

- Risk management plan, Pharmacovigilance, GMP Inspection, Pharmacopoeia -

Japanese Web Site

August 28, 2013

Pharmaceuticals and Medical Devices Agency

Purpose:

Globalization of development, manufacturing, trade, and marketing of pharmaceutical drugs has been progressing, and cooperation of regulatory activities amongst pharmaceutical regulatory agencies of each region has become a necessity. Nowadays, Asian countries have become significant in clinical development and manufacturing of drugs, and therefore, PMDA strives to strengthen the collaborative relationship with the Asian regulatory agencies.

This symposium was hosted by Thai FDA, the regulatory agency of Thailand, where regulations are becoming enriched, and advancement of pharmaceutical industry from various countries including Japan has been active. It was co-hosted by PMDA, the Japanese regulatory agency. The aim of this symposium was to enhance Thailand and Japan's mutual understandings, and to construct a basis in our cooperative system for pharmaceutical regulation and development.

Host：

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

1. Date (The symposium was already held)

October 24th (Thu)-25th (Fri), 2013

2. Venue

The Ambassador Hotel Bangkok

Address： 171 Soi Sukhumvit 11 (Chaiyot)
Khlong Toei Nua, Watthana, Bangkok 10110, Thailand

Tel: +66-2-254-0444

URL: http://www.amtel.co.th/

Japanese - Thai

3. Program

(Please click to read the presentation files)

Day 1 (October 24th)

Opening Remarks

MC: Dr. Nantana KAISAENG
(Office of International Affairs, Thai FDA)

(1) Dr. Boonchai Somboonsook
(Secretary-General, Thai FDA)

(2) Dr. Tatsuya Kondo
(Chief Executive, PMDA)

Keynote Lecture

Chair: Dr. Nantana KAISAENG
(Office of International Affairs, Thai FDA)

(1) Thai FDA Proactive Role and Proposing Cooperation with PMDA
Dr. Yuppadee Javroongrit
(Acting Senior Expert on Pharmaceuticals Standard, Thai FDA)

(2) PMDA update and future cooperation with Thailand
Mr. Masanobu Yamada
(Associate Center Director, PMDA)

Session 1

Chair: Mr. Somchai Preechathaweekit
(Director, Technical and Planning Division, Thai FDA)

Risk Management Plan and Pharmacovigilance: How to ensure the safety of medical products from the clinical trial until post marketing

(1) Ms. Wimon Suwankesawong
(Head of Health Product Vigilance Center, Thai FDA)

(2) Dr. Tharnkamol Chanprapap
(Head of New Drug Subdivision, Thai FDA)

(3) Dr. Shoji Takamatsu
(Office Director of the Office of Safety II, PMDA)

Discussion

Day 2 (October 25th)

Session 2

Chair: Dr. Nobumasa Nakashima
(Office of International Programs, PMDA)

Pharmacopeia
Dr. Mayumi Shikano
(Office Director of the Office of Standards and Guidelines Development, PMDA)

Recognized Pharmacopeia in registration system
Mr. Vinit USAVAKIDVIREE
(Director, Bureau of Drug Control, ThaiFDA)

Discussion

Session 3

Chair: Dr. Yuppadee Javroongrit
(Acting Senior Expert on Pharmaceuticals Standard, Thai FDA)

GMP inspection

(1) Mr. Paiboon Amatamahuthanab
(Post-marketing Control Division, Bureau of Drug Control, Thai FDA)

(2) Dr. Shingou Sakurai
(Office Director of the Office of GMP/QMS Inspection, PMDA)

Closing remarks

(1) Mr. Vinit Usavakidviree
(Director, Bureau of Drug Control, Thai FDA)

(2) Dr. Nobumasa Nakashima
(Office Director of the Office of International Programs, PMDA)