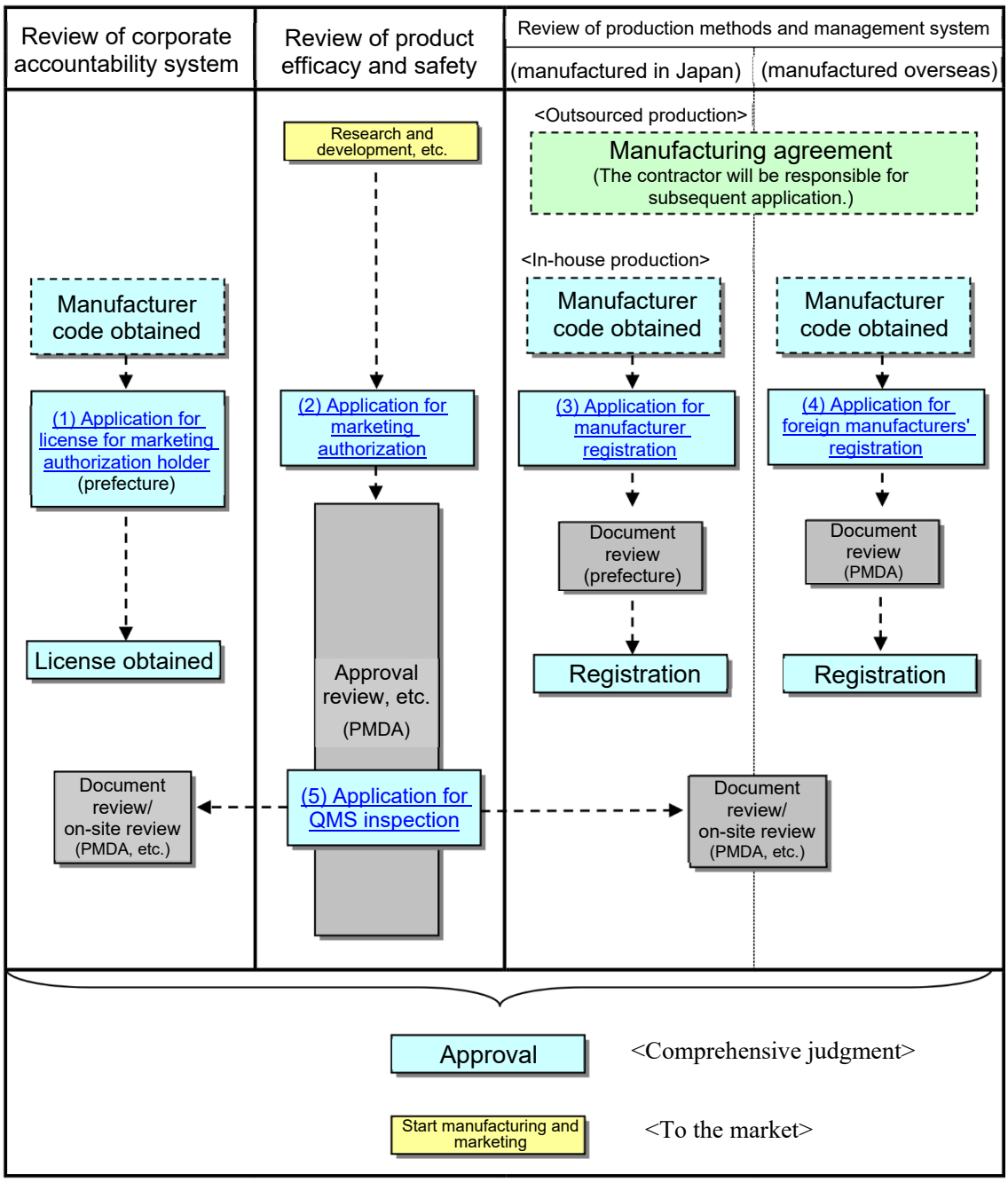
<Manufacturing and Marketing Procedures for In Vitro Diagnostics>

Commercial shipment (manufacturing and marketing) of in vitro diagnostics 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, registration, and approval of the regulatory authorities (the Ministry of Health, Labour and Welfare and the respective prefectures). This document briefly summarizes the procedures for manufacturing and marketing of in vitro diagnostics.

1. Flow of manufacturing and marketing

Regulatory review on three matters will be required before manufacturing and marketing an in vitro diagnostic in Japan. See below for the marketing authorization 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 an in vitro diagnostic.

- Authority to grant a license for marketing authorization holder

  License is granted by the respective prefectural governors.
  (Application documents should be submitted to the relevant office in the prefecture.)

