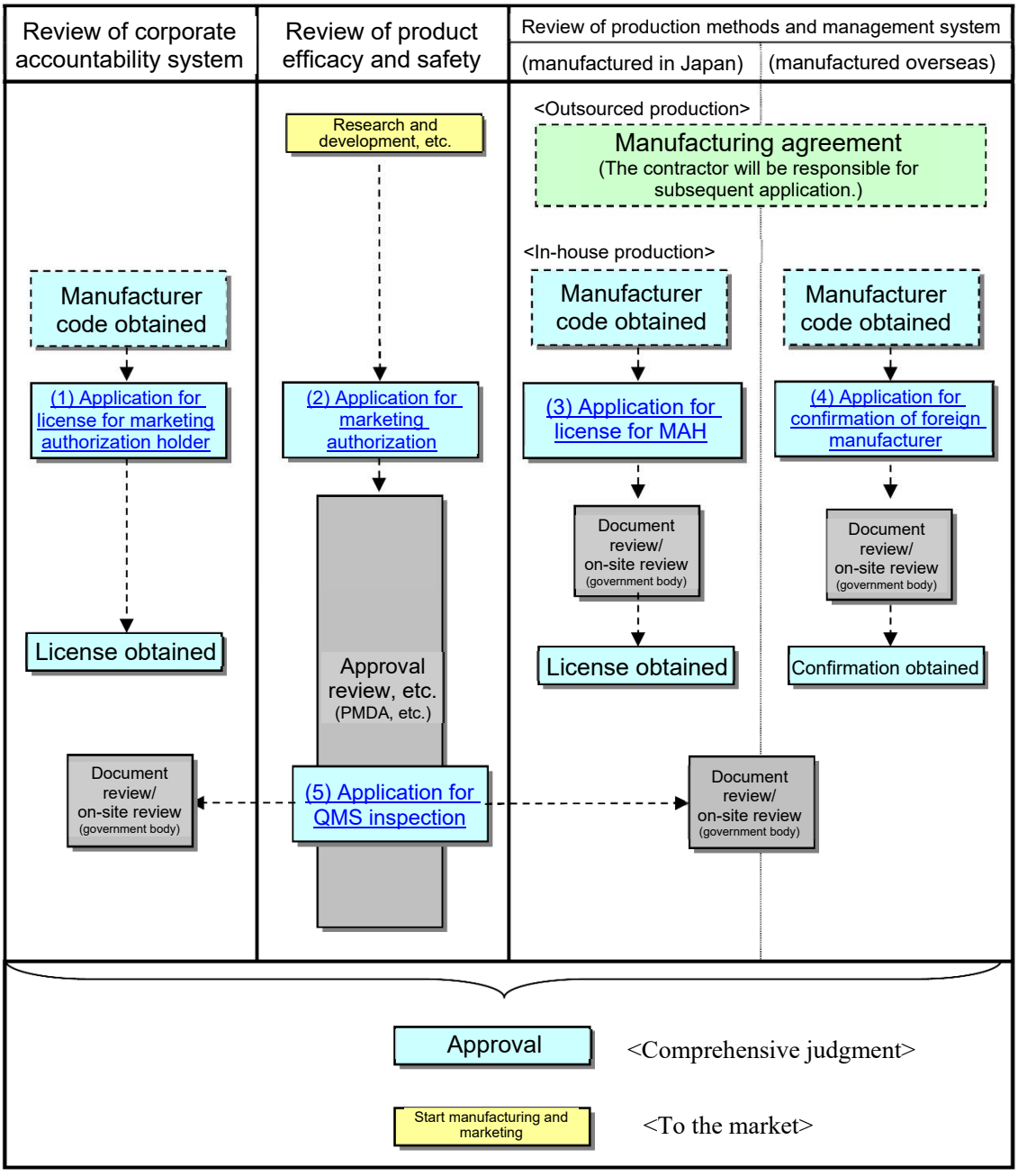
<Manufacturing and Marketing Procedures for Regenerative Medical Products>

Commercial shipment (manufacturing and marketing) of regenerative medical products 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 procedures for manufacturing and marketing of regenerative medical products.

