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Notification, September 15, 2017
Office of Manufacturing/Quality and Compliance,
Pharmaceuticals and Medical Devices Agency

Submission Documents for Application of Drug Compliance Inspection

(Revision of the previous version: Documents to be submitted to PMDA when applying for its pre-approval GMP inspection or periodic post-approval inspection of drugs or quasi-drugs, June 18, 2015)

In filing an application for GMP-compliance inspection when intending to obtain approval of drugs or quasi-drugs (hereinafter referred to as "drugs, etc."), when intending to obtain approval for partial change, or when intending to manufacture drugs, etc. for export specified in Article 80, Paragraph 1 (hereinafter referred to as "pre-approval compliance inspection") based on the provisions of Article 14, Paragraph 6 (including the cases where applied mutatis mutandis pursuant to Article 14, Paragraph 9 and Article 19-2, Paragraph 5) of the Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (hereinafter referred to as "PMD Law"), (Act No. 145 of 1960), or in filing an application for inspection after obtaining approval or inspection required every 5 years after initiation of manufacturing (hereinafter referred to as "periodic PoAI"), documents that are required to be submitted to the Pharmaceuticals and Medical Devices Agency (hereinafter referred to as "PMDA") have been specified in Article 50, Paragraph 2 (including the cases where applied mutatis mutandis pursuant to Article 111 and Article 264, Paragraph 2) of Ministerial Ordinance for Enforcement of PMD Law (Ministerial Ordinance No. 1 of 1961, hereinafter referred to as "Enforcement Regulation"); in "Ministerial Ordinance on Good Manufacturing Practice and Quality Management System (GMP/QMS) and Enactment, Revision, and Abolition of Ministerial Ordinances and Notices with the Enforcement of Act for Partial Revision of PMD Law and Blood Collection and Donation Services Control Act" (PFSB/CND Notification (Yakushokukanma-hatsu) No. 0330001 of Compliance and Narcotics Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, dated March 30, 2005); and in "Handling of Ministerial Ordinance on Good Manufacturing Practice for Drugs and Quasi-drugs" (PFSB/CND Notification (Yakushokukanma- hatsu) No. 0830-1 of Compliance and Narcotics Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, dated August 30, 2013) (hereinafter collectively referred to as "Enforcement Notifications"); as well as in "Documents to be submitted to PMDA when applying for its pre-approval GMP inspection or periodical post-approval inspection of drugs or quasi-drugs" (Office Memorandum of the Office of Manufacturing/ Quality and Compliance, PMDA, dated June 18, 2015).

This Notification is prepared as explained below by adding the intent of inquiries to require the documents specified in above and the points to consider in preparing documents to the description of "Submission Documents for Application of Drug Compliance Inspection" (Office Memorandum of the Office of Manufacturing/Quality and Compliance, PMDA, dated June 18, 2015) for the purpose of further rationalizing drug GMP compliance inspections. We ask you to be aware of the details and to notify relevant persons regarding this matter.

This Notification should be applied to applications to be submitted from October 1, 2017. (Note that applications may be continued to be submitted during a period until October 1, 2017 in accordance with the existing Notification.) With the initiation of application of this Notification "Documents to be submitted to PMDA when applying for its pre-approval GMP inspection or periodic post-approval inspection of drugs or quasi-drugs" (Office Memoradum of the Office of Manufacturing/Quality and Compliance, PMDA, dated June 18, 2015) will be abolished.

§1. Timing of inspection application

Standard administrative processing time required for GMP compliance inspection at PMDA is 6 months. Applications are to be submitted at an appropriate timing with consideration of the progress of the review for marketing authorization, the schedule or the status of process validation, etc.

§2. Method of submitting required documents to PMDA for inspection application

1. Fill out Checklist 1 or Checklist 2, which should all be attached to the inspection application form along

with the submission documents. An application, in princip**le,** will not be accepted if the inspection application form does not have its required documents attached. Make efforts to prepare Document well in advance considering the schedule for compliance inspection.

2. After submitting an inspection application, when the MF in-country caretaker or the manufacturing site subject to inspection is to directly send part of the submission documents to PMDA's Office of Manufacturing/Quality and Compliance, indicate the expected submission documents in the Checklist, which should be attached to the inspection application form. The applicant is to make adjustments in advance in order for documents to be submitted promptly after the inspection application. The inspection application may be withdrawn if the relevant documents are not submitted for long period regardless of having submitted the inspection application.
3. After submitting an inspection application when the MF in-country caretaker or the manufacturing site subject to inspection is to directly send part of the submission document to PMDA's Office of Manufacture/Quality and Compliance, the inspection applicant should notify the following points to the MF in-country caretaker or the manufacturing site subject to the inspection.
   1) On the outer package, indicate that GMP compliance inspection documents are included in it and write the name of the inspection applicant, name of the person who submitted the documents, name of the manufacturing site subject to inspection, as well as the systematic receipt number given at the GMP compliance inspection application and name of PMDA inspector. If the systematic receipt number and PMDA inspector have not been assigned yet, indicate "unassigned".
   2) If sending documents for multiple inspection applications in a single package, attach a list of those data specifying the name of the inspection applicant, name of the person who submitted the documents, name of the manufacturing site subject to inspection, as well as the systematic receipt number given at the GMP compliance inspection application and the name of PMDA inspector so as to enable to identify which system receipt number of packages.
   When the attached materials for one application is divided into plural packages, indicate so as to show the total quantity by giving numbers such as 1/3, 2/3, 3/3… and indicate the information specified in the above 2) on each package.

§3. Selection of representative products for a periodic inspection

If submitting an application for multiple products, their representative products should be selected based on clear rational in accordance with Enforcement Notifications. If possible, the representative products selected from each category should be those that have not been selected for past periodic inspections. Also indicate representative products that have been selected in the past periodic inspections. Note that proposed representative products may be asked to be changed if determined to be inappropriate.

