CMC Strategy Forum Japan 2021
Welcome and Introductory Comments

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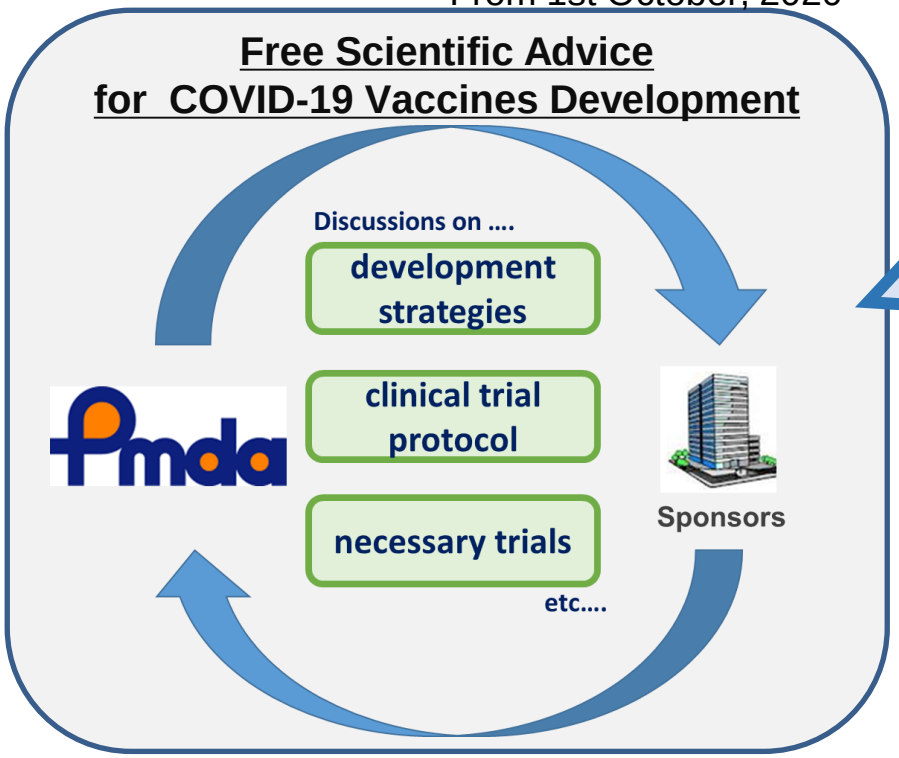
Disclaimer: The views and opinions expressed in this presentation are those of the presenter and should not necessarily represent the views and opinions of the PMDA.

PMDA'S ACTIONS AGAINST COVID-19 IN 2021

Close Interaction with Sponsors

Many different types of meetings with products developers such as…

From 1st October, 2020



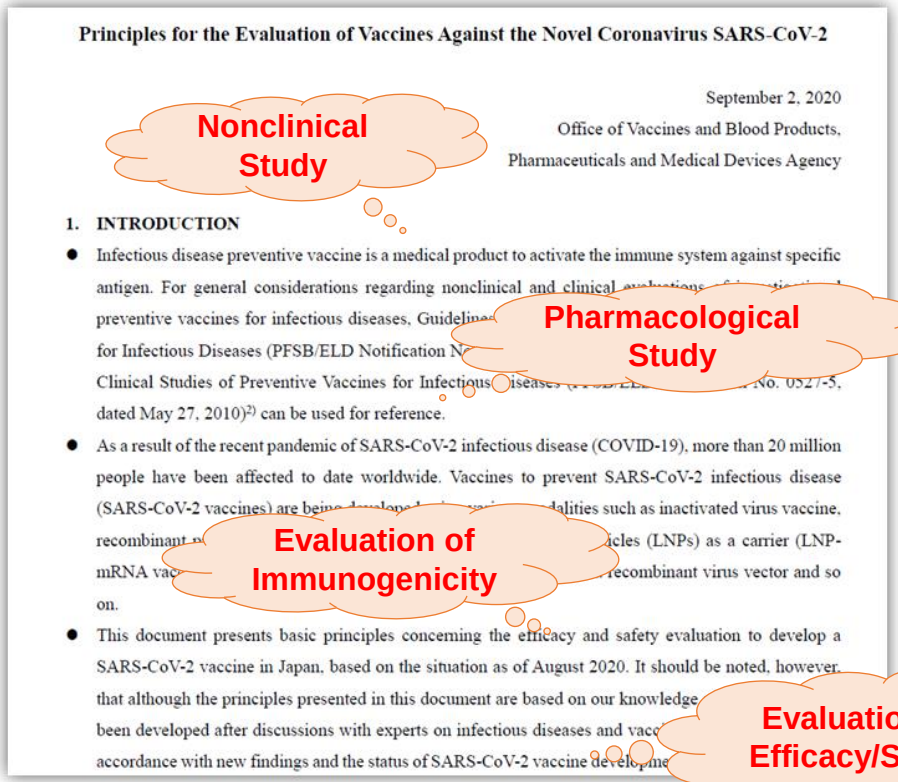
- **As many times as necessary**
- **No waiting time**
- **Free of charge**

