To: The Federation of Pharmaceutical Manufacturers’ Associations of JAPAN

Office of Manufacturing/Quality and Compliance,
Pharmaceuticals and Medical Devices Agency

Confirmation, etc. of the status of pre-approval GMP compliance inspection for new drugs

In order to deliver more effective and safer drugs more quickly to medical practice, the Pharmaceuticals and Medical Devices Agency (hereinafter referred to as “PMDA”) targets the ideal review period. The document for confirmation of the progress of pre-approval GMP compliance inspection is prepared as below from the viewpoint of smoother progress. We ask you to notify your members of the details.

1. Contact procedures regarding GMP compliance inspection
   (1) In the case that the documents of “Outline of product(s) subject to inspection (Form 1) and Outline of drug manufacturing site (Form 2 or Form 3),” which are required to be submitted in “Documents to be submitted to PMDA when applying for its pre-approval GMP inspection or periodic post-approval inspection of drugs or quasi-drugs” (Notification of the Office of Manufacturing/Quality and Compliance, PMDA, dated September 15, 2017), are appropriately attached when a GMP inspection application is being submitted, and accordingly the inspection is determined to be conducted on-site, the Division of Pharmaceuticals, Office of Manufacturing/Quality and Compliance of PMDA will notify the contact person indicated in the application for GMP compliance inspection by phone about 1 month after submitting the application for GMP compliance inspection. In case that the inspection is determined to be conducted desk-top, the contact for inquiries will be provided about 2 months after submitting the application for GMP compliance inspection.

When the documents “Outline of product(s) subject to inspection (Form 1) and Outline of drug manufacturing site (Form 2 or Form 3),” which are required to be submitted in the Notification mentioned above issued by the Office of Manufacturing/Quality and Compliance of PMDA are submitted at the time of the application for marketing approval, the inspection method is determined even before submission of the application for GMP compliance inspection. With regard to whether the GMP compliance inspection is to be conducted on-site or desk-top, the Division of Pharmaceuticals of the Office of Manufacturing/Quality and Compliance will notify the contact person indicated in the marketing approval application by phone about 1 month after submission of the application for marketing approval. However, the inspection method may change from desk-top to on-site according to the status to the application of GMP compliance inspection including any problems from results of reviews or from audits by foreign authorities. In such cases, the Division of Pharmaceuticals of the Office of Manufacturing/Quality and Compliance will
notify the contact person indicated in the application for GMP compliance inspection by phone within 1 month after submission of the application for GMP compliance inspection at the latest.

(2) When the documents of “Outline of product(s) subject to inspection (Form 1) and outline of drug manufacturing site (Form 2 or Form 3)” are submitted at the time of the application for marketing approval, those should be submitted in a paper file separately, and the items shown in Attachment 1 should be described on or attached to the relevant file.

2. Query regarding status of GMP compliance inspection

For any query regarding status of GMP compliance inspection conducted by PMDA, contact the Office of Manufacturing/Quality and Compliance (Tel. 03-3506-9446), using the standard flow and timeline of GMP compliance inspection shown in Attachment 2 for reference.

Before you call, the following information should be ready at hand. If the inspector is unknown or absent at the query, tell the fact that the call is for a query regarding status of pre-approval GMP compliance inspection for a new drug.

- Name of the person in charge from the applicant
- The systematic receipt number of the target application for GMP compliance inspection (or the systematic receipt number of the application for marketing approval)
- Name of the applied product
- Name of the manufacturing site
For the submission to

Office of Manufacturing/Quality and Compliance,

Pharmaceuticals and Medical Devices Agency

Outline of the product subject to inspection (Form 1) and outline of the manufacturing site (Form 2 or Form 3) for GMP Compliance Inspection

Name of the Product: ________________________________

Name of the Manufacturer: ________________________

Date: _
Flow of pre-approval GMP compliance inspection in the review for approval of new drugs

(A) Standard time-line

1. Application for GMP
2. Determination of the inspection
   - Desk-top inspection
   - On-site inspection
3. Issuance of observations
4. Improvement plan/report for observations
5. Notification of the result
   - Desk-top inspection
   - On-site inspection

* In case that the inspection is determined to be conducted on-site, the contact person is notified of it by phone.

* In some cases, the process of inquiry and response is repeated.

(B) Standard time-line in the case that the information of the manufacturing site is submitted at the time of submission of the approval application

1. Application for marketing
2. Determination of the inspection procedure (on-site or desk-top)
3. Application for GMP compliance inspection
4. Desk-top inspection
   - Inquiry
   - Response
5. Notification of the result
   - Desk-top inspection
   - On-site inspection

* If the inspection procedure is changed in this step, the contact person is notified of it by phone.

* The contact person indicated in the marketing approval application is notified of the inspection procedure (on-site or desk-top) by phone.

* In some cases, the process of inquiry and response is repeated.

* In some cases, the process of inquiry is not applicable or is repeated several times.

* In some cases, the process of inquiry is not applicable or is repeated.