PMDA Asia Training Center and U.S. FDA Pediatric Review Seminar

~Introduction of the training opportunities offered by the Pharmaceuticals and Medical Devices Agency (PMDA) and the Food and Drug Administration of the United States (U.S. FDA) ~

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PMDA Pediatric Drugs Working Group

Regulatory Authorities in JAPAN

Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare (MHLW)

MHLW

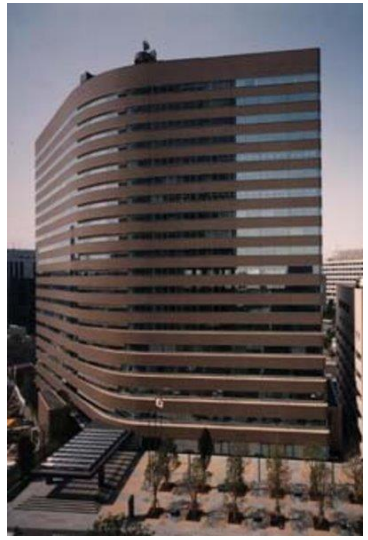
- **Final authorization of applications**
- **Publishing guidelines**
- **Advisory committee**
- **Supervising PMDA activities**

Pharmaceuticals and Medical Devices Agency (PMDA)

PMDA

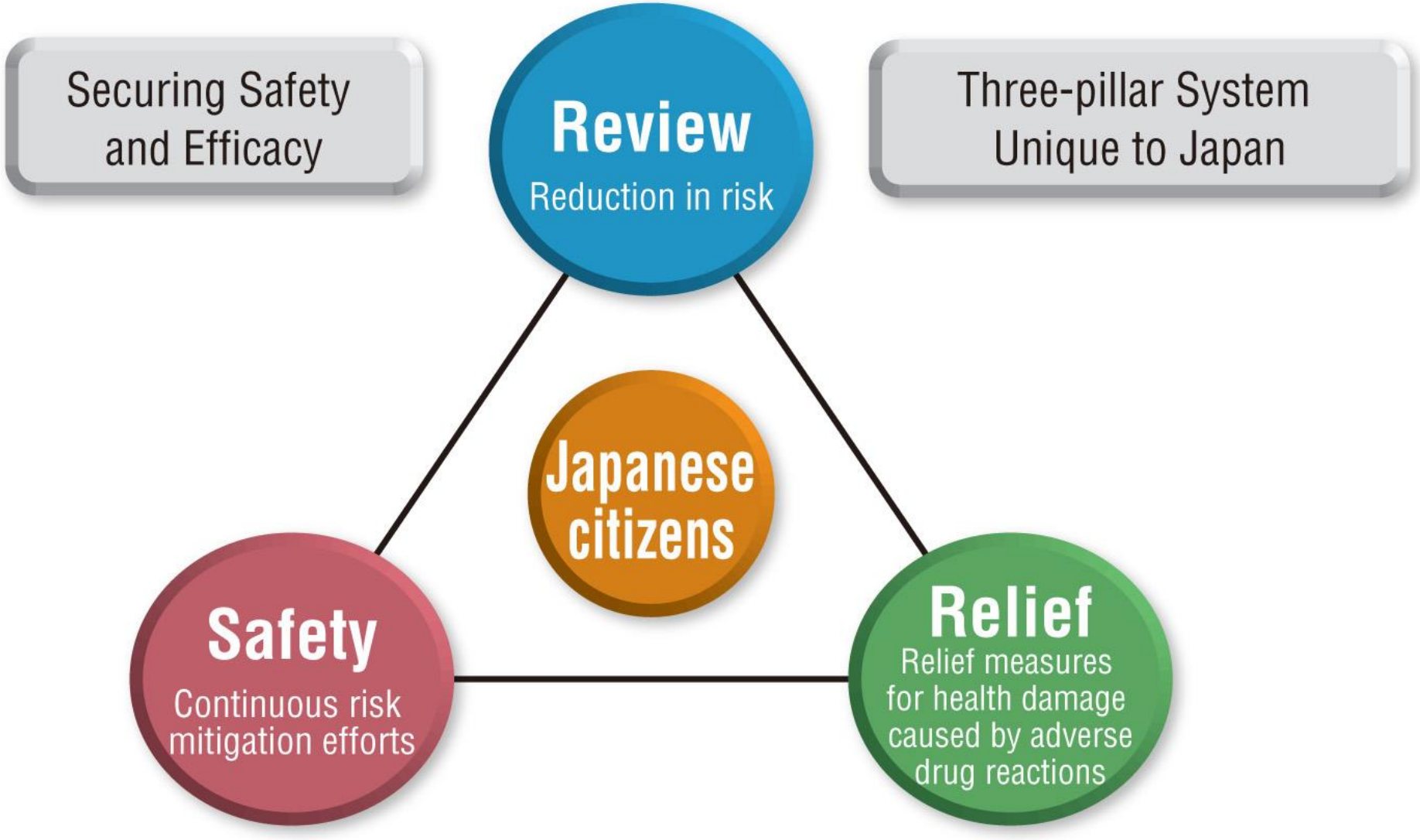
- **Scientific review for drugs, medical devices and regenerative medical products**
- **GCP, GMP inspection**
- **Consultation on clinical trials**
- **Safety measures**
- **Relief services**