§4. Documents required to be submitted to PMDA for inspection application

1. Documents required to be submitted for a new GMP compliance inspection applications are specified in Chapter 1, Section 3-9, (1) in Enforcement Notifications and in Attachment 1. Checklist 1 should be filled out and attached to the inspection application form along with the submission documents at the point when all the documents specified in Attachment 1 have been prepared.
2. Documents required to be submitted for periodic compliance inspection application are specified in Chapter 1, Section 3-9, (2) in the Enforcement Notifications and in Attachment 2. Fill out Checklist 2 and perform the application for periodic GMP compliance inspection at the point when all the documents specified in Attachment 2 been prepared.
3. Documents specified in above Section 2 in Attachment 1 and Section 2 in Attachment 2 are only the standard documents, and there may be cases where additional documents may be required to be submitted, such as a copy of manufacturing instructions/master batch records or a copy of testing records and manufacturing/testing procedures based on the product subject to inspection, the process subject to inspection, and the results of previous inspection. Follow the instructions of the inspector.
4. If there is no change from the documents that had been submitted to PMDA for the inspection application within the past 2 years, submission of documents may be omitted by indicating the information (the applicant's name of the past application, its systematic receipt number, product that was subject to be inspected, and application date) that can identify those documents.
5. If GMP compliance certificate of the MRA applicable product issued by the authority of the MRA country, a copy of certified details registered in Eudra GMDP data base, data with a certificate number for referring to the certified details, or GMP compliance inspection certificate, etc. issued by an authority of a country with which MOU is exchanged is available as an attachment, there are cases where

documents may be omitted.

1) In case of the pre-approval compliance inspection:
If GMP compliance certificate of the MRA applicable product issued by the authority of the MRA country, a copy of certified details registered in Eudra GMDP data base, or data with a certificate number for referring to the certified details are available as an attachment, documents specified in Section 2 in Attachment 1 (excluding those related to "Outline of the product, etc. subject to inspection and outline of the manufacturing site," "Documents on the manufacturing process," "Documents on testing," "Documents on the control of materials," "Documents on the status of process validation," and "Documents on the management status of Standards for Biological Ingredients") may be omitted. If GMP compliance inspection certificate issued by an authority of a country with which MOU is exchanged is available as an attachment, there are cases where documents may be omitted. Follow the instructions of the inspector.

2) In case of the periodic PoAI:
If GMP compliance certificate (original copy only) of the MRA applicable product issued by the authority of the MRA country, a copy of certified details registered in Eudra GMDP data base, or data with a certificate number for referring to the certified details are available as an attachment, documents specified in Section 2 in Attachment 2 (excluding those related to "Outline of the product, etc. subject to inspection and outline of the manufacturing site" and "Documents on the management status of Standards for Biological Ingredients") may be omitted. If GMP compliance inspection certificate (original copy only) issued by an authority of a country with which MOU is exchanged is available as an attachment, there are cases where documents may be omitted. Follow the instructions of the inspector.

6. If a site master file includes details that are at least equal to the above documents, submission of the site master file (Japanese or English) will allow the above documents to be replaced.

7. When submitting documents in which approval of its details of the description from the manufacturing supervisor (or the responsible person of the manufacturing site in the case of foreign manufacturer) cannot be confirmed (e.g., documents such as a summary prepared for the inspection, or documents not controlled by GMP), the manufacturing supervisor (or the responsible person of the manufacturing site in case of a foreign manufacturer) should declare that he/she is responsible for those details of the documents, and should provide a signature when submitting this declaration.
However, "Documents such as a summary prepared for the inspection," "Excerpt from the CTD," or "Documents which is not controlled with such as a document number controlled by GMP," etc. cannot be substituted for "Documents on the manufacturing process," which are the documents to be submitted when applying for its pre- approval compliance inspection. However, "Documents such as a summary prepared for the inspection" or "Excerpt from the CTD," etc. can be substituted for the flow diagram of the manufacturing processes and the document on water used for the manufacturing of "Documents on the manufacturing process," provided that the substitutes must be the documents in which approval of its details from the manufacturing supervisor (or the responsible person of the manufacturing site in the cases of foreign manufacturers) can be confirmed. Also, submit a statement, etc. (an original copy) to declare that the responsible person of the manufacturing site is responsible for the descriptions.

§5. Method of submitting written responses to inquiries

1. When a written response is submitted, pay attention to the following points.
1) Submit the written response (1 set) and the documents (1 set) in paper form.
2) When the written response and documents cannot be submitted by the due date, notify the inspector in advance the reason, and follow the instructions of the inspector.
3) Prepare the written response in Japanese, in principle. Submit the documents, in principle, in Japanese or in English. When documents are prepared in a foreign language other than English, prepare the summary in Japanese or in English. It is not considered necessary to translate all information in the documents into Japanese or English. Contact the inspector in advance, if the need of translation is unclear.
4) In the case that the descriptions of the application form for marketing approval or the MF are not finalized when inspection application is being submitted, submit the written response and documents on the GMP inspection after the review for marketing authorization on the manufacturing method and specifications of the products subject to inspection is almost completed and after the descriptions of the application form for marketing approval or the MF are almost

finalized.

5) When any change is made to the manufacturing process and specifications described in the application form for marketing approval or the MF during inspection, notify the inspector immediately, and then submit the latest manufacturing application form, MF, and necessary additional documents, etc. According to the content after the change, it should be reconfirmed that the manufacturing control and quality control can be implemented appropriately. Note that rapid actions are preferable as this re-inspection may take time.

§6. Miscellaneous

1. Whether the drug GMP compliance inspection is to be conducted on-site or desk-top will be decided depending on the risks such as manufacturing control or quality control (e.g, complexity of manufacturing process, level of risks in using the product), results of past on-site inspections, past non-conformities, any recalls and details of those recalls as mentioned in Enforcement Notifications and will be determined under the responsibility of PMDA, the inspection authority, taking into account the details of the submission documents as well.
2. Promptly notify the Office of Manufacturing/Quality and Compliance if it is expected to take long time in submitting documents or responding to inquiries from PMDA.

Attachment 1

Documents to be submitted to PMDA when applying for its pre-approval GMP inspection of Drugs or Quasi-drugs

Documents required to be submitted to PMDA when applying for its pre-approval GMP inspection have been specified in Article 50, Paragraph 2 (including the cases where applied mutatis mutandis pursuant to Article 111 and Article 264, Paragraph 2) of Enforcement Ordinance as "documents on manufacturing control and quality control of product subject to compliance inspection" and "documents on manufacturing control and quality control of manufacturing site subject to compliance inspection". Specifically, the required data are as follows:

§1. Documents specified in Enforcement Notifications

1. A copy of GMP compliance inspection results or GMP compliance inspection report of GMP inspection (including inspections conducted by other authorities) conducted over the past 2 years from the application date of the compliance inspection.
2. For the inspections of a foreign manufacturing sites, a GMP compliance certificate issued by a country with which MRA is concluded; a certificate issued by a country with which MOU is exchanged; or a WHO certificate or a GMP compliance certificate issued by the authority of a country in the case of countries other than the above countries.

