Provisional Translation (as of September 2023)*

PMDA/CPE Notification No. 325
July 3, 2023

To: (applicable stakeholders)

Director of Center for Product Evaluation
Pharmaceuticals and Medical Devices Agency

Procedure for Remote Inspection as a Part of Compliance Inspection on Drugs and Regenerative Medical Products

Pharmaceuticals and Medical Devices Agency (hereinafter referred to as "PMDA") conducts the following compliance inspections (hereinafter collectively referred to as "compliance inspection") under commission from the Minister of Health, Labour and Welfare.

- Document-based inspection and GCP on-site inspection for approval of drugs and regenerative medical products
- Document-based inspection and GPSP on-site inspection for interim evaluation, re-examination, and re-evaluation of drugs
- Document-based inspection and GPSP on-site inspection for regulatory review after conditional and time-limited approval, re-examination, and re-evaluation of regenerative medical products

Procedures for compliance inspection are specified in the following notifications (hereinafter collectively referred to as "former Notifications on Procedure").

- Procedure for document-based inspection and GCP on-site inspection on application data/documents for approval of drugs as well as that for document-based inspection and GPSP on-site inspection on application data/documents for re-examination, etc. of drugs (PMDA Notification No. 0520001 by Chief Executive of Pharmaceuticals and Medical Devices Agency dated May 20, 2022)
- Procedure for document-based inspection and GCP on-site inspection on application data/documents for approval of regenerative medical products as well as that for

* This English version of the Japanese Notification is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

document-based inspection and GPSP on-site inspection on application data/documents for re-examination, etc. of regenerative medical products (PMDA Notification No. 0525001 by Chief Executive of Pharmaceuticals and Medical Devices Agency dated May 25, 2022).

PMDA's inspectors (hereinafter referred to as "inspectors") have examined records/documents which form the basis of the inspected trials and studies from PMDA office remotely through the cloud system and video conferencing system (hereinafter referred to "Remote Inspection") in accordance with "Procedure for Remote Inspection as a Part of Compliance Inspection on Drugs and Regenerative Medical Products" (PMDA/CPE Notification No. 0525001 dated May 25, 2022, hereinafter referred to the "former Notification on Remote Inspection").

As a result of reviewing the handling of procedures for compliance inspections and the documents to be submitted, the following notifications were newly issued, and the former Notifications on Procedure were abolished.

- Procedure for document-based inspection and GCP on-site inspection on application data/documents for approval of drugs as well as that for document-based inspection and GPSP on-site inspection on application data/documents for re-examination, etc. of drugs (PMDA Notification No. 2771 by Chief Executive of Pharmaceuticals and Medical Devices Agency dated July 3, 2023)
- Procedure for document-based inspection and GCP on-site inspection on application data/documents for approval of regenerative medical products as well as that for document-based inspection and GPSP on-site inspection on application data/documents for re-examination, etc. of regenerative medical products (PMDA Notification No. 2772 by Chief Executive of Pharmaceuticals and Medical Devices Agency dated July 3, 2023)

In association with the above, the operation method of the policy, procedure, and points to be considered for the Remote Inspection was reviewed according to the actual situation, etc. of the Remote Inspection, and this notification shall come into effect on July 3, 2023. Please inform all of the members of your association about this notification.

Items specified in 2. (2), 2. (3) and 3. (4) in the Annex of this notification (i.e., timing of notification of the condition/scope for documentation to be submitted, timing of submitting documentation, timing of the Meeting on Uploaded Documentation, and the Pre-inspection period) shall be applied to the compliance inspections conducted on or

after August 1, 2023. Until then, the compliance inspections shall be conducted as before.

With the application of this notification, the former Notification on Remote Inspection shall be abolished.

