PMDA Updates

2025 Autumn

Index

Highlights

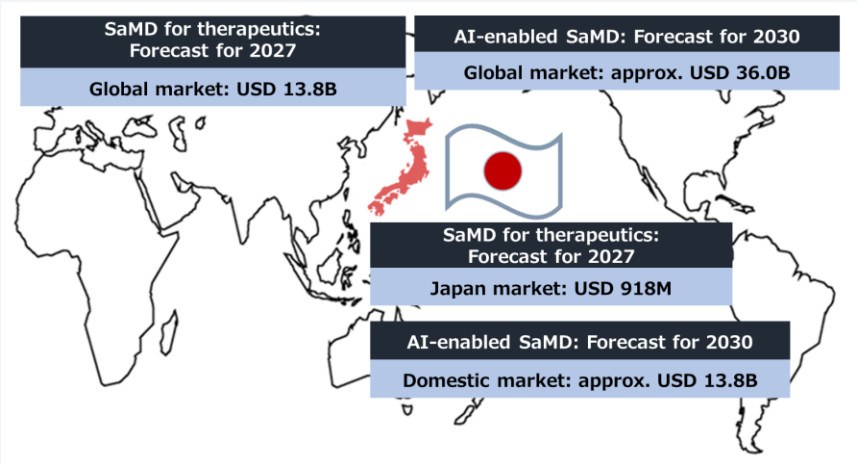
There has been a lot of news about generative AI, etc., produced by applying a large-scale language model. Software as a Medical Device (SaMD) is one of the areas that are often developed using such new technologies and have been actively developed worldwide. This article introduces the attractiveness of Japan to people who are interested in the development of SaMD from the perspectives of market and support for developers.

1. SaMD Market in therapeutics*

The market size of SaMD for medical treatment is expected to expand to USD 918 million by 2027

The global market and Japan market size are projected to reach USD 13.8 billion and USD 918 million, respectively, by 2027. In Japan, the aging population is driving the demand for digital technologies such as SaMD.

On September 6, 2023, the Ministry of Health, Labour and Welfare (MHLW) and the Ministry of Economy, Trade and Industry (METI) developed and announced DASH for SaMD2 (DX [Digital Transformation] Action Strategies in Healthcare for SaMD 2) to expand SaMD developed in Japan into international markets while further promoting practical use of SaMD. Such efforts are expected to further accelerate the development of SaMD both in Japan and abroad.



*Source: AMED-commissioned Survey “Final Report on the Study of Trends in SaMD Utilizing Digital Technologies (released)” (March 29, 2022)

What is SaMD? – Definition in the Pharmaceutical and Medical Device Act in Japan

SaMD refers to a medical device that is distributed as software (a medical device program), including one recorded on physical media. SaMD is classified into categories such as diagnostic (e.g., AI imaging) and therapeutic (e.g., smoking cessation application).

2. Development Support in Japan

What is DASH for SaMD 2?

SaMD is highly expected to be utilized in clinical settings, but as a new field, it has faced challenges in efficient practical use. DASH for SaMD was announced on November 24, 2020 as a framework to address those challenges.

To further promote practical use, the following points were considered necessary. On September 6, 2023, MHLW and METI published a new strategy, DASH for SaMD2 to strengthen the institutional framework.

- Clarification of various paths to commercialization (concept of two-step approval and evaluation indicators of SaMD for home use)
- Ensuring predictability from regulatory approval to insurance coverage
- Acceleration of R&D of SaMD originating in Japan and promotion of the use in international markets

Information platform on regulatory development

The development landscape of SaMD is evolving rapidly every day. A clear understanding of the marketing authorization system is key to efficiently developing and obtaining regulatory approval for SaMD. On the other hand, SaMD developers are often researchers in academia or start-up companies, and they may need support to better understand the regulatory system. For more information, please refer to the following:

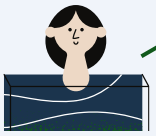
Platform: All information related to SaMD is compiled such as the concept and system of regulatory reviews for SaMD in Japan, as well as the approval performance!

YouTube: "Regulations on SaMD under the Pharmaceutical and Medical Device Act" and "Concept of Regulatory Review of SaMD" are explained in video!

A total of 47 Q&A on questions that arise during the development of SaMD (in Japanese): Start here if you're not sure!

FAQ

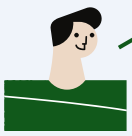
~ See some Q&As in "A total of 47 Q&A on questions that arise during the development of SaMD"!



