別紙１－２

宣誓書
Oath

（申請者）は、下記製造工程の区分に係る適合性調査に係る申請の内容に事実と齟齬がないこと、当該製造所における製造管理及び品質管理の方法が医薬品、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14条第２項第４号又は第19条の２第５項において準用する法第14条第２項第４号に該当していないこと、及び製造工程の区分に属する品目について、製造販売業者等との取決めの内容に基づき製造していることを宣誓します。

[Applicant] takes an oath that the contents of application for confirmation of conformity concerning the type(s) of manufacturing activity described below are at variance with the facts, that the methods of manufacturing control and quality control at the manufacturing establishment are not correspond to the provisions of Article 14, paragraph (2), item (iv) or Article 14, paragraph (2), item (iv) as applied mutatis mutandis pursuant to Article 19-2, paragraph (5) of the Act on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices, and that [the applicant] is in accordance with the contents of the agreement with marketing authorization holders, etc. with respect to manufacturing of products come into the type(s) of the manufacturing activity for confirmation.

記
Description

（製造所の名称）
[Name of the manufacturing establishment]
（製造所の所在地）
[Location of the manufacturing establishment]
（製造工程の区分）
[Type（s） of the manufacturing activity]

　　年　　月　　日
[Date of Oath]

住所
[Address]

調査対象製造業者等の責任者（所属・職名・氏名）
[Responsible Person (Name, Title, Post) of the Manufacturer, etc.
for the confirmation application]

（適合性調査権者）　殿
[Authority for the confirmation]