Working in close relationship with Ministry of Health, Labor and Welfare (MHLW)



PMDA's Three Major Services - Safety Triangle

Comprehensive risk management through the Three functions



PMDA : Pharmaceuticals and Medical Devices Agency

PMDA Asia Office

Established in **Bangkok**, the Kingdom of Thailand on July 1st, 2024

Toyama

Hokuriku branch (seminars for GMP & others)

Osaka

Kansai branch (consultation on research and development strategy)

Main office

PMDA Washington D.C. Office

Established in Washington D.C. on November 1st, 2024

Tokyo

Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC)

- PMDA-ATC was established in April 2016.
- PMDA-ATC has been approved as a Center of Excellence (CoE).
- Established to promote capacity building and human resource development through training seminars for Asian regulators.

Action policy of PMDA-ATC

Contribute to universal health coverage in Asia through developing a foundation for regulatory harmonization in the Asian region.

Visits sites and conducts lectures, case studies, and practical training.

Provides training tailored to local needs for more people.

Invites Asian regulatory representatives and offers training seminars.

Shares Japanese knowledge and experience in the regulation of pharmaceuticals and medical devices with Asian countries.

Contents of PMDA-ATC Training Seminars

Examples

- Pediatric Review
- Quality Control (Herbal Medicine)
- Pharmaceuticals Review
- Medical Devices Review
- Multi-Regional Clinical Trial (MRCT)
- GMP
- Pharmacovigilance

Seminar Schedule
https://www.pmda.go.jp/english/int-activities/training-center/0004.html

Contents of PMDA-ATC Training Seminars

Examples

- Pediatric Review

✓ No participation fee

✓ PMDA may provide flight tickets and accommodation as determined by PMDA.

Seminar Schedule
https://www.pmda.go.jp/english/int-activities/training-center/0004.html

PMDA-ATC Training Materials

Leaning videos (PMDA channel)

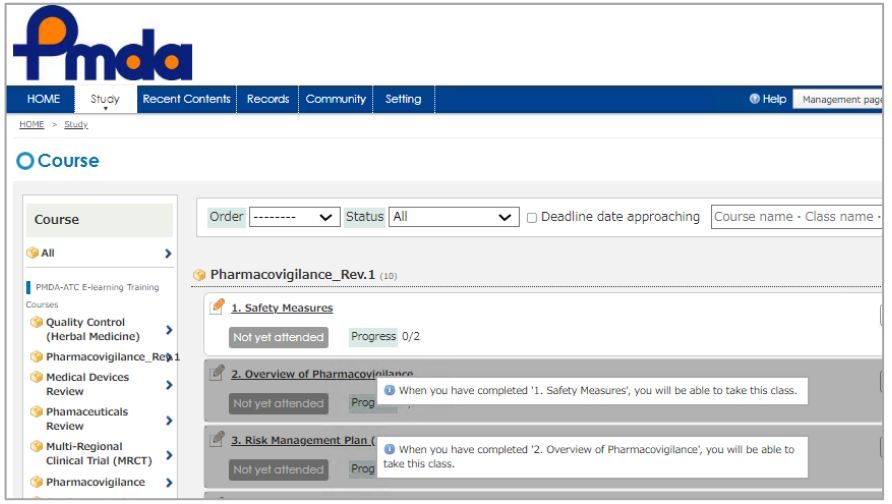
Category

- Pharmaceuticals
- Advanced Therapy Medicinal Products
- Medical Devices
- PMDA efforts

E-learning courses (regulators only)

Course list

- Pharmaceuticals
- Advanced Therapy Medicinal Products
- Herbal medicine
- Medical Devices



https://www.pmda.go.jp/english/int-activities/training-center/0003.html

To Enhance Pediatric Drug Development

- Because of a decrease in the number of children in major advanced countries/ regions, it becomes more and more difficult to conduct pediatric clinical trials of a certain scale leading to high level of evidences in single countries.
- Global collaboration is absolutely imperative.
- Participation from emerging countries/ regions is also essential.

