Camellia sasanqua

PMDA Updates

December, 2019

News

1. PIC/S Committee Meeting and Seminar 2019 in Toyama

From November 11 to 15, PIC/S (Pharmaceutical Inspection Co-operation Scheme) Committee Meeting and Seminar 2019 hosted by PIC/S, Ministry of Health, Labour and Welfare (MHLW), and PMDA was held in Toyama, Japan. Dr. Yasuhiro Fujiwara (Chief Executive), Dr. Yoshikazu Hayashi (Senior Executive Director), and Dr. Shingou Sakurai (Senior Director for Manufacturing/Quality and Compliance) from PMDA, Mr. Kazuhiko Mori (Councilor for Pharmaceutical Affairs) from MHLW, and Mr. Takakazu Ishii (Governor of Toyama Prefecture) participated in the Seminar.

At the Committee Meeting, progress of guideline development on the "PIC/S Guidance on Data Integrity" was reported. At the Seminar, lectures and workshops on quality assurance of sterile medicinal products designed for regulators were held, and about 160 people participated from the regions and countries of the world. Movies recorded at manufacturing sites were used as educational tools at the workshops and lively discussions were especially promoted among the participants.

This year, 5 years have passed since PMDA became the member of PIC/S in July, 2014. PMDA will continue actively contributing to the harmonisation of GMP standards and international cooperation.

Main venue of seminar

Welcome Remarks from Dr. Fujiwara

2. PMDA-ATC GMP Inspection Seminar 2019

From November 12 to 15, PMDA held a seminar entitled "PMDA-ATC GMP Inspection Seminar 2019" in Toyama prefecture. The purpose of this seminar was to learn the international harmonization in the GMP inspection. This seminar was composed of PMDA-ATC original session and the above-mentioned PIC/S Seminar 2019. A total of 6 regulators in charge of GMP inspection from Azerbaijan, Brazil, Malaysia, Philippines, and Taiwan participated in the seminar.

Lecture scene

In the PMDA-ATC original session, on the Day1, PMDA staff gave a lecture on the outline of PMDA and the introduction of PIC/S activities, and Toyama prefecture staff gave a lecture on the GMP compliance inspection. On Day4, the comprehensive discussion including the introduction of GMP inspection system from each participant's regulatory agency, was held. In the 2019 PIC/S Annual Seminar from Day 2 to 4, the participants learned about the quality assurance of sterile medicinal products from lectures which feature in the PIC/S GMP

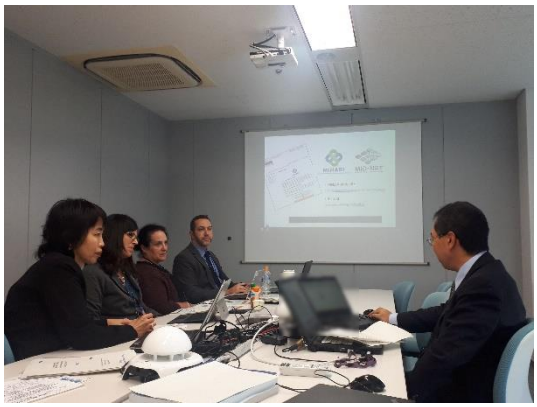
Guide Annex1, and group works on mock on-site and off-site inspection for sterile medicinal products utilizing video movie provided by manufacturing sites. The participants had active discussions throughout the seminar.

At the end of the seminar, the course completion certifications were handed to each participant by Dr. Sakurai.

Please refer to the following website for the details of PMDA-ATC GMP Inspection Seminar 2019.
https://www.pmda.go.jp/english/symposia/0155.html

3. Health Canada staff visits PMDA

Dr. Celia Lourenco (Director General of the Biologics and Genetic Therapies Directorate (BGTD)), Ms. Liz Anne Gillham-Eisen (Director, Office of Policy and International Collaboration, BGTD), Mr. Marc Lamoureux (Manager of Digital Health Division), and Dr. Bio Aikawa (Senior Advisor in the Director General's Office for Natural and Non-prescription Health Products Directorate) in Health Canada visited PMDA from November 13 to 14 to exchange information, including on PMDA's approach to AI technology and regenerative medicines. PMDA and Health Canada have been reinforcing cooperation through staff dispatch and bilateral meeting. During their stay, they were briefed on the practice at PMDA. The PMDA staff members from Office of International Programs, Office of New Drug, Office of Medical Devices, Office of Review Management, Office of Cellular and Tissue-based Products, Office of Pharmacovigilance, Office of Medical Informatics and Epidemiology, Office of OTC/Quasi-drugs, and Office of Generic Drugs took part in sharing their experience and discussing various topics with them. Also, they exchanged information on the latest trend in Canadian regulations and active question and answer sessions were followed.



