PMDA Updates

2025 Spring

Index

Highlights

Welcome to the “Consultation Service for Development in Japan”!

Do you know that the PMDA office was established in Washington, D.C., USA in November 2024? What are the pharmaceutical regulations related to drug and medical device development in Japan? If you are interested, please contact us!

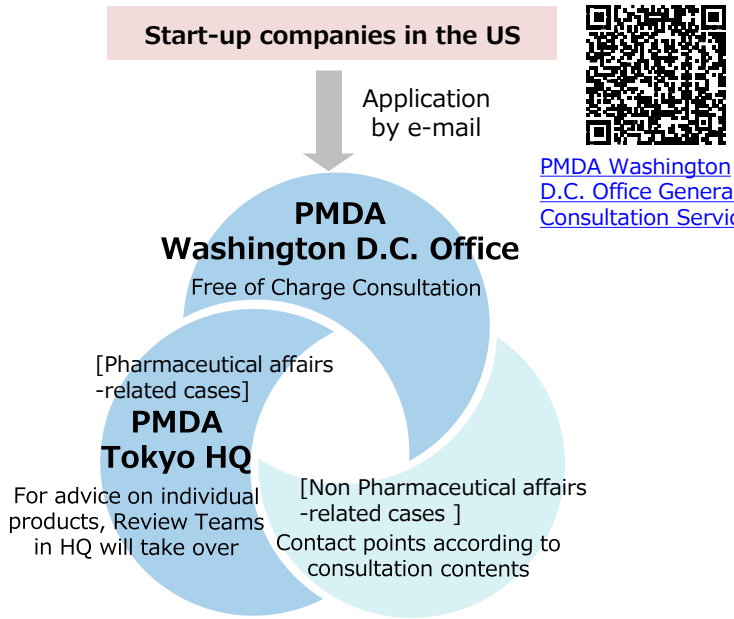
Roles of the PMDA Washington D.C. Office

In recent years, the developers of innovative medical products have been shifted to start-ups and venture companies mainly in the US. In March 2025, PMDA Washington D.C. office started a free general consultation on pharmaceutical affairs to introduce the characteristics of the Japanese regulatory system so that start-ups and venture companies in the US would be more familiar with the development in Japan.

For example, we will help you when you need to learn the procedures for development in Japan. We cooperate with the Tokyo Headquarters regarding the consultation on the development of individual medical products such as clinical development, when necessary.

For the start of development in Japan, it is expected to include not only pharmaceutical regulations but also the contents of consultation on business development. Therefore, we will give you an opportunity for beneficial consultation as much as possible with the cooperation of related government organizations, such as the Japan External Trade Organization (JETRO).

Image of consultation in the PMDA Washington D.C. Office



- General consultations are available in English.
- Consultation materials and explanations in Japanese are not required.
- The consultation is available between 10:00 a.m. and 5:00 p.m. EST.
- It is held in the PMDA Washington D.C. Office (face to face) or online.
- Since the main purpose is to introduce the characteristics of the Japanese regulatory system, we will not keep a record of consultation.

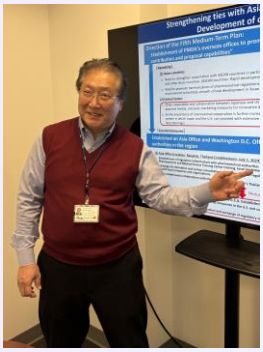
We will handle it.

The PMDA Washington D.C. Office in charge of general consultation is currently operated by three members.

Akihiro ISHIGURO
(Head)

Since 2004, I have been working at PMDA on post-marketing safety measures, reviews of new drugs, and international regulatory harmonization.

The PMDA Washington, D.C. office serves as a help desk for development in Japan and I will strive to provide general pharmaceutical affairs consultation so that applicants will be “glad to have the PMDA Washington, D.C. office”.