- Forms to be used

  Application for license for marketing authorization holder of in vitro diagnostics

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

* Contact the Pharmaceutical Affairs Division of the prefecture for the information on the application for license for 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 in vitro diagnostic has no problem in terms of performance and safety.

- Authority to grant a marketing authorization

  Granted by the Minister of Health, Labour and Welfare.
  (Application documents should be submitted to the PMDA.)

- Forms to be used

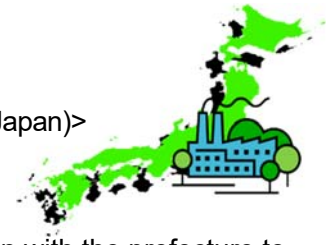
  Application form for marketing authorization for in vitro diagnostic
  Click here for the application form
  Application form for marketing authorization for in vitro diagnostic manufactured overseas
  Click here for the application form

- FD application and user fee information

  (*Electronic application using FD is recommended as a general rule)
  Click here for the FD application website.
  Click here for the user fee information (the government).
  Click here for the user fee information (the PMDA).

* Contact the Pharmaceutical Affairs Division of the prefecture for the information on the applicability of the in vitro diagnostic (whether the product is considered to be an in vitro diagnostic).

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



(3) Application for manufacturers' registration

- Description

  The manufacturer is required to file an application with the prefecture to demonstrate the manufacturer in Japan is capable of manufacturing the in vitro diagnostic and register the necessary manufacturing sites individually.

- Manufacturer registration

  Registered by the respective prefectural governors.
  (Application documents should be submitted to the relevant office in the prefecture.)

- Forms to be used

  Application form for registration of manufacturer of in vitro diagnostics
  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.
  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 manufacturing license.

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

(4) Application for foreign manufacturers' registration

- 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 in vitro diagnostic and register the necessary manufacturing sites individually.

- Foreign manufacturer registration

  Registered by the Minister of Health, Labour and Welfare.
  (Application documents should be submitted to the PMDA.)

- Forms to be used

  Application form for registration of foreign manufacturer of in vitro diagnostics

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

* Click here for the details of application for foreign manufacturer registration.

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

(5) Application for QMS inspection

- Description

  The manufacturer is required to file an application with the PMDA to demonstrate the manufacturing site conforms to the "GMP for in vitro diagnostics" and undergo an inspection.

- QMS inspection

  An inspection will be performed by the PMDA, etc.
  (Application documents should be submitted to the PMDA, etc.)

- Forms to be used

  Application form for GMP inspection for in vitro diagnostics
  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.
  Click here for the user fee information (the PMDA).

<Obtaining a manufacturer code>

- Description

  When the marketing authorization holder for in vitro diagnostics without a manufacturer code applies for a marketing authorization or a license for marketing authorization holder, or when the manufacturer of in vitro diagnostics 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 manufacturer of in vitro diagnostics applying for registration 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/index.html

4. Certified products and products exempt from approval (products to be notified)

In vitro diagnostics include approved products required to be approved as described in the text, certified products required to be certified, and products to be notified, which are not subject to approval.

Check the websites of registered certification bodies for application for certified products.

Submit a marketing notification for an in vitro diagnostic to the PMDA for products to be notified, which are not subject to approval.

- Forms to be used
  Marketing notification form for in vitro diagnostic
  Click here for the application form

Form 9 (related to Article 19, Article 114-2, and Article 137-2)

Go to TOP

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

Application for license for marketing authorization holder

<table>
<tr><td colspan="2">Name of the office with primary functions</td><td colspan="4"></td></tr>
<tr><td colspan="2">Address of the office with primary functions</td><td colspan="4"></td></tr>
<tr><td colspan="2">Type of license</td><td colspan="4"></td></tr>
<tr><td colspan="2">(in case of a corporation)
Name of the executive responsible for operations related to pharmaceutical affairs</td><td colspan="4"></td></tr>
<tr><td rowspan="2">Marketing supervisor-general (including the assistant pharmacist of the marketing supervisor-general, if appointed)</td><td>Name</td><td></td><td>Qualifications</td><td colspan="2"></td></tr>
<tr><td>Address</td><td colspan="4"></td></tr>
<tr><td rowspan="7">Disqualification of the applicant (including an executive responsible for operations related to pharmaceutical affairs in case of a corporation)</td><td colspan="4">(1) License was revoked pursuant to the provisions of Article 75, Paragraph 1 of the PMD Act, and less than 3 years have passed since the date of revocation.</td><td></td></tr>
<tr><td colspan="4">(2) Registration was revoked pursuant to the provisions of Article 75-2, Paragraph 1 of the PMD Act, and less than 3 years have passed since the date of revocation.</td><td></td></tr>
<tr><td colspan="4">(3) Sentenced to imprisonment or a heavier punishment, and less than 3 years have passed since the sentence was completed or the enforcement was ceased.</td><td></td></tr>
<tr><td colspan="4">(4) Violated the Narcotics and Psychotropics Control Act, the Poisonous and Deleterious Substances Control Act, or other laws and regulations related to pharmaceutical affairs or failed to comply with the disposition based thereon; and less than 2 years have passed since the day of violation.</td><td></td></tr>
<tr><td colspan="4">(5) Addicted to narcotics, cannabis, opium, or stimulants.</td><td></td></tr>
<tr><td colspan="4">(6) Unable to appropriately recognize, make judgement, or communicate as necessary for proper operation of the MAH due to mental impairment.</td><td></td></tr>
<tr><td colspan="4">(7) Not considered to have the knowledge and experience for proper operation of the MAH.</td><td></td></tr>
<tr><td colspan="2">Remarks</td><td colspan="4"></td></tr>
</table>

