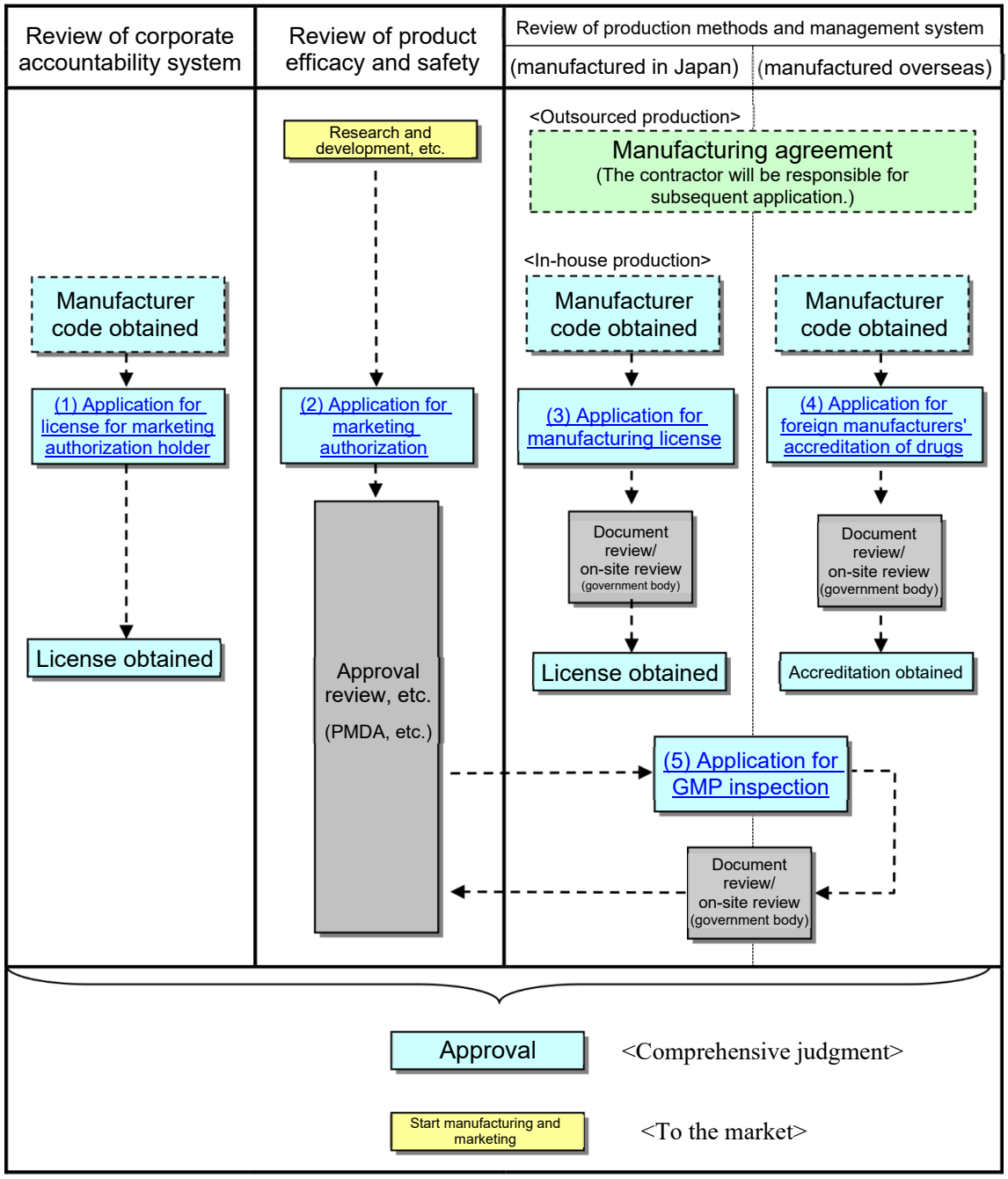
<Manufacturing and Marketing Procedures for Quasi-drugs>

Commercial shipment (manufacturing and marketing) of quasi-drugs to the market in Japan is regulated by the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (the PMD Act) and not allowed without permission and approval of the regulatory authorities (the Ministry of Health, Labour and Welfare and the respective prefectures). This document briefly summarizes the manufacturing and marketing procedures.

1. Flow of manufacturing and marketing

Regulatory review on three matters will be required before manufacturing and marketing a quasi-drug in Japan. See below for the procedures.



