PMDA Updates

June, 2011

News

1. GHTF Steering Committee (May 10 to 13)

As Japan's regulatory authority, PMDA and MHLW sent their representatives to GHTF Steering Committee meeting held in Brisbane, Australia. The Committee decided to invite public comments on GHTF draft proposal on safety reporting of serious adverse events. The work plans of the Study Groups were also discussed. The Committee confirmed Japan's chairpersonship starting this July. Also discussed was the regulator-led medical device harmonization forum to be founded soon.

2. The 5th DIA Annual Conference in Japan for Asian New Drug Development (May 10 to 11)

In the Conference held in Tokyo whose theme was to promote new drug development in East Asia, some of PMDA staffers discussed the following topics: safety reporting and pharmacovigilance, current status of GCP inspection, and pharmagenomics. In the panel discussion held at the end of the Conference, experts from Japan, China, Korea, and Taiwan discussed with the audience how clinical trials in Asian countries were to be enhanced. PMDA maintained PMDA Booth at the venue during the Conference and disseminated information on its activities by giving out its brochures and other materials as well as answering questions from the visitors.

3. PMDA concluded joint graduate school agreement with Musashino University (May 10)

As one of the activities to advance regulatory science, PMDA has been maintaining a joint graduate school program to exchange students and PMDA employees with graduate schools. On May 10, PMDA concluded a joint graduate school agreement with Musashino University Graduate School of Pharmaceutical Sciences, the seventh school participating in the program.

4. Second PMDA Reporting Conference "the latest trend of EMA and its current status on International collaboration" (May 24)

Mr. Yoshikazu Hayashi, PMDA's International Liaison Officer to EMA reported his activities in Europe in the Conference held at PMDA. The Session was open to the public. Besides Mr. Hayashi, two other PMDA employees, who recently completed their training in OECD and FDA of USA, also made speeches. The Session attracted an audience of approximately 70 participants, mostly from the pharmaceutical industry. A vigorous Q&A session followed the presentations.

< Safety Information >

Pharmaceuticals and Medical Devices Safety Information No. 279 (executive summary)
http://www.pmda.go.jp/english/service/pdf/precautions/PMDSI-279-d.pdf

Events

1. Conferences/meetings PMDA participates in

Date	Title	Location
June 11-16	ICH Steering Committee / Expert Working Group meetings	Cincinnati, USA
June 20-23	47th DIA Annual Meeting	Chicago, USA
July 4-5	AHC Workshop on Medical Device: Implementation of GHTF documents	Seoul, Korea