As described above, I hereby apply for a license for a marketing authorization holder of

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

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 A4 paper size.
2. Use ink to write in the standard block style.
3. Fill in the column of the 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, an in-vitro diagnostic, a quasi-drugs, a cosmetic, or a medical device; 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 MAH 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 MAH of drugs or in vitro diagnostics is a pharmacist, which of Article 86, Paragraph 1, Item 1 (a) or (b), Item 2 (a) to (c), Item 3 (a) or (b) or Article 114-49-2, Paragraph 1, Item 1 or 2 applies to the marketing supervisor-general if he/she is not a pharmacist, or which of Article 85-2, 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. Provide the name and address of both the marketing supervisor-general and the pharmacist assisting the marketing supervisor-general if the latter is appointed in the column of name, address, and qualifications of the marketing supervisor-general. Provide the qualifications of the marketing supervisor-general and the pharmacist registration number/date of the pharmacist assisting the marketing supervisor-general in 4. above in the column of qualifications.
6. Fill in the column (1) through (7) 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, and the column (4) with the fact and date of the violation. Write "See attachment" in this column and attach a medical certificate for the applicant's mental impairment if the disqualification (6) applies.
7. 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.
8. 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".
9. The applicant who has obtained a license for marketing authorization holder should provide the type of license for MAH and the license number in the column of remarks.

Form 63-8 (2) (related to Article 114-17) Go toTOP

Revenue stamp

Application form for marketing authorization for in vitro diagnostic

Name	Generic name		
	Brand name		
Intended use			
Shape, structure, and principle			
Ingredients involved in the reaction system			
Product specifications			
Usage			
Manufacturing method			
Storage method and shelf life			
Manufacturing site of the product to be marketed		Name	Registration number
Remarks			

I hereby apply for marketing authorization for an in vitro diagnostic.

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

(Note)

1. Use A4 paper size.
2. Submit one original and two duplicates of this application form.
3. Use ink to write in the standard block style.
4. Affix revenue stamps only to the original form. Do not postmark.
5. Fill out the column of storage method and shelf life only if the quality of the in vitro diagnostic cannot be ensured without a specific storage method or if a specific shelf life needs to be established for the in vitro diagnostic.
6. When there are two or more manufacturing sites, provide the information on each of the manufacturing sites in the column of the manufacturing site of the product to be marketed.
7. The proprietor of the pharmacy should provide the name of the pharmacy and the number and date of license in the column of remarks.
8. When applying for marketing authorization specified in Article 23-2-5, Paragraph 1 in accordance with Article 23-2-8, Paragraph 1 of the PMD Act, state to that effect in the column of remarks.

Form 63-22 (2) (related to Article 114-72) Go toTOP

Revenue stamp

Application form for marketing authorization for in vitro diagnostic manufactured overseas

Name	Generic name		
	Brand name		
Intended use			
Shape, structure, and principle			
Ingredients involved in the reaction system			
Product specifications			
Usage			
Manufacturing method			
Storage method and shelf life			
Manufacturing site of the product to be marketed		Name	Registration number
Remarks			

I hereby apply for marketing authorization for an in vitro diagnostic manufactured overseas.

MM/DD/YYYY

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

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

Designated holder of marketing authorization for foreign-manufactured medical devices, 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 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. Fill out the column of storage method and shelf life only if the quality of the in vitro diagnostic cannot be ensured without a specific storage method or if a specific shelf life needs to be established for the in vitro diagnostic.
6. When applying for marketing authorization specified in Article 23-2-17 in accordance with Article 23-2-8, Paragraph 1 as applied mutatis mutandis under Article 23-2-20 of the PMD Act, state to that effect in the column of remarks.

