Provisional Translation (as of August 2025).
This English document has been prepared for reference purpose only. In the event of inconsistency and discrepancy between the Japanese original and the English translation, the Japanese text shall prevail.

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List of documents to be submitted upon application for new compliance inspection (documents required by the compliance inspection authority)

I. This Document

1. This document contains a list of documents required according to the type of inspection, the facility classification, and whether the inspection is performed based on MRA or MOU as specified in 2-8 (1) D. "Other documents required by the compliance inspection authority" in Chapter 2 of II. Enforcement Notification in Attachment 1. "Documents to be submitted upon application for new compliance inspection" of “Submission of documents upon application for compliance inspection” (Administrative Notice dated August 2, 2023; hereinafter referred to as the "Administrative Notice"). New compliance inspections include the following inspections for drugs and quasi-drugs.
   (1) Inspection performed before obtaining marketing approval
   (2) Inspection performed before manufacturing drug for export
   (3) Inspection performed before obtaining partial change in manufacturing approval (hereinafter referred to as "partial change approval")
   (4) Inspection performed before obtaining review of post-approval change management protocol (hereinafter referred to as "PACMP")

2. The applicant is requested to check the latest approval information and submit the documents required in III. List of Documents Required by the Compliance Inspection Authority at the time of application for inspection. Refer to the Administrative Notice for the points to be considered concerning the contents of the documents and the method of submission.

3. Refer to this document for III.-7 (1) C "Other documents required by the PMDA" in Chapter 3 of the Enforcement Notification among the documents to be submitted upon application for new compliance inspection of regenerative medicine products.

4. The documents in III. List of Documents Required by the Compliance Inspection Authority are standard documents. Additional documents including copies of manufacturing instructions and records, test records, and copies of manufacturing and testing procedures may be required depending on the product subject to inspection, the process subject to inspection, and the results of the previous inspection. Follow the instructions of the inspector after the inspection starts.

II. Facility Classification

1. Specific examples of facilities are shown in the following table according to the facility classification (i to iii) in the respective table in III. List of Documents Required by the Compliance Inspection Authority.

Facility classification	Specific examples of facilities
i. Manufacturing site (excluding ii)	A facility where the following processes and related tests are performed Intermediate API manufacturing, API manufacturing, API milling, API subdivision, drug product manufacturing, tablet coating, primary packaging of drug product (e.g., PTP packaging, bottle filling), secondary packaging and labeling of drug product, assembly of injection kits, maintenance of working cell bank (WCB)
ii. Storage facility	A facility where only the "storage process" or "storage process and tests" are performed
iii. External laboratory	A facility listed as an "external laboratory" in the approval document

III. List of Documents Required by the Compliance Inspection Authority

1. Inspection performed before obtaining marketing approval or manufacturing drug for export

The applicant is requested to submit the documents shown in the table below based on the facility classification of the facility subject to inspection. Submit the required documents for all applicable classifications if two or more classifications apply to the facility.

(1) When a GMP compliance certificate for the MRA product issued by the authority of the MRA country, a copy of certificate registered in the EudraGMDP database, another document providing the certificate number for cross-checking of the certificate, or a GMP compliance certificate issued by the authority of the MOU country is available as part of the documents on the manufacturing site in the MRA or MOU country:

Table 1-1 Submission upon application for inspection: ●, required; x, not required

Document	Facility classification		
	i. Manufacturing site (excluding ii)	ii. Storage facility	iii. External laboratory
1. Outline of the product subject to inspection and the manufacturing site (1) Form 1	●	●	●
(2) Form 2 or Form 3	●	●	×
2. Document on the documents and the operating procedures (Attachment 5)	×	×	×
3. Document on the pharmaceutical quality system Outline of management review	×	×	×
4. Document on the manufacturing process	●	×	×
5. Document on the testing	●*1	●*1	●
6. Document on the control of raw materials	●*1	×	×
7. Document on the manufacturing history or the expected annual lot production	×	×	×
8. Document on the status of process validation	●*2	×	×
9. Document on the status of PST (only when aseptic procedures are included)	●	×	×

(2) Other than (1)

Table 1-2 Submission upon application for inspection: ●, required; x, not required

