Cerasus at Heian Shrine

PMDA Updates

April, 2017

News

1. The 11th IMDRF Management Committee Meeting

From March 14 to 16, the 11th International Medical Device Regulators Forum (IMDRF) Management Committee (MC) Meeting was held in Vancouver, Canada, and two staff members from PMDA's Office of International Programs attended as the MC Members. The first and the third day of the meeting were dedicated to the closed sessions for regulators and officially invited observers only, where, in addition to the guidance documents developed by each working group, new work items were discussed. In this meeting, the final documents of the Medical Device Adverse Event Terminology Working Group (chaired by PMDA) including terminologies for adverse event reporting, guidance document, SOP for maintenance of adverse event terminology were approved.

On the second day, an open IMDRF Stakeholder Forum was held with approximately 150 participants including Members from MC and industry, and active discussions were held on issues of interest to industries. The MC members from Japan provided an outline of recent regulatory efforts, and a progress report of the Medical Device Adverse Event Terminology Working Group, and participated in a panel discussion.

The next IMDRF MC Meeting will be held in Ottawa, Canada, on September 19-21, 2017.

The details of the 11th IMDRF MC Meeting are available at the following URL.

http://www.imdrf.org/meetings/meetings.asp

2. DIA 29th Annual EuroMeeting

From March 29 to 31, the DIA 29th Annual EuroMeeting was held in Glasgow, UK and was attended by Dr. Takao Yamori, Executive Director; Mr. Shinobu Uzu, Chief Safety Officer; Dr. Toshiyoshi Tominaga, Associate Executive Director for International Programs; Dr. Yoshiaki Uyama, Office Director of Office of Medical Informatics and Epidemiology and 4 staff members from PMDA, as well as Dr. Nobumasa Nakashima, Office Director for International Regulatory Affairs from MHLW. In the meeting, the "Updates of PMDA's Activities" session chaired by Dr. Tominaga included presentations on "PMDA's Efforts - Regulation and Innovation" by Dr. Yamori, "PMDA Update for Post-Market Safety and Quality Management" by Mr. Uzu and "Recent Regulatory Topics and International Cooperation of MHLW" by Dr. Nakashima. In this session, the participants actively exchanged views on MID-NET project and SAKIGAKE Designation System. In the "ICMRA - A Global Coalition of Medicines Regulators" session, Dr. Tominaga participated as a panelist in a discussion on ways for regulatory cooperation by ICMRA. Also, by giving lectures in the short course by Dr. Uyama and having an exhibition booth by staff members, PMDA took an active part in efforts to raise awareness of Japanese regulatory topics.

Dr. Tominaga (left end) as panelist in ICMRA session

(from left) Mr. Uzu, Dr. Yamori, Dr. Nakashima and Dr. Tominaga

The next meeting will be held on April 17-19, 2018 in Basel, Switzerland.

3. Call for application to PMDA-ATC GMP Inspection Seminar 2017 starts

PMDA Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC) will hold a seminar entitled "PMDA-ATC GMP Inspection Seminar 2017" from July 31 to August 4, 2017. This Seminar is designed for GMP inspectors from overseas regulatory authorities.

The Seminar includes lectures, group discussions and a mock inspection at an actual manufacturing site with the objective of acquainting the participants with Risk-based GMP Inspection. The Seminar is supported by Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S).

Please refer to the following web site for the details of PMDA-ATC GMP Inspection Seminar 2017.
http://www.pmda.go.jp/english/symposia/0107.html

Safety Information

PMDA Medical Safety Information No. 50, March 27, 2017

Precautions when setting syringe pumps
http://www.pmda.go.jp/english/safety/info-services/safety-information/0001.html

Risk Information which some safety measures might be taken (March 31, 2017)

- Caspofungin acetate
- Denosumab (genetical recombination) (drug products with the indication for osteoporosis)
- Pembrolizumab (genetical recombination)

http://www.pmda.go.jp/english/safety/info-services/drugs/risk-communications/0001.html

Pharmaceuticals and Medical Devices Safety Information No. 342, April 18, 2017

1. Precautions for Dependence Associated with Hypnotics-Sedatives, Anxiolytics, and Antiepileptics
2. Optimal Clinical Use Guidelines
3. Important Safety Information
   (1) Aluminum potassium sulfate hydrate/Tannic acid
4. Revision of Precautions (No. 283)
   Lamotrigine (and 37 others)
5 .List of Products Subject to Early Post-marketing Phase Vigilance
   (Posted on April 19, 2017)

http://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0015.html

Pharmaceuticals Revisions of PRECAUTIONS, April 20, 2017

- Denosumab (genetical recombination) (drug product with the indication for osteoporosis)
- Pembrolizumab (genetical recombination)
- Caspofungin acetate

http://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0005.html

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
May 11	2nd Korea-Japan Joint Symposium on Medical Products	Seoul
May 16	3rd Indonesia – Japan Symposium	Jakarta
May 27- June 4	ICH Week	Montreal

June 5-8	5th International Generic Drug Regulators Programme (IGDRP) meeting	Ottawa
June 17-22	DIA 53rd Annual Meeting 2017	Chicago
June 19	International Coalition of Medicines Regulatory Authorities (ICMRA) meeting	Chicago
June 26-30	PMDA-ATC Pharmaceuticals Review Seminar 2017	Tokyo

Reports from overseas

Our officers deliver lively reports of their activities at their stationed overseas authorities.