2. Key points of the flow

<Review of corporate accountability system>

(1) Application for license for marketing authorization holder

- Description

  The manufacturer is required to file an application with the prefecture to demonstrate its ultimate responsibility for the product on the market, the quality assurance, and the safety management before manufacturing and marketing a quasi-drug.

- Authority to grant a license for marketing authorization holder

  License is granted under the authority of the respective prefectural governors.
  (Application documents should be submitted to the relevant office of the prefecture.)

- Forms to be used

  Application form for license for quasi-drug marketing authorization holder

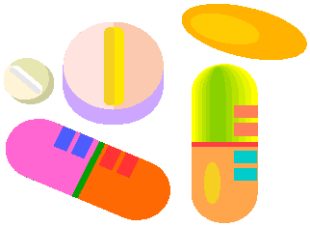
  Click here for the application form

- FD application and user fee information (*Electronic application using FD is recommended as a general rule)

  Click here for the FD application website.
  https://web.fd-shinsei.mhlw.go.jp

  Go to the website of the prefecture for the user fee information.

* Contact the Pharmaceutical Affairs Division of the prefecture for the information on the application for license for quasi-drug marketing authorization holder.



<Review of product efficacy and safety>

(2) Application for marketing authorization

- Description

  The manufacturer is required to file an application with the Ministry of Health, Labour and Welfare to demonstrate the quasi-drug has no problem in terms of performance and safety. Some quasi-drugs with established safety will be approved by prefectural governors.

- Authority to grant a marketing authorization

  Marketing authorization is granted under the authority of the Minister of Health, Labour and Welfare or the prefectural governors.
  (Application documents should be submitted to the PMDA or the relevant office of the prefecture.)

- Forms to be used

  Application form for quasi-drug marketing authorization

  Click here for the application form

  Application form for marketing authorization for drugs manufactured overseas

  Click here for the application form

- FD application and user fee information (*Electronic application using FD is recommended as a general rule)

  Click here for the FD application website.

  https://web.fd-shinsei.mhlw.go.jp

  Click here for the user fee information (the government).

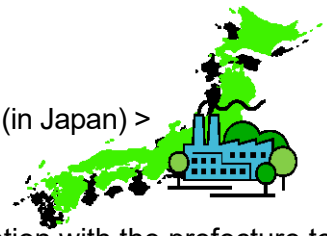
  http://web.fd-shinsei.mhlw.go.jp/application/list_drug2.html

  Click here for the user fee information (the PMDA).

  https://www.pmda.go.jp/review-services/drug-reviews/user-fees/0001.html

* Contact the Pharmaceutical Affairs Division of the prefecture for the information on the applicability of the quasi-drug (whether the product is considered to be a quasi-drug).

< Review of production methods and management system (in Japan) >



(3) Application for manufacturing license

- Description

  The manufacturer is required to file an application with the prefecture to demonstrate the manufacturer in Japan is capable of manufacturing the quasi-drug.

- Authority to grant a manufacturing license

  License is granted under the authority of the respective prefectural governors.
  (Application documents should be submitted to the relevant office of the prefecture.)

- Forms to be used

  Application form for license for quasi-drug marketing authorization holder

  Click here for the application form

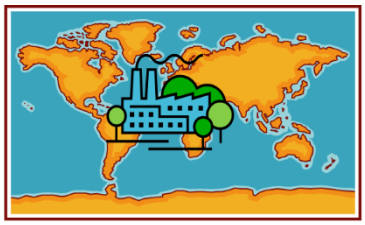
- FD application and user fee information (*Electronic application using FD is recommended as a general rule)

  Click here for the FD application website.
  https://web.fd-shinsei.mhlw.go.jp

  Click here for the user fee information (the government).
  http://web.fd-shinsei.mhlw.go.jp/application/list_drug2.html

  Go to the website of the prefecture for user fee information (prefecture).

* Contact the Pharmaceutical Affairs Division of the prefecture for the information on the application for quasi-drug manufacturing license.



<Review of production methods and management system (overseas)>

(4) Application for foreign manufacturers' accreditation

- Description

  The manufacturer is required to file an application with the Ministry of Health, Labour and Welfare to demonstrate the foreign manufacturer is capable of manufacturing the quasi-drug.

- Authority to grant foreign manufacturers' accreditation of drugs

  Foreign manufacturers' accreditation of drugs is granted under the authority of the Minister of Health, Labour and Welfare.
  (Application documents should be submitted to the PMDA.)

