PMDA Updates

October 2022

News

1. RAPS Convergence 2022

RAPS (Regulatory Affairs Professionals Society) Convergence 2022 was held in Phoenix, Arizona, U.S. from September 11 to 13. Dr. YAMAMOTO Haruko (Associate Executive Director) and three Medical Device Unit staff members from (Pharmaceuticals and Medical Devices Agency) PMDA participated in three sessions of the conference.

RAPS is a global organization that embraces experts in regulatory authorities, academia, pharmaceutical, and medical device industries, among others, for information exchange and education on the latest regulatory science on healthcare-related products. Many experts from various countries join the yearly RAPS Convergence. The PMDA further updates Japanese regulatory information, mainly regarding medical devices. Although RAPS Convergence was held virtually in the past few years owing to the COVID-19 pandemic, RAPS convergence 2022 was held offline for the first time in three years.

During the "Health Authority Forum: Japan" session, which approximately 70 people participated in, Dr. YAMAMOTO talked about the utilization of registry data and registry sustainability for medical devices' regulations; the other PMDA staff introduced fundamental concepts of the review regarding medical devices using artificial intelligence. This was followed by a discussion and Q & A sessions.

During the "Pediatric Medical Devices: Overcoming the Barriers" session, two PMDA members, a staff member from the Food and Drug Administration of the United States (U.S. FDA), and a representative from industries delivered presentations on the challenges and development acceleration for pediatric medical devices. The PMDA members introduced harmonization by conducting (HBD) activities for children, in which an industry-government-academia from the U.S. and Japan worked collectively to promote the development of medical devices, resulting in a Japanese national grant research project for accelerating the global clinical trial of pediatric medical devices and the utilization of real-world data for the regulatory use of pediatric medical devices. During the "Digital Health/Software as a Medical Device/mobile Apps and E-labeling/Wearables" session, a regulatory authority and an industry and certification body gave presentations on Software as a Medical Device etc. A PMDA member elaborated on the Japanese regulatory framework for software as a medical device and related topics. During every session, active discussions, which reflected the increasing international interest in Japanese regulations and efforts, were held.

The next RAPS annual conference will be held in Montreal, Quebec, and Canada, from September 11 to 13, 2023.

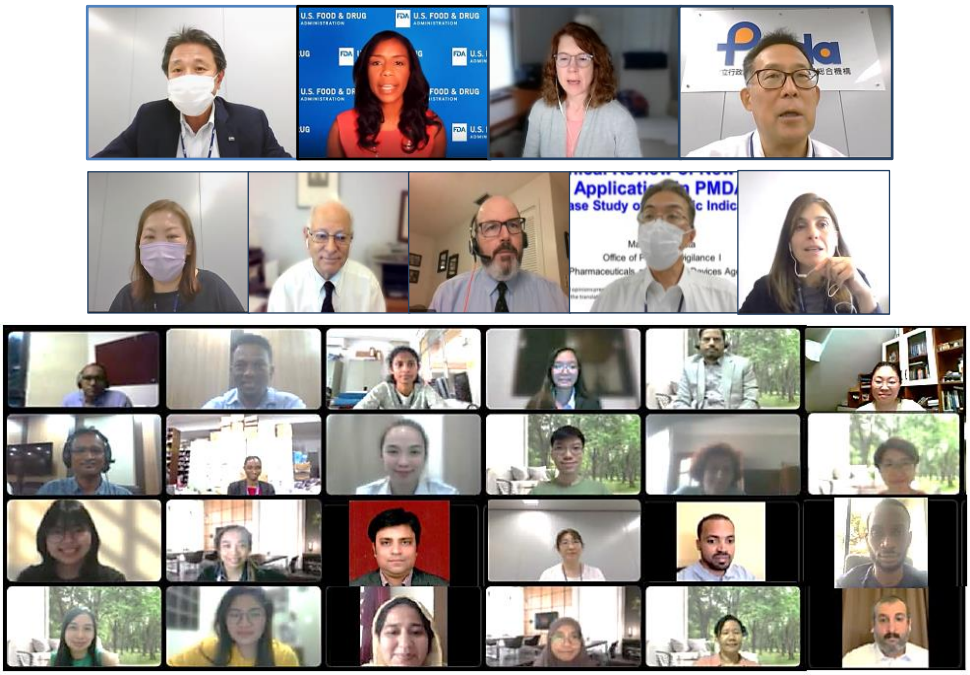
"Health Authority Forum: Japan" session
Dr. YAMAMOTO Haruko (Associate Executive Director)

2. PMDA-ATC & U.S. FDA Pediatric Review Webinar 2022

The PMDA held a webinar entitled "PMDA-ATC & U.S. FDA Pediatric Review Webinar 2022," from September 12 to 15, 2022. This webinar was intended for officials of overseas regulatory agencies involved in reviewing pediatric clinical trial applications and new drug applications for pediatric indications. A total of 28 regulators from Azerbaijan, China, Ethiopia, Ghana, India, Indonesia, Pakistan, the Philippines, Saudi Arabia, Sri Lanka, and Thailand joined the webinar.