(Points to consider)

1) Submit Compliance Certificate etc. issued by the country's relevant authority as specified in Section 3, Item 9 "Compliance Inspection" of the PFSB/CND Notification No. 0330001, dated March 30, 2005.
2) In the case of the compliance inspection of a manufacturing site in countries with which MRA is not concluded or with which MOU is not exchanged, submit Compliance Certificate, etc. issued by the country's relevant authority.
3) If a copy of certified details registered in Eudra GMDP database, or data with a certificate number for referring to the certified details are available as an attachment, there are cases where documents may be omitted. Follow the actual instructions of the inspector.

3. A copy of marketing approval document (or a copy of a manufacturing notification of export drugs).

§2. "Documents required by the compliance inspection authority" specified in Chapter 1, Section 3-9, (2), (d) in Enforcement Notifications

The following documents are only the standard documents. The "documents required by the compliance inspection authority" vary based on the product subject to inspection, process subject to inspection, and the results of previous inspection, etc. Follow the instructions of the inspector.

1. Outline of the product, etc. subject to inspection and outline of the manufacturing site
   1) Outline of product(s) subject to inspection (Form 1)

2) Outline of drug manufacturing site (Japanese manufacturing site) (Form 2) or outline of drug manufacturing site (foreign manufacturing site) (Form 3)

(Points to consider)

Applications pertaining to external testing laboratories do not require submission of Form 2 or Form 3; submit Form 1 filled out the necessary columns for the external testing laboratory. The information on the manufacturing site of the contract giver should be filled in the column of "Name of manufacturing site" and "Address of manufacturing site" in Form 1. As for the external testing laboratories subject to inspection, necessary information should be filled in the column of "External testing laboratory."

2. Documents on SOPs, etc.

Submit a list of SOPs, etc. (Attachment 5).

(Points to consider)

Attachment 5 can be downloaded from the homepage of PMDA.
(https://www.pmda.go.jp/review-services/gmp-qms-gctp/gmp/0001.html)

3. Documents on the manufacturing process

Submit a copy of the manufacturing record (for 1 batch): or the Master Batch Record of the product subject to inspection.

(Points to consider)

1) Specify the parts corresponding to the descriptions of the marketing approval application or the MF in the manufacturing record or the Master Batch Record.
2) If it takes a long time to show the parts corresponding to the descriptions of the marketing approval application etc. in the manufacturing records, etc., it is acceptable to submit the manufacturing record or the Master Batch Record in which necessary information is included in handwriting.
3) Confirm whether the descriptions in the marketing approval application or the MF differ from those in the manufacturing record or the Master Batch Record, and describe the confirmation result in the written response. When any difference is detected, the content and reason should be explained.
4) When any recovered solvent is used and the fact is not described in the marketing approval application or the MF, the process in which the recovered solvent is used should be described in the written response as a difference. When it is considered in the marketing approval review that the use of recovered solvent, if any, need not be described in the marketing approval application or the MF, describe as such in the written response, and submit it.

4. Documents on testing (In the case that the facility subject to inspection is mainly the manufacturing site for active pharmaceutical ingredients or products)

Submit copies of the testing records for the in-process control test, intermediates, product, etc. (for 1 batch) which are included in the marketing approval application or the MF of the product subject to inspection. It is acceptable to submit as a certificate of analysis (COA) only if the principles of the testing methods (HPLC, GC, etc.) and the test results are specified.

(Points to consider)

1) Specify the parts corresponding to the descriptions of the marketing approval application or the MF in the testing records.
2) Confirm whether the descriptions on testing in the marketing approval application or the MF differ from those in the testing records for the actual practices (procedures, items, and specifications) of the tests performed at the facility subject to inspection, and describe the confirmation result in the written response. When any difference is detected, the content and reason should be explained. (Example response: It is determined that XX may be omitted from the release test of the product based on the agreement between the marketing authorization holder and the manufacturing site. The agreement specifying the relevant part is attached.)

5. Documents on testing (In the case that the facility subject to inspection is mainly an external testing laboratory).

Submit the following documents on the testing methods of the product subject to inspection.

1) A copy of the SOPs for specifications and test methods
2) A copy of the testing records of the tests practically performed at the facility subject to inspection

(Points to consider)

Same as the points to consider mentioned above in the section 4.

6. Documents on the control of materials

For the product subject to inspection, submit a copy of the acceptance test results of the following raw materials and other materials (for 1 batch).

1) Materials whose specifications are established in the MF
2) Materials which are described in the “ingredients and contents or nature column” in the marketing approval application and materials whose specifications are established in the column of manufacturing process
3) Recovered solvents whose specifications are established in the marketing approval application or the MF
4) Purified water and water for injection used in the manufacturing

(Points to consider)

1) Specify the parts corresponding to the descriptions of the marketing approval application or the MF in the testing records.
2) Confirm whether the descriptions in the marketing approval application or the MF differ from those in the testing records, and describe the confirmation result in the written response. When any difference is detected, the content and reason should be explained.

7. Number of manufacturing batches, and number of scheduled annual manufacturing batches.

Submit lists presenting annual number of batches and the batch size of the product subject to inspection manufactured in the manufacturing site subject to inspection.

8. Documents on the status of process validation

1) Submit a copy of the prospective validation report including the following items in which the robustness of manufacturing process related to the product subject to inspection, which is described in the marketing approval application. (Validation at any change of the

manufacturing process should be included.)

(i) Process validation report for 3 batches at the commercial scale
If the robustness of manufacturing process was validated in an approach other than the process validation for 3 batches with the commercial batch production equipment, it should be explained that the validation with the approach used is at least equivalent to the validation based on the results in 3 batches.

(ii) It should be described whether any deviation occurred during the process validation. When any deviation occurred, provide a summary of the deviation, a summary of the corrective action and the preventive action, and an explanation on the current management status.

(iii) When any deviation occurred during the process validation, explain the rational to consider that the prospective process validation is effective regardless of occurrence of the deviation.

(Points to consider)

Make sure to submit documents applicable to the items (ii) and (iii) mentioned above without fail.

2) For the aseptic manipulation process, submit the copy of the most recent report of the process simulation tests results performed in the facilities and equipment for manufacturing of the product subject to inspection to assure sterilization, in which includes the following details. When it is an initial validation, submit the results of consecutive 3 runs as the process simulation tests results. In the case of a periodic validation, submit the results of one run.