Koki FUKUHARA
(Senior Technical Officer)

I have spent my career with a Japanese pharmaceutical company and have worked in the US for over 25 years. During that time, I have planned, executed, and managed clinical development and business development in the US, as well as clinical research with US government research institutes and several university medical schools.

Based on my experience, I support consultation services from the perspective of the development side.

Hiroyuki OKAYAMA
(Lead)

In 2011, I started to be engaged in operations such as finance, relief services for adverse health effects, and review fees at PMDA. At the PMDA Washington D.C. Office, I am in charge of general affairs such as procurement of goods and accounting operations.

This is the first time I am working in an overseas office, but I am going to set up the proper management system through daily communications with the PMDA Tokyo Headquarters.

For the future

The PMDA Washington D.C. Office strives to network to understand the characteristics of the healthcare industry in each state of the US in order to establish a system that allows US start-ups and venture companies to easily consult with PMDA.

To date, we have had an opportunity to meet and explain the role of the PMDA Washington D.C. Office and consultation services with the representative of AdvaMed Global Office, the largest medical device industry organization in the US, and members of the U.S.-Japan Business Council of U.S. Chamber of Commerce, the largest business network organization in the US, in addition to the Japanese domestic pharmaceutical and medical device industrial organizations.

In order to improve patient access to excellent medical products developed around the world, PMDA is going to make international contributions and strengthen its proposal capabilities as one of the three major regulatory authorities.

At the AdvaMed Global Office

At the U.S. Chamber of Commerce

News

International harmonization activities for medical device regulations

We chair the IMDRF in 2025!

IMDRF (International Medical Device Regulators Forum)

What is IMDRF?

This is an international forum in which regulatory authorities in various countries cooperate to create common guidance on regulations of medical devices and in vitro diagnostics from scientific and technical viewpoints. It aims to make it possible to deliver innovative and ground-breaking medical devices to patients faster and to take appropriate safety measures, etc.

Japan is one of the founding member countries of the IMDRF Management Committee and actively participates in various activities *1.

Japan is the chair of the IMDRF in 2025. PMDA, together with the Ministry of Health, Labour and Welfare, actively lead discussions on the direction of IMDRF activities (formulation of the 5-year strategic plan) , and the management of the working groups' activities and outcomes.

*1 Adverse Event Terminology, Quality Management System, Good Regulatory Review Practices, Regulated Product Submission, Personalized Medical Devices, clinical evidence for IVD, Software as a Medical Device and AI-related activities

Recent results (issuance/update of guidance)

AI-related activities

IMDRF have published the guiding principle of Good Machine Learning Practice (GMLP) compiling the major principles common to all countries that may be important for the development and use of medical devices using machine learning and post-marketing.

Artificial Intelligence/Machine Learning-enabled

Adverse Event Terminology

In order to ensure that adverse events and malfunctions are reported with common terms in countries worldwide, a glossary of adverse event-related terms and codes was developed, and it is reviewed and updated every year. In addition, the guidance document has been prepared so that appropriate terms are used when reporting.

Adverse Event Terminology

IMDRF 27th Session

- IMDRF 27th Session took place from March 10 to 14 in Tokyo (United Nations University).
- On Day 1 and Day 2, the session was open to the public and attended by approximately 650 attendees participated in the public meetings. From Day 3 onward, the MC meetings were held with member countries, the Regional Harmonization Initiatives (RHI), the industry, etc.

Close cooperation with stakeholders in the industry, etc.

On March 10, the IMDRF-Industry Joint Workshop was held, open to the public, with participants from regulatory authorities and the industry. We actively discussed the current issues and future direction related to the IMDRF 5-Year Strategy Plan from 2026 to 2030 and the reliance *2.

*2 The act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information, in reaching its own decision. (WHO Expert Committee on Specifications for Pharmaceutical Preparations, Fifty-fifth Report, Annex 10)

- For the details, see [IMDRF website link].