- Forms to be used

  Application form for foreign manufacturers' accreditation of quasi-drugs

  Click here for the application form

- FD application and user fee information (*Electronic application using FD is recommended as a general rule)

  Click here for the FD application website.

  https://web.fd-shinsei.mhlw.go.jp

  Click here for the user fee information (the government).

  http://web.fd-shinsei.mhlw.go.jp/application/list_drug2.html

  Click here for the user fee information (the PMDA).

  https://www.pmda.go.jp/review-services/drug-reviews/user-fees/0001.html

- Click here for the details of application for foreign manufacturers' accreditation.

  https://www.pmda.go.jp/review-services/drug-reviews/foreign-mfr/0004.html

<Review of production methods and management system (in Japan and overseas)>

(5) Application for GMP inspection

- Description

  The manufacturer is required to file an application with the prefecture to demonstrate the manufacturing site conforms to the "GMP for quasi-drugs" and undergo an inspection.

- GMP inspection

  Inspection will be performed by the prefecture.
  (Application documents should be submitted to the relevant office of the prefecture.)

- Forms to be used

  Application form for GMP inspection of a quasi-drug
  Click here for the application form

- FD application and user fee information (*Electronic application using FD is recommended as a general rule)

  Click here for the FD application website.
  https://web.fd-shinsei.mhlw.go.jp
  Click here for the user fee information (the PMDA).
  https://www.pmda.go.jp/review-services/drug-reviews/user-fees/0001.html

<Obtaining a manufacturer code>

- Description

  When quasi-drug marketing authorization holders without a manufacturer code applies for a marketing authorization or a license for marketing authorization holder, or when quasi-drug manufacturers applies for a manufacturing license, a "manufacturer code registration form" should be submitted to the Ministry of Health, Labour and Welfare on e-Gov to obtain a manufacturer code in advance.

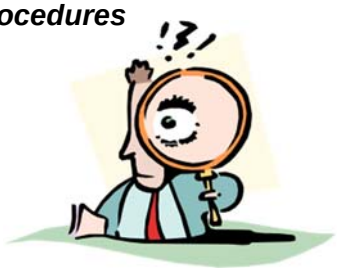
  Foreign manufacturers of quasi-drugs applying for an accreditation should also submit a "manufacturer code registration form" to the Ministry of Health, Labour and Welfare on e-Gov to obtain a manufacturer code in advance.

- Forms to be used

  Manufacturer code registration form

  Click here for the application form

3. Reference information for proceeding with the procedures



<Reference websites>

- FD application website
  https://web.fd-shinsei.mhlw.go.jp

- Ministry of Health, Labour and Welfare website
  https://www.mhlw.go.jp/

<Relevant books>

- References for regulatory applications

Publisher	<Name of the book>
Yakuji Nippo Co., Ltd.	Guide to quasi-drug and cosmetic regulations in Japan
	New Guide for FD Application: Drugs, Quasi-drugs, Cosmetics, and Medical Devices

Form 9 (Re: Article 19, Article 114-2, and Article 137-2) Go to TOP

Drug
In vitro diagnostic
Quasi-drug
Cosmetic
Medical device
Regenerative medical product

Application form for license for marketing authorization holder

Name of the office with primary functions					
Address of the office with primary functions					
Type of license					
Marketing supervisor-general		Name		Qualifications	
		Address			
Disqualification of the applicant (including an executive engaged in the operation if the applicant is a corporation)	(1) License was revoked pursuant to the provisions of Article 75, Paragraph 1 of the PMD Act.				
	(2) Registration was revoked pursuant to the provisions of Article 75-2, Paragraph 1 of the PMD Act.				
	(3) Sentenced to imprisonment or a heavier punishment				
	(4) Violated the pharmaceutical laws and regulations or failed to comply with the disposition based thereon				
	(5) Being under guardianship				
Remarks					

As described above, I hereby apply for an inspection for

Drug
In vitro diagnostic
Quasi-drug
Cosmetic
Medical device
Regenerative medical product

MM/DD/YYYY

Address (Location of the head office in case of a corporation)

Name (Name and name of its representative in case of a corporation)

To Prefectural Governor
Mayor of the city with a public health center
Mayor of the special ward

(Note)