Major changes from the former Notification on Remote Inspection are made on matters related to the policy, procedure, and points to be considered for Remote Inspection as follows:

- Positioning of the Remote Inspection with Pre-explanation is clarified in the policy of Remote Inspection
- The schedule of Remote Inspection (timing of notification of the condition/scope for documentation to be submitted, timing of submitting documentation, timing of Meeting on Uploaded Documentation, and the Pre-inspection period) is changed in the procedure for Remote Inspection
- It is clarified that the Main-inspection may not be conducted in the procedure for Remote Inspection
- Points to be considered related to the cloud system and video conferencing system are clarified
- Other necessary adjustments are made

End of Document

Annex

Procedure for Remote Inspection as a Part of Compliance Inspection on Drugs and Regenerative Medical Products

Pharmaceuticals and Medical Devices Agency (hereinafter referred to as "PMDA") conducts the following compliance inspections (hereinafter collectively referred to as "compliance inspection") under commission from the Minister of Health, Labour and Welfare.

- Document-based inspection and GCP on-site inspection for approval of drugs and regenerative medical products
- Document-based inspection and GPSP on-site inspection for interim evaluation, re-examination, and re-evaluation of drugs
- Document-based inspection and GPSP on-site inspection for regulatory review after conditional and time-limited approval, re-examination, and re-evaluation of regenerative medical products

Procedures for compliance inspection are specified in the following notifications (hereinafter collectively referred to as "Notifications on Procedure").

- Procedure for document-based inspection and GCP on-site inspection on application data/documents for approval of drugs as well as that for document-based inspection and GPSP on-site inspection on application data/documents for re-examination, etc. of drugs (PMDA Notification No. 2771 by Chief Executive of Pharmaceuticals and Medical Devices Agency dated July 3, 2023)
- Procedure for document-based inspection and GCP on-site inspection on application data/documents for approval of regenerative medical products as well as that for document-based inspection and GPSP on-site inspection on application data/documents for re-examination, etc. of regenerative medical products (PMDA Notification No. 2772 by Chief Executive of Pharmaceuticals and Medical Devices Agency dated July 3, 2023)

As described in the Notifications on Procedure, PMDA's inspectors (hereinafter referred to as "inspectors") may examine records/documents which form the basis of the inspected trials and studies (hereinafter referred to as "documentation") from PMDA office remotely through the cloud system or video conferencing system (hereinafter referred to as "Remote Inspection"). Details of the procedures for Remote Inspection are provided in the Annex.

1. Policy of Remote Inspection

A compliance inspection is usually conducted by examining documentation presented by an applicant, marketing authorization holder (MAH), sponsor, sponsor-investigator, clinical trial in-country representative, medical institution, and/or their external contractor (hereinafter referred to as "applicant, etc.") and interviewing them about inspected trials and studies according to the date and place of the inspection notified by PMDA in advance (hereinafter referred to as "usual compliance inspection").

In a Remote Inspection, on the other hand, the applicant, etc. submit documentation in advance, and then inspectors usually examine the documentation and interview the applicant, etc. in 2 steps of Pre-inspection and Main-inspection. In some cases, however, neither the prior submission of documentation nor Pre-inspection is conducted, but only the Main-inspection is conducted by examining all documentation and interviewing the applicant, etc.

In a usual compliance inspection, the inspector is directly presented by the applicant, etc. with only the parts to be examined from among a large volume of documentation and is provided with an explanation where necessary. On the other hand, in a Remote Inspection, the inspector himself/herself needs to identify where necessary information is provided in the documentation and check the contents. Therefore, in order to conduct efficient inspection, a meeting in which the applicant, etc. explain to the inspector about file location/structure of documentation submitted, outline of each operating procedure, and documents generated based on the operating procedure (hereinafter referred to as "Meeting on Uploaded Documentation") needs to be held as a part of Remote Inspection in principle. This type of inspection is called "Remote Inspection with Pre-explanation".

2. Procedure for Remote Inspection

(1) Prior communication about Remote Inspection

[1] PMDA informs the applicant, etc. of the intent to conduct Remote Inspection and whether it will be conducted as a Remote Inspection with Pre-explanation by e-mail or telephone at the time of scheduling as specified in the Notifications on Procedure, in principle. In addition, inspectors may have a pre-meeting regarding the Remote Inspection with the applicant, etc. where necessary and provide necessary information.