The next session in September is scheduled to be held in "Sapporo" from September 15 to 19.
The session on Days 1 and 2 is open to the public. We are looking forward to your participation!

Hope to see you in **Winter issue** for the follow-up!

PMDA promotes Regulatory Science (RS)

PMDA has been focusing on the promotion of RS to enhance the quality of three operations (review/safety/relief).

Designation as a research institution

On December 6, 2024, the Minister of Education, Culture, Sports, Science and Technology designated the Office of Regulatory Science Research, PMDA as a research institution for the Grants-in-Aid for Scientific Research (KAKENHI). From now on, we will actively conduct research utilizing the KAKENHI.

PMDA has published academic papers

PMDA members actively publish the results of RS research, etc. in peer-reviewed scientific journals. 33 English-language articles were published in 2022, 32 in 2023, and 47 in 2024. These articles are listed and released on the PMDA website. If you are interested in PMDA's RS research, please take a look at it.

Articles English

The Regulatory Science Activity Report was released for FY2023

In December 2024, PMDA released a report providing a summary of RS-related activity results for FY2023.

Regulatory Science Activity Report
Japanese Digital Book/English Digital Book

Anyone other than PMDA staff can easily understand PMDA's RS-related efforts. PMDA focuses on the promotion of RS through various activities including the following:

- Collaboration with external institutions such as universities and research institutions
- Promotion of scientific review
- Distribution of RS information
- Publication of English academic papers

We hope that it will be a useful source of information for you in understanding the RS activities of PMDA.

Topics

What is Early consideration?

Early Consideration is reference information and point of view at that time for promoting the practical application of new technologies and other innovations and the development of innovative pharmaceuticals, etc., although scientific knowledge and information have not yet been fully accumulated.

We hope that all those planning development will take into account the Early Consideration and consult with PMDA about development and evaluation of drugs as well as practical application of innovative techniques, resulting in successful, efficient and effective development.

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

See the details here English

Introduction of early consideration (1)

Points to Consider for the Design of Clinical Trials to Assess the Effects of Psychotropic Drugs on Driving Performance

Backgrounds

Many package inserts of psychotropic drugs approved in Japan stipulate that patients should not be engaged in the operation of machinery involving risks such as driving a car. However, recent psychotropic drugs have been shown to reduce sedative side effects making them more tolerable. Therefore, we consider that investigating the effect of each therapeutic drug on driving performance and appropriately calling attention according to the results of the investigation will not only secure the safety for patients but also contribute to the improvement of opportunities to provide appropriate therapeutic drugs to patients.

Based on this, the Ministry of Health, Labour and Welfare issued “the Guideline for evaluating the effects of psychotropic drugs on motor vehicle driving performance” in January 2023.

This Early Consideration supplements the considerations for developers in planning clinical trials to evaluate the effects of psychotropic drugs on driving performance.

Points to consider

- For consideration of the effect on driving performance, the evaluation of “persistence of clinically meaningful impairment” is important.
- For evaluation of “persistence of clinically meaningful impairment,” it is recommended to investigate the temporal relationship of the onset, duration, and tolerance for "adverse events affecting driving," which have been defined based on the pharmacokinetics, pharmacological characteristics, etc. of an investigational drug.
- When planning and conducting a driving study, it is important to evaluate the impact on driving performance and its durability.

See the details here

English

Introduction of early consideration (2)

Statistical Considerations When Planning Phase I Clinical Trials in Oncology - From the Safety Perspective

In drug development, a survey (hereinafter referred to as "30-day-CTN Review") is to be conducted to prevent healthcare and hygiene hazards in clinical trial notifications when the study drug is administered to humans for the first time in Japan.

For oncology drugs, the “Check List for 30-day-CTN Review on an Initial Clinical Trial Notification (Oncology Drugs) Japanese / English” has been made public to reduce the burden on PMDA of preparing inquiries and on the sponsor of preparing responses to those inquiries. This Early Consideration specifically introduces the points to consider, etc. when adopting dose-escalation designs based on the statistical considerations for the purpose of further reducing the aforementioned burdens.