1. Use JIS A4 paper size.
2. Use ink to write in the standard block style.
3. Fill in the column of type of license with the applicable type of license among those listed in Article 12, Paragraph 1 or Article 23-2, Paragraph 1 of the PMD Act if the applicant is a marketing authorization holder of drugs, in-vitro diagnostics, quasi-drugs, cosmetics, or medical devices; license for marketing authorization holder of a regenerative medical product if the applicant is a marketing authorization holder of regenerative medical products; or license for marketing authorization holder of pharmacy-compounded drugs if the applicant is a marketing authorization holder of pharmacy-compounded drugs.
4. Fill in the column of qualifications of marketing supervisor-general with the name of the pharmacist and the pharmacist registration number/date if the marketing supervisor-general of the marketing authorization holder of drugs or in vitro diagnostics is a pharmacist, or which of Article 85, Paragraph 1 and 2, Article 114-49, Paragraph 1 and 2, or Items in Article 137-50, Paragraph 1 of the PMD Act applies to the marketing supervisor-general of a marketing authorization holder of quasi-drugs, cosmetics, medical devices, or regenerative medical products.
5. Fill in the column (1) through (5) of disqualifications of the applicant with "none" if none of the disqualifications apply. Fill in the column (1) and (2) with the reason and the date, the column (3) with the charge, punishment, date of conviction, and date of completing the sentence or date on which the enforcement was ceased, if applicable, the column (4) with the fact and date of the violation, and the column (5) with "yes" as appropriate.
6. The marketing authorization holder of pharmacy-compounded drugs should provide the license number for establishing a pharmacy and the date of license in the column of remarks.
7. The marketing authorization holder of quasi-drugs specified in Article 20, Paragraph 2 of the PMD Act should fill in the column of remarks with "newly designated quasi-drug."
8. The applicant who has obtained a license for marketing authorization holder should provide the type of license for marketing authorization holder and the license number in the column of remarks.

Form 22 (related to Article 38) Go to TOP

Revenue stamp

Drug
Quasi-drug Application form for marketing authorization
Cosmetic

Name	Generic name				
	Brand name				
Ingredients and composition or chemical entity					
Manufacturing method					
Dosage and administration					
Indications					
Storage method and shelf life					
Specifications and test methods					
Manufacturing site of the product to be marketed	Name	Address	License or accreditation category	License or accreditation number	
Manufacturing site of the drug substance	Name	Address	License or accreditation category	License or accreditation number	
Remarks					

I hereby apply for marketing authorization for Drug / Quasi-drug / Cosmetic

MM/DD/YYYY

Address (Location of the head office in case of a corporation)

Name (Name and name of its representative in case of a corporation)

To: Minister of Health, Labour and Welfare
Prefectural Governor

(Note)

1. Use JIS A4 paper size.
2. Submit one original and two duplicates of this application form to the Minister of Health, Labour and Welfare. Submit one original and one duplicate to the Prefectural Governor.
3. Use ink to write in the standard block style.
4. Affix revenue stamps only to the original applications other than the application for marketing authorization for drugs specified in Article 80, Paragraph 1, Item 1 and Paragraph 2, Item 5 of the Ordinance and quasi-drugs designated by the Minister of Health, Labour and Welfare specified in the same Items. Do not postmark.
5. Provide the name of the country where the product is imported from, the name of the marketing authorization holder or the manufacturer, and the brand name in the country where the product is imported from in the column of manufacturing methods when the product to be marketed is a cell/tissue therapy drug.
6. When the space in the column of manufacturing methods is not enough to describe all the manufacturing methods, write "See the attachment" in the column and attach a separate sheet.
7. Fill out the column of storage method and shelf life only if the quality of the drug cannot be ensured without a specific storage method or if a specific shelf life needs to be established for the drug.
8. Do not provide the specifications and the test methods for cosmetics.
9. When there are two or more manufacturing sites, provide the information on each of the manufacturing sites in the column of manufacturing site of the product to be marketed or the column of manufacturing site of drug substance.
10. Indicate which of Article 26, Paragraph 1, 3, or 4 or Article 36, Paragraph 1 or 3 applies in the column of license or accreditation category.
11. The proprietor of the pharmacy should provide the name of the pharmacy and the number and date of license in the column of remarks.
12. When applying for marketing authorization specified in Article 14, Paragraph 1 in accordance with Article 14-3, Paragraph 1 of the PMD Act, state to that effect in the column of remarks.