[2] PMDA confirms the schedule of Pre-inspection and the method of submitting documentation with the applicant, etc. by e-mail preferably 1 to 2 months before the Main-inspection.

[3] The applicant, etc. should submit documentation to the inspectors by the method indicated in (a). If it is difficult to submit documentation by the method

indicated in (a), the applicant, etc. should submit by the method indicated in (b).

(a) Uploading documentation through the cloud system

(b) Submitting documentation through the Electronic Study Data Submission System specified in III 2 in Annexes 1 and 2 of the Notifications on Procedure (hereinafter referred to as the "Gateway System")

However, the applicant, etc. may submit documentation by saving it in electronic media (CD, DVD, or Blu-Ray Disc) and sending them to the Office of Non-clinical and Clinical Compliance I, PMDA only if it is permitted in III 2 in Annexes 1 and 2 of the Notifications on Procedure. If the documentation is submitted by the method shown in (b) or by the method of saving and sending it in electronic media, the applicant, etc. should submit Attached Form 21 as Cover Letter based on III 3 in Annexes 1 and 2 of the Notifications on Procedure. If it is difficult, for some reason, to submit documentation either by (a) or (b), or by saving documentation in electronic media and sending it, the applicant, etc. should consult the inspectors whether paper documentation is acceptable. If the paper documentation is accepted, the applicant, etc. should submit this as specified in 3. (4) [2].

[4] If the applicant, etc. submit documentation by the method indicated in [3] (a), inspectors provide information necessary for setting the cloud system to the applicant, etc.by e-mail as soon as possible.

[5] If the applicant, etc. submit the documentation by the method indicated in [3] (a), they should issue an account to each inspector to access the cloud system and also provide a user manual of the cloud system specified in 4. (2) [5] as appropriate.

(2) Submission of documentation

[1] In usual compliance inspection, inspectors notify the applicant, etc. of the condition/scope of documentation to be submitted on the day of or one day before the inspection. In Remote Inspection, inspectors notify the applicant, etc. of the condition/scope preferably by 10:00 am, 20 business days before the Main-inspection. If any concern is found at the prior check, etc., inspectors may change the condition/scope and request the applicant, etc. to submit additional documentation where necessary.

[2] The applicant, etc. should submit documentation to the inspectors by a method indicated in (1) [3] by 1 business day before the start of Pre-inspection (16 business days before the Main-inspection). If the applicant, etc. submit the documentation by the method indicated in (1) [3] (a), they should inform the

inspectors of having submitted the documentation. If it is inevitably difficult to submit these by the deadline, the applicant, etc. should consult the inspectors.

[3] If a presentation on the organizational structure is necessary in the Main-inspection, the inspectors make a request for it to the applicant, etc. at the time of notification of the condition/scope shown in [1], in principle. However, if the inspectors deem it necessary to request a presentation during the Pre-inspection, they request it promptly.

(3) Pre-inspection

[1] Usually, conducting a Pre-inspection takes inspectors 15 business days. During this period, inspectors examine the documentation submitted by the applicant, etc. and identify unclear points and concerns. If any unclear point or concern is found, inspectors send inquiries to the applicant, etc. by e-mail and other means as appropriate. If there are any unclear points in the documents submitted based on the Notifications on Procedure or in the preparation for specifying the condition/scope, inspectors send inquiries even before the Pre-inspection.

[2] When notified of the conduct of Remote Inspection with Pre-explanation by PMDA, the applicant, etc. should hold the Meeting on Uploaded Documentation of about half a day to one day through the video conferencing system at the timing of 15 business days before the Main-inspection in principle. The schedule for the Meeting on Uploaded Documentation may be changed at around 10 to 14 business days before the Main-inspection depending on the PMDA's overall schedule of the compliance inspection. If it is necessary to adjust the schedule due to overseas holidays, etc., the inspectors should be informed in advance.

