PMDA Updates

May, 2011

News

1. As of 1 April 2011, PMDA staff size has increased to 648.

The total number of the agency's regular employees is 648, of whom 415 are in Drug/Medical Devices review division, 133 are in Office of Safety as of 1 April 2011. PMDA increased the number of employees by 43 compared to the same day last year.

2. PMDA has started the training for new recruits. (April 4-May 27)

The training program runs for approximately two months starting from April 4, 2010.
The trainees include those joining PMDA during FY 2010. This intensive program consists of an induction course, specialized courses for new drug application review, safety information analysis, etc., a human skills course, and instructions on expected awareness as PMDA members. Besides PMDA's executives and expert reviewers, notable researchers, the industry representatives, sufferers from adverse drug reactions, and officials from the Ministry of Health, Labour and Welfare delivered lectures.

3. PMDA held a seminar for newcomers to the medical device industry. (April 7)

The seminar, held in cooperation with Japan Electronics and Information Technology Industries Association (JEITA), provided basic information, such as the outline of Pharmaceutical Affairs Act and basic steps from development to application for approval, to manufacturers of electric appliances, electronic components and materials who are considering new entry into the medical device industry. Attending the seminar were 77 aspirants, who deepened their understanding of the regulations on medical devices.

4. Dr. Kondo, the Chief Executive of PMDA, delivered a lecture on PMDA's safety measures. (April 22)

In his presentation " PMDA's Efforts in its Safety Measures -current and future-" in the 97th Seminar for Experts of Regulatory Affairs, hosted by Pharmaceutical and Medical Device Regulatory Science Society of Japan, Dr. Kondo explained PMDA's current situation regarding its improvement in the system for collecting, analyzing, evaluating and providing safety Information, as part of the Agency's Second Midterm Plan. Then he introduced MIHARI project (Medical Information for Risk Assessment Initiative), the project to develop methodology to utilize electronic health information for safety measures, and PMDA's effort to increase subscribers to "PMDA Medi-Navi", the agency's e-mail alert service disseminating important safety information regarding pharmaceuticals and medical devices. Dr. Kondo also outlined PMDA's new system of

life-cycle monitoring of drug safety, which started this April. Under the system, information on adverse drug reaction is assessed by one of its 12 assessment teams, now increased from former 8, each staffed with a risk manager as the interface between review department and safety department. The assessment teams are organized according to the therapeutic classes of drugs, corresponding to PMDA's new drug application reviewing teams. Safety information of a drug will be evaluated on a more consistent basis from its development to post-marketing surveillance phases.

< Safety Information >

Pharmaceuticals and Medical Devices Safety Information No.278, March 23, 2011
http://www.pmda.go.jp/english/service/precautions_2010.html

Events

1. Conferences/meetings PMDA (co-)hosted

Date	Title	Location
May 24	Reporting Session "the latest trend of EMA and its current status on international collaboration"	PMDA's Office

2. Conferences/meetings PMDA participates in

Date	Title	Location
May 11-13	GHTF Steering Committee	Brisbane, Australia
May 16-18	3rd DIA China Annual Meeting	Beijing, China
June 11-16	ICH Steering Committee / Expert Working Group meetings	Cincinnati, USA
June 20-23	47th DIA Annual Meeting	Chicago, USA