Written with ChatGPT

Overview

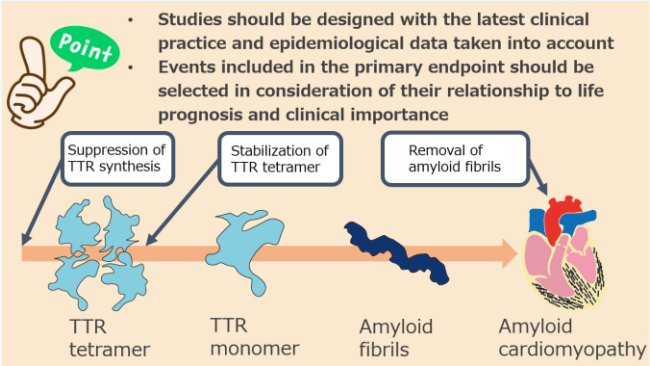
- Basic principles of evaluation of dose-escalation designs in 30-day-CTN review
- Points for the operating characteristics and contents in evaluation that require an examination and explanation in evaluating the dose-escalation design and the operating characteristics

See the details here English

Introduction of early consideration (3)

Points to consider in the clinical development of drugs for transthyretin amyloid cardiomyopathy

Transthyretin amyloid cardiomyopathy (ATTR-CM) is a type of systemic amyloidosis, a designated intractable disease, characterized by the deposition of transthyretin (TTR)-derived amyloid in the myocardium, leading to functional impairment. Today’s advances in imaging diagnostic techniques and changes in diagnostic criteria have led to an increase in more-early diagnosed cases of ATTR-CM. Accordingly, consideration of development strategies based on changes in diagnostic systems and a decreased morbidity rate due to early treatment intervention in clinical development of ATTR-CM therapeutic drugs. Based on the above-mentioned conditions, the following is a summary of the items to consider before planning clinical trials aimed at the development of therapeutic drugs for ATTR-CM.

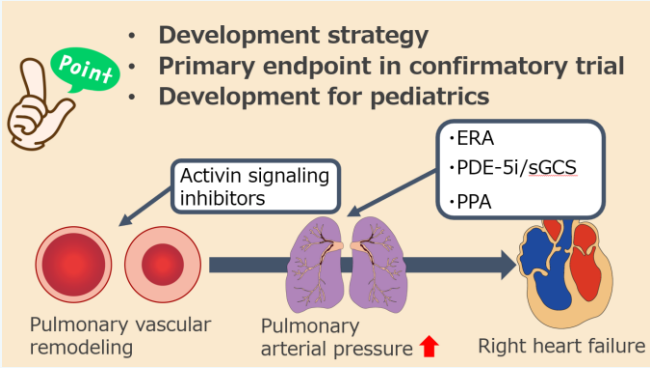


See the details here English

Introduction of early consideration (4)

Consideration in the development of drugs for pulmonary arterial hypertension

Pulmonary arterial hypertension (PAH) is a serious disease resulting in right heart failure and even death due to increased pulmonary arterial pressure and pulmonary vascular resistance caused by constriction and remodeling of pulmonary vessels. So far, several PAH therapeutic drugs have been approved in Japan while the development of other PAH therapeutic drugs is underway as medical needs remain for patients whose prognosis has not been sufficiently improved by these treatments and for pediatric patients. Based on the above-mentioned conditions, the following is a summary of the items to consider before planning clinical trials aimed at the development of therapeutic drugs for PAH.