Discussion with Dr. Daisaku Sato
(Chief Management Officer of PMDA)

With Executive Directors of PMDA (from left to right, Dr. Takao Yamori (1st), Mr. Takanori Sueoka (6th))

4. ICH meeting in Singapore

The 9th International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) met in Singapore from November 16 to 21. The 34 PMDA staff members attended, including Dr. Nobumasa Nakashima (Senior Director for International Programs) and Dr. Junko Sato (Office Director, Office of International Programs), and Mr. Naoyuki Yasuda (Office Director, Office of International Regulatory Affairs, MHLW) attended with other officers from MHLW.

Group photo of participants

Main outcomes from the meeting included the adoption by the Regulatory Members of the Assembly of the 3 draft guidelines of Q12 (Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management), E9 (R1) (Addendum: Statistical Principals for Clinical Trials), and M9 (Biopharmaceutics Classification System-based Biowaivers). Bioequivalence for Immediate-Release Solid Oral Dosage Forms was adopted as a new topic (M13) and agreed to initiate its work. ICH Assembly also agreed to initiate work for ICH Q3E Guideline; Impurity: Assessment and Control of Extractables and Leachables for Pharmaceuticals and Biologics, which had been adopted in last ICH meeting in Amsterdam with

a delayed start time. A proposal for the revision of the ICH Q9 Guideline on Quality Risk Management was also endorsed with a delayed start time.

Due to an expired term of previous appointees, the elections of ICH Assembly and Management Committee (MC) Chairs and Vice Chairs were conducted. Dr. Nakashima was re-elected as MC Vice Chair for another term.

The next ICH meeting will be held from May 23 to 28, 2020, in Vancouver, Canada.

5. PMDA-ATC Medical Devices Seminar 2019

From November 25 to 29, PMDA held a seminar entitled "PMDA-ATC Medical Devices Seminar 2019". This seminar was designed for medical devices and in vitro diagnostics (IVDs) reviewers from overseas regulatory authorities and 29 regulators from Argentina, Azerbaijan, Bangladesh, Brazil, Ethiopia, India, Indonesia, Laos, Malaysia, Myanmar, Nigeria, Peru, Philippines, Russia, Saudi Arabia, Taiwan, Thailand, and Vietnam participated.

Front row from left to right, Dr. Fukuda (Office Director, Office of International Cooperation) (1st), Dr. Nakashima (Senior Director for International Programs) (2nd), Dr. Hayashi (Director, Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs) (3rd) Dr. Kensuke Ishii (Senior Training Coordinator) (4th)

This seminar was held as the Center of Excellence (CoE) pilot workshop for medical devices under the APEC-LSIF-RHSC (Asia-Pacific Economic Cooperation, Life Sciences Innovation Forum, Regulatory Harmonization Steering Committee).

Speakers were invited from PMDA, MHLW, academia, and industries. Lectures in the seminar delivered topics including medical device regulations, international regulatory harmonization such as Global Harmonization Task Force (GHTF) and International Medical Device Regulators Forum (IMDRF), review of medical devices and IVDs, third party certification systems, Good Clinical Practice (GCP), Good Laboratory Practice (GLP) and Quality Management System (QMS) inspections, and post-marketing safety measures. Group works in case studies using review examples of new medical devices and IVDs and a panel discussion on the theme of development, practical application and international deployment of medical devices were also provided. In addition, site visit to manufacturing facilities of endoscope recommended by The Japan Federation of Medical Devices Associations were provided. The participants actively engaged in discussions throughout the seminar.

On the final day of the seminar, the course completion certificates were handed to each participant by Dr. Fujiwara (Chief Executive of PMDA).