[3] If requested by inspectors, the applicant, etc. should provide appropriate documentation and respond to inquiries on unclear points and concerns promptly.

[4] In addition to the Meeting on Uploaded Documentation, the applicant, etc. should explain the documentation and the contents of responses to inquiries by themselves or at the request of inspectors, through video conferencing system to the inspectors.

[5] Inspectors inform the applicant, etc. of whether the Main-inspection will be conducted and concerns to be examined and interviewed at the Main-inspection by e-mail by noon, 1 business day before the Main-inspection (for inspection on a clinical study not involving Japan, 2 business days before the Main-inspection). This, however, shall not apply to any case where the response is

submitted by the applicant, etc. immediately before the above communication or additional unclear points or concerns are found after the above communication.

[6] Even if the applicant, etc. respond about concerns to be examined and interviewed at the Main-inspection before the Main-inspection, they should explain them at the Main-inspection.

(4) Main-inspection

[1] Inspectors examine documentation not provided at the Pre-inspection through the video conferencing system and interview the applicant, etc. about unclear points and concerns identified during the Pre-inspection.

[2] If requested by inspectors, the applicant, etc. should present the appropriate documentation and respond to inquiries on unclear points and concerns promptly.

[3] If all unclear points and concerns are resolved in the Pre-inspection and it is judged unnecessary to conduct the Main-inspection by inspectors, the Main-inspection may not be conducted.

(5) Post-inspection

The applicant, etc. should take actions on the unresolved concerns at the Main-inspection according to direction by inspectors as soon as possible. In such a case, the applicant, etc. can provide supplementary explanation on those concerns through the video conferencing system.

3. Points to be considered for preparation of documentation

(1) General matters

It is not necessary for the applicant, etc. to prepare all documentation but those to be presented to the inspectors at a usual compliance inspection. Some pieces of documentation may be specified with condition/scope to be submitted, while some pieces are not. After the compliance inspection is determined to be conducted as Remote Inspection, the applicant, etc. should start with the preparation of documentation that are not specified with condition/scope to be submitted. After the condition/scope is notified, the applicant, etc. should proceed with preparing documentation specified with the condition/scope. In the end, the applicant, etc. should submit both type of documentation. If the applicant, etc. have limited experience with compliance inspections or Remote Inspection, or in other necessary cases, the inspectors may request the applicant, etc. to explain the contents of documentation in advance. If there are any unclear points about the method of providing documentation, or a supplementary explanation is needed on the

documentation, the applicant, etc. should proceed with the preparations as soon as possible by requesting inspectors to have a pre-meeting and other approaches.

(2) Points to be considered for providing documentation (electromagnetic records)

[1] The applicant, etc. should submit all the required documentation at a Pre-inspection in principle. If the applicant, etc. want to present documentation through the video conferencing system at Main-inspection, they should communicate this matter with the inspectors and do so. In addition, if there are documentation that have been submitted as documents of Annex 2 or 6 specified in the Notifications on Procedure, the applicant, etc. should communicate this matter with the inspectors. If these have to be additionally provided as documentation, the inspectors direct the applicant, etc. to do so.

[2] The applicant, etc. should consider the following points as well so that the inspectors can readily access the target documentation.

- The applicant, etc. should submit a document showing the folder structure, etc. with the documentation, and should also send it by e-mail.
- In the document showing the folder structure, etc., it is desirable to set hyperlinks to electronic files retained in the cloud system.
- If one folder contains many documents and thus it is deemed difficult to find documents, the applicant, etc. should make efforts such as creating lower folders for each category of documents.
- The applicant, etc. should provide supplementary documents necessary for the inspectors to access the documentation. The applicant, etc. should include, in the supplementary documents, the following information:
  - Name of the written procedure
  - Effective date (version number) of the written procedure
  - Outline of the procedure
  - Names of documents generated
  - File locations of documents
  - Other information necessary for efficient conduct of the Remote Inspection

  Then, the applicant, etc. should upload the supplementary documents to the cloud system with the documentation. In addition, at the request of inspectors, the applicant, etc. should submit the supplementary documents by e-mail or through the Gateway System to PMDA (excluding information included in a management sheet, etc. separately submitted).