Q **Can't we get support from the research and development stage to business development of SaMD? (Excerpted from Q9 of Q&A)**

A The PMDA conducts consultations on regulatory development policies, etc. based on the intentions of developers. In addition, through following platforms, you can receive support from experienced advisors in areas such as business planning, fundraising, and compliance with relevant regulations including the Pharmaceuticals and Medical Devices Act. Since each platform offers different types of support, please consult them according to the stage and needs of your development.

- Medical Innovation Support Office (MEDISO)
- Healthcare Innovation Hub (InnoHub)
- Medical Device InCubation platform (MEDIC) (in Japanese):



Q **How should we consult about products under development? (Excerpted from Q10 of Q&A)**

A In each stage of development from the pre-development or the early stage of development to approval application, the PMDA provides guidance and advice on clinical trials, etc. of SaMD in response to requests from marketing authorization holders, etc.

Q **What are the main points of discussion in the marketing authorization review? (Excerpted from Q39 of Q&A)**

A A marketing authorization review is conducted based on the clinical needs that triggered the development, development concepts, design concepts, etc. In addition, the publicly available guidance on marketing authorization and development "2.2.1. Basic Viewpoints, (5) Other Issues not Related to Individual Products" specifies items that are required to be evaluated in all marketing authorization application for SaMD.

What is two-step approval?

For SaMD, "two-step approval" scheme may be applied, allowing marketing approval to be granted at an early stage of development as the first-step can be applied. The merit is that the product can be launched earlier in the development stage by obtaining the first-step approval limited to the "intended use or effects" that can be shown from the existing exploratory study results, etc.. In addition, it is also possible to obtain the second-step approval with its full intended use after clinical evidence is established based on the experience of use in clinical practice including post-marketing clinical trials data and real-world data, etc.

News

PMDA Washington, D.C. Office Inauguration Ceremony

This article introduces the proceedings of the Japan-U.S. Joint Session and Inaugural Reception, which were held with the attendance of numerous representatives from Japanese and U.S. government agencies, as well as pharmaceutical and medical device-related organizations and industries in both countries.

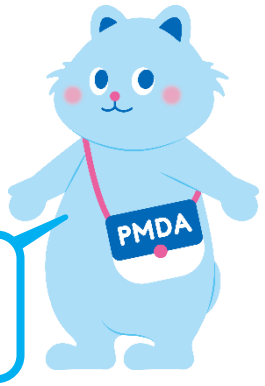
The PMDA held an Inauguration Ceremony at Le Meridien Washington, D.C. – The Madison Hotel on September 10, 2025, to formally announce the opening of its Washington, D.C. Office. Approximately 160 attendees presented, including representatives from U.S. government agencies such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (HHS), the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Advanced Medical Technology Association (AdvaMed), and representatives from the Ministry of Health, Labour and Welfare (MHLW), the Embassy of Japan in the United States of America , the Federation of Pharmaceutical Manufacturers' Association in Japan (FPMAJ), the Japan Pharmaceutical Manufacturers Association (JPMA), and the Japan Federation of Medical Devices Association (JFMDA), as well as representatives of Japanese and U.S. pharmaceutical and medical device industries.

Japan-U.S. Joint Session

Dr. Yasuhiro Fujiwara, the PMDA Chief Executive, emphasized in his opening remarks the significance of establishing the Washington D.C. office as a "bridge" to foster trust and collaboration between Japanese and U.S. officials with the aim of advancing public health. As guest of honor, Ms. Graham Grace, Deputy Commissioner for Policy, Legislation, and International Affairs at the FDA expressed her hope that the FDA-PMDA collaboration over the past 20 years would be further strengthened by the opening of the Washington D.C. office. Afterward, representatives from industry associations in Japan and the U.S. offered congratulatory remarks celebrating the opening of the Washington, D.C. office. Dr. Daisaku Sato, Councilor for Pharmaceutical Affairs of the MHLW, introduced Japan's activities to enhance its drug discovery and regulatory environment. He further emphasized the importance of a regulatory science-based review system and the necessity of Japan-U.S. cooperation to continue ensuring early patient access to innovative medical products. Dr. Akihiro Ishiguro, Head of the Washington D.C. Office, outlined the office's latest activities and expressed his determination to contribute to the PMDA's internationalization efforts as a "bridge" for strengthening Japan-U.S. cooperation.

Inaugural Reception

This event provided a valuable networking opportunity to share the significance and role of the Washington D.C. Office with attendees and to gain their understanding and encouragement for future activities.