Form 53 (related to Article 102) Go to TOP

Revenue stamp	Foreign manufactured	Drug / Quasi-drug / Cosmetic	Application form for marketing authorization

Name	Generic name				
	Brand name				
Ingredients and composition or chemical entity					
Manufacturing method					
Dosage and administration					
Indications					
Storage method and shelf life					
Specifications and test methods					
Manufacturing site of the product to be marketed	Name	Address	License or accreditation category	License or accreditation number	
Manufacturing site of the drug substance	Name	Address	License or accreditation category	License or accreditation number	
Remarks					

I hereby apply for marketing authorization for foreign manufactured Drug / Quasi-drug / Cosmetic.

MM/DD/YYYY

Address: In Japanese _____

In foreign language (Location of the head office in case of a corporation)

Name: In Japanese _____

In foreign language (Name and name of its representative in case of a corporation)

Designated holder of marketing authorization for foreign-manufactured pharmaceuticals, etc.

Address (Location of the head office in case of a corporation)

Name (Name and name of its representative in case of a corporation)

To: Minister of Health, Labour and Welfare

(Note)

1. Use JIS A4 paper size.
2. Submit one original and two duplicates of this application form.
3. Use ink. Write Japanese in the standard block style.
4. Affix revenue stamps only to the original application form. Do not postmark.
5. When the space in the column of manufacturing methods is not enough to describe all the manufacturing methods, write "See the attachment" in the column and attach a separate sheet.
6. Fill out the column of storage method and shelf life only if the quality of the drug cannot be ensured without a specific storage method or if a specific shelf life needs to be established for the drug.
7. Leave the column of specifications and the test methods blank for cosmetics.
8. When applying for marketing authorization specified in Article 19-2 in accordance with Article 14-3, Paragraph 1 as applied mutatis mutandis under Article 20 of the PMD Act, state to that effect in the column of remarks.

Form 12 (related to Article 25 and Article 137-8) Go to TOP

Revenue stamp

Drug
Quasi-drug
Cosmetic
Regenerative medical product

Application form for manufacturing license

Name of the manufacturing site				
Address of the manufacturing site				
Type of license				
Outline of the buildings and facilities of the manufacturing site				
Manager or responsible engineering supervisor	Name		Qualifications	
	Address			
Disqualification of the applicant (including an executive engaged in the operation if the applicant is a corporation)	(1) License was revoked pursuant to the provisions of Article 75, Paragraph 1 of the PMD Act.			
	(2) Registration was revoked pursuant to the provisions of Article 75-2, Paragraph 1 of the PMD Act.			
	(3) Sentenced to imprisonment or a heavier punishment			
	(4) Violated the pharmaceutical laws and regulations or failed to comply with the disposition based thereon			
	(5) Being under guardianship			
Remarks				

As described above, I hereby apply for an inspection for

Drug
Quasi-drug
Cosmetic
Regenerative medical product

MM/DD/YYYY

Address (Location of the head office in case of a corporation)

Name (Name and name of its representative in case of a corporation)

To: Director-General of the Regional Bureau of Health and Welfare
Prefectural Governor
Mayor of the city with a public health center
Mayor of the special ward

(Note)

1. Use JIS A4 paper size.
2. Submit one original and two duplicates of this application form to the Director-General of the Regional Bureau of Health and Welfare. Submit one original and one duplicate to the Prefectural Governor, the mayor of the city with a public health center, or the mayor of the special ward.
3. Use ink to write in the standard block style.
4. Affix revenue stamps only to the original application form to be submitted to the Director-General of the Regional Bureau of Health and Welfare. Do not postmark.
5. State which of Items in Article 26, Paragraph 1 to 3 or Article 137-9, Paragraph 1 applies in the column of type of license.
6. When the space in the column of buildings and facilities of the manufacturing site is not enough to provide all relevant information, write "See the attachment" in the column and attach a separate sheet.
7. Fill in the column of qualifications of manager or responsible engineering supervisor with the name of the pharmacist and the pharmacist registration number/date if the manager is a pharmacist, or which of Items in Article 91, Paragraph 1 and 2 applies to the responsible engineering supervisor.
8. Fill in the column (1) through (5) of disqualifications of the applicant with "none" if none of the disqualifications apply. Fill in the column (1) and (2) with the reason and the date, the column (3) with the charge, punishment, date of conviction, and date of completing the sentence or date on which the enforcement was ceased, if applicable, the column (4) with the fact and date of the violation, and the column (5) with "yes" as appropriate.
9. Manufacturer of pharmacy-compounded drugs should provide the license number for establishing a pharmacy and the date of license in the column of remarks.
10. The applicant who has obtained another type of manufacturing license should provide the type of manufacturing license and the license number in the column of remarks.