(i) Provide a clear explanation of the process validated in the process simulation tests.

(ii) Explain that the conditions of the process simulation tests (number of units filled, interventions, etc.) are the worst case based on the actual manufacturing practices.

9. Documents on the management status of the Standards for Biological Ingredients

Submit data that show the management of the Standards for Biological Ingredients for the applied product. For example, submit an original copy of a statement to declare that the manufacturing site uses only the raw materials which conform to the Standards for Biological Ingredients, copies of the procedure to confirm that the raw materials used confirm to the Standards for Biological Ingredients, the quality agreement with the supplier of raw materials, the certificate of analysis prepared based on the quality agreement with the supplier, and relevant documents. If no raw materials applicable to the Standards for Biological Ingredients are used, describe as such in the written response.

(Points to consider)

If an original copy of the statement is not available, its copy is acceptable. If no raw materials applicable to the Standards for Biological Ingredients are used, make sure to describe as such in the written response without fail.

10. Documents on testing (In the case that the facility subject to inspection is mainly an external testing laboratory).

Submit the following documents on the testing methods of the product subject to inspection.

1) A copy of the SOPs for specifications and test methods
2) A copy of the testing records of the tests practically performed at the facility subject to inspection

(Points to consider)

Same as the points to consider mentioned above in the section 4.

11. Documents on the control of materials

For the product subject to inspection, submit a copy of the acceptance test results of the following raw materials and other materials (for 1 batch).

1) Materials whose specifications are established in the MF
2) Materials which are described in the “ingredients and contents or nature column” in the marketing approval application and materials whose specifications are established in the column of manufacturing process
3) Recovered solvents whose specifications are established in the marketing approval application or the MF
4) Purified water and water for injection used in the manufacturing

(Points to consider)

1) Specify the parts corresponding to the descriptions of the marketing approval application or the MF in the testing records.
2) Confirm whether the descriptions in the marketing approval application or the MF differ from those in the testing records, and describe the confirmation result in the written response. When any difference is detected, the content and reason should be explained.

Attachment 2

Documents to be submitted to PMDA when applying for its periodic GMP inspection of Drugs or Quasi-drugs

Documents required to be submitted to PMDA when applying for its pre-approval GMP inspection have been specified in Article 50, Paragraph 2 (including the cases where applied mutatis mutandis pursuant to Article 111 and Article 264, Paragraph 2) of Enforcement Ordinance as "data on manufacturing control and quality control of product subject to compliance inspection" and "data on manufacturing control and quality control of manufacturing site subject to compliance inspection". Specifically, the required data are as follows:

§1. Documents specified in Enforcement Notifications

1. A copy of notification of GMP compliance inspection results or GMP compliance inspection result report of GMP inspection (including inspections conducted by other authorities) conducted over the past 2 years from the application date of the compliance inspection.
2. For inspections on foreign manufacturing sites, a compliance certificate issued by a country with which MRA is concluded; a certificate issued by a country with which MOU is exchanged; or a WHO certificate or a GMP compliance certificate issued by the authority of a country in the case of countries other than the above countries.

   (Points to consider)

   1) Submit Compliance Certificate etc. issued by the country's relevant authority, etc. as specified in Section 3, Item 9 "Compliance Inspection" of the PFSB/CND Notification No. 0330001, dated March 30, 2005.
   2) In the case of the compliance inspection of a manufacturing site in countries with which MRA is not concluded or with which MOU is not exchanged, submit Compliance Certificate, etc. issued by the country's relevant authority, etc. Only in the case of a periodic PoAI, submit an original copy.
   3) If a copy of certified details registered in Eudra GMDP database, or data with a certificate number for referring to the certified details are available as an attachment, there are cases where documents may be omitted. Follow the actual instructions of the inspector.

3. A copy of marketing approval document (or a copy of a manufacturing notification of drugs for export)
4. Copies of partial change approvals over the past 5 years.
5. Copies of minor change notifications over the past 5 years.
6. If applications for two or more products are made simultaneously, the applicant should categorize applications by worksite, workroom, area, equipment etc., select representative products for each category, and submit documents that show reasons for such categorizations and selections. (If representative products are selected in line with these rules, documents indicated in 1. through 5. may be limited to those concerning the representative products.)

   (Points to consider)

   In principle, representative products should be those that have not been selected in the

preceding periodic PoAI.

7. Any recalls over the past 5 years of the product whose applications being submitted (if there have been recalls, submit their summary)
8. Declaration (refer to Enforcement Notifications for the declaration form (Attachment 1-3-1))

§2. "Documents required by the compliance inspection authority" specified in Chapter 1, Section 3-9, (2), (h) in Enforcement Notifications

1. Outline of the product subject to the inspection and outline of the manufacturing site
   1) Outline of the product(s) subject to inspection at the manufacturing site (Form 1)
   2) Outline of the drug manufacturing site (for a manufacturing sites in Japan) (Form 2) or outline of the drug manufacturing site (for a manufacturing sites in a foreign country)(Form 3). Applications pertaining to external testing institutions do not require submission of Form 2 or Form 3; submit Form 1 with the column filled out necessary columns for external testing institutions.

(Points to consider)

The document of Form 1 "Outline of product(s) subject to inspection" should be submitted for all products subject to inspection.

2. Documents on the manufacturing process

Upon confirming the following matters, the supervisor for manufacture at the manufacturing site subject to inspection (or the responsible per at the manufacturing site of the foreign manufacturer and also the Master File (MF) in-country caretaker if MF is to be used, should submit an original copy of a declaration with the signatures shown in Attachment 3 or 4.
There should be no discrepancy between the manufacturing process (including process parameters, in-process testing items, and control limits), specifications of all products subject to inspection and the content of the marketing approval document or the MF.

(Points to consider)

1) The content to be declared in Attachment 3 or Attachment 4 is different from the content in the declaration (Attachment 1-3-1) mentioned in Enforcement Notifications. Both declarations should be submitted.
2) When any recovered solvent is used and the fact is not described in the marketing approval application or the MF, it should be described in the written response as a difference together with the process in which the recovered solvent is used. When it is considered in the marketing approval review that the use of recovered solvent, if any, need not be described in the marketing approval application or the MF, describe as such in the written response, and submit it.

