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PMDA

PHARMACEUTICALS AND MEDICAL DEVICES AGENCY



- Established in 2004
- The agency provides three key services:
 - ✓ Regulatory **review** of drug, vaccine, medical devices and regenerative medical products
 - ✓ Post-marketing **safety** measures
 - ✓ **Relief** service for adverse health effects

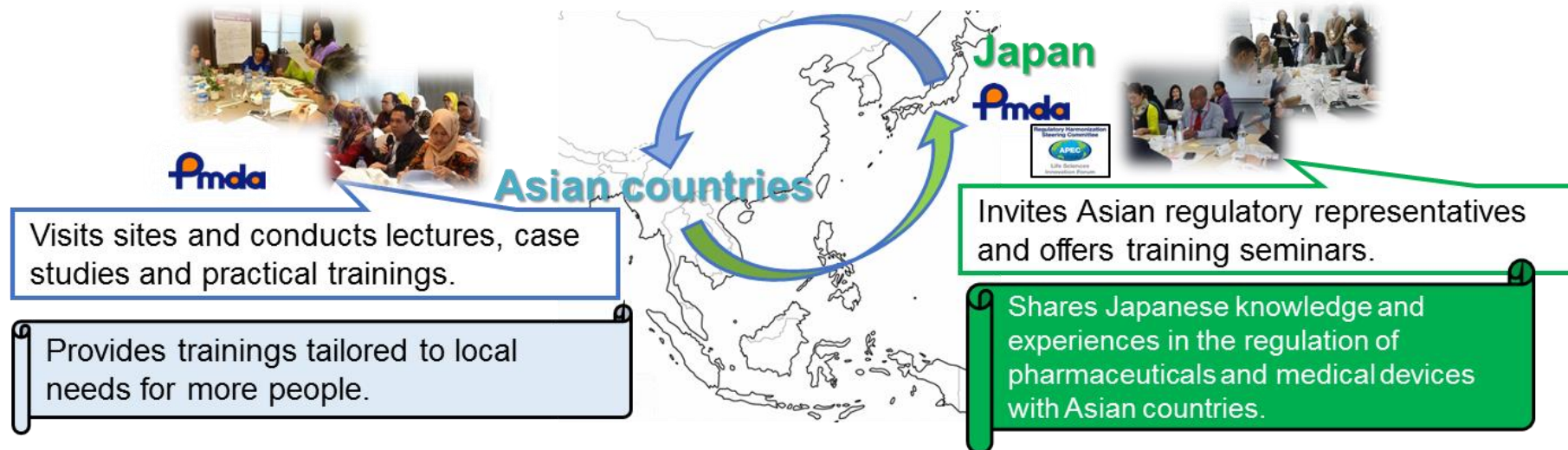
Ensuring the quality, efficacy and safety of medical products

PMDA-ATC

ASIA TRAINING CENTER FOR PHARMACEUTICALS AND MEDICAL DEVICES REGULATORY AFFAIRS

Action Policy of PMDA-ATC

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



TRAINING SEMINAR

Planned Trainings: FY2022 (April 2022 – March 2023)

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

No.	Title	Contents	Date
1	PMDA-ATC Quality Control (Herbal Medicine) Webinar 2022	Quality Control (Herbal Medicine)	August 23-25, 2022
2	PMDA-ATC & U.S. FDA Pediatric Review Webinar 2022	Pediatric Medicines Review	September 12-15, 2022
3	PMDA-ATC GMP Webinar 2022	Good Manufacturing Practice (GMP)	October 25-26, 2022
4	PMDA-ATC Medical Devices Workshop 2022※	Medical Devices Review	November 14-16, 2022
5	PMDA-ATC Medical Devices Webinar 2022	Medical Devices Review	November 28-30, 2022
6	PMDA-ATC Pharmaceuticals Review Webinar 2022	Pharmaceuticals Review	December 6-8, 2022
7	PMDA-ATC with National Cancer Center MRCT Webinar 2022※	Multi-Regional Clinical Trial (MRCT)	January 16-19, 2023
8	PMDA-ATC Pharmacovigilance Webinar 2023※	Pharmacovigilance	February 6-9, 2023

※APEC-LSIF-RHSC CoE Workshop

PARTICIPATING REGULATORY AUTHORITIES

➤ Report of the PMDA-ATC Quality Control (Herbal Medicine) Webinar 2021

<https://www.pmda.go.jp/english/symposia/0212.html>

“From June 22 to 24, PMDA held a webinar entitled “PMDA-ATC Quality Control (Herbal Medicine) Webinar 2021“. This webinar was designed for officials of overseas regulatory agencies engaged in drug reviews, and attended by 31 regulators from Azerbaijan, Brazil, India, Indonesia, Malaysia, Myanmar, Philippines, Singapore, Taiwan, Thailand, **Uganda**, Vietnam and **Zimbabwe**.”

