DEPARTMENT OF HEALTH
DRUG OFFICE
LICENSING AND COMPLIANCE DIVISION
MANUFACTURERS REGULATORY UNIT
Room 3817, 38/F, Revenue Tower,
5 Gloucester Road, Wanchai, Hong Kong
Tel.: 2594 7647 Fax: 3904 1225

衞生署藥物辦公室
牌照及監察科製
藥商監管分組
香港灣仔告士打道 5 號
稅務大樓 38 樓 3817 室
電話：2594 7647 傳真：3904 1225

Request Form for Assessment of GMP Compliance for Manufacturer Outside Hong Kong by the Drug Office

要求藥物辦公室對在香港以外地方的製造商進行 GMP合規評審的申請書

A. General Information

甲. 一般資料

1. Category: **類別：**	☐ Application for initial registration of pharmaceutical product 藥劑製品的初註冊申請 ☐ Application for change of registered particulars 更改註冊詳情的申請 ☐ Application for renewal of product registration 藥劑製品註冊續期申請
2. Name of the product(s) & Hong Kong registration number(s), if applicable: **藥劑製品名稱及香港註冊編號（如適用）：**	
3. Name of applicant: **申請人姓名／名稱：**	
4. Address of applicant: **申請人地址：**	
5. Information of contact person of applicant: **申請人的聯絡人資料：** Name: 姓名： Telephone number: 電話號碼： Email address: 電郵地址：	

B. Information of Manufacturer Outside Hong Kong & Product(s)
乙. 在香港以外地方的製造商及藥劑製品的資料

1. Name of the manufacturer outside Hong Kong:
在香港以外地方的製造商名稱：

2. Full address of the manufacturing facility:
製藥設施的完整地址：

3. Postal code of the manufacturing facility:
製藥設施的郵政編碼：

4. Telephone number of the manufacturing facility:
製藥設施的電話號碼：

5. Global Positioning System (GPS) co-ordinates of the facility in WGS84* format:

製藥設施以 WGS84*格式表示的全球定位系統坐標：

*WGS84: World Geodetic System／世界大地坐標系統

(in decimal degrees, to at least 4 decimal places, e.g. latitude "22.279800" & longitude "114.171800" represent Revenue Tower, 5 Gloucester Road, Wanchai, Hong Kong where the office of Manufacturers Regulatory Unit locates)

（以十進制度為單位，小數點後最少標明四位數字，例如緯度「22.279800」及經度「114.171800」即表示製藥商監管分組辦公室位處的香港灣仔告士打道 5 號稅務大樓）

Latitude 緯度 ： _____.____

Longitude 經度： _____.____

6. Type(s) of products in this application
此申請所涉藥劑製品的分類

☐ Human biological pharmaceutical product
人用生物藥劑製品

☐ Human chemical pharmaceutical product
人用化學藥劑製品

☐ Human vaccine
人用疫苗

☐ Pharmaceutical substance
藥劑物質

☐ Medical Gases
醫療氣體

☐ Veterinary biological pharmaceutical product
動物用生物藥劑製品

☐ Veterinary chemical pharmaceutical product
動物用化學藥劑製品

☐ Veterinary vaccine
動物用疫苗

☐ ATP¶- gene therapy product
先進療法製品 – 基因療法製品

☐ ATP¶- somatic cell therapy product
先進療法製品 – 體細胞療法製品

☐ ATP¶- tissue engineered product
先進療法製品 – 組織工程製品

ATP¶: Advanced Therapy Products

7. Dosage form(s) of the product(s) in this application
此申請所涉藥劑製品的劑型

Sterile product(s)
無菌製品

☐ Injections 注射劑 ☐ Vaccines 疫苗 ☐ Eye drops 滴眼液

☐ Large volume parenterals (in volume of at least 100ml)
大容量注射劑（容量不少於 100 毫升）

☐ Others, please specify:
其他，請註明：

Method of sterilization or preparation
滅菌或配製方法

☐ Terminal sterilization: 最終滅菌： ☐ Moist heat 濕熱 ☐ Dry heat 乾熱 ☐ Radiation 輻射

☐ Aseptically prepared with sterile filtration 以過濾除菌及無菌操作配製 ☐ Blow / Fill / Seal 吹塑／灌裝／密封