様式第十八 (第三十五条、第百三十七条の十八関係)
Form No.18 (related to Article 35 and Article 137-18)

Go to TOP

収入印紙
revenue stamp

Drug
Quasi-drug
Regenerative medical product
drug

Application form for foreign manufacturers' accreditation

Application for accreditation of foreign quasi-drug manufacturer
regenerative, cellular therapy and gene therapy products

製造所の名称 Name of the manufacturing establishment		
製造所の所在地 Location of the manufacturing establishment		
認定の区分 Accreditation categories		
製造所の構造設備の概要 Outline of the buildings and facilities of the manufacturing establishment		
製造所の責任者 The person responsible for the manufacturing establishment	氏名 Name	
	住所 Address	
申請者(法人にあつては、その業務を行う役員を含む。)の欠格条項 Applicant's disqualifications (including those of the executives engaged in the services in case of a i)	(1) 法第 75 条の 4 第 1 項の規定により認定を取り消されたこと History of having accreditation being canceled pursuant to the provision of Article 75-4, Paragraph 1	
	(2) 法第 75 条の 5 第 1 項の規定により登録を取り消されたこと History of having registration being canceled pursuant to the provision of Article 75-5, Paragraph 1	
	(3) 禁錮以上の刑に処せられたこと History of a court sentence of imprisonment or a severer punishment	
	(4) 薬事に関する法令又はこれに基づく処分に違反したこと Violation of Japanese laws and regulations related to pharmaceutical affairs or measures taken in accordance with these laws and regulations	
	(5) 後見開始の審判を受けていること Having received a order for commencement of guardianship	
備考 Remarks		

上記により、医薬品 / 医薬部外品 / 再生医療等製品 の外国製造業者の認定を申請します。

I hereby apply for the accreditation of the foreign drug / quasi-drug / regenerative, cellular therapy and gene therapy products manufacturer indicated above.

年 Year　月 Month　日 Day

住所 Address
邦文 Japanese
外国文 Foreign language
(法人にあつては、主たる事務所の所在地 Location of the head office in case of a corporation)

氏名 Name
邦文 Japanese
外国文 Foreign language
(法人にあつては、名称及び代表者の氏名 Name and name of its representative in case of a corporation)

厚生労働大臣　殿
To Minister of Health, Labour and Welfare

(注意)
(Notes)

1 用紙の大きさは、日本工業規格 A4 とすること。
Use paper of Japanese Industrial Standards Size A4.

2 この申請書は、正副 2 通提出すること。
Applicant should submit one original and one copy of it.

3 字は、墨、インク等を用い、邦文にあつては、楷書ではつきりと書くこと。
Fill in the form with clear writing with inks, etc.

4 収入印紙は、正本にのみはり、消印をしないこと。
Put revenue stamp only on the original, not on its copy. Do not cancel it.

5 認定の区分欄には、第 36 条第 1 項及び第 2 項各号又は第 137 条の 19 各号のいずれに該当するかを記載すること。
Identify in the column of "Accreditation categories" which category specified under Article 36, Paragraph 1 and 2 or Article 137-19 is applied.

6 製造所の構造設備の概要欄にその記載事項のすべてを記載することができないときは、同欄に「別紙のとおり」と記載し、別紙を添付すること。
In case there is not enough space to fill in all the information in the column "Outline of the buildings and facilities of the manufacturing establishment", write "see attached paper" in the column and attach another paper on which all the information is written.