Participation in 3rd International Rare Diseases Research Consortium (IRDiRC) Conference

The International Rare Disease Research Consortium (IRDiRC) promotes research and development in the field of rare diseases through international cooperation, and Japan Agency for Medical Research and Development (AMED) is its member from Japan.

The third IRDiRC Conference[1)] was held in February, where various topics related to research and development in the field of rare diseases were presented. In the conference, I had an opportunity to make a presentation and Q&A with regulators in other countries, and provided activities related to regulatory aspects in Japan to enable patients with rare diseases to early access to necessary drugs, mainly focusing on Orphan Drug Designation System.

The conference had participants from all over the world, including academia and industry, many of whom listened to the presentation about Japanese regulatory system sincerely with active Q&A session. I am pleased if my participation at this time will contribute to improving access to necessary drugs by deepening the understanding of supports for development of orphan drugs in Japan and letting stakeholders turn to Japan more.

1) http://irdirc-conference.org/conference-program/

Mr. Hideyuki Kondo
PMDA's International Liaison Officer stationed at EMA in the United Kingdom

FIP/USP/AAPS Workshop on Nanomedicines

The workshop on nanomedicine was co-hosted by International Pharmaceutical Federation (FIP), American Association Pharmaceutical Scientists (AAPS) and United States Pharmacopeial Convention (USP) at the USP headquarters on March 20-22[1)]. Stakeholders from academia, industry, and regulatory agencies in Europe and the U.S. participated in this workshop and they gave presentations on strategies and challenges for quality characterization of nanomedicine, analytical technologies required for evaluation on quality of nanomedicine, regulatory trends in nanomedicines and efforts on international harmonization of regulations concerning nanomedicines and others. In addition, they conducted vigorous discussions on these topics in question-and-answer periods of each session.

The progress of USP's standard setting activity on nanomedicines was introduced in this workshop. In one of the presentations, the necessity for a general chapter describing general properties of nanomedicines was explained. The speaker also showed that USP should develop new general chapters on testing procedure such as dynamic scattering for particle size determination and zeta potential, and update some of the existing chapters to evaluate nanomaterials which are materials of nanomedicines.

Japanese pharmacopoeia (JP) has also started to discuss standard setting of nanomedicines because the number of approved nanomedicines is increasing. Therefore, I would like to facilitate information-sharing regarding nanomedicine between USP and JP while paying attention to trends on nanomedicines in the U.S. including USP so that standards for nanomedicines could be consistent between USP and JP.

1) http://www.usp.org/sites/default/files/events/workshops/2016/nanomedicines-technical-and-regulatory-perspectives/e-program-download-link-2017-03-20_0.pdf

Dr. Yujiro Kameyama
PMDA's Liaison Officer stationed at USP in the U.S.A

Providing Drug Safety Information by U.S. FDA - Drug Safety Communications

U.S. FDA publishes Drug Safety Communications (DSC) on their webpage to provide patients and health care providers with easy access to important and timely drug safety information[1]. DSCs include important information for patients and health care providers for proper medicinal product use. In addition, DSCs also provide a summary of the data the U.S. FDA assessed to develop the DSC and references information related each DSC topic.

Once a safety signal is detected, the Office of Surveillance and Epidemiology may conduct a review of cases reported to FDA Adverse Events Reporting System (FAERS), a literature search, an epidemiological evaluation and other evaluations to understand better the safety issue. Once the evaluation has been completed, U.S. FDA may require a change to the product label. The process of publishing a DSC includes collaborations with other offices or departments (e.g. Office of Communications, Office of New Drug, etc.).

Just as PMDA publishes drug safety information in English on its webpage in Japan, the U.S. FDA has made available Spanish language versions of DSCs on its webpage since July 2011. Furthermore, U.S. FDA provided the audio-based drug safety information via its Drug Safety Podcasts[2] . A DSC is critical information to patients who use medicinal products; therefore, it is important to distribute them through multiple channels.

1) https://www.fda.gov/Drugs/DrugSafety/ucm199082.htm
2) https://www.fda.gov/Drugs/DrugSafety/DrugSafetyPodcasts/default.htm

Mr. Takashi Misu
PMDA's Officer at CDER, U.S. FDA in the U.S.A