Streamlined development for COVID-19 products

https://www.pmda.go.jp/review-services/f2f-pre/strategies/0010.html (Japanese only)

Publishing Principles on Evaluation of COVID-19 Vaccines

Published on 2 September, 2020



Principles for the Evaluation of Vaccines Against the Novel Coronavirus SARS-CoV-2

September 2, 2020
Office of Vaccines and Blood Products,
Pharmaceuticals and Medical Devices Agency

1. INTRODUCTION

- Infectious disease preventive vaccine is a medical product to activate the immune system against specific antigen. For general considerations regarding nonclinical and clinical evaluations of [illegible] preventive vaccines for infectious diseases, Guidelines [illegible] for Infectious Diseases (PFSB/ELD Notification No. [illegible] Clinical Studies of Preventive Vaccines for Infectious Diseases (PFSB/ELD Notification No. 0527-5, dated May 27, 2010)[2] can be used for reference.
- As a result of the recent pandemic of SARS-CoV-2 infectious disease (COVID-19), more than 20 million people have been affected to date worldwide. Vaccines to prevent SARS-CoV-2 infectious disease (SARS-CoV-2 vaccines) are being developed [illegible] modalities such as inactivated virus vaccine, recombinant [illegible] particles (LNPs) as a carrier (LNP-mRNA vaccine), [illegible] recombinant virus vector and so on.
- This document presents basic principles concerning the efficacy and safety evaluation to develop a SARS-CoV-2 vaccine in Japan, based on the situation as of August 2020. It should be noted, however, that although the principles presented in this document are based on our knowledge [illegible] been developed after discussions with experts on infectious diseases and vaccines [illegible] accordance with new findings and the status of SARS-CoV-2 vaccine development [illegible]