If representative products are selected in line with the rules in Chapter 1, Section 3-9 (2) (e) in Enforcement Notifications, documents indicated in following 3. and 4. may be limited to those concerning the representative products, except for 3. (3) "Review on all batches that did not conform to established specifications and on the inspection of those batches."

3. Data on product quality review

Submit a copy of the summary of the product quality review from its most recent report within the past 2 years regarding the representative products or products subject to inspection, or otherwise submit a summary of this report that has been separately compiled. If the product quality review has not conducted within the past 2 years, explain the reason and submit the report of the product quality review conducted after the date of previous inspection (a copy of the summary) or otherwise submit a summary of this report that has been separately compiled.

This should include the name of the group (limited to the cases where the review was conducted upon grouping the representative products and other products; include the scientific validity and grounds for grouping the products) that was subject to review, review period, review results and discussions (including discussions on revalidation results), summary of corrective action and preventive action (including plans) that were taken based on the review results, and the name and seal or signature of the reviewer (the name and seal or signature will not be necessary on the copy if its original copy already has the responsible person's name and seal or signature on it).

If the report of the product quality review does not include the following items of review results and a separate review has been conducted on these items, data on these review results should be submitted. If the following items were not subject or applicable to product quality review, describe the reason clearly.

(Points to consider)

The review results should include not only the word of "Compliance." The information including the summary on the justification for the determination of "Compliance" should be submitted. Additionally, confirm before submission of the written response that the review results for the required items are completely included.

(1) Review on results of testing at receipt of raw materials and other materials
It should include discussions on the appropriateness of results of testing at receipt of critical raw materials and other materials (including packaging materials [especially those from new supplier]) and of supplier evaluation.

(2) Review on results of critical process control and of quality control results of final products
It should include discussion on the validity of process control specifications and product specifications based on statistical analysis results.

(3) Review on all batches that did not conform to established specifications and on the inspection of those batches
It should include a summary and discussion on corrective action and preventive action that were based on the results of investigation on the reason why the product subject to review. did not conform to specifications in its manufacturing.

(Points to consider)

The results of "Review on all batches that did not conform to established specifications and on the inspection of those batches" should be submitted, not being limited for the representative products but for all products subject to inspection.

(4) Review on all major deviations or non-conformity, related inspections, and effectiveness of corrective action and preventive action that were consequently taken corrective action and preventive action should be handled as matters related to (8) in the next review period if their effectiveness could not be clarified during the review period.

(5) Review on all changes in processes or analytical methods
It should include a discussion on whether there was any impediment as a result of changes.

(6) Review on stability monitoring results and on all unfavorable trends
It should include a discussion on batches, other than those that were subject to planned stability monitoring, on which stability monitoring was conducted for reasons of change or deviations, along with the reason why it was conducted.

(Points to consider)
As for the stability monitoring conducted for reasons of change or deviations, indicate the relevant batches.

(7) Review on all returns, quality information, and recalls related to quality and on investigation on their causes which was conducted at the time
It should include a discussion on the cause of frequent similar returns, receiving quality information, or recalls, along with the results of trend analysis.

(8) Review on the appropriateness of corrective actions that were taken in the past on processes or equipment
It should include a discussion on whether corrective actions that were taken on processes and facilities in manufacturing the representative products were appropriate regarding those whose effectiveness could not be clarified in past review periods.

(9) Qualification status of relevant equipment and utilities
It should include results of confirming systematic qualification of equipment and utilities (e.g., HVAC, water, compressed air) (including calibration of equipment, and routine inspection and periodic maintenance of utilities)

(Points to consider)
Describe the utilities subject to review clearly.

(10) Review on management of contract partners
It should include results of confirming that agreements concluded with external testing laboratory are in their latest state.

(Points to consider)
When there are no contract partners, describe as such in the written response.

4. Documents on the status of validations

Submit the copy of the most recent report of the process simulation tests results on aseptic manipulation process for assuring sterilization among validations that have been conducted after

the preceding inspection for representative products or products subject to inspection. When it is an initial validation, submit the results of consecutive 3 run tests as the process simulation tests results. In the case of a periodic validation, submit the results of 1 run test.

(i) Provide a clear explanation of the process validated in the process simulation tests.

(ii) Explain that the conditions of the process simulation tests (number of units filled, interventions, etc.) are the worst case based on the actual manufacturing practices.

5. Documents on the management status of Standards for Biological Ingredients

Submit data that show the management of Standards for Biological Ingredients for representative products and other products subject to inspection. For example, submit an original copy of a statement to declare that the manufacturing site uses only the raw materials which conform to the Standards for Biological Ingredients, the procedure to confirm that the raw materials used conform to the Standards for Biological Ingredients, the quality agreement with the supplier of raw materials, the certificate of analysis prepared based on the quality agreement with the supplier, and relevant documents. If no raw materials applicable to the Standards for Biological Ingredients are used, describe as such in the written response.

(Points to consider)

If an original copy of the statement is not available, its copy is acceptable. If no raw materials applicable to the Standards for Biological Ingredients are used, make sure to describe as such in the written response without fail.

Attachment 3

To: Office Director,
Office of Manufacturing/Quality and compliance,
Pharmaceuticals and Medical Devices Agency

Statement

It is hereby certified that there is no discrepancy between the manufacturing process(es), specification(s) and analytical test method(s) of (Product(s) subjected to inspection) in (Name of manufacturing site) and the content(s) described in the Marketing Approval Document.

Product(s) subjected to be inspected: (Please specify all the products to be inspected.)

Name of manufacturing site:

Address of manufacturing site:

(The name of responsible person of the site) YYYY/MM/DD
(Title) Date

Attachment 4

To: Office Director,
Office of Manufacturing/Quality and compliance,
Pharmaceuticals and Medical Devices Agency

Statement

It is hereby certified that there is no discrepancy between the manufacturing process(es), specification(s) and analytical test method(s) of (Product(s) subjected to inspection) in (Name of manufacturing site) and the content(s) described in the registered DMF.

Product(s) subjected to be inspected: (Please specify all the products to be inspected.)

Name of manufacturing site:

Address of manufacturing site:

(Name of responsible person of the site) YYYY/MM/DD
(Title) Date

(Name of DMF in-country representative) YYYY/MM/DD
(Title) Date

様式 1
Form 1

当該製造所における調査対象品目等に関する概要
Outline of Product(s) Subject to Inspection

平成　年　月　日現在
As of DD/MM/YY

製造販売業者の氏名（法人にあっては、名称及び代表者の氏名） Name of marketing authorisation holder	
品目名 Product name	
製造所の名称 Name of manufacturing site	
製造所の所在地 Address of manufacturing site	

調査対象品目等に関する情報　　該当する□にレ点を記載してください。
Information of product(s) subject to inspection
Please put X in the appropriate boxes.