Please visit these websites!

- Details on the role of the Washington, D.C. office
- Consultation requests for the Washington D.C. office
- The Washington D.C. office website

PMDA supports quality management at manufacturing sites - GMP/GCTP risk communication activities -

Stable supply of safe and reliable drugs to the public requires promotion of more effective monitoring and guidance related to GMP *1 and GCTP *2.

Therefore, the PMDA has been conducting various risk communication activities by releasing drug quality information widely since FY2022 to activate self-inspections at manufacturing sites and exchanges of opinions among the industry, government, and academia, along with the strengthening of monitoring and guidance. For example, as seen in GMP findings, such activities include the release of "Orange Letter," which gives a summary of cases where prompt publicity to the entire industry and attention calling are considered useful, and the holding of "GMP Round Table" aimed to solve problems and exchange opinions for securing quality by the industry, government, and academia.

We make the GMP/GCTP Annual Report (AR) every year that provides inspection results, analyses of what has been pointed out, questionnaire survey results, etc. as well as these activity details in order to “visualize drug quality information.”

This issue introduces the contents of attention from AR of the FY2024 edition.

1. Manufacturing sites located all over the world are subjected to the inspection

On-site GMP inspection is conducted not only in Japan but also in manufacturing sites located all over the world including Asian regions such as China and India, Europe and the US (Figure 1). We could not conduct an overseas inspection due to the influence of COVID-19 before, but the inspection has been gradually resumed since 2022. In particular, the inspection in China has been rapidly increasing in recent years.

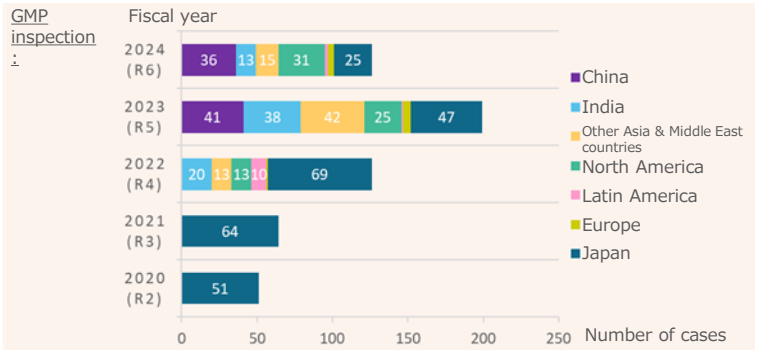


Figure 1 On-site GMP Inspection by Country/Region

*1 Good Manufacturing Practice (GMP) [for Drugs and Quasi-drugs]
*2 Good Gene, Cellular, and Tissue-based Products Manufacturing Practice

2. What are frequently pointed out in the inspection?

AR introduces the frequency of pointing out findings to manufacturing sites. Common problems that were pointed out are “deviation control” and “change control,” which was caused by insufficient communication to the marketing authorization holder in many cases.

In addition, a list of the problems that were pointed out is open to the public so that self-inspection will be more actively performed at each manufacturing site. In addition, to make a better use of the list for voluntary improvement activities at manufacturing sites, the backgrounds why such problems were pointed out are also stated in the FY2024 version.

Many of them were issued to overseas manufacturing sites. Based on this situation, we would like to distribute information more aggressively overseas, in such a way of issuing English translations of our notifications.

3. What is the content of the "Orange Letter"?

In FY2024, the PMDA released 6 Orange Letters.

Orange Letter No. 14 provides a case in which the responsible unit only at an overseas manufacturing site was judged not to have to “control changes” in changing the test method. It is necessary for overseas manufacturing sites to understand the approved matters and sufficiently communicate with the marketing authorization holder, etc.

Orange Letter No. 19 provides a case in which the evaluation of the impact on the drug quality was insufficient in "Stability Monitoring." This case was pointed out for a domestic manufacturing site, but a similar case was also pointed out at overseas manufacturing sites. It is necessary to appropriately evaluate inconvenient study results without arbitrarily excluding or neglecting them.

4. Questionnaire for future risk communication activities

We have established a questionnaire website to deliver information that more precisely meets your needs in the next AR and beyond. If you read the AR, please feel free to share your opinions.

We will continue to provide information and data that are useful for GMP/GCTP activities at manufacturing sites.

Topics

Introduction of Early Consideration

What is Early Consideration?

It is the PMDA's view on the direction of development at the point when information, etc. have not been sufficiently accumulated.

