

Department of Health, Executive

Yuan

The application is in compliance with
Good Manufacturing Practice for
Medical Devices
(Medical device importers/
manufacturers)

Application Reason:

First time application or application for additional
product items

Follow-up

Original QSD Number :

Original approved registration number:

Valid date:

Overseas factory investigation

Repeated evaluation

Original application number:

Application Date:

1. Applicant

Name of Pharmaceutical Manufacturer: (Chinese)

Address of Pharmaceutical Manufacturer: (Chinese)

License Number of Pharmaceutical Manufacturer:

Person-in-Charge of Pharmaceutical Manufacturer:

Telephone Number: - Fax: -

Contact Person: Contact Telephone Number: -

2. Basic Information of Factory

2.1 Factory Name:

2.2 Factory E-mail:

2.3 Factory Address:

(Country):

2.4 Person-in-Charge of Factory:

2.5 Contact Telephone Number: -

2.6 Fax: -

- * **Instruction: For follow-up applications, please submit applications in accordance with Article 9 of Regulations Governing Inspection of Pharmaceutical Manufacturers three months before the certificate expiry date.**

			Valid Date of Certificate:
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(If the space in this form is not enough, please list and describe as an attachment)

3.5 Since the QSD approved registration was obtained, has the original factory had any changes? (This is applicable for follow-up applications for inspection)

Yes (Please choose)

<input type="checkbox"/>	Change of company's dominion	<input type="checkbox"/>	Organizational changes	<input type="checkbox"/>	Quality system changes	<input type="checkbox"/>	Expansion of production line
<input type="checkbox"/>	Other (Please state)						

No changes

3.6 Other important records (eg. obtaining quality system certificate, history of factory name changes, original factories please provide related documents):

(If the space in this form is not enough, please list and describe as an attachment)

3.7 Does the original factory establish the reporting procedures to health administration by the pharmaceutical manufacturers, holding the permit for medical devices, when injury events occur due to the medical devices? (In accordance with regulations of Paragraph 8 of Article 145 of the Standard for the Establishment of Pharmaceutical Factories; please refer to ISO 13485:1996 Sub-Clause 4.14.1/ ISO 13485:2003 Sub-Clause 8.5.1)

Yes Name of procedural document:

Document number:

Establishing date:

No

3.8 Does the original factory establish the reporting procedures for event explanation (please refer to Paragraph 6 of Article 98 of Standard for the Establishment of Pharmaceutical Factories)? (In accordance with Paragraph 9 of Article 145 of the Standard for the Establishment of Pharmaceutical Factories, please refer to ISO 13485:1996 Sub-Clause 4.14.1/ ISO 13485:2003 Sub-Clause 8.5.1)

Yes Name of procedural document:

Document number: Establishing date:

No

3.9 Does the original factory establish the reporting procedures for the recall of products from the market? (In accordance with the related regulations stated in Article 80 of the Pharmaceutical Affairs Act, and principles for drug recall, please refer to ISO 13485:1996 Sub-Clause 4.14.1/ ISO 13485:2003 Sub-Clause 8.5.1)

Yes Name of procedural document:

Document number: Establishing date:

No

4. Medical devices in the application for importation:

Item:	
Name of Medical Device (fill in according to the classification of medical devices)	(Chinese) :
	(English) :
<input type="checkbox"/> New product item	
<input type="checkbox"/> Follow-up product item	Original approved registration number: <input type="text"/>
	License number for medical devices related to this product item has been obtained: (for reference only) <input type="text"/>
Brief description of product functions and characteristics:	Purpose (Please state): <input type="text"/>
	Classification and grading code: <input type="text"/>
	Is this product item an implantable or actively implantable medical appliance? <input type="checkbox"/> Yes <input type="checkbox"/> No
	Does this product item contain software? <input type="checkbox"/> Yes <input type="checkbox"/> No
	Does this product item contain drugs? <input type="checkbox"/> Yes <input type="checkbox"/> No
	Sterilization requirement: <input type="checkbox"/> Sterilized Sterilization methods: <input type="checkbox"/> Ethylene Oxide <input type="checkbox"/> Radiation <input type="checkbox"/> Moist Heat <input type="checkbox"/> Other (Please state) <input type="checkbox"/> Sterilization prior to use <input type="checkbox"/> Sterilization not required
	Are the ingredients of this product derived from human or animal cells or tissues? <input type="checkbox"/> Yes (Origin: <input type="checkbox"/> Human <input type="checkbox"/> Bovine <input type="checkbox"/> Goat) <input type="checkbox"/> Swine <input type="checkbox"/> Other (Please state) <input type="checkbox"/> No

Note: For the applications for more than one product item, please copy this form and fill in one form for each product. Please fill in the purpose and functions of each product in detail)

5. Examination mode you apply for (note: each application can only apply for one appropriate mode of examination. If you like to change the examination mode, please submit a new application. Blank forms can be left out)
- 5.1 Simplified mode of American factories (please fill in the form in appendix 1)
 - 5.2 Simplified mode of European Union technical cooperation program (or countries/areas that sign for cooperation with Taiwan) (Please fill in the form in appendix 2)
 - 5.3 Standard QSD mode 1: (For the application that the quality system of original factories was established according to chapters 2 to 21 in volume 4 of the Standard for the Establishment of Pharmaceutical Factories, please fill in the form in appendix 3)
 - 5.4 Standard QSD mode 2: (For the application that the quality system of original factories was established according to CNS 15013(ISO 13485 : 2003 version), please fill in the form in appendix 4)
 - 5.5 Overseas factory investigation mode (please fill in the form in appendix 5)

Please fill in this form by typing in Chinese or English.