Form 63-2 (related to Article 114-9)

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Medical device
In vitro diagnostic

Application for in vitro diagnostic manufacturer registration

Name of the manufacturing site					
Address of the manufacturing site					
(in case of a corporation) Name of the executive responsible for operations related to pharmaceutical affairs					
Manager or responsible engineering supervisor		Name		Qualifications	
		Address			
Disqualification of the applicant (including an executive responsible for operations related to pharmaceutical affairs in case of a corporation)	(1)	License was revoked pursuant to the provisions of Article 75, Paragraph 1 of the PMD Act, and less than 3 years have passed since the date of revocation.			
	(2)	Registration was revoked pursuant to the provisions of Article 75-2, Paragraph 1 of the PMD Act, and less than 3 years have passed since the date of revocation.			
	(3)	Sentenced to imprisonment or a heavier punishment, and less than 3 years have passed since the sentence was completed or the enforcement was ceased.			
	(4)	Violated the Narcotics and Psychotropics Control Act, the Poisonous and Deleterious Substances Control Act, or other laws and regulations related to pharmaceutical affairs or failed to comply with the disposition based thereon; and less than 2 years have passed since the day of violation.			
	(5)	Addicted to narcotics, cannabis, opium, or stimulants.			
	(6)	Unable to appropriately recognize, make judgement, or communicate as necessary for proper operation of the manufacturer due to mental impairment.			
	(7)	Not considered to have the knowledge and experience for proper operation of the manufacturer.			
Remarks					

As described above, I hereby apply for a license for a marketing authorization holder of

Medical device
In vitro diagnostic

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

(Note)

1. Use A4 paper size.
2. Submit one original of this application form.
3. Use ink to write in the standard block style.
4. 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 114-52, Paragraph 1 to 3 applies to the responsible engineering supervisor.
5. Fill in the column (1) through (7) 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, and the column (4) with the fact and date of the violation.
6. Write "design" in the column of remarks if the manufacturing site performs design work.

様式第六十三の五 (第百十四条の十五関係)
Form No.63-5 (related Article 114-15)

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収入印紙 revenue stamp

医療機器
体外診断用医薬品　外国製造業者　登録申請書

Application for the registration of foreign　medical device in vitro diagnostic　manufacturer

製造所の名称 Name of the manufacturing establishment		
製造所の所在地 Location 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、薬事に関する業務に責任を有する役員を含む。)の欠格条項 Applicant's disqualifications (including those of the executives responsible for the services of pharmaceutical affairs in case of a corporation)	(1) 法第 75 条の 4 第 1 項の規定により認定を取り消され、取消しの日から 3 年を経過していない者 Applicant whose accreditation was canceled pursuant to the provision of Article 75-4, Paragraph 1 and who is awaiting a lapse of 3 years from the date of said rescission	
	(2) 法第 75 条の 5 第 1 項の規定により登録を取り消され、取消しの日から 3 年を経過していない者 Applicant whose registration was canceled pursuant to the provision of Article 75-5, Paragraph 1 and who is awaiting a lapse of 3 years from the date of said rescission	
	(3) 禁錮以上の刑に処せられ、その執行を終わり、又は執行を受けることがなくなつた後、3 年を経過していない者 Applicant who has a history of a court sentence of imprisonment on severer punishment and has not passed 3 years since the execution was completed or no longer received	
	(4) 法、麻薬及び向精神薬取締法、毒物及び劇物取締法その他薬事に関する法令で政令で定めるもの又はこれに基づく処分に違反し、その違反行為があつた日から 2 年を経過していない者 Applicant who has a history of violation of Law, Narcotics and Psychotropics Control Law, Poisonous and Deleterious Substances Control Law or other laws and regulations related to pharmaceutical affairs specified by Cabinet Order and has not passed 2 years since its date of the disposition	
	(5) 麻薬、大麻、あへん又は覚醒剤の中毒者 Addict on narcotics, cannabis, opium or stimulant	
	(6) 精神の機能の障害により外国製造業者の業務を適正に行うに当たつて必要な認知、判断及び意思疎通を適切に行うことができない者 Applicant who cannot properly perform the necessary recognition, judgement and communication to perform the work of foreign manufacturers properly due to mental dysfunction	
	(7) 外国製造業者の業務を適切に行うことができる知識及び経験を有すると認められない者 Applicant who is not recognized as having knowledge and experience to properly carry out the work of foreign manufacturers	

備考 Remarks	

上記により、医療機器 体外診断用医薬品 の外国製造業者の登録を申請します。

I hereby apply for the registration of the foreign medical device in vitro diagnostic manufacturer indicated above.