Nonclinical Study

Pharmacological Study

Evaluation of Immunogenicity

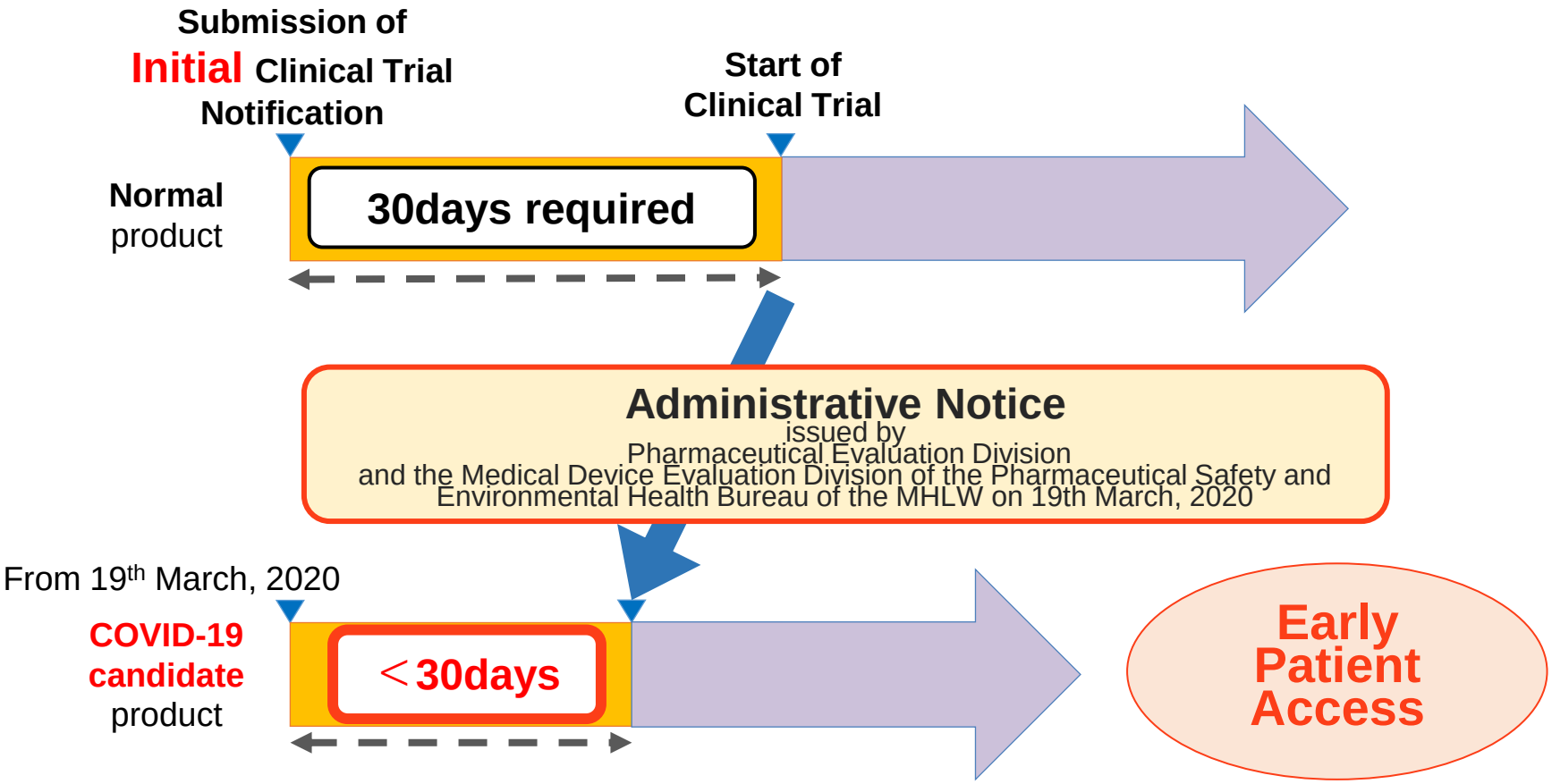
Evaluation of Efficacy/Safety

etc….

Strong tools to help vaccine developers advance their development faster

※ Guidance on the COVID-19 Vaccines (PMDA)
https://www.pmda.go.jp/files/00023 7021.pdf