(3) Points to be considered for conversion of documentation from paper into electromagnetic records

[1] The applicant, etc. should scan the documentation if it is paper documentation. The applicant, etc. should establish a procedure for scanning paper documentation and follow it. The applicant, etc. should confirm the following points about the electronic documentation obtained by scanning.

- They are clear with adequate contrast.
- They are consistent with the paper documentation in terms of the number of pages.
- Both sides of each paper have been scanned if applicable.

For files created by scanning paper documentation, it is acceptable that no functions shown in 4. (2) [1] can be used.

[2] Inspectors may request the applicant, etc. to present original paper documentation where necessary.

[3] The applicant, etc. should consult inspectors how to handle documentation for which scanning is difficult.

(4) Points to be considered for mail delivery of documentation

[1] If the documentation is to be submitted in electronic media (CD, DVD, or Blu-ray Disc), the applicant, etc. should send documentation in such electronic media to the Office of Non-clinical and Clinical Compliance I, PMDA by 1 business day before the start of Pre-inspection (16 business days before the Main-inspection). PMDA destroys the submitted electronic media upon notification of the inspection result in principle, but not return them.

[2] If the paper documentation is to be submitted, the applicant, etc. should send paper documentation to the Office of Non-clinical and Clinical Compliance I, PMDA by mail. In addition, the following points should be noted as well.

- The due date of submission is determined through communication with the inspectors irrespective of the Pre-inspection period.
- The number of days (desirably) from receipt of the documentation to return will be 5 business days.
- If there is any problem, the applicant, etc. should consult with the inspectors.
- If any concern is found, the inspectors send inquiries to the applicant, etc. by e-mail or telephone as appropriate. If the applicant, etc. cannot respond to the inquiries without the documentation, they should respond after the documentation are returned.
- The applicant, etc. should bear the expenses for mail delivery (submission and return of documentation).

(5) Points to be considered for documentation prepared in a language other than

Japanese or English

[1] The applicant, etc. should consider the following points when providing the documentation.
- The documentation should be submitted after the document title, section names, etc. in the document are translated into Japanese or English.
- If inspectors separately request a translation of a specific document, the document should be translated.
- The method of translation is not particularly specified, but the applicant, etc. should check that the contents are understandable.

[2] The applicant, etc. should consider the following points at the Main-inspection.
- The applicant, etc. should employ an interpreter and the like to explain the contents of the documentation.
- The applicant, etc. should be careful when employing an interpreter and the like because the time for the Main-inspection may be longer than usual and the number of days of the Main-inspection may be increased due to the time difference and other reasons.

[3] If there are any unclear points about [1] and [2], the applicant, etc. should make inquiries to inspectors.

4. Points to be considered for the cloud system and video conferencing system

(1) Common points

[1] The applicant, etc. should conclude a contract with a service provider of the system and bear the expenses for use of the system (except for the expenses for PMDA's access to the system), and should not use free services.

[2] The applicant, etc. should specify the procedure for setting the system and set the system in accordance with the procedure. If any problem occurs at the time of setting, the applicant, etc. should review the setting procedure so that no problem should occur in the next and subsequent Remote Inspections.

[3] The applicant, etc. should ensure security of the system. If any unauthorized access occurs because of a security vulnerability and communication interception by fault of the service provider, the applicant, etc. should take appropriate actions including stopping use of the system. If there is any point to be considered by PMDA to ensure the security, the applicant, etc. should inform the inspectors in advance. The log should not be checked for purposes other than ensuring security such as preventing unauthorized access.

[4] The applicant, etc. should take appropriate preventive actions for sound leakage and unauthorized access by communication interception on devices

and lines used for connections.