年 Year　月 Month　日 Day

邦文
Japanese

住所 Address	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） 邦文 Japanese
氏名 Name	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、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、正本にのみ貼り、消印をしないこと。
Put revenue stamp only on the original and do not cancel it.

5 申請者の欠格条項の(1)欄から(7)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記載すること。
Describe "No" in each column of (1), (2), (3), (4), (5), (6)and (7) if an applicant doesn't meet any conditions of its disqualifications. If an applicant meets one or more conditions of its disqualifications, describe as below.
Column (1) and (2) : The date (year, month, day) and its ground for the cancellation.
Column (3) : The date (year, month, day) of the final judgment of the crime, sentence and the date (year, month, day) of the completion of its execution.
Column (4) : The fact and the date (year, month, day) of its violation(s).

Form 63-11 (related to Article 114-28)

Go to TOP

Medical device
In vitro diagnostic Application form for inspection

Name of the office with primary functions				
Address of the office with primary functions				
Number and date of license for MAH				
Product subject to application	Generic name			
	Brand name			
	Application receipt number or approval number			
	Date of application or approval			
Category				
Manufacturing site	Name	Address	Registration number	Manufacturing process
Amount of user fees				
Remarks				

As described above, I hereby apply for a license for a marketing authorization holder of

Medical device
In vitro diagnostic

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

(Note)

1. Use A4 paper size.
2. Use ink to write in the standard block style.
3. 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.

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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 a foreign manufacturer)										
Applicant	Furigana									
	Name									
	Address or location									
	Phone number									
	Manufacturer code of the applicant							0	0	0
Manufacturing site, etc.	Furigana									
	Name of the manufacturing site, etc.									
	Address									
	Phone number									
Date of submission										
Type of business		1. Manufacturing and marketing		2. Manufacturing		3. Repair		4. Overseas manufacturing		
Category of product		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 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".
   The applicant without a registered manufacturer code (nine-digit manufacturer code ending with "000") should circle both 1. Manufacturer code of the applicant and 2. Manufacturer code of the manufacturing site, etc. to register a manufacturer code of the manufacturing site, etc.
5. Provide the name of the prefecture where the manufacturing site, etc. to be licensed is located in the column of "Prefecture where the manufacturing site, etc. is located (name of the country in case of a foreign manufacturer)." Provide the name of the country in case of a foreign manufacturer.
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 columns of "Address or location" and "Address."
   Provide also the name of the country in case of a foreign manufacturer. Use abbreviations as necessary since the maximum number of characters that can be registered is 120. When applying for accreditation or registration of a foreign manufacturer, provide the same information in the application form, etc.
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 manufacturer code of the applicant (nine-digit manufacturer code ending with "000") if it has been registered in the column of "Manufacturer code of the applicant."
12. Provide the date of submission of the registration form in the column of "Date of submission."
13. Circle the category of business to be registered in the column of "Category of business."
14. Circle the category of product to be registered in the column of "Category of product."
15. Provide other relevant information in the column of "Remarks."

Form 63-21 (2) (related to Article 114-47) Go to TOP

Marketing notification form for in vitro diagnostic

<table>
<tr><td colspan="2">Number and date of license for MAH</td><td colspan="2"></td></tr>
<tr><td rowspan="2">Name</td><td>Generic name</td><td colspan="2"></td></tr>
<tr><td>Brand name</td><td colspan="2"></td></tr>
<tr><td colspan="2">Intended use</td><td colspan="2"></td></tr>
<tr><td colspan="2">Shape, structure, and principle</td><td colspan="2"></td></tr>
<tr><td colspan="2">Ingredients involved in the reaction system</td><td colspan="2"></td></tr>
<tr><td colspan="2">Product specifications</td><td colspan="2"></td></tr>
<tr><td colspan="2">Usage</td><td colspan="2"></td></tr>
<tr><td colspan="2">Manufacturing method</td><td colspan="2"></td></tr>
<tr><td colspan="2">Storage method and shelf life</td><td colspan="2"></td></tr>
<tr><td colspan="2" rowspan="2">Manufacturing site of the product to be marketed</td><td>Name</td><td>Registration number</td></tr>
<tr><td></td><td></td></tr>
<tr><td colspan="2">Remarks</td><td colspan="2"></td></tr>
</table>

I hereby submit a notification of manufacturing and sales of an in vitro diagnostic.

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

(Note)

1. Use A4 paper size.
2. Submit one original and one duplicate of this notification form.
3. Use ink to write in the standard block style.