

PMDA Updates

August, 2010

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1. Medical and Welfare Sub Committee of the Evaluation Committee on Independent Administrative Institutions : August 17 2010

PMDA reported its business results for FY 2009 to Medical and Welfare Sub Committee of the Evaluation Committee on Independent Administrative Institutions last month. The final assessment was delivered from the Committee. It graded all of PMDA's business result as "A" which is the second highest out of five.

2. Pledging Ceremony : August 24 2010

For the Ceremony commemorating "the monument" that embodies the spirit of prevention of drug-induced suffering, built in front of the building of Ministry of Health, Labour and Welfare, the chief executive of PMDA delivered a special talk to all of the PMDA employees. He emphasized in his speech that PMDA must make utmost effort to ensure the safety and efficacy of drugs / medical devices.

3. PMDA 5th International Symposium on Biologics : August 26 2010

With the advancement of medical research and the growing worldwide interest in cell/tissue-based products as a backdrop, PMDA held the 5th symposium with its theme of "Quality and non-clinical evaluation of the cell/tissue-based products". The invited speakers were the experts from the regulatory agencies in the US and EU, the professor from Center for iPS Cell Research and Application (CiRA) Kyoto University. They delivered their presentations on regulations, cutting-edge research situations and their views on the quality and non-clinical evaluation of the cell/tissue-based products. The Panel Discussion allowed time for the audience to ask questions. The speakers exchanged their views on the latest topics.

< Safety Information >

●Pharmaceuticals and Medical Devices Safety Information No.271, July 2010

The articles in this issue describe the following information

- Precautions in Handling of Bipolar Electrode U'sed along with Electrosurgical Device
- Important Safety Information (Olmesartan Medoxomil and Yokukansan)
- Revisions of PRECAUTIONS section of package inserts (Phenytoin (and 5 others))
- List of products subject to Early Post-marketing Phase Vigilance

For more details: <http://www.pmda.go.jp/english/service/pdf/precautions/PMDSI-271.pdf>

<Events >

1. Training Seminars PMDA offers

Dates	Title	Location
November 29 – December 3	PMDA Training Seminar	PMDA Office Tokyo

PMDA is pleased to announce its first PMDA Training Seminar for International Regulatory Authorities. The First PMDA Training Seminar is designed for officials who are reviewing drugs/biologics. In this program, PMDA experts will present 1) General descriptions of PMDA's role in regulation, 2) Scientific PMDA review process.

PMDA is now inviting participants publicly through its website.

For more details: http://www.pmda.go.jp/english/upcoming/201008_seminar.html

2. Conferences/meetings PMDA participates in

Dates	Title	Location
September 13-15	The 3 rd China-Korea-Japan Director-Generals Meeting and Asia-Pacific Economic Cooperation(APEC) MRCT Work Shop	Seoul
September 16-18	APEC - The Life Sciences Innovation Forum (LSIF) - Regulatory Harmonization Steering Committee (RHSC) meeting	Sendai , Japan