Please refer to the following website for the details of PMDA-ATCMedical Devices Seminar 2019.
https://www.pmda.go.jp/english/symposia/0154.html

English translations of review reports

The followings are current information about English version of review reports on PMDA website.

Pharmaceuticals

http://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Brand Name	Non-proprietary Name	Posting date
Evenity [Initial Approval]	romosozumab (genetical recombination)	December 4
Rozlytrek [Initial Approval]	entrectinib	December 4
Prevymis [Initial Approval]	letermovir	December 4
Rosuzet [Initial Approval]	ezetimibe / rosuvastatin calcium	December 4

Medical Devices

http://www.pmda.go.jp/english/review-services/reviews/approved-information/devices/0003.html

Brand Name	Non-proprietary Name	Posting date
FoundationOne CDx Cancer Genomic Profile	・ analysis program for genetic mutation (to acquire comprehensive genomic profiling for cancer) ・ analysis program for somatic mutation (to determine the eligibility of each patient for treatment with antineoplastic agents)	December 10

Safety Information

Medical Devices Revisions of PRECAUTIONS (November 22, 2019)

・ Revision of Precautions for Artificial Ventilator, etc. Expected to be Used at Home

https://www.pmda.go.jp/english/safety/info-services/devices/0002.html

Pharmaceuticals and Medical Devices Safety Information No. 368 (November 26, 2019)

1. Initiative of Revision of the Manuals for Management of Various Serious Adverse Drug Reactions (Part 3)
2. Important Safety Information
   1. Vonoprazan fumarate
3. Revision of Precautions (No. 308)
   Vonoprazan fumarate (and 3 others)
4. List of Products Subject to Early Post-marketing Phase Vigilance

http://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0017.html

Pharmaceuticals Revisions of PRECAUTIONS (December 3, 2019)

・ Mecasermin (genetical recombination)
・ Atezolizumab (genetical recombination)
・ Osimertinib mesilate
・ Bilastine

http://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0007.html

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
January 20-23	PMDA-ATC MRCT Seminar 2020	Tokyo
February 3-6	PMDA-ATC Pharmacovigilance Seminar 2020	Tokyo
February 5-6	4th Japan-India Medical Products Regulatory Symposium	Tokyo
February 7-8	APEC-LSIF-RHSC meeting	Putrajaya
February 13-14	PMDA-ATC Pharmaceuticals Review Seminar 2020 in Jakarta, Indonesia	Jakarta

Reports from overseas

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

Summary of my dispatch at USP

Since I visited The United States Pharmacopeia (USP) as a Liaison in July 14th, 2018, I've worked for the development of collaboration between USP and The Japanese Pharmcopoeia (JP)/PMDA and arrangement of issues between both of the organizations. As a summary of my activity, I had the honor of giving a presentation for USP staffs about overview of JP/PMDA, history &mission of Liaison, and program to establish prospective collaboration on December 5.

Thorough my dispatch period, USP kindly provided the opportunity to learn many kind of topics. I could learn about Support program for developing countries in USP (PQM/PQM+)[1)], as well as latest discussion on quality such as Continuous Manufacturing[2)], Analytical Lifecycle Management[3)], Excipients with Functionality etc. which USP has discussed to adopt to recent changes of methods and policy of quality control. On the other hands, I also introduced JP/PMDA and their activity at the Committee and internal event in USP, and could contribute to deepen mutual understandings between USP and JP/PMDA. I'd like to contribute development of collaboration between USP and JP/PMDA by taking advantage of experience and personal relationship which I have obtained through this dispatch.

Finally, I would like to extend my deepest appreciation to Dr. Kevin T Moore (Senior Manager, Pharmacopeial Collaboration) and other USP staffs, people from academia or industry who shared interesting knowledge and discussions for me in conferences etc. through my dispatch. Also, I'm sincerely grateful to PMDA staffs for supporting my dispatch.

1) https://www.pmda.go.jp/files/000228949.pdf
   https://www.pmda.go.jp/files/000229497.pdf
2) https://www.pmda.go.jp/files/000227919.pdf
3) https://www.pmda.go.jp/files/000226517.pdf

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