[5] If any critical security problem occurs in the system, the applicant, etc. should promptly communicate this incident with PMDA. The applicant, etc. and PMDA should decide to suspend or postpone the Remote Inspection. The timing of re-start and its method should be determined through discussion.

(2) Points to be considered for the cloud system

[1] The applicant, etc. should issue to each inspector an account with read-only access authority that can use the following functions in principle to connect and operate the cloud system.

- Text search
- Text copy
- Sort & Filter function of Excel files

From the viewpoint of preventing erroneous operations, the applicant, etc. should avoid issuing an account with authorities for editing, downloading, etc. wherever possible. If the applicant, etc. issue an account with any other authority for some reason, it should be accepted by the inspectors in advance, and the applicant, etc. should communicate the points to be considered. In this case, if an inspector performs erroneous operations such as downloading a file by mistake, he/she should take appropriate actions such as deleting the file or by other means. However, if the applicant, etc. cannot accept such erroneous operations, they should not use the system. In addition, if it is judged from the download history, etc. that unauthorized access is suspected, such as when all documents have been downloaded, the applicant, etc. should stop use of the system and inform the inspectors.

[2] Even if an applicant, etc. has used the same cloud system as the previous Remote Inspections, the cloud system may take time to re-connect or may be inactivated. Thus, the applicant, etc. should make sure to conduct the connectivity test for each inspection. At the time of the connectivity test, the applicant, etc. should upload a file for which the functions shown in [1] can be tested. For the Sort & Filter function of Excel files, it is acceptable to upload a file within which a filter is set in advance.

[3] If any change or addition of an inspector is made, an additional account should be issued as required. The same account should not be issued to more than one inspector.

[4] The applicant, etc. should retain the documentation in the cloud system and accounts of the inspectors until the result of inspection is notified. After the applicant, etc. receives the notification of the inspection result, access to the

cloud systems by the inspectors should be restricted and deletion or deactivation of the account be performed promptly from the viewpoint of security.

[5] When the applicant, etc. use the system for Remote Inspection for the first time, they should provide the inspectors with a user manual of the cloud system which is available for any kind of compliance inspections. The user manual should include the following contents.

- Operation method
- Account issuance method
- No-operation timeout time
- Log-in/authentication method (whether one-time password is used)
- Other requirements (recommended browser, etc.)

If the user manual is updated, the applicant, etc. should provide the revised version at the next Remote Inspection.

[6] The applicant, etc. should consider the following points as well.

- The inspectors without their account will not access or operate the cloud system but may look at the screen that another inspector operates with his/her account.
- The inspectors access the cloud system through PMDA's network system. For cloud system that cannot be connected through or are not available in PMDA's network system (e.g., a system requiring installation of an application, change of security settings, and/or download of a file), the applicant, etc. should change the method of submitting documentation (electromagnetic records), for example, by utilizing other cloud systems.
- If two-step authentication is set up for access to cloud systems, a system that allows authentication using a cellular phone number (SMS or voice call) or e-mail address should be used, and the authentication function that requires installation of an application, etc. should not be used.
- The applicant, etc. should confirm the file formats accessible through the cloud system (e.g., PDF, Word, Excel) before upload of documentation.
- Any cloud system which takes a long time to access may not be able to be used for Remote Inspection in the future.
- The applicant, etc. should consult inspectors about whether folders (including eTMF) containing documents other than those to be provided may be utilized. If hyperlinks to electronic files in the cloud system can be set in the document showing the folder structure, etc., it may be possible to submit together with the documents other than those to be submitted.

(3) Points to be considered for the video conferencing system

[1] The applicant, etc. should make appropriate arrangements such as sending the inspectors a meeting invitation.

[2] The applicant, etc. should conduct the connectivity test immediately before the start of the video conference especially when there are any concerns about the connection to the video conferencing system.