☐ Other sterilization method, please specify:
其他滅菌方法，請註明：

Non-sterile product(s)
非無菌製品

☐ Tablets / capsules 片劑／膠囊劑

☐ Oral liquids (including granules for oral liquids) 口服液體劑（包括口服液體劑用的顆粒劑）

☐ Buccal & throat preparations 口腔黏膜及咽喉用製劑

☐ External liquids 外用液體劑

☐ Creams / ointments 乳膏劑／軟膏劑

☐ Rectal preparations 直腸用製劑

☐ Gas cylinders 氣瓶

☐ Others, please specify:
其他，請註明：

8. Total number of production suites in this facility:
此設施的生產間總數：

(please indicate location in the layout)
（請在平面圖上註明其位置）

9.	**Number of production suites involved in this application:** **此申請所涉生產間數量：** (please indicate location in the layout) （請在平面圖上註明其位置）	
10.	**Any of the production suites in this facility inspected by a regulatory authority in the past 3 years?** **過去三年，此設施是否有任何生產間曾獲監管機構巡查？** (If the answer is Yes, please provide a list of inspections) （如果答案為「是」，請編製清單列出有關巡查情況）	☐ Yes 是 ☐ No 否
11.	**Total number of products registered in Hong Kong which are manufactured in this facility:** **由此設施製造的香港註冊藥劑製品總數：**	
12.	**Total number of registered products manufactured in this facility (including those listed in this application) being supplied to Hong Kong in the past 3 years:** **過去三年由此設施製造並曾供應香港的註冊藥劑製品總數（包括此申請中列出的藥劑製品）：**	
13.	**Any of the products in Answer to Question 12 being supplied to the Hospital Authority, the Department of Health or other Government Department(s) under contract in the past 3 years?** **承上題，當中是否有任何藥劑製品在過去三年曾按合約供應予醫院管理局、衞生署或其他政府部門？**	☐ Yes 是 ☐ No 否
	If the answer is Yes, please specify the name and registration number of the product(s): 如果答案為「是」，請註明有關藥劑製品的名稱及註冊編號：	
14.	**Product(s) manufactured in this facility allowed to be marketed in the country or region where the facility is situated?** **由此設施製造的藥劑製品是否獲准於所在國家或地區銷售？**	☐ Yes 是 ☐ No 否
	If the answer is No, please provide details: 如果答案為「否」，請提供詳細資料：	

15.	**Any quality related drug recall in the past 3 years?** **過去三年是否曾因質量的原因回收藥物？**	☐ Yes 是 ☐ No 否
	If the answer is Yes, please provide details: 如果答案為「是」，請提供詳細資料：	
16.	**GMP certificate or status suspended, OR marketing authorisation or equivalent relating to the products from this facility suspended or revoked in the past 3 years?** **過去三年，GMP 證書或合規狀況是否曾被暫時吊銷，或此設施所生產藥劑製品的相關銷售許可或同等許可是否曾被暫時吊銷或撤銷？**	☐ Yes 是 ☐ No 否
	If the answer is Yes, please provide details: 如果答案為「是」，請提供詳細資料：	
17.	**Any PIC/S Member Authority has been invited to conduct inspection to any production suite in this facility in the past?** **過去曾否邀請PIC/S會員機構對此設施的有任何生產間進行巡查？** (If the answer is Yes, please provide details, including whether inspection has been conducted and the related details) (If the answer is No, please provide the reason of not inviting other PIC/S Members Authority to conduct inspection) （如果答案為「是」，請提供詳情，包括是否已進行巡查及相關資料） （如果答案為「否」，請提供未有邀請PIC/S會員機構進行巡查的原因）	☐ Yes 是 ☐ No 否

Note: Please use a separate sheet if there is insufficient space to answer to any of the above questions.
備註：如表格空間不敷使用，請另附紙張回答上述問題。

C. Required Documents and Information
丙 需要提交的文件及資料

Please ensure items, in English or in Chinese, in the following checklist have been submitted with this request form.
請確保下列核對表所提及的文件（英文本或中文本）已與此申請表一同提交。