Please check the details of the Early Consideration related to the development area and field on the PMDA website.

See the details here English

Early Consideration (1)

Points to consider for externally controlled trials

In the development of drugs, etc., if it is difficult to conduct a randomized controlled trial due to the small number of patients, an open-label single-arm trial may be conducted and the results may be evaluated by comparing with the results of an external group (external control). Other clinical trial populations and RWD may be used as external controls. However, in any case, the lack of a randomization raises issues of comparability and bias. In light of these limitations of external controls, this Early Consideration specifically introduces points to consider for the design and analysis of results of externally controlled trials.

See the details here English

Early Consideration (2)

Points to consider for clinical development of drugs intended for treatment of antimicrobial-resistant gram-negative bacterial infections

The spread of drug resistance in pathogens such as bacteria is considered a major issue of global public health. In particular, for infections caused by gram-negative bacteria resistant to existing antimicrobial drugs (hereinafter referred to as “antimicrobial-resistant GNBI”), treatment options are limited. Therefore, the development of new effective antimicrobial drugs is expected.

The MHLW issued "Guidelines for Clinical Evaluation of Antibacterial Drugs" in October 2017. However, descriptions of the development of drugs indicated for treatment of antimicrobial-resistant GNBI are limited. For drug development for antimicrobial-resistant GNBI, it may be difficult to plan and conduct clinical studies in a sufficient size / design due to the limited number of subjects in Japan and overseas. Against such background, this Early Consideration provided points to consider in the clinical development of drugs intended for treatment of antimicrobial-resistant GNBI, taking into account recent clinical trial consultations, regulatory review cases, etc.

Overview

- Development strategy for drugs intended for treatment of antimicrobial-resistant GNBI, proposed of indications at the time of application for marketing approval
- Points to consider for the following items in the design of clinical trials in patients with antimicrobial-resistant GNBI:

✓ Efficacy and safety evaluation
✓ Enrollment of patients suspected of having antimicrobial-resistant GNBI
✓ Statistical analysis and sample size setting

See the details here English

Early Consideration (3)

Points to consider for nonclinical safety matters when submitting the initial clinical trial notification

For the purpose of smooth confirmation of initial clinical trial notification, we have summarized the contents of inquiries that have been frequently made in recent years from the viewpoint of toxicity evaluation. This Consideration provides basic concepts on information provision on non-clinical safety, avoidance of pregnancy, rules for inclusion of lactating women, etc. Concrete examples of descriptions in the informed consent form, etc. are shown as appendices.

See the details here English

Early Consideration (4)

Points to consider for the discussion with the PMDA using the ICH S1B (R1) guideline and in the approval application

In the past, 2 types of carcinogenicity studies (rats and mice) were performed in carcinogenicity evaluation of drugs, but based on the issuance of ICH S1B (R1) guideline, it is now possible to consult with the PMDA about the appropriateness of exemption from rat carcinogenicity studies. This Early Consideration provides points to consider specifically at the time of consultation and approval application (materials to be submitted at the time of a pre-consultation meeting, points to consider in the case of global development, points to consider when new results or information are obtained, materials to be submitted at the time of approval application, location of storage, etc.) in a Q&A format.

*: Safety consultations for drugs (consultation on ICH S1B (R1) Guideline)

See the details here English

Early Consideration (5)

Points to consider for clinical evaluation of drug-drug interactions using endogenous biomarker

In 2024, the ICH M12 guideline, which provides general recommendations on how to evaluate the potential for drug-drug interactions (DDIs) of investigational drugs in drug development, was notified. The guideline presents the potential use of endogenous biomarkers that are substrates of drug metabolic enzymes and transporters as an emerging approach for clinical evaluation of DDIs.

This Early Consideration states the points to consider in conjunction with the ICH M12 guideline when endogenous biomarkers are used to assess the potential of an investigational drug as a precipitant, and is expected to facilitate the smooth implementation of the evaluation of DDIs using endogenous biomarkers in Japan.

