

Office Memorandum  
July 29, 2008

Office of Compliance and Standards  
Pharmaceuticals and Medical Devices Agency

## **Documents required by PMDA for the Application of GMP Compliance Inspection**

The documents to be attached when applying for the GMP compliance Inspection are described in Article 50 of the Enforcement Regulations of the Pharmaceutical Affairs Law and “Enactment, Revision, or Repeal of Ministerial Ordinances and Notices Related to the Standards for Manufacturing Control and Quality Control of Drugs and Medical Devices (GMP/QMS) for the Enforcement of the Law for Partial Revision of the Pharmaceutical Affairs Law and the Blood Collection and Donation Services Law (PFSB/CND Notification No. 0330001 dated March 30, 2005). Among the “other documents required by the compliance Inspection authority” described in 9-(1)d and (2)h under Section 3 Compliance Inspection of Chapter 1 General Provisions in the above notification, the following documents are now to be submitted at the time of applying for the inspection. Accordingly, you are requested to follow the instructions below.

### **1. Documents to be submitted**

- (1) Outline of Product(s) Subject to Inspect (Form 1)
- (2) Outline of Drug Manufacturing Site (domestic manufacturing site: Form 2, foreign manufacturing site: Form 3)

### **2. Description Method for Documents**

- (1) Outline of product(s) subject to inspect at the manufacturing site

The outline of the product(s) subject to inspect at the manufacturing site shall be described in Form 1. Please note the followings.

- 1) In each item, check all applicable boxes.
- 2) In the Column of “Confirmation pursuant to Article 10 of GQP Ministerial Ordinance”, check “conducted by third party” if conducted by a person other than the marketing authorization holder even when it was conducted onsite. In that case, describe the actual conductor (e.g. Japanese Agent XX, consulting firm YY, etc.).

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<sup>1</sup> Note: This document is a tentative translation of the original version of the Office Memorandum.

- 3) In the column of “Contract testing laboratories”, describe the in-house testing laboratories and outside laboratories separately. If there is more than one laboratory, add columns for the descriptions.
- 4) Describe the contract testing laboratories, only when the tests included in the marketing approval application are conducted. Include the name of the test for each of the raw material, in-process control, and release test.

In addition, the descriptions of the quality testing for components; such as active ingredients, excipients, and water for injection etc., if those are listed in the column of Compositions and Amount or Properties, then it should also be included in the descriptions of the tests. However, the descriptions of the tests for environmental monitoring etc. are not required.

## (2) Outline of Manufacturing Site

The outline of the manufacturing site, at which the product(s) subject to inspect is manufacturing, should be submitted using the Form 2 or 3.  
Please note the following points.

- 1) QC is an abbreviation for Quality Control and it means a quality control department (department in charge of analyses and tests).
- 2) QA is an abbreviation for Quality Assurance and it means a quality assurance department. The department which combines the QC and QA departments is called quality department.
- 3) For the manufacturing site where the QC and QA are not separated, enter the number of employees in the quality department in the QC column and enter 0 in the QA column.
- 4) For the number of manufactured products, not only the products related to the relevant marketing approval holder, but also all the products manufactured in the manufacturing site should be included.
- 5) In the column of “Information on the manufacturing site”, not only the facility related to the product(s) to be inspected, but also all the area of the site should be included.
- 6) In the column of “History of GMP inspections by regulatory authorities during the past 5 years” (including the overseas authorities), the inspections conducted for the products other than the ones subject to be inspected should also be included.
- 7) In the column of “History of product recall or unsuccessful inspection by a regulatory authority”, not only the events related to the product(s) subject to be inspected, but also all the events concerning the manufacturing site should be included.

- 8) In the column of “Contact in Japan”, the person, who is appropriate to make a contact with the inspector of PMDA regarding to the relevant foreign manufacturing site, should be indicated.
  - 9) In the column of “Information of the product subject to the inspection”, English name has to be attached, and it should be the name which is used in Japan.
3. Points to be noted for the Submission
- (1) Until the end of September 2008, the application for the inspection will be accepted even if it is not accompanied by Form 1 - 3. However, after the above date, the forms should be submitted at the same time to apply. If corrections are made in the contents of the forms by the time of application submit to the time of inspection, inspector may ask to re-submit the forms.
  - (2) Submit the Form 1 and 2, or 3 as a set.
  - (3) When submitting a partial change approval application, only the outline of the manufacturing site which subject to be changed is required.
  - (4) For the information on the manufacturing site, if there is any confidential information to the marketing authorization holder, indicate the related inspection information by including the name of the marketing authorization holder, product name, etc. In such case, the manufacturer, etc. is possible to submit the documents directly to the Office of Compliance and Standards of PMDA.

