様式第七十五の六の二(第百三十七条の三十四の二関係)
Form No.75—6—2 (related to Article 137—34—2)

# 再生医療等製品区分適合性調査申請書

Application for examination of conformity regarding type of manufacturing of regenerative, cellular therapy and gene therapy products

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|---|---|
| 調査を受けようとする製造所の名称<br>Name of the manufacturing establishment to be examined | |
| 調査を受けようとする製造所の所在地<br>Location of the manufacturing establishment to be examined | |
| 製造業の許可区分又は再生医療等製品外国製造業者の認定区分<br>License category of the manufacturer, or accreditation category of the foreign regenerative, cellular therapy and gene therapy products manufacturer | |
| 製造業の許可番号及び年月日又は再生医療等製品外国製造業者の認定番号及び年月日<br>Number and date of the license for the manufacturer, or of the accreditation for the foreign regenerative, cellular therapy and gene therapy products manufacturer | |
| 調査を受けようとする製造工程の区分<br>Types of the manufacturing activities to be examined | |
| 製造品目数<br>Number of the product items | |
| 製造販売業者数<br>Number of the marketing license holders in Japan | |
| 調査手数料金額<br>Amount of examination fee | |
| 備考<br>Remarks | |

上記により、再生医療等製品の区分適合性調査を申請します。

I hereby apply for the examination of conformity regarding type of manufacturing of regenerative, cellular therapy and gene therapy products.

年　月　日
Year　Month　Day

住所
Address
(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
(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)

独立行政法人医薬品医療機器総合機構理事長
To Chief Executive of the Pharmaceuticals and Medical Devices Agency　殿

(注意)
(Note)

1　用紙の大きさは、A4とすること。
Use paper of Japanese Industrial Standard Size A4.

2　字は、墨、インク等を用い、楷書(かい)ではつきりと書くこと。
Fill in the form with clear writing with inks etc.,.

3　製造業の許可区分又は再生医療等製品外国製造業者の認定区分欄については、第137条の8又は第137条の18の各号のいずれに該当するかを記載すること。
Identify in the column of “License category of the manufacturer, or accreditation category of the foreign regenerative, cellular therapy and gene therapy products manufacturer” which category specified under Article 137―8 or Article 137―18 is applied.

4　製造業の許可番号及び年月日又は再生医療等製品外国製造業者の認定番号及び年月日欄については、法第23条の22第1項の許可又は第23条の24第1項の認定を受けようとする者である場合は、許可又は認定申請受付番号及び申請年月日を記載すること。
Identify in the column of “Number and date of the license for the manufacturer, or of the accreditation for the foreign regenerative, cellular therapy and gene therapy products manufacturer” the receipt number and the date of the application for license or accreditation, in case that applicant is going to have a license under Article 23―22, Paragraph 1, or an accreditation under Article 23―24, Paragraph 1 of the Act.

5　調査を受けようとする製造工程の区分欄については、医薬品、医療機器等の品質、有効性及び安全性の確保等に関する法律第二十三条の二十五第七項に規定する再生医療等製品の製造工程の区分を定める省令第2条各号のいずれに該当するかを記載すること。また、製造品目数欄に申請区分に属する製造品目の数、製造販売業者数欄に当該製造品目を製造販売する製造販売業者数を記載すること。
Identify in the column of “Types of the manufacturing activities to be examined” which manufacturing type as provided in Article 2 of Ministerial Order specifying manufacturing types of regenerative, cellular therapy and gene therapy products under Article 23―25 Paragraph 7 of the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics is applied. In addition, identify in the column of “Number of the product items” how many product items covered with the applied manufacturing type, and in the column of “Number of the marketing license holders in Japan” how many marketing license holders in Japan related to those product items.

6　独立行政法人医薬品医療機器総合機構理事長に申請する場合にあつては、医薬品、医療機器等の品質、有効性及び安全性の確保等に関する法律関係手数料令において定める適合性調査手数料を機構の口座に払い込んだことを証する書類の写しを裏面に貼付(ちょうふ)すること。
In case where the application is submitted to Chief Executive of the Pharmaceuticals and Medical Devices Agency, attach to the reverse of this form a copy of the document proving payment of examination fee specified under the Cabinet Order for Fees related to the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics through a bank transfer to the account of the Pharmaceuticals and Medical Devices Agency.