Document	Facility classification		
	i. Manufacturing site (excluding ii)	ii. Storage facility	iii. External laboratory
1. Outline of the product subject to inspection and the manufacturing site (1) Form 1	●	●	●
(2) Form 2 or Form 3	●	●	×
2. Document on the documents and operating procedures (Attachment 5)	●	●	●
3. Document on the pharmaceutical quality system Outline of management review	●	●	×
4. Document on the manufacturing process	●	×	×
5. Document on the testing	●*1	●*1	●
6. Document on the control of raw materials	●*1	×	×
7. Document on the manufacturing history or the expected annual lot production	●	×	×
8. Document on the status of process validation	●*2	×	×
9. Document on the status of PST (only when aseptic procedures are included)	●	×	×

Submit a document on the status of compliance with the Standards for Biological Ingredients if Facility Classification i applies in the application for compliance inspection of a regenerative medical product.

*1 Not required if no testing is performed

*2 Not required for the processes after the secondary packaging

2. Inspection performed before obtaining partial change approval or PACMP

Different documents are required depending on the change described in the partial change approval or the PACMP. The applicant is requested to submit the documents shown in the table below based on the change classification A to E. Of the documents shown in the table below, submit only the documents on the change described in the partial change approval or the PACMP if classification B or C applies.

Submit the documents required according to all the applicable classifications if two or more facility classifications and classifications of change apply.

Classification of change	A. Addition of manufacturing site / B. Addition or change of manufacturing method / C. Addition or change of specifications or test method D. Addition of storage facility / E. Addition of external laboratory

(1) When a GMP compliance certificate for the MRA product issued by the authority of the MRA country, a copy of certificate registered in the EudraGMDP database, another document providing the certificate number for cross-checking of the certificate, or a GMP compliance certificate issued by the authority of the MOU country is available as part of the documents on the manufacturing site in the MRA or MOU country:

Table 2-1 Submission upon application for inspection: ●, required; x, not required

Document	Facility classification			
	i. Manufacturing site (excluding ii)		ii. Storage facility	iii. External laboratory
	Classification of change			
	A, B	C	C, D	C, E
1. Outline of the product subject to inspection and the manufacturing site (1) Form 1	●	●	●	●
(2) Form 2 or Form 3	●	●	●	×
2. Document on the documents and the operating procedures (Attachment 5)	×	×	×	×
3. Document on the pharmaceutical quality system Outline of management review	×	×	×	×
4. Document on the manufacturing process	●	×	×	×
5. Document on the testing	●*1	●	●*1	●
6. Document on the control of raw materials	●*1	×	×	×
7. Document on the manufacturing history or the expected annual lot production	×	×	×	×
8. Document on the status of process validation	●*2	×	×	×
9. Document on the status of PST (only when aseptic procedures are included)	●	×	×	×

(2) Other than (1)

Table 2-2 Submission upon application for inspection: ●, required; x, not required

Document	Facility classification						
	i. Manufacturing site (excluding ii)			ii. Storage facility		iii. External laboratory	
	Classification of change						
	A	B	C	C	D	C	E
1. Outline of the product subject to inspection and the manufacturing site (1) Form 1	●	●	●	●	●	●	●
(2) Form 2 or Form 3	●	●	●	●	●	×	×
2. Document on the documents and the operating procedures (Attachment 5)	●	×	×	×	●	×	●
3. Document on the pharmaceutical quality system Outline of management review	●	×	×	×	●	×	×
4. Document on the manufacturing process	●	●	×	×	×	×	×
5. Document on the testing	●*1	●*1	●	●	●*1	●	●
6. Document on the control of raw materials	●*1	●*1	×	×	×	×	×
7. Document on the manufacturing history or the expected annual lot production	●	×	×	×	×	×	×
8. Document on the status of process validation	●*2	●*2	×	×	×	×	×
9. Document on the status of PST (only when aseptic procedures are included)	●	●	×	×	×	×	×

Submit a document on the status of compliance with the Standards for Biological Ingredients if Facility Classification i applies in the application for compliance inspection of a regenerative medical product.

*1 Not required if no testing is performed

*2 Not required for the processes after the secondary packaging