製造施設・設備機器 +Buildings, facilities and equipment	原薬製造を含む一次包装工程までの製造に係る From APIs manufacturing to the primary packaging 建物： Buildings: □ 専用　□ 共用（一部共用を含む） Dedicated　Shared(including partially shared) 製造区域： Manufacturing areas: □ 専用　□ 共用（一部共用を含む） Dedicated　Shared(including partially shared) 製造設備機器： Facilities and equipment: □ 専用　□ 共用（一部共用を含む） Dedicated　Shared(including partially shared)

	＊いずれかが「共用（一部共用を含む』に該当する場合には、それを共用する製品等が： When buildings, manufacturing areas or facilities equipment correspond to “shared (including shared)”, please provide information of the sharing them by putting X in the appropriate box(es). □高生理活性物質（ある種のステロイド類（性ホルモン、活性の強いステロイド等）や細胞毒性のある抗がん剤のように強い薬理作用又は毒性を有する物質等） Highly bioactive substances (including strong pharmacological and/or toxic substances such as sorts of steroids (e.g. sex hormones and strong steroids) or cytotoxic anticarcinogens) □ペニシリン系抗生物質　□β ラクタム系抗生物質 Penicillin antibiotics　β-lactam antibiotics □上記に該当なし　□開示なし None of the above　Not to be disclosed
	二次包装工程以降の製造に係る施設・設備機器： Buildings, facilities and equipment in and after the secondary packaging □ 専用　□ 共用（一部共用を含む） Dedicated　Shared(including partially shared)
製造工程の範囲 Manufacturing process	□ 原薬中間体製造 Manufacturing of API intermediates □ 原薬製造 Manufacturing of APIs □ 原薬の一部工程（原薬の粉砕等） Part of API manufacturing process (Milling of APIs, etc.) □ 原薬の小分 Subdividing of APIs □ 製剤製造 Manufacturing of drug products □ 製剤の一部工程（製剤のコーティング等） Part of drug product manufacturing process (Coating of drug products, etc.) □ 製剤の小分（PTP 包装、ボトル充填等） Subdividing of drug products (PTP packaging, bottle filling, etc.) □ 包装・表示 Packaging/Labeling □ 保管 Storage

製品情報 Product information	□ 生物学的製剤等 Biological product, etc. □ 放出調節製剤 Modified release drug product □ シリンジ注射剤 Syringe injection drug □ 輸液 Infusion fluid □ 粉末注射剤 Powder injection drug □ 凍結乾燥注射剤 Lyophilized injection drug □ 溶液注射剤 Liquid for injection □錠剤、カプセル剤、散剤、顆粒剤 Tablets, Capsules, Powders, Granules □軟膏剤、クリーム剤、外用液剤、坐剤 Ointments, Creams, Liquids and Solutions for Cutaneous Application, Suppositories for Rectal Application □吸入剤、吸入エアゾール剤 Inhalations, Metered-Dose Inhalers □点眼剤、眼軟膏剤 Ophthalmic Preparations, Ophthalmic Ointments □貼付剤 Patches □スプレー剤 Sprays for Cutaneous Application □生薬関連製剤 Crude Herbal Medicine related Preparations □ その他（　　剤） Others (dosage form：　　)

原薬情報 Information of APIs	□ 新規有効成分 New active ingredients □ 既存有効成分 Existing active ingredients
MF 利用 MF registration ■ 有 Registered ■ 無 Not registered	＊この枠内より、該当するものを一つまたは複数選択してください。 ＊Please put X in the appropriate boxes from this area. □ ワクチン Vaccine □ 遺伝子組換え、細胞培養応用 Recombinant DNA technology-applied or cell culture derived drugs □ 抗血清 Antiserum □ 高生理活性物質（ある種のステロイド類（性ホルモン、活性の強いステロイド等）や細胞毒性のある抗がん剤のように強い薬理作用又は毒性を有する物質等） Highly bioactive substances (including strong pharmacological and/or toxic substances such as sorts of steroids (e.g. sex hormones and strong steroids) or cytotoxic anticarcinogens) □ ペニシリン系抗生物質 Penicillin antibiotics □ β ラクタム系抗生物質 β-lactam antibiotics □ ヘパリン様物質 Heparin-like compounds □ ヒト由来物質 Human-derived materials □生薬（原薬としての） Crude herbal medicine (as API) □ビタミン Vitamin □上記に該当なし（　　） None of the above （　　）
	□ 無菌原薬 Sterile APIs □ 非無菌原薬 Non-sterile APIs

	□ 日局収載品 Products listed in Japanese pharmacopoeia □ 食品添加物 Food additives □ その他（　　） Others(　　)

製造方法（無菌製剤）[5] Manufacturing method (Sterile preparations)[6]	■ 無菌操作法　Aseptic processing ■ 最終滅菌法 Terminal sterilization ■ その他 Others (　　)
プロセスバリデーションの実施状況（定期適合性調査の場合は記載不要） PV status	□実製造機器／実製造スケール／連続 3 バッチの条件で を実施した。又は実施する予定である。(実施月　[7]：　平成　年　月から　月) PV was (will be) conducted under the following conditions: Use of commercial batch production equipment/ Commercial batch scale / Continuous 3 batches.　(Date[8]: MM/YY～MM/YY) □実製造機器／実製造スケール／連続 3 バッチ以外の条件 PV を実施した。又は実施する予定である。(実施月：　平成　年　月から　月) PV was (will be) conducted under the other conditions. (Date:　MM/YY～MM/YY)
GQP 省令第 7 条基づく取決め Agreement in accordance with GQP Ordinance Article 7	□ 有（取決め日　　年　　月　　日） Concluded (Date of agreement：DD/MM/YY) □ 無（ドラフトを含む）(取決め予定日：　　年　月　日) Not concluded (including draft agreement) （Expected date of agreement：DD/MM/YY）
外部試験検査機関[9]	機関の名称 Name of the laboratory

[5] 当該製造所の製造工程がいずれかの工程を含む場合のみ、□にレ点を記載してください。

[6] Please put X in the appropriate boxes only if the manufacturing process of the site has any of these operations.