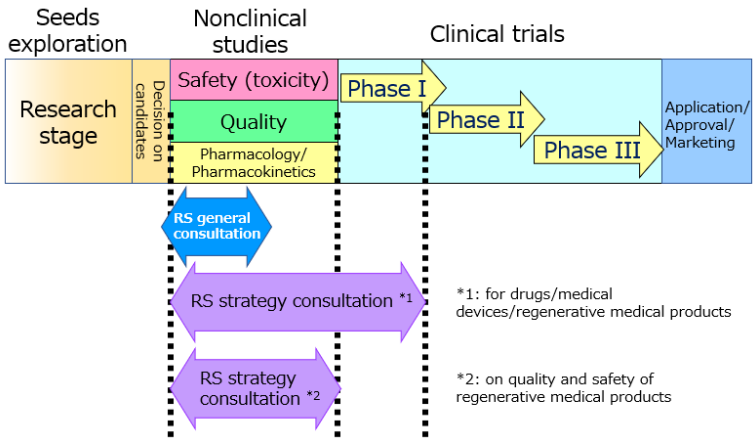
See the details here English

Series

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

- Volume 1: Utilization of the Regulatory Science (RS) General Consultation -

RS general consultation/strategy consultation



PMDA provides "consultation services" to scientifically discuss and provide advice with developers on plans for nonclinical studies and clinical trials in the development stage as well as on other measures to ensure the quality of products.

As part of the services, PMDA has RS general consultations/strategy consultations as consultation services for academia and start-ups/venture companies with no development experience or inexperienced based on the PMD Act.

This time, we introduce what you can consult at RS general consultation and also show you where the application should be filed.

What is RS general consultation?

In the RS general consultation, we will explain the related regulations and reference guidelines etc. from the development of medical products to the acquisition of approval in Japan, and exchange opinions regarding general questions and concerns that the applicant has about regulations. For the appropriateness of individual specific development plans, etc., we will introduce you of RS strategy consultation.

What are the advantages of RS general consultation?

RS general consultation is aimed to help academia, start-ups, and venture companies understand to some extent the actual status of regulations that seems tough to handle. We believe that consultation will make the developer's own image of the development strategy more specific, leading to efficient development strategy planning. In addition, the consultation can make it possible to increase the predictability of development such as the assumption of the timing of discussions with PMDA on individual specific development plans.

Furthermore, we consider that you can use the RS general consultation effectively to smoothly shift from the consultation at the PMDA Washington D.C. Office (see page 2) to discussions on individual specific development planning at Tokyo Headquarters.

How to make an effective consultation?

If you (applicant) explain the characteristics of the product being developed, the intended clinical positioning, and background information such as the development stage of the product, we can narrow the guidelines down to be referred to and give you more useful information.

In addition, at the advanced stage of development, we may have concrete individual discussions on the sufficiency of endpoints and concerns about the study plan for evaluation at the Review Division of the developed product. At that time, we would like to share the above-mentioned background information within PMDA, leading to the smooth consultation process.

How to apply for consultation?

The application for RS general consultation is accepted by e-mail. Please sent the application form and consultation materials by e-mail.

For details, please see here and use RS general consultation effectively.

RS General Consultation

RS general consultation

Target	Academia, start-ups and venture companies
Purpose	Based on the contents of research, seeds, etc., deepen the understanding of the general flow for acquisition of approval, points to consider, etc.
What you can consult	• Exchange of opinions on general questions and concerns about the regulations of the applicant, related notifications • Details of RS strategy consultation project, flow of RS strategy consultation, scope of consultation
Time required	About 20 minutes per consultation
Expenses	No consultation fees required (Since the main purpose is to introduce the characteristics of the Japanese regulatory system, we do not keep a record of consultation.)

In the next Summer issue, we will introduce RS consultations at the Kansai Branch.

Information

Focus on activities of Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC)!

The PMDA-ATC was established in 2016. Since then, we have provided training for the purpose of cooperating with overseas regulators to establish the infrastructure for regulations on medical products. Training is categorized by theme, and various seminars take place for overseas regulators throughout the year. See the Seminar Schedule for more information. The information to recruit participants will also be linked from this page, so please be sure to apply if you are a member of the regulatory authority and interested in this.