In addition to the PMDA, lecturers from the U.S. FDA and the European Medicines Agency (EMA) were also invited. Recorded lectures by PMDA and U.S. FDA staff members were provided before the webinar as preliminary training material. The lectures covered an overview of new drug applications, physiology, and clinical pharmacology in pediatric populations, extrapolation of efficacy from other population data, and ethical considerations for clinical trials among children.

On the second and third days, the attendees collectively explored case studies provided by the PMDA and the U.S. FDA, on topics such as the review of a pediatric application, modeling and simulation, and ethical issues in pediatric clinical trial design. There was also a wrap-up Q&A session on the final day, in which the PMDA, U.S. FDA, and EMA participated; it provided a multifaceted learning opportunity for the participants, who actively engaged in all the discussions.



From the top left: Mr. UZU Shinobu (Director of the Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs, PMDA), Dr. Dionna Green (U.S. FDA), Dr. Donna Snyder (U.S. FDA), Dr. FUJIWARA Yasuhiro (Chief Executive of PMDA)
In the middle: Webinar lecturers
At the bottom: Webinar participants

Please refer tothe following website for details on the PMDA-ATC & U.S. FDA Pediatric Review Webinar 2022.
https://www.pmda.go.jp/english/symposia/0236.html

3. The 22nd IMDRF Management Committee Meeting

The 22nd International Medical Device Regulators Forum (IMDRF) Management Committee (MC) meetings were held on September 12 to 16 in Sydney, Australia; Dr. KUSAKABE Tetsuya (International Coordination Officer) and a staff member from the Office of International Programs of the PMDA attended them in person; a staff member from the Office of International Programs of the PMDA and a staff member from the Ministry of Health, Labour, and Welfare (MHLW) attended them virtually. The meetings were conducted in a hybrid format and chaired by Therapeutic Goods Administration from Australia.

On September 12, joint workshops between the IMDRF and industry groups, the Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association (DITTA), and Global Medical Technology Alliance (GMTA), were held. In the IMDRF-DITTA joint workshop, based on the topic, standards for health software, regulators and

industry groups shared their experiences and challenges regarding the speed of reviews for software and the development of new and current standards. The MHLW introduced the needs and challenges of developing a comprehensive standard for medical device software from a regulatory perspective. In the joint workshop with GMTA, under the topic of AI and medical devices, regulators and industry groups shared the current situation and outlook on AI and medical device technologies and products.

The IMDRF Stakeholder Forum, which the IMDRF MC members and industry stakeholders attended, was held on September 13. It involved presentations on the latest information from each IMDRF country or region, progress reports of each WG, and the interests and concerns of industry groups, among others. The MHLW reported on trends in medical device regulations, including those for software as a medical device.

The participants, over 200 virtually and over 100 in person, actively exchanged views at the workshops and the IMDRF Stakeholder Forum.

On September 14, an open meeting to exchange views on the IMDRF's activities with regulatory members, observers (official and invited), industries, and other related groups, was held.

On September 15 and 16, a closed meeting for regulatory members and observers (official) to discuss draft guidance documents and future work items, was held. At the meeting, guidance for Personalized Medical Devices – Regulatory Pathways (N58) and guidance for Personalized Medical Devices Production Verification and Validation (N74) developed by the personalized medical device (PMD) WG were approved as public consultation documents. Additionally, a new work item to revise four guidance documents on quality management systems (N10, N15, N17, and N18) was approved.

The next IMDRF MC Meeting, which will be chaired by the European Commission, will be held in March 2023.

