DEPARTMENT OF HEALTH
DRUG OFFICE
TRADERS LICENSING AND COMPLIANCE DIVISION
MANUFACTURERS REGULATORY UNIT
Room 2550, 25/F, Wu Chung House,
213 Queen's Road East, Wanchai, Hong Kong
Tel. 2961 8162 Fax: 3904 1225

衞生署藥物辦公室
藥商牌照及監察部
製藥商監管組
香港灣仔皇后大道東 213 號
胡忠大廈 25 樓 2550 室
電話 : 2961 8162 傳真 : 3904 1225

Request Form for Drug Office GMP inspectors to conduct inspections of overseas manufacturers

Category : ☐ New application ☐ Renewal application, HK Reg. number:
Name of the product:
Name of the applicant:
Address of the applicant:
Applicant's contact name and telephone number:

Information relating to the overseas manufacturer

Name of the Overseas Manufacturer:
Full Address of the manufacturing facility:
Postal Code of the manufacturing facility:
Telephone number of the manufacturing facility:
Global Positioning System (GPS) Co-ordinates of the facility (in Degree/ Minutes/ Seconds) :

1. Type of products applied in the application

☐ Human products ☐ Biologics ☐ Active Pharmaceutical Ingredients

☐ Veterinary products ☐ Others, please specify

2. Type(s) of dosage form in the application

☐ **Sterile products**

☐ Injections ☐ Vaccines ☐ Eye / Nasal drops

☐ Large Volume Parenterals (in volume of at least 100ml)

☐ Others, please specify

Method of sterilization or preparation

☐ Terminal sterilization ☐ Moist heat ☐ Dry Heat ☐ Radiation

☐ Aseptically prepared with sterile filtration ☐ Blow/Fill/Seal

☐ Other sterilization method, please specify

☐ **Non-sterile products**

☐ Tablets/ capsules ☐ Oral liquids (incl. granules for oral liquids)

☐ Oral gel/ oral paste / gargles ☐ External liquids

☐ Creams / ointments ☐ Suppositories / enemas / pessaries

☐ Others, please specify

3. Total no of production suites in the facility : (please indicate their location in your layout)

4. No of production suites that are involved in this application :(please indicate their location in your layout)

5. Has any of the production suites in this facility been inspected by a regulatory authority in the past 3 years ? ☐Yes ☐No

If the answer is Yes, please provide details

6. Total number of products registered in Hong Kong which are manufactured by the facility in the application :

7. Total number of registered products manufactured in this facility (including those listed in this application) which have been supplying into Hong Kong in the past 3 years :

8.	**Any of the products in Answer to Question 7 which have been actively supplying to the Hospital Authority or the Department of Health under contract in the past 3 years ?** ☐ Yes ☐ No
	If the answer is Yes, please specify the names and registration number of the products
9.	**Are the products manufactured by the facility in this application allowed to be marketed in the country where the facility is situated** ? ☐ Yes ☐ No
	If the answer is NO, please provide details
10.	**Any quality related drug recall in the past 3 years** ? ☐ Yes ☐ No
	If the answer is Yes, please provide details :
11.	**Has the GMP certificate or status been suspended or the Marketing Authorisation or equivalent relating to the products from this facility be suspended or revoked in the past 3 years** ? ☐ Yes ☐ No
	If the answer is Yes, please provide details

Note: Please use a separate sheet if there is insufficient space tor answer to any of the above questions

Please ensure the following items have been submitted with this Questionnaire

1.	An up-to-date Site Master File in English or in Chinese (Both hard copy and electronic file in pdf are required)	☐

2.	Layouts of the facility in both A3 size colour print (and in pdf)	☐
3.	A digital media containing digital copy of Site Master File and Layouts in pdf (any media in the form of a CD, DVD, Blu-ray, or USB flash drive are acceptable)	☐
4.	History of GMP inspections by other drug regulatory authorities	☐
5.	Photocopies of GMP certificate(s)	☐
6.	Master Formula of the product(s) in your application to the Drug Registration Unit of Drug Office	☐
7.	Manufacturing and testing methods of the product(s) in your application to the Drug Registration Unit of Drug Office	☐
8.	Process validation reports of the product(s) in your application to the Drug Registration Unit of Drug Office	☐

Note: Master formulae, manufacturing and testing methods as well as process validation reports (Items 6, 7 and 8) of products not included in the application may ONLY be required on request.

Important message to the applicant

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 overseas manufacturer as stated in this request form. The cost of inspection will depend on a lot of factors including the location of the manufacturer, type of the manufacturing facilities, etc.; and will be calculated on full recovery basis to include all cost relating to the overseas inspection such as staff cost, travelling expense on case-by-case basis. **The charges are non-refundable.**

After initial review of the supporting documents, Drug Office will inform the applicant for the cost of the inspection and payment arrangement.

Please submit the completed form together with the relevant documents to :

Senior Pharmacist, Manufacturers Regulatory Unit,
Drug Office, Department of Health,
Room 2550, 25/F, Wu Chung House,
213 Queen's Road East, Wanchai, Hong Kong

Signature _____ Company Seal _____

Name (Block Letters) _____ Date _____