[7] 調査申請時に未実施の場合は、実施予定月を記載してください。

[8] If PV is not completed at the time of submitting GMP compliance application, please write a scheduled date.

[9] 外部試験検査機関の利用に関しては、自社の他の試験検査施設とそれ以外の外部試験検査機関とを分け、複数ある場合には欄を追加して記載するようにしてください。また、外部試験検査機関を利用して行う試験については、「原料試験」「工程内管理試験」又は「出荷試験」のいずれか該当する箇所に記載してください。なお、有効成分、賦形剤、注射用水等承認（申請）書の「成分及び分量又は本質」欄に記載された成分の品質試験 に関する記載も必要です。ただし、環境モニタリング等に係る試験検査に関する記載は不要です。

（利用する場合に記載すること） External testing laboratory[10] （if applicable） □ 自社の他施設 （グループ会社[11]を含む） In-house Laboratory (including affiliated companies[12]) □ 外部 Contract laboratory	機関の所在地 Address 電話 Telephone: □ 原料試験 Raw material test 試験名： Name of the test: □ 工程内管理試験 In-process control test 試験名： Name of the test: □ 出荷試験 Release test 試験名： Name of the test:

[10] If utilizing testing laboratories, please clearly indicate in-house testing laboratory or external testing laboratories. If there are multiple laboratories, please add the column as you needed. Please breakdown the outsourcing tests to “Raw material”, “In-process” and “Release”. Do not forget to put all external laboratories where conducting all tests indicated in application (eg, API, excipients, WFI etc.). Exclude the laboratories which conducting the Environmental monitoring test (eg. Microbial test, Identification of bacteria etc.).

[11] 統一的な品質保証体制にある場合

[12] Manufacturers managed under the same quality control systems

様式３
Form 3

医薬品製造所概要（外国製造所用）
Outline of Drug Manufacturing Site (Foreign Manufacturing Site)

平成　年　月　日現在
As of DD/MM/YYYY

製造所の名称 Name of manufacturing site	
製造所の所在地 Address of manufacturing site	
国内連絡先 Contacts in Japan	業者名 Name of the company_____ 担当者 Contact person_____ 電話 Phone_____ _____ E-mail_____

認定番号 Accreditation No.	当初認定年月日 Date of initial accreditation
認定の期限 Expiry date	認定の区分 Accreditation category

従業員数（パート社員等を含む）
Numbers of employees　(including part-time employees)

全従業員数 Total	製造部門 Manufacturing department	QC 部門 QC department	QA 部門 QA department
人	人	人	人

製造所の責任者
Responsible person of the site
(Qualified person in the EU, or head of quality unit in other countries)

氏名 Name	職名 Job title
電話 Phone_____ E-mail _____	_____

製造所で製造しているすべての品目数（すべての品目数の内、日本向けの品目 数を（　）内に記載）
（例:50 品目製造しており 50 品目の内 10 品目が日本向けの場合:　50 (10)　）
Number of manufactured products (Number of products exported to Japan should be described in parenthesis.)
(eg. If the site manufactures 50 products and 10 out of 50 products are exported to Japan: 50(10))

	原薬・中間体 Manufacturing of APIs/Intermediates	製剤化工程 Manufacturing of drug Products	一次包装工程以降 After primary packaging	二次包装工程以降・表示・保管のみ Secondary packaging・Labeling・Storage
製造品目数 Number of products				
高生理活性物質 Highly bioactive substances				
ペニシリン系抗生物質 Penicillin antibiotics				
β ラクタム系抗生物質 β-lactam antibiotics				

注）１．高生理活性物質とは、ある種のステロイド類（性ホルモン、活性の強いステロイド等）や細胞毒性のある抗がん剤のように強い薬理作用又は毒性を有する物質等をいう。
２．原薬の小分けに関しては､「原薬・中間体」の欄に記載。

Note)
1. "Highly bioactive substances" include strong pharmacological and/or toxic substances such as some sorts of steroids (e.g. sex hormones, and strong steroids) or cytotoxic anticarcinogens.
2. In cases of subdividing manufacture of APIs, please fill in the Manufacturing of API/Intermediate column.

調査対象品目の状況
Information of the products subject to the inspection

品目名（英語名も併記のこと） Names of the products (Please specify English names as well)	当該製造所での製造開始時期 Commercial manufacture started from (MM/YY)	当該製造所製造品の欧米流通開始時期 Marketing in EU and US started from (MM/YY)	当該製造所製造品の国内流通開始時期 Marketing in Japan started from (MM/YY)

施設情報　①
Information of the manufacturing site I

製造所敷地面積 Area of the site	倉庫面積 Area of the warehouse
製造施設面積 Area of the manufacturing facilities	試験検査施設面積 Area of the testing laboratory

施設情報②（使用している重要なコンピュータ化システム）
Information of the manufacturing site II
(Overall function of major computer system adopted in the manufacturing site)

重要なコンピュータ化システムの名称 Name of major computer system	□ERP　□MES　□LIMS　□DCS □その他 Others（　　）□使用なし(N/A)

過去 5 年間の行政機関からの査察の有無
History of GMP inspections by regulatory authorities over the past 5 years.

行政機関名 Name of regulatory authorities	時期 Inspection date	対象品目名 Name of inspected products	結果 Inspection results	実地か書面かの別 Type of inspection (On-site/Desk-top)

過去 5 年間の回収、GMP 不適合の有無（有の場合には概要を記載）
History of product recall or GMP non-compliance over the past 5 years (Please specify details.)

Points to note for filling in Form 2 and Form 3

- The "QC department" (Quality Control) refers to a quality control department (a department in charge of testing) whereas the "QA department" (Quality Assurance) refers to a quality assurance department. Thus, "Quality department" is functionally divided into the "QC department" and "QA department."

- For a manufacturing site where the Quality department is not divided into QC department and QA department, please fill the total number of employees in the Quality department in the column of "QC department" and fill "0" in the column of "QA department."

- In the column of "Number of products," please fill the number of all the products manufactured at the manufacturing site including, but not limited to, those subject to inspection application.

- In the column of "Information of the manufacturing site," please fill applicable information on the entire parts of the manufacturing site including, but not limited to, those of the products subject to inspection application.

- In the column of "History of GMP inspections by regulatory authorities over the past 5 years," please fill applicable information on the history of GMP inspections (Such information should include those conducted by overseas authorities) for all the products manufactured at the manufacturing site including, but not limited to, those subject to inspection application.