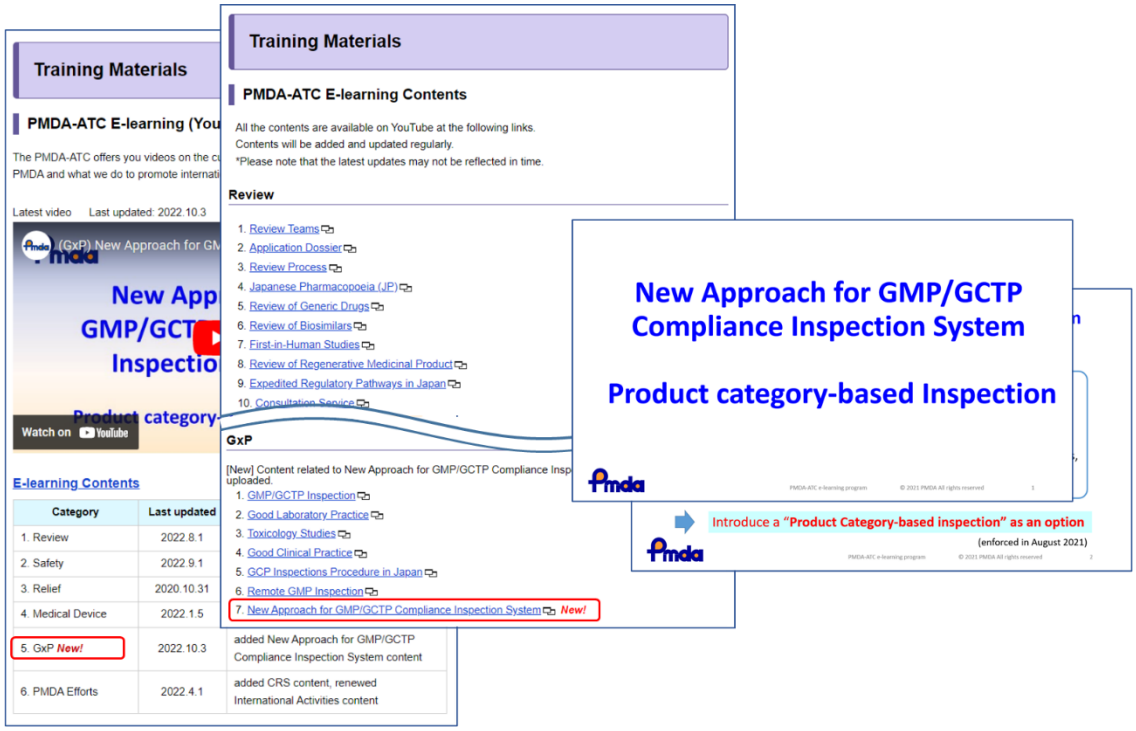
The detailed outcomes of the IMDRF MC meeting are available on the following website:
https://www.imdrf.org/documents/australia-virtual-meeting-outcome-statement-o

4. PMDA-ATC E-learning Updated Content Information

The PMDA-ATC E-learning system has been in operation since January 2020. This month, we are pleased to announce the release of a new content video entitled "New Approach for GMP/GCTP Compliance Inspection System" in the "GxP" category.

Conventionally, GMP/GCTP compliance inspection should be conducted every five years after product approval and upon application from the Manufacturing Authorization Holder. This content introduces the process of the "Product category-based Inspection" of the manufacturing site, which has been added as an optional method for conventional GMP/GCTP compliance inspection.

Please follow this link to access the e-learning website:
https://www.pmda.go.jp/english/int-activities/training-center/0003.html



5. Call for Applications: PMDA-ATC with NCC MRCT Webinar 2023

The PMDA Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC) is pleased to announce the "PMDA-ATC with NCC MRCT Webinar 2023", in collaboration with the National Cancer Center hospital Japan (NCC). This webinar will be held on January 10 (preliminary session) and from 16 to 19, 2023. This webinar was designed mainly for new drug application reviewers from overseas regulatory authorities.

The webinar is aimed at providing the participants with opportunities to further enhance the regulatory systems in the respective countries or regions and promote the establishment of a global platform for medical innovation by learning points to consider for MRCT protocol design and planning, clinical operation, clinical data evaluation, clinical trials beyond the COVID-19 pandemic, Asian clinical trial network expansion, etc.

The webinar is held as a Center of Excellence (CoE) workshop of the Asia-Pacific Economic Cooperation Life Sciences Innovation Forum, Regulatory Harmonization Steering Committee (APEC-LSIF-RHSC). However, the webinar is open to regulators of non-APEC economies. All the participants should take the PMDA-ATC MRCT e-learning course before attending the live sessions. In September, the PMDA-ATC MRCT e-learning course was updated to include content entitled "Trial Conduct amidst the COVID-19 Pandemic".