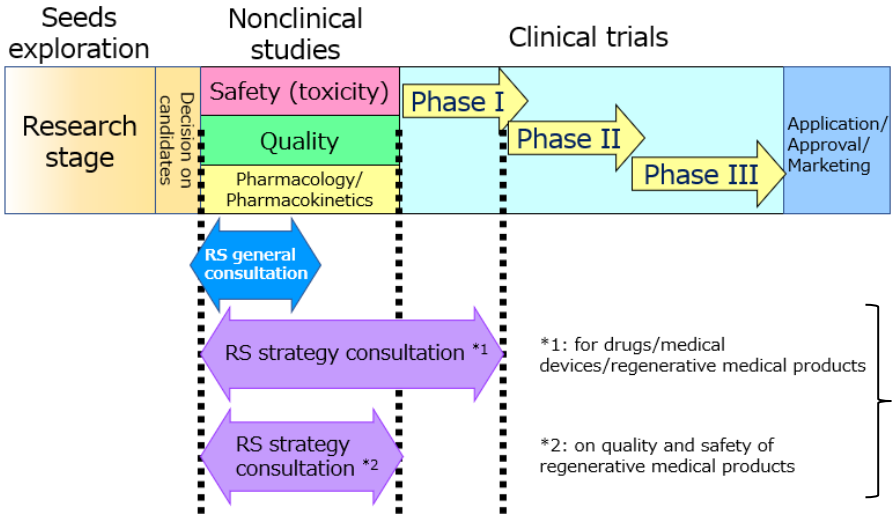
See the details here English

Series

Do you know the consultation system that is easy to use for those in academia and start-ups/venture companies?

- Volume 3: The Key to Success is Pre-consultation Meetings! -

RS general consultation/strategy consultation

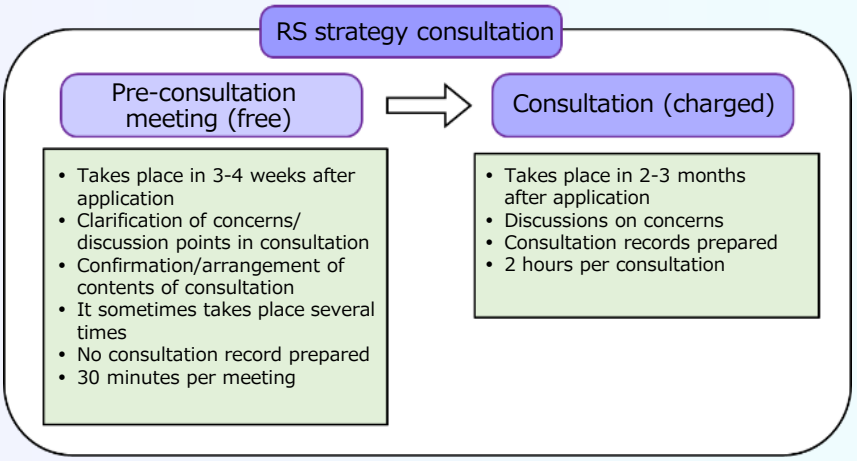


This issue introduces tips for effective use of pre-consultation meetings on RS strategy consultation. For RS general consultation, please refer to the Spring issue (English).

What is RS strategy consultation?

In an RS strategy consultation, we evaluate the supporting data and discuss the data evaluation from a scientific point of view regarding the sufficiency of the evaluation items and the appropriateness of the study plan proposed by the applicant/developer, and prepare a formal consultation record that provides a summary of the PMDA's views, etc.

In order to make this consultation smooth and effective, we have a RS strategy consultation (pre-consultation meeting) beforehand participated by the review team in charge of the consultation.



How to effectively utilize pre-consultation meetings?

Concretely showing the concerns of the applicant/developer at the pre-consultation meeting will clarify the points of discussion at the subsequent consultation. This will also provide specific explanation and supporting data for the concern.

If the applicant/developer themselves have not clarified their problems, concerns, and how to handle them, it may take time to review the contents, which will thereby make meaningful discussions and opinion exchange in the consultation difficult.

Application is accepted by e-mail. Please submit the application form and consultation materials by e-mail. A dedicated website is available. Please check the details here (English).

Points to sort out issues and concerns! – Case Studies: Drugs -

Please organize the following points, etc. and consider whether it is possible to construct a data package that can scientifically and logically explain the intended indication and dosage and administration.

◆ Clinical positioning ◆ Mechanism of action of active ingredient ◆ Characteristics of drug product
◆ Data already obtained and data to be obtained in the future, etc.

Introduction of the activities of overseas offices

Part 2 Asia Office - Looking back on the activities in a year -

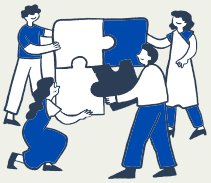
Atsushi Kitahara, Head of the PMDA Asia Office

Time flies. One year has passed since the establishment of our Asia Office. This page introduces the memory of activities, etc. for a year after the establishment.