Create a new path for better medicines for children

- ✓ Global Harmonization
- ✓ Beyond the borders
  - – Among Regulators, Industries, Health Care Professionals, Patients/ Patients' Care Givers
  - – Between Countries/ Regions

PMDA Asia Training Center & U.S. FDA Pediatric Review Seminar

Once a year since 2018

- To promote pediatric drug development globally
- To assist capacity building related to pediatric drug development in Asia and other countries/regions

- This seminar is intended for regulatory authority officials who are engaged in the review of pediatric drug development programs.
- This seminar covers current pediatric guidelines and practices in the U.S. and Japan, and provides the opportunity for the participants to share current pediatric guidelines and practices in their respective countries and regions.
- Case study sessions on pediatric drug development programs are also planned for small group discussions among the participants.
- Face to face meetings between the US FDA, the PMDA and participants took place if they want.
- We invite a lecturer from the EMA.

Announcement of the PMDA-ATC & U.S. FDA Pediatric Review Seminar 2024

Key Objectives

- ✓ To learn the scientific, ethical and regulatory considerations when evaluating drug products being developed for the pediatric population.
- ✓ To learn the global standard guidelines relating to the review of drug products being developed for the pediatric population.
- ✓ To learn the current practice and issues in the review of drug products being developed for the pediatric population when data are collected in adults and the pediatric population of other ethnic groups.
- ✓ To learn basics of the Modeling and Simulation for pediatric drug development.

Who Should Apply

- Regulators ONLY (Intermediate level)
- Employees of regulatory authorities with working experience of pharmaceuticals review, particularly in the pediatric field for over 3 years.
- English will be used in the lectures and discussions during the seminar. Participants need an ability to readily communicate in English.
- All participants are recommended to take self-learning lecture videos prior to attending the seminar.

Agenda of the PMDA-ATC & U.S. FDA Pediatric Review Seminar 2024

Day 1 Monday, July 22	Day 2 Tuesday, July 23	Day 3 Wednesday, July 24	Day 4 Thursday, July 25
9:30-10:00 **Registration**	9:30-10:00 **Registration**	9:30-10:00 **Registration**	9:30-10:00 **Registration**
10:00-10:20 **Opening Ceremony**	10:00-11:00 **Session 5 (PMDA)** **The use of existing knowledge in pediatric drug development**	10:00-11:00 **Session 8 (PMDA)** **Practical considerations for using existing knowledge in pediatric review: From PMDA experience**	10:00-14:00 **Session 11 (FDA)** **Case study 3** **Pediatric Clinical Pharmacology** - Lecture Pediatric PharmacoKinetics/PharmacoDynamics - Group Work Modeling/Simulation
10:20-11:00 **Session 1 (PMDA)** **Introduction for Pediatric Drug Development**			
11:00-12:20 **Session 2 (FDA & PMDA)** **- U.S. FDA New Drug Regulation and Pediatrics** **- PMDA Pediatric Regulation in Japan**	11:00-12:00 **Session 6 (FDA)** **Pediatric Extrapolation**	11:00-12:00 **Session 9 (FDA)** **Ethical consideration in pediatric clinical trials**	
12:20-13:50 **Lunch break** (90m)	12:00-13:30 **Lunch break** (90m)	12:00-13:30 **Lunch break** (90m)	11:40-13:00 **Lunch break** (80m)
13:50-15:20 **Session 3 (Participants)** **Round Table Discussion** **- Introduction of Pediatric Regulations by participants**	13:30-16:20 **Session 7 (PMDA)** **Case study 1 / Group work** **Practical Applications** - Introduction - Group Discussion	13:30-16:20 **Session 10 (FDA)** **Case study 2 / Group work** **Ethical Analysis** - Introduction (20 m.) - Group Discussion (90 m.)	**(Session 11 cont.)** - Group presentation - Q&A, Wrap up
Break (10m)	Break (10m)	Break (10m)	13:50-14:20 **Session 12** **Wrap-up (PMDA, FDA)** **Q&A for all session**
15:30-16:10 **Session 4 (EMA)** **EU Paediatric Regulation**	- Group presentation - Q&A, Wrap up	- Group presentation - Q&A, Wrap up	Break (10m)
16:10-16:20 Evaluation for Day 1	16:20-16:30 Evaluation for Day 2	16:20-16:30 Evaluation for Day 3	14:30-14:40 **Closing Ceremony**
16:40-18:00 **Get together**	16:30-17:30 Optional G to G meeting (@30 m.) ・country A ・country B	16:30-17:30 Optional G to G meeting (@30 m.) ・country C ・country D	14:40-14:50 Evaluation for Day 4 & Overall 15:00-16:00 Optional G to G meeting (@30 m.) ・country E ・country F