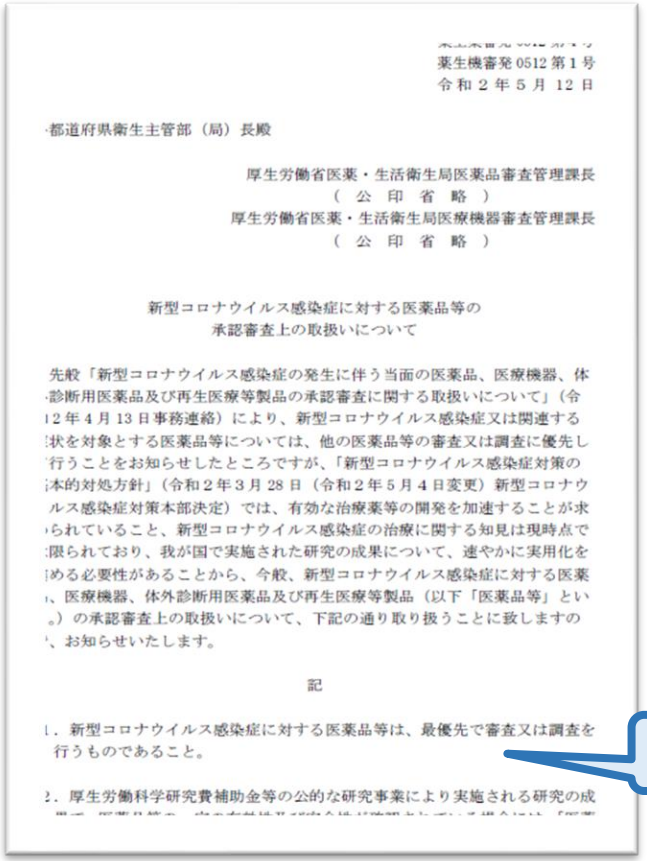
Allowing Quick Start of Clinical Trials



https://www.pmda.go.jp/english/int-activities/0001.pdf

Speedy Approvals of COVID-19 Products

Administrative Notice issued in 12 May, 2020※1



薬生機審発 0512 第 1 号
令和 2 年 5 月 12 日

都道府県衛生主管部（局）長殿

厚生労働省医薬・生活衛生局医薬品審査管理課長
（ 公 印 省 略 ）
厚生労働省医薬・生活衛生局医療機器審査管理課長
（ 公 印 省 略 ）

新型コロナウイルス感染症に対する医薬品等の
承認審査上の取扱いについて

先般「新型コロナウイルス感染症の発生に伴う当面の医薬品、医療機器、体
診断用医薬品及び再生医療等製品の承認審査に関する取扱いについて」（令
12 年 4 月 13 日事務連絡）により、新型コロナウイルス感染症又は関連する
状を対象とする医薬品等については、他の医薬品等の審査又は調査に優先し
行うことをお知らせしたところですが、「新型コロナウイルス感染症対策の
本的対処方針」（令和 2 年 3 月 28 日（令和 2 年 5 月 4 日変更）新型コロナウ
ルス感染症対策本部決定）では、有効な治療薬等の開発を加速することが求
られていること、新型コロナウイルス感染症の治療に関する知見は現時点で
限られており、我が国で実施された研究の成果について、速やかに実用化を
める必要性があることから、今般、新型コロナウイルス感染症に対する医薬
、医療機器、体外診断用医薬品及び再生医療等製品（以下「医薬品等」とい
。）の承認審査上の取扱いについて、下記の通り取り扱うことに致しますの
、お知らせいたします。

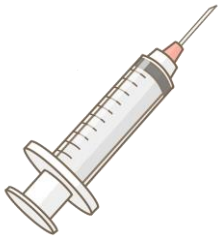
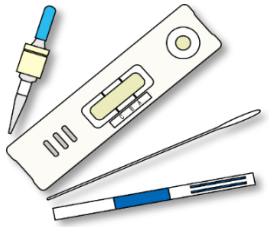
記

1．新型コロナウイルス感染症に対する医薬品等は、最優先で審査又は調査を
行うものであること。

2．厚生労働科学研究費補助金等の公的な研究事業により実施される研究の成

Publishing Approval Information in English
URL: https://www.pmda.go.jp/english/about-pmda/0002.html

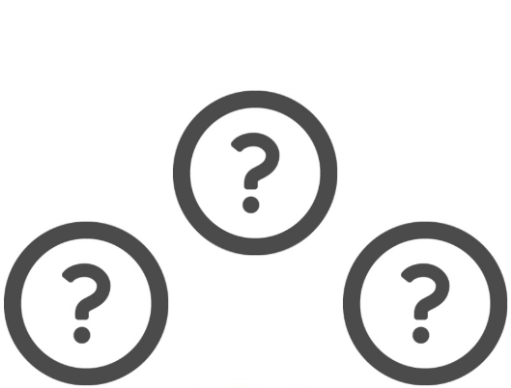
The number of approved products（As of 5 October, 2021）

Drugs	Vaccines	Medical Devices	IVDs
			
4 product	**3** product	**23** products	**75** products

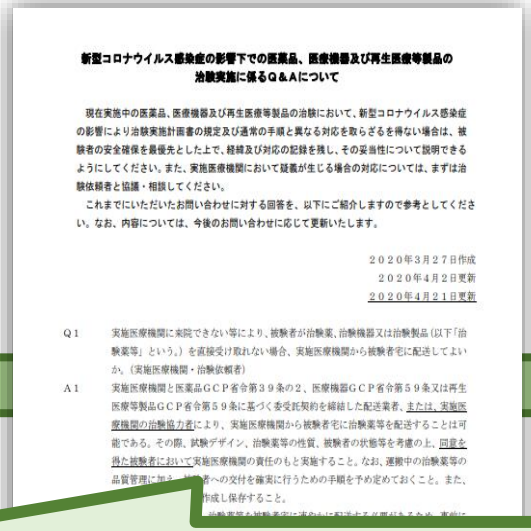
Priority review for COVID-19 candidate products

※1
https://www.pmda.go.jp/files/000235010.pdf

Q&A on Management of Clinical Trials during COVID-19 Pandemic



Sponsors



新型コロナウイルス感染症の影響下での医薬品、医療機器及び再生医療等製品の治験実施に係るＱ＆Ａについて

現在実施中の医薬品、医療機器及び再生医療等製品の治験において、新型コロナウイルス感染症の影響により治験実施計画書の規定及び通常の手順と異なる対応を取らざるを得ない場合は、被験者の安全確保を最優先とした上で、経緯及び対応の記録を残し、その妥当性について説明できるようにしてください。また、実施医療機関において疑義が生じる場合の対応については、まずは治験依頼者と協議・相談してください。