1 Direct dialogue to build trust

We visited regulatory authorities in ASEAN countries on a regular basis and exchanged opinions directly on problems with the introduction of international pharmaceutical regulatory guidelines.

- Thailand (twice)
- Vietnam (twice)
- Indonesia (twice)
- Philippines
- Malaysia



The authorities in such countries said, "We are closer to the PMDA now, which allows smoother communication." I feel they expect more from the existence of this office than ever.

2 For expansion of the "reference country" system

ASEAN countries have been establishing a system in which drugs, etc. approved in Japan can be approved in a simplified review route. Currently, arrangements for a relevant system are ongoing in Vietnam, and the Asia Office supports the activities.

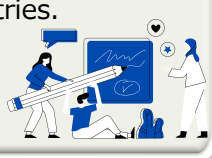
The approval system differs among countries, and so does the challenge when the simplified review is used. As the system is used more, the issues will be clarified. This will allow us to discuss how to cooperate with each other.

The Asia Office will continue working hard so that the simplified review using the reference country system will be widely used and we can deliver drugs quickly to many Asian patients.

3 Sharing of problems and addressing solutions

Many companies and medical institutions to visit our office, and actively exchanged opinions on the local regulatory status and what the office did. Since the same request is sometimes received from multiple companies, we will scrutinize the contents and negotiate to solve the issues through dialogue with regulatory authorities in each country.

We visit medical institutions with a view to conducting joint clinical trials so that new drugs can be used simultaneously in ASEAN countries. We promote dialogue on clinical trial systems and regulatory cooperation.



4 Expanding recognition throughout stronger outreach

Through public relations activities, we will work to make more people, including ASEAN countries, aware of the existence and role of our Asia Office, leading to joint development and regulatory coordination in Asia.

- Presentations at International Symposium for Asia Regulatory Coordination
- Offering information on the website of the Asia Office
- Participation in various events and meetings

The Bangkok earthquake that occurred at the end of FY2024 did not cause any major damage to the Asia Office, but the walls and ceilings partially needed repairing. Since renovation work was expected just before the earthquake for the anteroom to install a new logo, it was reborn as a well-lit and well-organized space. We look forward to your visit to the refreshed Asia Office with the new logo.

In the upcoming Winter issue, we will feature the activities of the PMDA Washington D.C. office

Information 1
Introduction of activities in Asia

ATLAS-ARISE-PMDA International Symposium

To commemorate the 5th anniversary of ATLAS*, the ATLAS-ARISE-PMDA International Symposium was held on October 3 (Bangkok, Kingdom of Thailand). The representative of clinical research institutions and regulatory authorities in Asian countries including Japan participated in the symposium to discuss the cooperation for promoting clinical studies in Asian regions.

It was confirmed that regulators, academia, and industry will collaborate to promote the clinical trial ecosystem in Asia while adapting to changes in the trial environment.

*Clinical trial network established by the National Cancer Center Japan with clinical research institutions in Asia

Participation in APEC RHSC

The APEC and RHSC meetings took place in Incheon, Korea from July 31 to August 1. (Chairperson: Mark Abdoo, Assistant Deputy Commissioner [USFDA]; Deputy Chairperson: Naoyuki Yasuda, Executive Officer [PMDA]).

The RHSC is an organization that promotes the regulatory coordination of medical products in the APEC region through training that utilizes existing international guidelines, etc. The PMDA is the leading country in multiple areas and provides training as PMDA-ATC.

In addition to the past activities, we had policy dialogue at this meeting to have in-depth discussions on various issues in the area from a policy perspective. There are three challenges: implementation of ICH E17 guidelines (global clinical trials), measures against intractable diseases (development of orphan products), and promotion of reliance. The results of the dialogue were organized into the framework of the existing RHSC or whether other measures would be considered, which shows the direction of the future meeting.

Joint statement upon 10 years since memorandum conclusion with the Ministry of Food and Drug Safety (MFDS) of Korea

The MHLW/PMDA and MFDS announced on July 25 a "joint statement" to confirm the continued cooperation of both countries in the future in commemoration of the 10th anniversary of the conclusion of a memorandum of cooperation * (link to the joint statement).

Japan and Korea have promoted regulatory harmonization activities for 10 years. The joint statement confirms that both countries will continue to share their knowledge and continue to collaborate.

On the previous day, a signing ceremony for the confidentiality arrangement in the Medical Device Single Audit Program (MDSAP) was held. Based on this, our further efforts to improve the efficiency of inspection of medical devices will be enhanced in Japan and South Korea.