PMDA-ATC also provides online Training Materials on regulatory affairs, with general, easy-to understand content on the Pmda Channel (YouTube videos) for the public, and more expertized content on the e-learning course dedicated to overseas regulators. Contents are updated as needed. Please check them on a regular basis.

PMDA will promote the enhancement and harmonization of regulatory standards centered on Asia through the efforts of ATC, and further strengthen the cooperation system.

PMDA-ATC
PMDA Asia Training Center for pharmaceuticals and medical devices regulatory affairs

PMDA-ATC in numbers

Total number of seminars held by PMDA-ATC (FY2016-2024)

120 times

Total number of Pmda Channel (YouTube) videos released by PMDA-ATC

48 videos

Total number of e-learning course videos for overseas regulatory authorities released by PMDA-ATC

58 videos

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)
Spikevax Intramusclar Injection	Coronavirus (SARS-CoV-2) RNA Vaccine (Active ingredients: (a) Elasomeran, (b) Elasomeran and Imelasomeran, (c) Elasomeran and Davesomeran, (d) Andusomeran*	Prevention of disease caused by SARS-CoV-2 infection (COVID-19).	March 10, 2025 (October 24, 2023)
(a) Dupixent 300 mg Syringe for S.C. Injection (b) Dupixent 300 mg Pen for S.C. Injection (c) Dupixent 200 mg Syringe for S.C. Injection	Dupilumab (Genetical Recombination)*	Chronic spontaneous urticaria in patients who have not responded sufficiently to conventional treatments.	March 10, 2025 (February 9, 2024)
Awiqli Injection FlexTouch 300 Units, Awiqli Injection FlexTouch 700 Units	Insulin Icodec (Genetical Recombination)*	Diabetes mellitus in cases where insulin therapy is indicated.	April 4, 2025 (June 24, 2024)
Jaypirca Tablets 50 mg, Jaypirca Tablets 100 mg	Pirtobrutinib*	Relapsed or refractory mantle cell lymphoma with resistance or intolerance to other BTK inhibitors.	May 8, 2025 (June 24, 2024)

*Japanese Accepted Name (modified INN)

Medical Devices

Review Reports: Medical Devices

Brand Name	Term Name	Intended Use	Posting Date (Approval Date)
SENTINEL Cerebral Protection System	Central circulatory catheter for trapping embolus	A distal embolic protection device designed to temporarily place filters at the aortic bifurcation (brachiocephalic artery and left common carotid artery) for capturing and removing substances causing embolization during transcatheter aortic valve replacement (TAVR).	April 4, 2025 (July 24, 2024)

Regenerative Medical Products

Review Reports: Regenerative Medical Products

Brand Name	Non-proprietary Name	Indication or Performance	Posting Date (Approval Date)
Breyanzi Suspension for Intravenous Infusion	Lisocabtagene maraleucel	The following types of relapsed or refractory large B-cell lymphoma: • Diffuse large B-cell lymphoma, primary mediastinal large B-cell lymphoma, transformed indolent non-Hodgkin lymphoma, high-grade B-cell lymphoma Relapsed or refractory follicular lymphoma Breyanzi, however, is intended only for patients with no history of the transfusion of chimeric antigen receptor-positive T cells targeting CD19 antigen	April 4, 2025 (August 16, 2024)
Akuugo Suspension for Intracranial Implantation (Conditional and time-limited approval)	Vandefitemcel	The product is intended to be used for improvement of chronic motor paresis associated with traumatic brain injury by transplanting into the brain by stereotactic brain surgery.	April 28, 2025 (July 31, 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)
PSB/PED Notification No. 0718-1 PSB/PSD Notification No. 0718-1	Partial Revision of the "Procedures for Developing Post-marketing Study Plans for Drugs" (note) The contents of the Administrative Notice (August 15, 2024) have been reflected. EN/JP1,2	Taking into consideration the recent change in the drug discovery environment, international harmonization and the past achievement in the post-marketing safety measures in Japan, a notification of "Procedures for Developing Post-marketing Study Plans for Drugs" issued by the Ministry of Health, Labour and Welfare has been revised.	March 12, 2025 (July 18, 2024)
PSEHB/PED Notification No. 1212-5	Handling of Elemental Impurities in Behind-the-counter/Over-the-counter Drugs EN/JP	Handling policy on elemental impurities in behind-the-counter drugs and over-the-counter drugs are summarized in this notification. In addition to basic views such as scope and timing of application, handling of the products approved before the ministerial announcement of Supplement I to the 18th edition of the Japanese Pharmacopoeia and the products for which a new approval application will be submitted after the announcement of Supplement I are shown in this notification.	April 9, 2025 (December 12, 2022)

