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)

収入印紙
revenue stamp

医　薬　品
医薬部外品　外国製造業者　認定申請書
再生医療等製品

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

manufacturer
products

様式第十八を次のように改める。

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 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)薬事に関する法令で政令で定めるもの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	
備考 Remarks		