- In the column of "History of product recall or GMP non-compliance over the past 5 years," please fill the presence or absence and the outline of the applicable cases of all the products manufactured at the manufacturing site including, but not limited to, those subject to inspection application.

- In the column of "Contacts in Japan," please fill information on the appropriate contact points for the inspector of PMDA.

Checklist 1

Pre-approval GMP Compliance Inspection Application or Inspection Application for Partial Change
List of attached data for Inspection application

Precaution at an inspection application

1. <u>All documents listed in the checklist below should be prepared for the inspection application.</u>
2. <u>This checklist should be attached to the GMP compliance inspection application form.</u>
3. Prepare the documents with plenty of time in advance with GMP consideration of the schedule for the compliance inspection application.

Applicant's name	Ex: ● Pharmaceutical Company	Application date	DD/MM/YYYY
Product subject to inspection			
Name of Manufacturing site subject to inspection			
Registration number of the Master file (MF) subject to the inspection	Ex 1: ●●MF●●●●●● Ex 2: Not applicable		
Remarks			

Pre-approval or partial change: Data required to be submitted for Compliance inspection application		Put circle un the column below if the documents have been attached. Draw a slash through those that are not applicable. Ex 3: ○ Ex 4: Will be submitted by the MF in-country caretaker by DD/MM/YYYY Ex 5: Will be directly sent from the manufacturing site to the Office of Manufacturing/Quality and Compliance by DD/MM/YYYY
(*1)	1. A copy of Notification/Report on GMP compliance inspection results within the past 2 years	(*3)
	2. GMP compliance certificate issued by a MRA partner country	(*3)
	3. A copy of the marketing approval document (manufacturing notification of drugs for export)	(*3)
(*2)	1. Outline of the product subject to inspection and outline of the manufacturing site (1) Form 1	(*3)
	(2) Form 2 or Form 3	(*3)

(*1) Those specified in the Enforcement Notifications.

(*2) A part of "data required by the compliance inspection authority" specified in Chapter 1, Section 3-9, (2), d. in Enforcement Notifications.

(*3) Make sure to attach data when submitting the application for the GMP compliance inspection. Explain the reason if there are data that cannot be submitted at the inspection application due to special circumstances regarding the product subject to inspection. Cases where data cannot be submitted at the inspection application due to delay in preparing/submitting data are not regarded as special circumstances. Submit the inspection application at the time point when all the data have been made ready.

Checklist 2

Periodic post-approval GMP Compliance Inspection Application
List of attached data for Inspection application

Precaution at an inspection application

1. All data listed in the checklist below should be prepared for the inspection application.
2. This checklist should be attached to the GMP compliance inspection application form.
3. Prepare the data with plenty of time in advance with GMP consideration of the schedule for the compliance inspection application.

Applicant's name	Ex: ● Pharmaceutical Company	Application date	DD/MM/ YYYY
Product subject to inspection			
Name of Manufacturing site subject to inspection			
Registration number of the Master file (MF) subject to the inspection	Ex 1: ●●MF●●●●●● Ex 2: Not applicable		
Remarks			

Periodic: Data required to be submitted for GMP Compliance inspection application		Put circle in the column when the documents that have been attached. Draw a slash through those that are not applicable. Ex 3: ○ Ex 4: Will be submitted by the MF in-country caretaker by DD/MM/YYYY Ex 5: Will be directly sent from the manufacturing site to the Office of Manufacturing/Quality and Compliance by DD/MM/YYYY
(*1)	1. A copy of Notification/Report on GMP compliance inspection results within the past 2 years	(*3)
	2. Compliance certificate issued by a MRA partner country	(*3)
	3. A copy of the marketing approval document (manufacturing notification of drugs for export)	(*3)
	4. Copies of partial change approval documents over the past 5 years	(*3)
	5. Copies of minor change notifications over the past 5 years	(*3)
	6. Document explaining the rational for ~~to~~ selecting the representative products	(*3)
	7. Any recalls over the past 5 years related to the product to be applied (summary of those recalls)	(*3)
	8. Declaration (refer to Enforcement Notifications for the Form)	(*3)
(*2)	1. Outline of the product subject to inspection and outline of the manufacturing site (1) Form 1	(*3)
	(2) Form 2 or Form 3	(*3)
	2. GMP organization chart and data on the quality assurance system	(*3)
	3. Documents on the manufacturing process	(*3)
	4. Manufacturing results	(*3)
	5. Documents on product quality review	(*3)
	6. Documents on the status of validations	(*3)
	7. Documents on management of Standards for Biological Ingredients	(*3)

(*1) Those specified in Enforcement Notifications.

(*2) A part of "documents required by the compliance inspection authority" specified in Chapter 1, Section 3-9, (2), h. in

Enforcement Notification. If a GMP compliance certificate of a MRA product issued by the authority of MRA country (original copy only; this may be substituted, however, with a copy of certified details registered in Eudra GMDP data base, or data with a certificate number for referring to the certified details) or GMP compliance certificate (original copy only) issued by the authority of a country with which MOU is exchanged is available as the attachment, there are cases where data may be omitted (excluding those specified in (1) and (7)). Follow the actual instructions of the inspector.

If a person other than the inspection applicant (e.g., manufacturing site subject to the inspection, MF in-country caretaker) is directly send documents to PMDA, the applicant should make adjustments so that those data are submitted to PMDA promptly after the inspection application.

(*3) Make sure to attach documents when submitting application for the GMP compliance inspection. Explain the reason if there are documents that cannot be submitted at the inspection application due to special circumstances regarding the product subject to inspection. Cases where data cannot be submitted at the inspection application due to delay in preparing/submitting data are not regarded as special circumstances. Submit the inspection application at the point when all the documents have been made ready.

(*4) Promptly submit them at the time or after the GMP compliance inspection application. When submitting them after the application, indicate the date on which those data are expected to be submitted, as shown in Ex. 4 and Ex. 5.

Attachment 5

List of SOPs, etc.

SOPs, etc.	Name of SOP at the site	SOP Number	the latest Revision	Explain why any SOP isn't set up (if applicable)
SOPs for Management of Release				
SOPs for Validation (including SOPs for Process Validation and SOPs for Cleaning Validation)				
SOPs for Change Control				
SOPs for Deviation Control				
SOPs for handling quality-related information				
SOPs for Recall				
SOPs for Self-inspection				
SOPs for Training				
SOPs for Document and Record Management				
SOPs for Product Quality Review				
SOPs for Management of Supplier of Materials				