Document Type & No.	Title	Summary	Posting Date (Issue Date)
Administrative Notice	Question and Answer (Q&A) about Handling of Elemental Impurities EN/JP	The topic specified in the notification issued by the Director of Pharmaceutical Evaluation Division of the Pharmaceutical Safety and Environmental Health Bureau, MHLW (PSEHB/PED Notification No. 1228-7, December 28, 2020) and the Director of Pharmaceutical Evaluation Division of the Pharmaceutical Safety and Environmental Health Bureau, MHLW (PSEHB/PED Notification No. 1212-5, December 12, 2022) are summarized in this notification, together with newly adding the views underlying quasi-drugs, etc.	April 9, 2025 (June 25, 2024)
Administrative Notice	Partial revision of "Guidance on Drug-Agnostic Companion Diagnostics" EN/JP	The Pharmaceuticals and Medical Devices Agency has recently compiled the points to consider in compliance with the Ministerial Order on Quality Management System (QMS) for Medical Devices and In Vitro Diagnostics (Order of MHLW No. 169 of 2004) in the development of drug-agnostic companion diagnostics, etc. and has partially revised the Guidance.	April 14, 2025 (May 22, 2024)
PSB/PED Notification No. 0319-1 PSB/MDED Notification No. 0319-1	Revision of "Points to consider for application for approval of drugs to be administered based on specific biomarkers that were developed by investigator-initiated clinical trials in patients with rare cancer" EN/JP	We have recently organized policy on the approval application when in vitro diagnostics or medical devices that have been approved for other indications are used as a clinical trial assay to identify subjects in the investigator-initiated clinical trial in patients with rare cancer.	April 14, 2025 (March 19, 2024)
PSB/PED Notification No. 1004-4 PSB/PSD Notification No. 1004-1	Points to Consider When Registry Data are utilized for Partial Change Approval Applications or Revision of Electronic Package Insert for Prescription Drugs EN/JP	In order to further promote the utilization of real-world data, the points to consider when registry data are utilized in procedures for partial change approval applications or revision of the electronic package insert for prescription drugs has been compiled.	April 15, 2025 (October 4, 2024)
PMDA/CPE Notification No. 1618 PMDA/CRS Notification No. 15	Initiatives to Promote Pediatric Drug Development EN/JP	As its initiatives to promote pediatric drug development, this document outlines PMDA's basic principles on pediatric drug development and important considerations to be taken into account during clinical trial consultations for adult drug development.	April 18, 2025 (March 21, 2025)
PMSB/ELD Notification No. 1023-2	Partial Revision of "Handling of Conditional Approval of Drugs" EN/JP	Based on the discussions at the "Review Committee on Regulatory Affairs to Strengthen Drug Discovery and Development/Ensure Stable Supply," this notification clarified the target products, requirements, and operational procedures for which the use of the conditional approval system should be considered.	April 30, 2025 (October 23, 2024)
PMSB/ELD Notification No. 1023-3	Basic Principles on Japanese Clinical Trial Data for Drugs for Rare Diseases, etc., for Which Confirmatory Clinical Trials Have Been Conducted Only Overseas EN/JP	This notification elucidates the cases where it is considered possible to file an application for approval without clinical trial result in Japanese patients, while ensuring the efficacy and safety of the drug in Japanese patients.	April 30, 2025 (October 23, 2024)