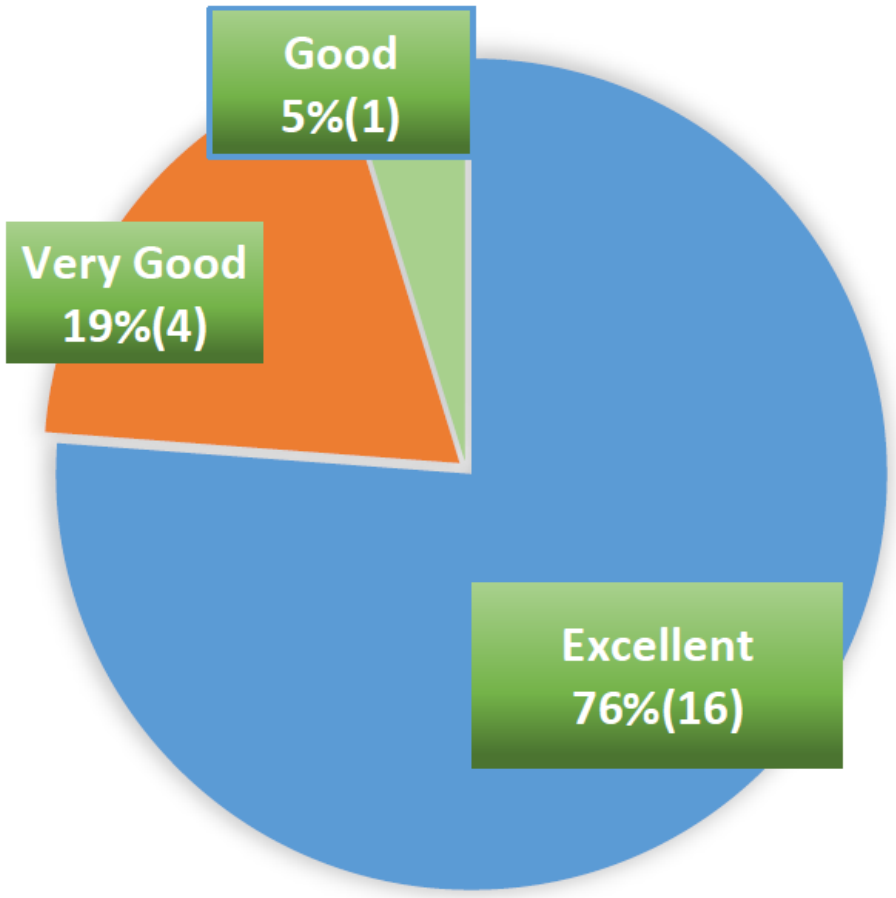
Participants by Country/Regulatory Authority of PMDA-ATC & U.S. FDA Pediatric Review Seminar 2024

Number of participants: 22
Number of Countries: 10

Country	Regulatory Authority
Bangladesh	DGDA (Directorate General of Drug Administration-Bangladesh)
Bhutan	DRA (Drug Regulatory Authority-Bhutan)
Egypt	EDA (Egyptian Drug Authority-Egypt)
Ethiopia	EFDA (Ethiopian Food and Drug Administration)
Indonesia	Indonesian FDA (BPOM)
Malaysia	NPRA (National Pharmaceutical Regulatory Agency-Malaysia)
Pakistan	DRAP (Drug Regulatory Authority of Pakistan)
Peru	DIGEMID (Dirección General de Medicamentos, Insumos y Drogas –Peru)
Philippines	FDA Philippines (Food and Drug Administration Philippines)
Thailand	Thai FDA (Food and Drug Administration –Thailand)

Participants Survey Results of PMDA-ATC & U.S. FDA Pediatric Review Seminar 2024

Overall Satisfaction



Number of responses: 21
Excellent: 76%
More than Very Good: 95%
More than Good: 100%

Take home message

- PMDA-ATC Seminars are held periodically, with a different theme for each seminar.
- Pediatric Review Seminar is offered by the PMDA and the U.S. FDA once a year.
  - To promote pediatric drug development globally
  - To assist capacity building related to pediatric drug development in Asia and other countries/regions
- Collaboration and Harmonization beyond the borders is essential for better medicine for children.

Thank You

Michiyo Sakiyama, M.D.

Associate Senior Scientist for Clinical Medicine

Office of Vaccines and Blood Products

Pediatric Drugs Working Group

Pharmaceuticals and Medical Devices Agency (PMDA)

Website of PMDA Pediatric Drugs Working Group:

https://www.pmda.go.jp/english/rs-sb-std/rs/0007.html