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# PMDA Updates

**June, 2012**

## *News*

### 1. New Director of Center for Product Evaluation appointed (June 1)

PMDA appointed Dr. Takao Yamori, former Deputy Director of the Cancer Chemotherapy Center, Japanese Foundation for Cancer Research, as its Director of the Center for Product Evaluation on June 1, 2012. Before this appointment,, an Executive Director of PMDA had concurrently served as the Center Director. The appointment of Dr. Yamori is aimed at improving and enhancing the activities at the Center for Product Evaluation.

In order to reinforce regulatory review and the collaboration with academia, PMDA also created new positions of Deputy Center Directors in the Center for Product Evaluation and appointed Dr. Akihiro Umezawa and Dr. Ichiro Sakuma as Deputy Center Directors for Cellular and Tissue-based Products and for Medical Devices, respectively. Dr. Umezawa maintains his current position as Deputy Director of the National Research Institute for Child Health and Development. So does Dr. Sakuma, as Director of the Medical Device Development and Regulation Research Center, School of Engineering, the University of Tokyo.

### 2. Chief Executive of PMDA's visit to Indonesian health authority (May 21)

The National Agency of Drug and Food Control (NADFC) of Indonesia and the Japan International Cooperation Agency (JICA) co-hosted the "Seminar on Regulation in Ensuring Drug and Food Safety and Their Current Situation" in Jakarta, Indonesia on May 21, 2012. Dr. Tatsuya Kondo, Chief Executive of PMDA, delivered a lecture on the outline of PMDA's activities and current situation. Mr. Shinobu Uzu, Director of the Office of New Drug I at PMDA also explained Japan's regulatory system, focusing on regulatory review of new drugs. In addition, the first Japan-Indonesia bilateral meeting was held on the following day. In the meeting, the regulatory authorities of the two countries agreed to develop a closer cooperative relationship, in which Japan will provide support for capacity building of NADFC officials. As for cooperation in capacity building, PMDA have been organizing PMDA Training Seminars to foreign regulators since 2010. PMDA has also given assistance for training programs hosted by JICA with participants from NADFC in the past.

### 3. DIA 4th Annual China Meeting (May 20 to 23)

The DIA 4th Annual China Meeting was held in Shanghai, China from May 20 to 23, 2012. Dr. Toshiyoshi Tominaga, Director of the Office of International Programs; Dr. Norihiko Yoda, Director of the Office of New Drug III; and other staff members from PMDA attended the meeting. In the PMDA Update session, the PMDA speakers delivered presentations on the strengthening of PMDA's drug review including initiatives to reduce total review times, as well as the current situation and future direction of Pharmaceutical Affairs Consultation on R&D Strategy. In the same session, a speaker from the pharmaceutical industry also introduced successful examples of drug development utilizing clinical trial consultations provided by PMDA. This session gathered over 100 participants and the presentations were followed by vigorous exchange of opinions in the Q&A session. This was the first session to introduce PMDA's activities in DIA China Meeting.

# Events

## Conferences/Meetings PMDA (co-)hosted

| Date | Title | Location |
|---|---|---|
| June 7 | PDG Symposium 2012 | Tokyo, Japan |

## Conferences/Meetings PMDA participates in

| Date | Title | Location |
|---|---|---|
| June 2-7 | ICH Meeting | Fukuoka, Japan |
| June 5-6 | Pharmacopoeial Discussion Group Meeting | Tokyo, Japan |
| June 24-28 | DIA 48th Annual Meeting | Philadelphia, the U.S. |