Upcoming Events

Booth exhibition and individual consultation at the 31st Annual Meeting of Japan Society of Gene and Cell Therapy

Booth exhibition of PMDA and individual consultation will be conducted at the 31st Annual Meeting of Japan Society of Gene and Cell Therapy (July 23-25 at Hotel Gajoen Tokyo). For persons who may develop regenerative medical products in Japan or those who may consult with PMDA in the future, the contents and procedures of the consultation service provided by PMDA will be introduced, and also opinions will be exchanged within the general range regarding the contents of consultation and arrangement of points at issue for efficient consultation on developed products (The details of individual consultation will be released on the PMDA website in advance). We would appreciate it if you could use it as an opportunity to participate in academic conferences to help future product development.

See you at the DIA 2025 Global Annual Meeting, and the BIO International Convention 2025

PMDA will be participating in the DIA 2025 Global Annual Meeting (June 15-19, Washington D.C.) and the BIO International Convention 2025 (June 16-19, Boston) with attendees including Yasuhiro FUJIWARA, Chief Executive, Akihiro ISHIGURO, Head of PMDA Washington D.C. Office.

To foster the development of innovative medical products in Japan, especially those originating in the US, we have organized a session program hosted by Japan, along with individual consultations with PMDA staff to answer your question. We will provide clear, in-person introduction to Japanese regulations and the advantages of developing medical products in Japan. If you plan to participate in either event, we encourage you to participate in our sessions and consultations.

Please feel free to share this opportunities with anyone you know who might be interested in medical product development in Japan.

PMDA

Please visit our booth!

DIA 2025 Global Annual Meeting

◆ Application for individual consultation
DIA 2025 Global Annual Meeting

◆ PMDA Virtual Booth
DIA 2025 Global Annual Meeting
PMDA Virtual Booth

BIO International Convention 2025

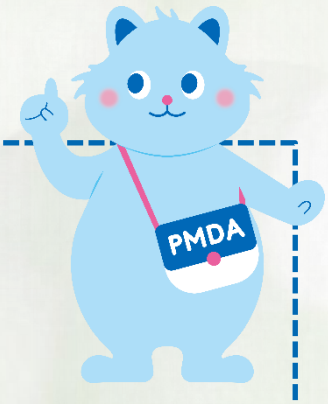
◆ BIO website: BIO International Convention 2025

Special information

We will introduce PiMTTO, a newcomer to PMDA!

Nice to meet you! I am PiMTTO.
I've joined PMDA as it celebrated its 20th anniversary.
I would like to deliver various information to you on PMDA Updates from now on. Thanks!

I was named "PiMTTO" with "PM" of PMDA and "together" of our Purpose, "Making everyone's lives brighter together," combined.
I would like to help create a world where every one can lead healthy lives, working together with everyone at PMDA and around the world.



PROFILE

Birthday	April 1 (Date of establishment of PMDA; date on which the PMDA's Purpose was officially announced)
Gender	None
Character	Serious, honest, and willing to take on challenges. Well-informed and highly dependable.
Hobbies	Collecting information about drugs and medical devices, storing those information right away in the pochette (i.e. a purse with a shoulder strap) that can keep as much as PiMTTO wants.
Special abilities	Retrieving those gathered information at the right time to make good use. Always being positive and thrilled to work on any matters.
Workplace	Based in the PMDA Offices (Tokyo, Kansai and Hokuriku areas in Japan, Washington D.C., Asia), PiMTTO is flying around Japan and the world.

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