これまでにいただいたお問い合わせに対する回答を、以下にご紹介しますので参考としてください。なお、内容については、今後のお問い合わせに応じて更新いたします。

２０２０年３月２７日作成
２０２０年４月２日更新
２０２０年４月２１日更新

Ｑ１　実施医療機関に来院できない等により、被験者が治験薬、治験機器又は治験製品（以下「治験薬等」という。）を直接受け取れない場合、実施医療機関から被験者宅に配送してよいか。（実施医療機関・治験依頼者）

Ａ１　実施医療機関と医薬品ＧＣＰ省令第３９条の２、医療機器ＧＣＰ省令第５９条又は再生医療等製品ＧＣＰ省令第５９条に基づく委受託契約を締結した配送業者、または、実施医療機関の治験協力者により、実施医療機関から被験者宅に治験薬等を配送することは可能である。その際、試験デザイン、治験薬等の性質、被験者の状態等を考慮の上、同意を得た被験者において実施医療機関の責任のもと実施すること。なお、運搬中の治験薬等の品質管理に加え、[illegible]者への交付を確実に行うための手順を予め定めておくこと。また、[illegible]作成し保存すること。

Sponsors

Provides **alternative measures** that can be taken when the process predetermined in the **study protocol is not deemed feasible due to the COVID-19 situation**.

Initially published on 27 March, 2020

https://www.pmda.go.jp/english/int-activities/0002.pdf

COOPERATION WITH ASIAN COUNTRIES

APEC-LSIF-RHSC

(Asia-Pacific Economic Cooperation – Life Sciences Innovation Forum – Regulatory Harmonization Steering Committee)

Japan as co-Chair with the United States.

PWAs	Champion Economies
MRCT/GCP inspection	**Japan**, Thailand
Pharmacovigilance	Republic of Korea
Biotherapeutics	Republic of Korea
Advanced Therapies	Singapore
Good Registration Management	Chinese Taipei, **Japan**
Global Supply Chain Integrity	the United States
Medical Devices	**Japan**, the United States, Republic of Korea

Champion economies lead activities for Priority Work Areas (PWAs).

PMDA is **endorsed as Center of Excellences (CoEs) for "MRCT/GCP inspection", "Pharmacovigilance", and "Medical Device"** PWA to provide training seminars to promote regulatory convergence, capacity and cooperation.

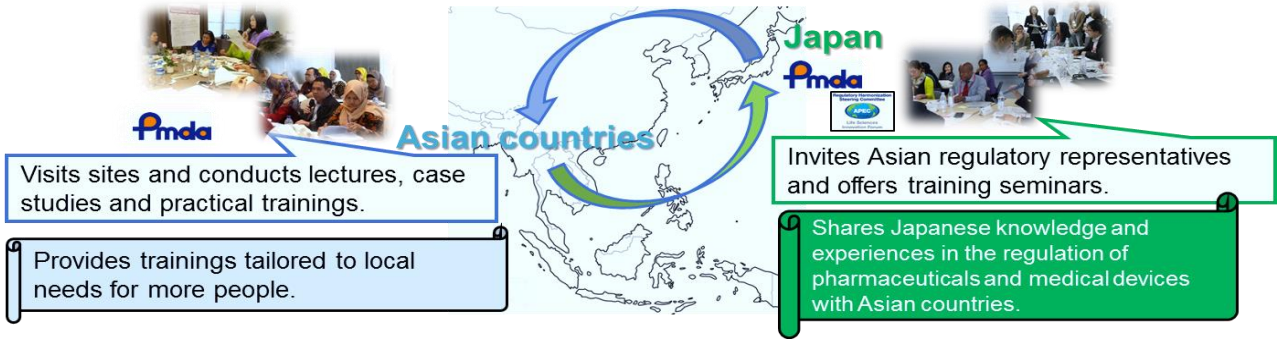
Capacity Building Activities at PMDA

Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs

- Established in April, 2016.
- Endorsed as Centers of Excellence (CoE) of APEC-LSIF-RHSC
- 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.