Please refer the following website for details on PMDA-ATC in collaboration with the National Cancer Center MRCT Webinar 2023:

- For entry details on the PMDA-ATC MRCT Webinar 2023.
  https://www.pmda.go.jp/english/symposia/0244.html

- For details on the PMDA-ATC MRCT e-learning course and its entry.
  https://www.pmda.go.jp/english/int-activities/training-center/0006.html

6. Call for Applications: PMDA-ATC Pharmacovigilance Webinar 2023

The PMDA Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC) will organize the "PMDA-ATC Pharmacovigilance Webinar 2023" on January 30 (preliminary session) and from February 6 to 9 (live session), through a web conference system. This webinar is designed for overseas regulatory authority officials engaged in pharmacovigilance activities.

The webinar is aimed at providing participants with opportunities to further enhance the regulatory systems in their respective countries or regions by learning the basics of regulations; the participants will also learn Evaluation of Benefit/Risk Balance, the End-to-End Labeling process, Pharmacovigilance of the COVID-19 vaccine, risk management plans, Pharmacoepidemiology, utilize Real World Data (RWD), etc.

This webinar is offered as a Center of Excellence (CoE) workshop of the Asia Pacific Economic Cooperation, Life Science Innovation Forum, Regulatory Harmonization Steering Committee (APEC-LSIF-RHSC). However, the webinar is open to non-APEC economies. All the participants of the webinar took the PMDA-ATC Pharmacovigilance e-learning course before attending the live sessions.

Please refer the following website for details on the PMDA-ATC Pharmacovigilance Webinar 2023:

- For entry details on the PMDA-ATC Pharmacovigilance Webinar 2023.
  https://www.pmda.go.jp/english/symposia/0245.html

- For details on the PMDA-ATC Pharmacovigilance E-learning course and its entry requirements.
  https://www.pmda.go.jp/english/int-activities/training-center/0006.html

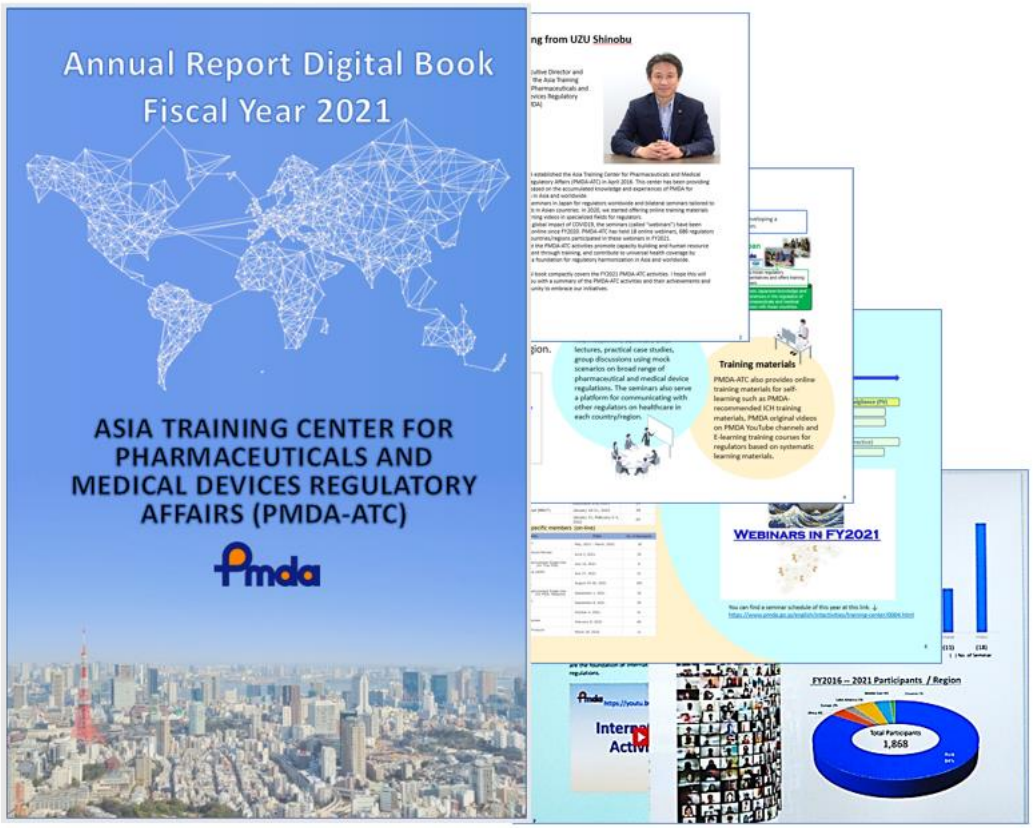
7. PMDA-ATC Digital Book

The activities and achievements of the PMDA Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC) in the last fiscal year were summarized in a digital book entitled "PMDA-ATC Annual Report Digital Book Fiscal Year 2021". This book has records of the PMDA-ATC webinar, PMDA-ATC E-learning course, and YouTube videos provided by PMDA-ATC through FY2021 in 10 pages.