Item / 項目
1. Hard copy of an up-to-date Site Master File; and the soft copy in PDF file formatted to be searchable. 最新的現場主文件（Site Master File）副本，以及其可攜式文件格式(PDF)文件的電子檔案，且內文格式須經處理並已轉化為可搜尋形式。
2. Legible coloured copy of layouts of the manufacturing facility (including production, quality control, storage and ancillary areas) of at least A3 size; and the soft copy in PDF file formatted to be searchable. 設施平面圖的彩色副本（包括生產、品質控制、貯存及輔助區），須清晰可讀，而尺寸最少須達 A3，以及其可攜式文件格式(PDF)文件的電子檔案，且內文格式須經處理並已轉化為可搜尋形式。
3. A list of GMP inspections by other drug regulatory authorities in the past 3 years, including the date and name of authority for each inspection 過去三年由其他藥物監管機構進行的 GMP 巡查清單（包括每次巡查的日期及機構名稱）
4. Copy of manufacturing authorisation, or relevant documents 製造商生產許可或相關文件
5. Master formula of the product(s) in this application last submitted to the Drug Registration Unit of Drug Office 最近一次就此申請所涉藥劑製品提交予藥物辦公室藥物註冊分組的原版配方
6. Method of analysis for all tests stated in the specifications of the product(s) in this application last submitted to the Drug Registration Unit of Drug Office 最近一次就此申請所涉藥劑製品提交予藥物辦公室藥物註冊分組的規格資料中列出的所有測試的化驗分析方法
7. Process validation protocol and report of the product(s) in this application 此申請所涉藥劑製品的工藝驗證方案及報告
8. Latest report of product quality review of the product(s) in this application 此申請所涉藥劑製品最新的質量回顧報告
9. Certificate of the release of biological products or vaccines issued by competent authority (if applicable) 由官方機構發出的生物製劑或疫苗的放行證書（如適用）
10. Declaration provided by the manufacturer to confirm that the drug regulatory authority of the county or region where the manufacturer is located has been informed or has no objection to the PIC/S GMP inspection of the manufacturer by the Drug Office. 製造商提供的聲明，確認製造商所在國家或地區的藥物監管當局得悉或不反對由藥物辦公室對該製造商進行PIC/S GMP視察

Note: Other information not included above may be required on request.
備註：本署或會要求申請人提交核對表未有提及的其他資料。

D. Important Message to the Applicant regarding Inspection at Manufacturer Outside Hong Kong

丁. 給申請人就對香港以外的製造商進行巡查的重要訊息

The Drug Office of the Department of Health is responsible for providing executive and professional support to the Pharmacy and Poisons Board of Hong Kong in drug registration matters. Upon assessment of GMP compliance as requested by the applicant, the Drug Office GMP inspectorate may consider the need of inspection, and inspection may be arranged only when it will not affect the Drug Office's schedule for inspections of local manufacturer by the Drug Office. This inspection is carried out upon the request of the applicant of the initial product registration according to Regulation 37(3) of the Pharmacy and Poisons Regulations, Cap. 138A, Laws of Hong Kong or correspondingly the request of the registration certificate holder of the registered product(s). The whole inspection process includes preparation work, on-site inspection, report writing and review. The applicant will be responsible for the cost of inspection of the manufacturer outside Hong Kong as stated in this request form. The cost of inspection will depend on multiple factors including the location of the manufacturer, type of the manufacturing facilities, etc. This will be calculated on a case-by-case basis for full recovery of all cost associated with the overseas inspection such as staff cost and travelling expenses. **The charges are non- refundable.**

If inspection is required, Drug Office will inform the applicant for the cost of the inspection and payment arrangement after initial review of the supporting information.

衞生署藥物辦公室就藥物註冊事宜向香港藥劑業及毒藥管理局提供行政及專業支援。藥物辦公室GMP巡查組將於GMP合規評審過程中決定是否要進行巡查，而有關巡查亦只會於不會影響藥物辦公室對本港藥廠的視察進度的情況下作出安排。這項巡查是應藥劑製品初註冊申請人的要求並根據香港法例第 138A 章《藥劑業及毒藥規例》第 37(3)條的規定進行，或者視申請所屬類別而應註冊藥劑製品註冊證明書持有人的要求而進行。整個巡查過程包括前期準備工作、實地巡查、報告撰寫及審核。申請人須承擔本署巡查此申請書列出的香港以外製造商所涉費用。巡查費用取決於眾多因素，包括製造商所在地、製藥設施的類別等。計算費用時會因應每宗個案情況，以全數收回海外巡查所涉費用（例如員工費用、出差旅費等）為基礎釐定。**費用一經收取後恕不退還。**