7 申請者の欠格条項の(1)欄から(5)欄までには、当該事実がないときは「なし」と記載し、あるときは、(1)欄及び(2)欄にあつてはその理由及び年月日を、(3)欄にあつてはその罪、刑、刑の確定年月日及びその執行を終わり、又は執行を受けることがなくなつた場合はその年月日を、(4)欄にあつてはその違反の事実及び違反した年月日を、(5)欄にあつては「ある」と記載すること。
Write down "No" in each column of (1), (2), (3), (4) and (5) if an applicant doesn't meet any conditions of its disqualifications. If an applicant meets one or more conditions of its disqualifications, please write down as below.
   (1) The date(year, month, day) and grounds for cancellation.
   (2) The date(year, month, day) and grounds for cancellation.
   (3) Crime, sentence, the date(year, month, day) of final judgment, the date(year, month, day) of sentence/parole completion.
   (4) Description and the year of the violation(s).
   (5) "Yes"

Form 25 (related to Article 50)

Go to TOP

Drug
Quasi-drug Application form for inspection

Name of the office with primary functions		
Address of the office with primary functions		
Manufacturing license number and date		
Name of the manufacturing site subject to inspection		
Address of the manufacturing site subject to inspection		
Name of the manufacturer (name and name of its representative in case of a corporation)		
Address of the manufacturer (location of the head office in case of a corporation)		
Category of manufacturing license or foreign manufacturers' accreditation of drugs		
Number and date of manufacturing license or foreign manufacturers' accreditation of drugs		
Application product	Generic name	
	Brand name	
	Application receipt number or approval number	
	Date of application or approval	
Amount of user fees		
Remarks		

As described above, I hereby apply for an inspection for Drug
Quasi-drug

MM/DD/YYYY

Address (Location of the head office in case of a corporation)

Name (Name and name of its representative in case of a corporation)

To: Chief Executive, Pharmaceuticals and Medical Devices Agency
Prefectural Governor

(Note)

1. Use JIS A4 paper size.
2. Use ink to write in the standard block style.
3. Indicate which of the Items in Article 26, Paragraph 1 or 2 or Article 36, Paragraph 1 or 2 applies in the column for the category manufacturing license or foreign manufacturers' accreditation of drugs.
4. Attach a copy of the document certifying that the inspection fees specified in the Cabinet Order on Fees related to the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices has been paid to the PMDA's account to the back of the application form submitted to the Chief Executive of the Pharmaceuticals and Medical Devices Agency.

Go to TOP
Form 1

Manufacturer code registration form

Category of manufacturer code		1. Manufacturer code of the applicant 2. Manufacturer code of the manufacturing site, etc.
Prefecture where the manufacturing site is located (Name of the country in case of an application for overseas manufacturing)		
Applicant	Furigana	
	Name of the applicant	
	Address or location	
	Phone number	
Manufacturing site, etc.	Furigana	
	Name of the manufacturing site, etc.	
	Address or location	
	Phone number	
Date of submission		MM/DD/YYYY
Type of business		1. Manufacturing and sales 2. Manufacturing 3. Repair 4. Overseas manufacturing
		(1) Drug (2) Quasi-drug (3) Cosmetic (4) Medical device
		(5) In vitro diagnostic (6) Regenerative medical product
Remarks		

* [Manufacturer code]
* [Date of numbering]

Address (location of the head office in case of a corporation)
Name (name and name of its representative in case of a corporation)
Contact person (name, phone number, and fax number)

(Note)

1. Use JIS A4 paper size.
2. Write in the standard block style.
3. Leave the columns marked with * blank.
4. Circle the manufacturer code to be registered in the column of "Category of manufacturer code." If the manufacturer code of the applicant (nine-digit manufacturer code ending with "000") has not been registered, circle both 1. Manufacturer code of the applicant and 2. Manufacturer code of the manufacturing site, etc. and submit to the prefecture where the manufacturing site, etc. is located.
5. Provide the name of the prefecture where the manufacturing site, etc. to be licensed is located in the column of "Prefecture."
6. Provide the furigana of the name of the applicant and the name of the manufacturing site, etc. in hiragana in the respective column of "Furigana." Omit "kabushikigaisha" from the furigana of the company name starting with "kabushikigaisha."
7. Provide the name of the applicant (name of the corporation) accurately in the column of "Name" when registering the manufacturing code of the applicant.
8. Provide the name of the manufacturing site to be licensed accurately in the column of "Name of the manufacturing site, etc." when registering the manufacturing code of the manufacturing site.
9. Provide the address accurately, starting with the name of the prefecture, in the column of "Address or location."
10. In the column of "Phone number", provide the same phone number of the manufacturing site, etc. as that in the column of "Name" or "Name of the manufacturing site, etc."
11. Provide the date of submission of the registration form in the column of "Date of submission."
12. Circle the category of business to be registered in the column of "Category of business."
13. Provide the manufacturer code of the applicant (nine-digit manufacturer code ending with "000") if it has been registered together with other relevant information in the column of "Remarks."