Report of the PMDA-ATC Quality Control (Herbal Medicine) Webinar 2021

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Before attending the webinar, participants took the PMDA-ATC E-learning course, “Quality Control (Herbal Medicine)” covering the following: Regulation and Review Process of OTC Drugs; Japanese Pharmacopoeia (JP), Japanese Standards for Non-Pharmacopoeial Crude Drugs (Non-JP Crude Drug Standards); Approval Standards for Over-the-Counter Kampo Medicines and Crude Drug Preparations; and Evaluation process and GMP inspection by prefectural authorities.

E-LEARNING

e-Learning Training Courses | Pharmaceuticals and Medical Devices Agency (pmda.go.jp)

<https://www.pmda.go.jp/english/int-activities/training-center/0006.html>

E-learning Training Courses

Training Courses for specialized fields

The PMDA-ATC offers you videos regarding some specialized fields in the regulator-only website.
PMDA-ATC E-learning portal; <https://www.pmda-atc-elearning.site/>

To start the training courses, please register by the following steps:

- 1) Access to the application page, please fill in the form and submit it.
(<https://www12.webcas.net/form/pub/pmda-atc/e-learning02>)
- 2) Please select the course(s) of your interest from the list.
- 3) After checking your application by the secretariat, PMDA-ATC will send you Login ID and password normally within 5 business days.
- 4) The viewing period of the course(s) is about two months. Your login ID will become invalid at the end of the following two months.
- 5) A certificate of completion of the course can be issued.

Course List

Course	Duration	Last updated
1. Quality Control (Herbal Medicine) Updated!	78 min	2022.06.08
2. Medical Devices Review Updated!	107 min	2022.07.26
3. Pharmaceuticals Review	98 min	2021.08.31
4. Multi-Regional Clinical Trial (MRCT)	85 min	2021.10.20
5. Pharmacovigilance	135 min	2021.10.29

Apply for E-learning Training Courses
(Regulator only)

- Training for regulators
- Pre-registration required
- Currently the following courses are available
 - ✓ Quality Control (Herbal Medicine)
 - ✓ Medical Devices Review
 - ✓ Pharmaceuticals Review
 - ✓ Multi-Regional Clinical Trial (MRCT)
 - ✓ Pharmacovigilance

E-LEARNING

Training Materials | Pharmaceuticals and Medical Devices Agency (pmda.go.jp)


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

Training Materials

PMDA-ATC E-learning (YouTube)

The PMDA-ATC offers you videos on the current topics, introduction to the main services of PMDA and what we do to promote international regulatory harmonization.

Latest video Last updated: 2022.8.1



E-learning Contents

Category	Last updated	Note
1. Review New!	2022.8.1	added Review of OTC Drugs content
2. Safety	2020.10.31	added post-marketing safety content
3. Relief	2020.10.31	added "relief system for ADRs" content
4. Medical Device	2022.1.5	added COVID-19 test kit content
5. GxP	2022.5.2	added Remote GMP Inspection content
6. PMDA Efforts	2022.4.1	added CRS content, renewed International Activities content

- Prepared for public use
- No registration required
- Currently the following courses are available
 - ✓ Quality Control (Herbal Medicine)
 - ✓ Medical Devices Review
 - ✓ Pharmaceuticals Review
 - ✓ Multi-Regional Clinical Trial (MRCT)
 - ✓ Pharmacovigilance

FOR FURTHER INFORMATION

PMDA's Profile of Services

- <https://www.pmda.go.jp/files/000241469.pdf>

Upcoming events and symposia

- <https://www.pmda.go.jp/english/symposia/0044.html>

Seminar Schedule

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

e-Learning Training Courses for regulators

- <https://www.pmda.go.jp/english/int-activities/training-center/0006.html>

Training Materials (PMDA-ATC e-Learning program for public)

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