Details of the webinar and E-learning course are shown in the pop-up slideshow.

Please follow the link below to access the digital book:

https://www.pmda.go.jp/english/int-activities/training-center/0001.html



English Translations of Review Reports

The following links provide the latest information on the English versions of the review reports on the PMDA website.

Pharmaceuticals

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

Brand Name	Non-Proprietary Name	Posting Date

Lonasen [Partial Change Approval]	Blonanserin	September 21, 2022
Nuvaxovid [initial approval]	Recombinant Coronavirus (SARS-CoV-2) Vaccine	September 28, 2022

Medical Devices

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

Brand Name	Generic Name	Posting date
Celution Cell Therapy Kit SUI [initial approval]	Adipose tissue separation kit	September 15, 2022

Safety Information

Pharmaceuticals and Medical Devices Safety Information No. 395 (September 27, 2022)

1. Revision of Precautions regarding the Co-administration of Riociguat with HIV Protease Inhibitors
2. Important Safety Information
    1. Ramucirumab (genetical recombination)
3. Revision of Precautions (No. 335)
   Hydroxychloroquine Sulfate (and 5 others)
4. List of Products Subject to Early Post-marketing Phase Vigilance

https://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0020.html

Pharmaceuticals Revisions of PRECAUTIONS (October 12, 2022)

- Loxoprofen sodium hydrate (oral dosage form) (prescription drug)
- Methotrexate
- Ipilimumab (genetical recombination)
- Nivolumab (genetical recombination)
- Pembrolizumab (genetical recombination)
- Itraconazole (tablets, capsules)
- Itraconazole (oral solution)
- Itraconazole (injections)
- Preparations containing loxoprofen sodium hydrate (oral dosage form) (OTC drugs)
- Pemafibrate

https://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0010.html

Events

Conferences/Meetings that the PMDA will participate in or host

Date	Title	Location
November 7-9	ICMRA Summit	Dublin
November 12-16	ICH meeting	Incheon
November 14-16	APEC Center of Excellence Workshop: PMDA-ATC Medical Devices Workshop 2022*	Virtual

November 16-17	IPRP meeting	Incheon
November 28-30	PMDA-ATC Medical Devices Webinar 2022	Virtual
December 6-8	PMDA-ATC Pharmaceuticals Review Webinar 2022	Virtual
December 8	ICH Fund Training Forum	Tokyo

* APEC-LSIF-RHSC CoE Workshop

Reports from Overseas

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

Stakeholder engagement

EMA has been active in multi-stakeholder engagement, with two recent meetings/workshop taking place.

1. Multi-stakeholder workshop: Patient experience data in medicines development and regulatory decision-making [1)]
2. ACT EU Multi-stakeholder Meeting on Decentralised Clinical Trials [2)]

The "Patient experience data in medicines development and regulatory decision-making Multi-stakeholder workshop" was held on 21st September 2022 and its purpose was to achieve a common understanding on what constitutes "patient experience data", including patient engagement, patient preferences and patient reported outcomes, and reflect on medicines development and regulatory assessments. It also considered how direct patient data collection from real-world healthcare can be leveraged and used, and how to agree on priorities to enhance the collection and use of patient experience data.

The other meeting, ATC EU Multi-stakeholder meeting on Decentralised clinical trials (DCTs) was held on 4th October 2022 hosted by the Accelerating Clinical Trials in the EU (ACT EU) programme. The EU DCT project group presented the work of the European medicines regulatory network on decentralised clinical trials collaboration and helped understanding and sharing perspective on this type of clinical trials for all areas of the research community. DCTs introduce new approaches to the conduct of clinical trials that aim to make clinical trials more easily accessible and convenient.

EMA actively holds such multi-stakeholder meetings and workshops that include not only industries but also patients. While such efforts are underway in Japan as well, activities that will lead to the provision of faster, safer, and more reliable drug products by hearing opinions from various sources will continue to attract a great deal of attention in the future.

1) Multi-stakeholder workshop: Patient experience data in medicines development and regulatory decision-making: https://www.ema.europa.eu/en/events/multi-stakeholder-workshop-patient-experience-data-medicines-development-regulatory-decision-making
2) ACT EU Multi-stakeholder Meeting on Decentralised Clinical Trials: https://www.ema.europa.eu/en/events/act-eu-multi-stakeholder-meeting-decentralised-clinical-trials

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