Capacity Building Activities at PMDA

Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs

Trainings provided in 2021 (Webinar)

Seminars (open to all regulators)

Contents	Date	Participants
Multi-regional clinical trials	Jan 18-21	8 Countries/regions
Pharmacovigilance	Feb 1-4	15 Countries/regions
Quality Control (Herbal Medicine)	June 22-24	13 Countries/regions
GRM (APEC GRM CoE Workshop)	Sep 14-16	12 Countries/regions
Pediatric Review(with U.S.FDA)	Sep 21-24	13 Countries/regions
Medical Devices	Nov 15-17	
GMP	Nov 25-26	
Pharmaceuticals Review	Dec 6-8	

Other Seminars (for specific members)

Contents	Date	Members
Regenerative medicinal products review	Mar 19	NPRA, Malaysia
Pharmaceuticals Review etc.	May, 2021- March, 2022	SFDA, Saudi Arabia
Regenerative medicinal products review	June 3	CDSCO, India
Medical Devices Review (Reprocessed single-use medical devices)	July 16	Thai FDA
GMP	July 27	FDA Philippines
Medical Devices Review	Aug 25-26	AMDC member states
Medical Devices Review (Reprocessed single-use medical devices)	Sep 1	MDA, Malaysia
GCP	Sep 8	FDA Philippines
Pharmacovigilance	Oct 4	NPRA, Malaysia

Capacity Building Activities at PMDA

Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs

Trainings planned in 2022 (Webinar)

APEC Center of Excellence Workshop

PMDA-ATC with National Cancer Center

MRCT Webinar 2022

Date

Preliminary Session: January 11, 2022 14:00-15:00

Live sessions: January 18 - 21, 2022 14:00 – 17:00*

(all time in JST; UTC+9) *Ending time varies

APEC Center of Excellence Workshop

PMDA-ATC Pharmacovigilance

WEBINAR 2022

Date

Preliminary Session: January 25, 2022 14:00-15:00

Live Sessions: January 31- February 4, 2022 14:00-16:30*

(all time in JST; UTC+9) * Ending time varies

PMDA-ATC E-learning Contents

Training Materials

PMDA-ATC E-learning

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.

Measures against COVID-19 Last updated: 2021.4.1

click! **E-learning Contents**

Category	Last updated
1. Review	2021.11.1 ***New***
2. Safety	2020.10.31
3. Relief	2020.10.31
4. Medical Device	2020.11.4
5. GXP	2021.9.1
6. PMDA Efforts	2020.10.31

Videos related to review, postmarketing safety measures of pharmaceuticals and medical devices, the relief system and other contents are available.

PMDA-ATC E-learning Training Courses

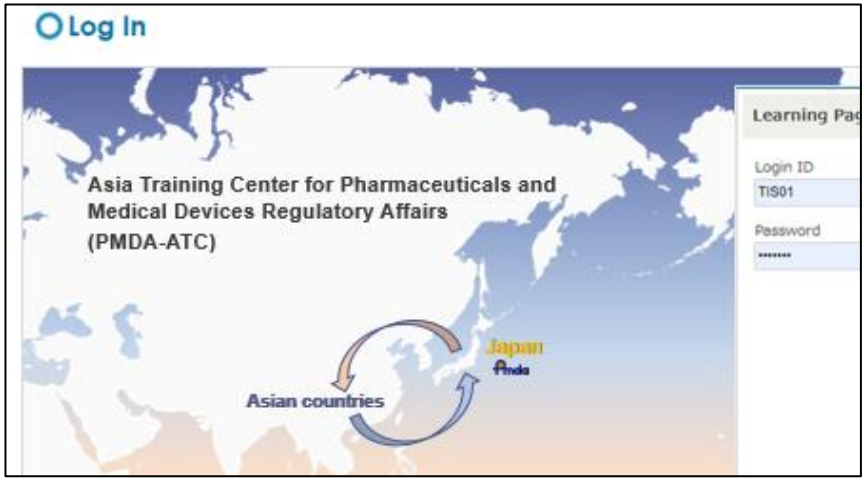
E-learning Training Courses

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-learning01)
2) Please select one course from the list on the application form and submit it.
3) If you wish to take multiple courses, please submit the application form for each course.
4) PMDA-ATC will send you Login ID and password normally within 5 business days.
5) The viewing period of one course is two months. You can watch it for 2 months starting from the date you received the e-mail to inform you of the start of the course.
   Please note that your login ID will become invalid after 2 months.
6) A certificate of completion of the course can be issued.



Course	Duration	Last updated
1. Quality Control (Herbal Medicine)	108 min	2021.04.15
2. Medical Devices Review	134 min	2021.08.04
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)

Thank You !

Hiroyuki Arai

Director of Center for Product Evaluation

Pharmaceuticals and Medical Devices Agency