1. Flow of manufacturing and marketing

Regulatory review on three matters will be required before manufacturing and marketing a regenerative medical product in Japan.



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 regenerative medical product.

- 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 form for license for marketing authorization holder of regenerative medical product
  Click here for the application form

- FD application and user fee information (*Electronic application using FD is recommended as a general rule)
  Click here to go to 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 regenerative medical product 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 regenerative medical product

  Click here for the application form

  Application form for marketing authorization for regenerative medical product 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 to go to the FD application website
  Click here for the user fee information (the government).
  Click here for the user fee information (the PMDA).

* Contact the Medical Device and Regenerative Medical Product Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare for the information on the applicability of the regenerative medical product (whether the product is considered to be a regenerative medical product).

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

(3) Application for manufacturing license

- Description
  The manufacturer in Japan is required to file an application with the Ministry of Health, Labour and Welfare to start manufacturing regenerative medical products.

- Authority to grant a manufacturing license
  License is granted by the Director-General of the Regional Bureau of Health and Welfare.
  (Application documents should be submitted to the relevant office in the prefecture.)

- Forms to be used
  Application form for manufacturing license for regenerative medical product
  Click here for the application form

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

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

(4) Application for foreign manufacturers' accreditation

- Description

  The foreign manufacturer is required to file an application with the Ministry of Health, Labour and Welfare to obtain accreditation to start manufacturing regenerative medical products.

- Authority to grant foreign manufacturers' accreditation of regenerative medical products

  Accreditation is granted by 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 regenerative medical products

  Click here for the application form

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

  Click here to go to the FD application website
  Click here for the user fee information (the government).
  Click here for the user fee information (the PMDA).

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

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

(5) Application for GCPT inspection

- Description
  The manufacturer is required to file an application with the PMDA to demonstrate the manufacturing site conforms to the "GMP for regenerative medical products" and undergo an inspection.

- GCTP inspection
  Inspection will be performed by the PMDA.
  (Application documents should be submitted to the PMDA.)

- Forms to be used
  Application form for GCTP inspection for regenerative medical products
  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 of regenerative medical products without a manufacturer code applies for a marketing authorization or a license for marketing authorization holder, or when the manufacturer of regenerative medical products 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.

  The foreign manufacturer of regenerative medical products 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/index.html

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

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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				
(in case of a corporation) Name of the executive responsible for operations related to pharmaceutical affairs				
Marketing supervisor-general (including the pharmacist assisting the marketing supervisor-general, if appointed)	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 MAH due to mental impairment.	
	(7) Not considered to have the knowledge and experience for proper operation of the marketing authorization holder.	
Remarks		

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 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 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, 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 manufacturing authorization holder of pharmacy-compounded drugs if the applicant is a MAH 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 manufacturing authorization holder 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 manufacturing 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 manufacturing 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 manufacturing 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 of manufacturing authorization holder should provide the type of license for manufacturing authorization holder and the license number in the column of remarks.

Form 75-2 (related to Article 137-21)

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Revenue stamp

Application form for marketing authorization for regenerative medical product

Approval number				Date of approval	
Classification					
Name	Generic name				
	Brand name				
Indications					
Shape, structure, ingredients, quantity, or principle					
Manufacturing method					
Specifications and test methods					
Dosage and administration or usage					
Storage method and shelf life					
Manufacturing site of the product to be marketed	Name	Address	License or accreditation category	License or accreditation number	
Remarks					