At a bilateral meeting with MFDS

At the MDSAP signing ceremony

PMDA-ATC Review of Cell therapy and Gene therapy products Seminar 2025 for South-East Asian countries

"The PMDA-ATC Review of Cell therapy and Gene therapy products Seminar 2025 for South-East Asian countries" took place in Tokyo from July 15 to 17. In this seminar, each regulatory authority reviewer in Southeast Asia learned about regulations and review points for the review of cell therapy products and gene therapy products in a case study using concrete examples. There were a lot of questions and the seminar was very exciting.

We released reports on this seminar and the seminars held since June this fiscal year.
Please take a look at the seminar on the day and impressions of the participants from the link below.
List of seminars | Pharmaceuticals and Medical Devices Agency (pmda.go.jp)

* "MEMORANDUM OF COOPERATION between the Ministry of Food and Drug Safety of the Republic of Korea and the Ministry of Health, Labour and Welfare of Japan on Medical Products Regulatory Dialogue and Cooperation Framework": The memorandum states that Japan and Korea are going to build up efforts for regulatory -harmonization.

Special Information

Interview

PMDA A to Z: Step Inside

This is a new section where the PMDA Staff directly introduce the PMDA to you. The first-time speakers are three from Public Relations Division: Esaki-san (Director), Shirotani-san, and Asada-san. They are key members of the secretariat responsible for editing PMDA Updates. The topic is about the large-scale renewal made in this spring.

Part 1: Behind the Major Renewal of the PMDA Updates
- Public Relations Division -

The point is outreach

Esaki: One of the major points in renewal is outreach. Since this is a publication that is read by many people overseas as well, mainly by the Asian regulatory authorities, the Public Relations Division and the Office of International Programs (at that time) worked together to put more effort into the sending better information.

In order to clarify the new target image, we also interviewed with various people who were familiar with venture capital and overseas pharmaceutical companies. To be honest, I was always surprised because I found that the pharmaceutical administration and R&D environment in Japan was very poorly known. I think the impact affects the way of editing this newsletter.

Another point is that, based on the idea of trying to know each other more about a wide range of the PMDA's operations, we placed PR coordinators in all divisions. This made it easier for us to gather so-called "news." As they kindly cooperated in the preparation of articles, we have successfully written a variety of articles.

We hope to help lower the bar for R&D in Japan.

Shirotani: In the US where most of the new drugs have been developed in recent years, the greater presence of the PMDA will have a positive impact not only in Japan but also in Asian countries. I will be glad if PMDA Updates help lower the bar for R&D in Japan.

Asada: Among the three speakers, I was the last to join the Public Relations Division and am involved in editing PMDA Updates. It is my first experience to think of “ideal readers” concretely, not vaguely offering information, while editing articles. I always learn something from it.

Shirotani: After this renewal effort, I have recognized again the importance of in-depth thinking of what we want to deliver to whom. These days, I keep targets in all public relations matters in mind, not limited to PMDA Updates. The choice of words will change considerably.

Esaki: I remember we struggled a lot to decide a title. We select soft expressions whenever possible, avoiding formal wording. However, translation work into the English edition is still difficult.

Shirotani: If sentences are translated directly based on the Japanese edition, similar English expressions appear. We carefully selected each word in preparing the Japanese manuscript, though.

Asada: Even though we try to change, we seem to have been back to the conventional PMDA (lol).

Esaki: The second round of renewal, the edition for Summer 2025, was better arranged than the edition for Spring. We would like to get many comments from readers who have read the English edition.

- To Readers -

As members of the Office of International Strategy and Planning worked hard to additionally distribute to new companies and organizations, we have more and more viewers.
I hope to receive opinions like “this section is great” and “I want more information on that” from many readers and edit the newsletter accordingly.