如需要進行巡查，藥物辦公室對有關資料完成初步審核後，會通知申請人相關的巡查費用及付款安排。

E. Declaration of Applicant
戊. 申請人聲明

We wish to request and confirm accepting the Drug Office GMP inspectorate to conduct assessment of GMP compliance when required or upon request, including but not limited to inspection of the aforementioned manufacturing facility (after confirmation of quotation), and to provide the documents as required. We hereby also declare that the information given in this Request Form is true and correct.
我們欲要求並確認接受藥物辦公室GMP巡查組在必要時或應要求進行GMP合規評審，包括但不限於巡查上述製藥設施（於確認報價後），並提交所需文件。我們現亦聲明此申請書內所填報的資料，均全屬確實無誤。

Signature:
簽署：

Company Stamp:
公司蓋印：

Full name of signatory:
簽署人全名：

Date:
日期：

Please submit the completed form together with the relevant information to:
Senior Pharmacist, Manufacturers Regulatory Unit,
Drug Office, Department of Health,
Room 3817, 38/F, Revenue Tower,
5 Gloucester Road, Wanchai, Hong Kong

請將填妥的申請書及相關資料提交予：
香港灣仔告士打道 5 號
稅務大樓 38 樓 3817 室
衞生署藥物辦公室
牌照及監察科
製藥商監管分組
高級藥劑師

Statement of Purposes
用途聲明

Purpose of Collection

收集資料的目的

This personal data is provided by applicants for the purpose of requesting assessment of GMP compliance of manufacturer outside Hong Kong by the Drug Office. The provision of personal data is voluntary. If you do not provide sufficient information, we may not be able to process your application.

申請人因應要求藥物辦公室對在香港以外地方的製造商進行GMP合規評審巡查的申請，須申請書提供相關的個人資料。個人資料的提供是出於自願。如果你不提供充份的資料，我們可能無法處理你的申請。

Classes of Transferees

接受轉介人的類別

2. The personal data you provide are mainly for use within the Department of Health and the Pharmacy and Poisons Board. Apart from this, the data may only be disclosed to parties where you have given consent to such disclosure or where such disclosure is allowed under the Personal Data (Privacy) Ordinance.

你所提供的個人資料，主要由衞生署和藥劑業及毒藥管理局使用。除此之外，這些資料祇會向有你同意的團體透露，或是根據《個人資料(私隱)條例》允許的情況下才會透露。

Access to Personal Data

查閱個人資料

3. You have a right of access and correction with respect to personal data as provided for in sections 18 and 22 and Principle 6 of Schedule 1 of the Personal Data (Privacy) Ordinance. Your right of access includes the right to obtain a copy of your personal data. A fee may be imposed for complying with a data access request.

根據《個人資料(私隱)條例》第18條及22條以及附表1第6原則所述，你有權查閱及修正個人資料，包括有權取得你於上述的情況下所提供的個人資料。應你的查閱資料要求而向你提供資料時，可能要向你徵收費用。

Enquiries

查詢

5. Enquiries concerning the personal data provided, including the making of access and corrections, should be addressed to:

有關所提供個人資料 (包括查閱及修正資料)的查詢，應送交：

Senior Pharmacist
Licensing and Compliance Division
Drug Office
Department of Health
Room 3817, 38/F, Revenue Tower,
5 Gloucester Road,
Wan Chai, Hong Kong.
Tel: 2961 8028

香港灣仔告士打道5號
稅務大樓38樓3817室
衞生署藥物辦公室
牌照及監察科
高級藥劑師
電話：2961 8028

Compliance with the Prevention of Bribery Ordinance

遵守《防止賄賂條例》

Under the Prevention of Bribery Ordinance (Cap. 201), any person who, without lawful authority or reasonable excuse, (a) whether in Hong Kong or elsewhere, offers any advantage to a public servant as an inducement to or reward for that public servant's performing or abstaining from performing exercise of his duties, or (b) offers any advantage to a public servant while having dealings of any kind with the government department or public body in which he is employed, commits an offence.

《防止賄賂條例》(香港法例第 201 章) 訂明，任何人士無合法權限或合理辯解 (a) (不論在香港或其他地方) 向公職人員提供任何利益，作為其執行或不執行職務的誘因或報酬，或 (b) 與政府部門或公共機構有任何事務往來時，向受僱於該政府部門或公共機構的公職人員提供任何利益，均屬犯法。