I hereby apply for marketing authorization for a 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: 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. Provide the classification according to Appended Table 2 of the Order in the column of classification.
6. Provide the number of conditional or time-limited approval in the column of approval number if applicable according to Article 23-26, Paragraph 1 of the PMD Act. Otherwise, write "none."
7. Provide the date of conditional or time-limited approval in the column of date of approval if applicable according to Article 23-26, Paragraph 1 of the PMD Act. Otherwise, write "none."
8. Provide the name of the country where the product is imported from, the name of the MAH 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 regenerative medical product.
9. 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.
10. Indicate which of Items of Article 137-9 or Article 137-19 applies in the column of license or accreditation category.
11. When applying for marketing authorization specified in Article 23-25, Paragraph 1 in accordance with Article 23-28, Paragraph 1 of the PMD Act, state to that effect in the column of remarks.

Form 75-17 (related to Article 137-68)

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Revenue stamp

Application form for marketing authorization for regenerative medical product manufactured overseas

Approval number				Date of approval	
Classification					
Name	Generic name				
	Brand name				
Indications					
Shape, structure, ingredients, quantity, or principle					
Manufacturing method					
Specifications and test methods					
Dosage and administration or usage					
Storage method and shelf life					
Manufacturing site of the product to be marketed	Name	Address	License or accreditation category	License or accreditation number	
Remarks					

I hereby apply for marketing authorization for a regenerative medical product manufactured overseas.

MM/DD/YYYY

In Japanese

Address In foreign language

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

In Japanese

Name In foreign language

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

Designated holder of marketing authorization for foreign-manufactured regenerative medical products

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. Provide the classification according to Appended Table 2 of the Order in the column of classification.
6. Provide the number of conditional or time-limited approval in the column of approval number if applicable according to Article 23-26, Paragraph 1 of the PMD Act. Otherwise, write "none."
7. Provide the date of conditional or time-limited approval in the column of date of approval if applicable according to Article 23-26, Paragraph 1 of the PMD Act. Otherwise, write "none."
8. 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.
9. When applying for marketing authorization specified in Article 23-25, Paragraph 1 in accordance with Article 23-28, Paragraph 1 as applied mutatis mutandis under Article 23-40 of the PMD Act, state to that effect in the column of remarks.

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

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Revenue stamp	Drug Quasi-drug Cosmetic Regenerative medical product	Application form for manufacturing license

Name of the manufacturing site				
Address of the manufacturing site				
Category of license				
Outline of the buildings and facilities 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

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 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 25, Paragraph 1 to 3 or Article 137-8 applies in the column of category 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 (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.
9. The 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 category of manufacturing license or registration should provide the category of manufacturing license and the license number or the registration 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)

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Form No. 18 (related to Article 35 and Article 137-18)

収入印紙 revenue stamp

Drug
Quasi-drug
Regenerative medical product

Application form for foreign manufacturers' accreditation

Application for accreditation of foreign

drug
quasi-drug
regenerative, cellular therapy and gene therapy

manufacturer

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 themanufacturing 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 ofa 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 andregulations 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

manufacturer indicated above.

products

年　　月　　日
Year Month 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、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 認定の区分欄には、第 35 条第 1 項及び第 2 項各号又は第 137 条の 18 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 35, Paragraph 1 and 2 or Article 137-18 is applied.

6 製造所の構造設備の概要欄にその記載事項の全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(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 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 75-5 (related to Article 137-31)

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Application form for GCTP inspection for regenerative medical products

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 regenerative medical products		
Number and date of manufacturing license or foreign manufacturers' accreditation of regenerative medical products		
Product subject to application	Generic name	
	Brand name	
	Application receipt number or approval number	
	Date of application or approval	
Amount of user fees		
Remarks		

I hereby apply for an inspection for a 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: Chief Executive, Pharmaceuticals and Medical Devices Agency

(Note)

1. Use A4 paper size.
2. Use ink to write in the standard block style.
3. Indicate which of Items of Article 137-9 or Article 137-19 applies in the column of category of license or category of foreign manufacturers' accreditation.
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.

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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."