[3] The applicant, etc. should inform the inspectors of the name and department of participants in advance by e-mail. The applicant, etc. should verify identities of the participants in a manner pre-specified by the applicant, etc. If an additional person who is not informed to the inspectors in advance participates in the video conference, applicant, etc. should inform the inspectors about his/her name and department in advance.

[4] The applicant, etc. should prepare necessary number of communication lines (usually 1 or 2 lines) after consulting with the inspectors.

[5] If the applicant, etc. record audio of the video conference to make internal records, they should obtain permission from PMDA in advance. The applicant, etc. should not record the video conference or use the audio recording function of the video conferencing system. The recorded audio data should be used only internally for compliance inspection and must not be leaked out through external use (presentation at a conference, etc.) or the Internet. In addition, upon notification of the inspection result, the applicant, etc. should delete such data immediately. If inspectors record audio in PMDA, they take the same action.

[6] The applicant, etc. should consider the following points as well.

- Any video camera function should be turned on when speaking and otherwise turned off unless required. Any microphone should be muted unless required.
- If the participants need to have an internal meeting during the video conference, the applicant, etc. should ask the inspectors for permission in advance.
- If unknown participant is found during the video conference, the applicant, etc. should force unknown participant out.
- If the inspection takes a long time or involves an interpreter, the break time should be arranged by mutual agreement.

5. Others

[1] PMDA posts information necessary for efficient and effective implementation

of Remote Inspection (examples of documentation to be specified with condition/scope for submission, matters subject to Meeting on Uploaded Documentation, etc.) on the PMDA's website and modifies the content where necessary.

[2] PMDA separately posts the schedule of Remote Inspection related to application data/documents for approval of drugs and regenerative medical products (related to quality studies and nonclinical studies) on the PMDA's website. Remote Inspection related to application data/documents for approval of drugs and regenerative medical products (related to quality studies and nonclinical studies) and application data/documents for approval of generic drugs shall not be conducted as Remote Inspection with Pre-explanation in principle.

[3] PMDA determines a period of Pre-inspection, etc. excluding business days during consecutive holidays and company-wide simultaneous holidays (e.g., summer holidays) requested by the applicant, etc. In addition, PMDA may change a period of Pre-inspection, etc. taking account of circumstances of the product.

[4] PMDA makes efforts to understand the implementation status and problems of Remote Inspection and, based on them, revises this notification where necessary.

[5] If conduct of a compliance inspection as Remote Inspection becomes necessary instead of scheduled usual compliance inspection, PMDA informs the applicant, etc. of this matter and consults them about the inspection schedule.

[6] Since it is inefficient to convert paper documentation into electromagnetic records solely for enabling Remote Inspection, the applicant, etc. should consider making efforts to computerize the documentation and utilizing the computerized data for normal work as well. When promoting computerization of documents, the applicant, etc. should also refer to "Basic Principles on Utilization of Electromagnetic Records in Clinical Trial-related Documents" (PFSB/ELD Administrative Notice dated July 1, 2013).

[7] When conducting document-based inspection and GPSP on-site inspection for application data/documents for interim evaluation, re-examination, and re-evaluation of drugs, or application data/documents for regulatory review after conditional and time-limited approval, re-examination, and re-evaluation of regenerative medical products by the method of Remote Inspection, applicable terms in this notification shall be replaced as needed, such as replacement of "clinical trial" with "post-marketing clinical trial."

[8] When the Office of Non-clinical and Clinical Compliance I or II conducts various types of consultations in accordance with “Implementation Guidelines for Clinical Trial Consultation and Confirmation of Certification, etc., Conducted by the Pharmaceuticals and Medical Devices Agency” (PMDA Notification No. 0302070 by Chief Executive of Pharmaceuticals and Medical Devices Agency dated March 2, 2012) by the method of Remote Inspection, the provisions of this notification shall apply mutatis mutandis, and applicable terms shall be replaced as needed, such as replacement of “applicant” and “inspection” with “applicant of consultation” and “consultation,” respectively.