

PMDA Updates

June 2024

News

1. ICH Day and DIA China 2024 Meeting

To enhance the ICH Guidelines' ability in China, the ICH Day was held on May 16. Subsequently, the DIA China 2024 Meeting was held from May 17 to 19. Mr. YASUDA Naoyuki (Associate Executive Director for International Programs) participated in both meetings held in Suzhou, China, in person.

Mr. YASUDA presented "Current implementation and challenges in Japan" at the ICH Day. He stressed future views on the collaboration of the guidelines in connection to new modalities and electronic infrastructures. Two PMDA staff members input the current guidelines' topics online.

Mr. YASUDA also chaired the "Japan Town Hall" at the DIA China 2024 Meeting with two speakers from the Japan Pharmaceutical Manufacturers Association, while all the speakers shared information about the PMDA's future plan, reclarification of pharmaceutical regulations in Japan, efficient clinical development, and so on, from the perspectives of both the government and industry. Through the panel discussion and questions from the floor, an active exchange of opinions took place, in particular, the necessity of Phase 1 trials as well as Japanese financial support for orphan drug development.

Through in-person participation and direct communication, the PMDA strengthened relations with Chinese regulators directly and enhanced the mutual understanding of pharmaceutical regulations.



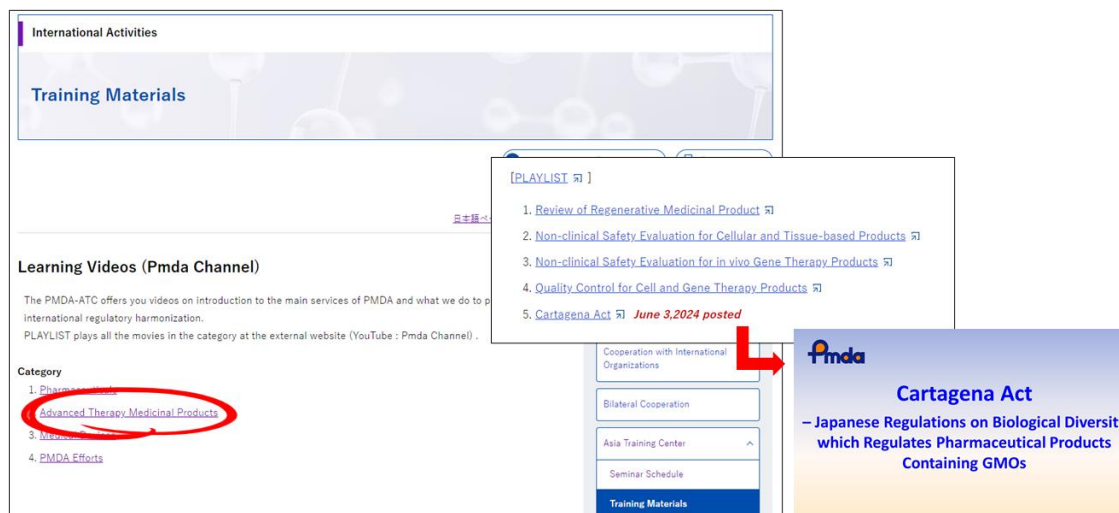
Mr. YASUDA Naoyuki (Associate Executive Director for International Programs) as a speaker in "ICH Day"

2. PMDA-ATC: Release of New Learning Video Content

The PMDA-ATC provides online learning videos that offer an overview of pharmaceutical and medical device regulations in Japan and PMDA's services. This month, the PMDA is pleased to announce the release of a new video content, entitled "Cartagena Act" in the "Advanced Therapy Medicinal Products" category of the PMDA-ATC Learning Videos.

The Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms, also known as the Cartagena Act, covers the use of genetically modified organisms (GMOs) in Japan.

This video explains the purpose of the Cartagena Act and how it is applied to the development process of biologics such as gene therapy products using genetic modification technology.



Please follow the link below to access the learning video content:

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

Medical Devices

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

Brand Name	Term Name	Posting date
TRUPULSE Generator [Initial Approval]	Percutaneous cardiac coagulation/ablation electrosurgical unit	May 21, 2024
VARIPULSE Pulsed Field Ablation Catheter [Initial Approval]	Cardiac ablation catheter	May 21, 2024
Duolith SD1 Ultra [Partial Change Approval]	Extracorporeal shockwave skin ulcer treatment device	May 24, 2024

Safety Information

Pharmaceuticals and Medical Devices Safety Information No. 410 (June 5, 2024)

1. Drug-induced Enterocolitis Syndrome
2. Revisions of PRECAUTIONS (No. 350)
 - (1) Rivaroxaban (and 4 others)
3. List of Products Subject to Early Post-marketing Phase Vigilance

<https://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0022.html>

Pharmaceuticals Revisions of PRECAUTIONS (June 11, 2024)

- Brimonidine tartrate
- Brimonidine tartrate/brinzolamide
- Ripasudil hydrochloride hydrate/brimonidine tartrate
- Brimonidine tartrate/timolol maleate
- Finerenone
- Posaconazole
- Voriconazole
- Carglumic acid

<https://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0012.html>

Events

Conferences/Meetings that the PMDA will participate in or host

Date	Title	Location
July 16–17	2024 DIA Singapore Annual Meeting	Singapore
July 22–25	PMDA-ATC & U.S. FDA Pediatric Review Seminar 2024	Tokyo (PMDA)

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PMDA Website: <https://www.pmda.go.jp/english/index.html>

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