Information 2

English Translations of Review Reports

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

Drugs

Review Reports: Drugs

Brand Name	Non-Proprietary Name	Indication	Posting Date (Approval Date)
Tasfygo Tablets 35 mg	Tasurgratinib Succinate*	Unresectable FGFR2 fusion gene-positive biliary tract cancer that has progressed after cancer chemotherapy.	August 14, 2025 (September 24, 2024)
Rozebalamin for Injection 25 mg	Mecobalamin*	Slowing the progression of functional impairment in patients with amyotrophic lateral sclerosis (ALS).	September 22, 2025 (September 24, 2024)
Datroway for Intravenous Drip Infusion 100 mg	Datopotamab Deruxtecan (Genetical Recombination)	Hormone receptor-positive and human epidermal growth factor receptor 2 (HER2)-negative unresectable or recurrent breast cancer in patients who have previously been treated with chemotherapy.	September 29, 2025 (December 27, 2024)
Tauvid Injection	Flortaucipir (^{18}F)	The support of selection of patients with mild cognitive impairment and mild dementia due to Alzheimer's disease, for whom donanemab (genetical recombination) is indicated.	October 7, 2025 (December 27, 2024)
Kostaive Intramuscular Injection	Coronavirus (SARS-CoV-2) RNA Vaccine	The prevention of disease caused by SARS-CoV-2 infection (COVID-19).	October 7, 2025 (September 13, 2024)

*Japanese Accepted Name (modified INN)

Medical Devices

Review Reports: Medical Devices

Brand Name	Term Name	Intended Use	Posting Date (Approval Date)
Aveir LP	Implantable leadless cardiac pacemaker	An implantable electrode integrated cardiac pacemaker is intended to be percutaneously placed in the right heart using a catheter.	August 26, 2025 (September 27, 2024)
GORE EXCLUDER Thoracoabdominal Branch Endoprosthesis	Aortic stent graft	An aortic stent graft system is used for the treatment of patients with thoracoabdominal aortic aneurysms and pararenal abdominal aortic aneurysms who are difficult to treat with conventional surgical repair.	September 2, 2025 (November 22, 2024)

English Translations of Notifications and Administrative Notices

We introduce the latest information on the English versions the notifications and administrative notices published on the PMDA website.

Document Type & No.	Title	Summary	Posting Date (Issue Date)
Administrative Notice	Questions and Answers (Q&A) on Basic Principles of Biological Safety Evaluation Required for Application for Marketing Approval of Medical Devices EN/JP	Questions and Answers (Q&A) on Basic Principles of Biological Safety Evaluation Required for Application for Marketing Approval of Medical Devices	July 11, 2025 (March 11, 2025)
Others	Review Points of Biological Safety Evaluation for Market Approval of Medical Devices EN/JP	In this document, the review points show about the biological safety evaluation among the evaluations required for medical device regulatory applications in Japan are organized and published together with the information of international standard ISO 10993-1 or JIS T 0993-1.	July 11, 2025 (June 4, 2025)
PSEHB/ELD Notification No. 0407-1	Guidance on Clinical Evaluation of Travelers' Vaccines, etc. EN/JP	This guidance summarizes the principles of clinical evaluation of travelers' vaccines, etc. and points to consider for their smooth development.	September 24,2025 (April 7, 2016)
Administrative Notice	Rationalization of descriptions in the specification column in approval application forms for prescription drugs EN/JP	Examples of rationalized descriptions for the specifications of residual solvents, test for preparations, ICP atomic emission spectrometry/mass spectrometry, identification test (infrared spectrophotometry), identification test (ultraviolet-visible spectrophotometry), and identification test (qualitative test) are summarized.	October 6, 2025 (January 28, 2022)
Administrative Notice	Notes on the Principles on Bioequivalence Studies of Oral Solid Dosage Forms with Manufacturing Process Changes EN/JP	This material on quality-related studies to be conducted for the change control of post-approval partial changes in the manufacturing process of oral solid immediate-release, enteric-coated, or extended-release formulations is intended to assure bioequivalence between the formulations before and after the manufacturing process change.	October 6, 2025 (April 19, 2013)
PFSB/ELD Notification No. 0616-1	Handling of Prescription Drugs Having Different Crystalline Forms, etc. EN/JP	The points to consider when applying for approval of drugs containing drug substances having different crystalline forms or hydrates/anhydrides are summarized.	October 6, 2025 (June 16, 2011)
PSEHB/PED Notification No. 0309-1 PSEHB/CND Notification No. 0309-1	Handling of Changes to Approved Product Information Pertaining to the Quality of Drugs EN/JP	Rules were established for the purposes of ensuring appropriate changes to approved product information associated with changes to the manufacturing process, etc. of drugs and promoting smooth changes to the manufacturing process, etc.	October 6, 2025 (March 9, 2018)

PMDA Updates © 2009-2025 PMDA

Subscribe

If you'd like to start or cancel your email subscription to PMDA Updates, please contact us at the following email address.

E-mail:pmda_update@pmda.go.jp

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

For Industry - for development in Japan: https://www.pmda.go.jp/english/int-activities/industry/0001.html

Contact: https://www.pmda.go.jp/english/contact/0001.html