様式 1  
Form 1

当該製造所における調査対象品目に関する概要  
**Outline of Product(s) Subject to be inspected at Manufacturing Site**

平成 年 月 日現在  
As of yyyy, mm, dd

製造販売業者名 Name of Marketing Authorization Holder	
品目名 Product Name	
製造所の名称 Name of Manufacturing Site	
所在地 Address	

調査対象品目等に関する情報

該当する□にレ点を記載して下さい。

Information on the Product(s) subject to be inspected

Check the applicable boxes

製造設備機器 Manufacturing Facility and Equipment	製造（包装除く）Manufacturing (excl. packaging): <input type="checkbox"/> 専用 Dedicated <input type="checkbox"/> 共用 Shared <input type="checkbox"/> 一部共用 Partially shared 包装工程のみ Only packaging: <input type="checkbox"/> 専用 Dedicated <input type="checkbox"/> 共用 Shared <input type="checkbox"/> 一部共用 Partially shared
製造工程の範囲 Range of Manufacturing Process	<input type="checkbox"/> 原薬中間体製造 Manufacturing of API intermediate <input type="checkbox"/> 原薬製造 Manufacturing of API <input type="checkbox"/> 原薬の一部工程（原薬の粉碎等） Partial process of API (Milling of API, etc.) <input type="checkbox"/> 原薬の小分 Subdividing of API <input type="checkbox"/> 製剤製造 Manufacturing of drug product <input type="checkbox"/> 製剤の一部工程（製剤のコーティング等） Partial process of drug product (coating of drug product, etc.) <input type="checkbox"/> 製剤の小分（PTP 包装、ボトル充填等） Subdividing of drug product (PTP packaging, bottle filling, etc.) <input type="checkbox"/> 包装・表示 Packaging/Labeling <input type="checkbox"/> 保管 Storage
製品情報 Product Information	<input type="checkbox"/> 生物学的製剤等 Biological drug product, etc. <input type="checkbox"/> 放出調節製剤 Modified release drug product <input type="checkbox"/> シリンジ注射剤 Syringe injection drug <input type="checkbox"/> 輸液 Infusion fluid <input type="checkbox"/> 粉末注射剤 Powder injection drug <input type="checkbox"/> 凍結乾燥注射剤 Lyophilised injection drug <input type="checkbox"/> 溶液注射剤 Liquid for injection <input type="checkbox"/> その他（ 剤） Other (dosage form)



様式 2  
Form 2

医薬品製造所概要（国内製造所用）  
**Outline of Drug Manufacturing Site**  
**(Domestic Manufacturing Site)**

（以下省略）  
(The rest is omitted.)

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 yyyy, mm, dd

製造所名 Name of Manufacturing Site			
所在地 Address			
国内連絡先 Contact in Japan	業者名 Name of Company _____		
	担当者 Contact Person _____		
	電話 Phone _____ FAX _____		
	E-mail _____		
認定番号 Accreditation No.	当初認定年月日 First Acquired Date of Accreditation		
認定の期限 Expiry Date	認定の区分 Accreditation Category		

従業員数（パート社員等も含む）  
Number of Employees (including part time employees)

全従業員数 Total	人	製造部門 Manufacturing	人	QC 部門 QC	人	QA 部門 QA	人
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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 _____	FAX _____		
E-mail _____			

製造品目数（日本への輸出品目数は（ ）で記載）  
**Number of product(s) manufactured. (Number of product(s) exported to Japan should be described in parenthesis)**

	原薬・中間体 API, Intermediate	製剤 Drug Product	小分 Subdividing Manufacture	包装・表示・保管 Packaging・ Labeling・Storage	合計 Total
製造品目数 Number of product(s)					

## 調査対象品目の状況

## Information of the product(s) subject to the inspection

品目名（英語名も併記のこと） Name of the product(s) (English name should be attached)	当該製造所での製造開始時期 Starting time of the commercial manufacture of the product(s) at the site	当該製造所製造品の欧米流通開始時期 Starting time of the marketing of the product(s) in EU and in the US	当該製造所製造品の国内流通開始時期 Starting time of the marketing of the product(s) in Japan

## 施設情報

## Information of the manufacturing site

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

## 過去5年間の行政機関からの査察の有無（実地か書面かの別も記載）

History of GMP inspections by regulatory authorities during the last 5 years (Please specify whether the inspection was onsite or document)

行政機関名 Name of the regulatory authority	時期 Time Period	対象品目名 Name of product(s) inspected	結果 Results of the inspection

## 過去5年間の回収、GMP不適合の有無（有の場合は概要を記載）

History of product recall or unsuccessful inspection by a regulatory authority during the last 5 years (Please specify the detail if the situation occurred)

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