I declare the following statements:

- 1. The information provided in the application is true.
- 2. The quality system documents submitted are the latest valid version.
- 3. After obtaining approved registration, for any changes of the original factories such as change of address, expansion or addition of more medical devices, the company will submit an application in accordance with the Pharmaceutical Affairs Act and the Regulations Governing Inspection of Pharmaceutical Manufacturers.

If actions are made against the above statements, the company will accept that the application can be rejected or revoked, and bear related legal responsibilities.

Stamp of declarer
pharmaceutical
company:

Stamp of person in
charge of
pharmaceutical
company:

Appendix 1 Simplified mode of American factories (only applicable for factories in the USA, Puerto Rico, Guam etc)

<input type="checkbox"/>	5.1.1	Establishment Inspection Report as provided by FDA
	<input type="checkbox"/>	According to Exchange of Letters, the Department of Health can obtain it from FDA through TECRO → AIT.
	<input type="checkbox"/>	Manufacturers provide it itself.
	<input type="checkbox"/>	The latest date when FDA conducted on-site inspection at the original factories: (Please submit the statement letter from original factories)
<input type="checkbox"/>	5.1.2	CFG as provided by FDA: <input type="checkbox"/> Original copy <input type="checkbox"/> Photocopy The original copy is in the application, numbered (Please fill in the application number)
<input type="checkbox"/>	5.1.3	The qualified certificate that is as valid as the GMP standard for medical devices (ISO 13485 certificate)
		Certificate issuing institution:
		Valid date of the certificate:
<input type="checkbox"/>	5.1.4	The original copy of approved certificate (applicable for follow-up applications)

Appendix 2 Simplified mode of European Union technical cooperation program (or countries/areas that sign for cooperation with Taiwan) (only applicable for factories in countries of European Union, and for the investigation representative institutions only, which participated in “Taiwan-European Union Factory Investigation Report and Technical Cooperation Program”, or the countries/areas that have signed the agreement for cooperation).

<input type="checkbox"/>	5.2.1	The institutions of factory investigation and verification of European Union (or the counties/areas that have signed the agreement for cooperation) (Please click): <input type="checkbox"/> BSI PS <input type="checkbox"/> G-med <input type="checkbox"/> mdc <input type="checkbox"/> NSAI <input type="checkbox"/> TÜV PS <input type="checkbox"/> TÜV Rheinland PS <input type="checkbox"/> KEMA <input type="checkbox"/> DGM <input type="checkbox"/> AMTAC <input type="checkbox"/> MEDCERT <input type="checkbox"/> SGS(UK) <input type="checkbox"/> UL (UK) <input type="checkbox"/> Other institutions recognized by health administration: Institution name:		
<input type="checkbox"/>	5.2.2	The report of the latest date when European Union (or the countries/areas that have signed the agreement for cooperation) conducted on-site inspection at the original factories: date of factory investigation:		
<input type="checkbox"/>	5.2.3	The qualified certificate that is as valid as the GMP standard for medical devices (ISO 13485 certificate)		
<input type="checkbox"/>		Certificate issuing institution: <table border="1" data-bbox="344 1279 1423 1384"> <tr> <td data-bbox="344 1279 667 1384">Valid date of the certificate:</td> <td data-bbox="667 1279 1423 1384"></td> </tr> </table>	Valid date of the certificate:	
Valid date of the certificate:				
<input type="checkbox"/>	5.2.4	The certificate issued by the highest health administration in the area of the original factories: <input type="checkbox"/> Original copy <input type="checkbox"/> Photocopy The original copy is in the application, numbered (Please fill in the application number)		
<input type="checkbox"/>	5.2.5	The original copy of approved certificate (applicable for follow-up applications)		

Appendix 3 Standard QSD mode 1: (For the application that the quality system of original factories was established according to chapters 2 to 21 in volume 4 of the Standard for the Establishment of Pharmaceutical Factories)

<input type="checkbox"/>	5.3.1	The qualified certificate that is as valid as the GMP standard for medical devices		
		Certificate citing standard:	<input type="checkbox"/> The certificate for manufacture and sale as provided by the highest health administration (applicable for the products made in the USA, and the certificate should clearly state that the manufacturer complies with Current Good Manufacturing Practice for medical devices in the USA)	
			<input type="checkbox"/> The quality system standard that is equivalent to ISO 13485:1996. Standard name: _____ (Please provide the proof that the standard is equivalent to ISO 13485:1996)	
		Certificate issuing institution:		
		Date of factory investigation:		
<input type="checkbox"/>	5.3.2	Quality system documents		
<input type="checkbox"/>	A.	Quality handbook number:	Issuing date:	Version:
<input type="checkbox"/>	B.	Document catalogue		
<input type="checkbox"/>	C.	Quality system procedural document		
		Requirements of GMP standard	Procedural document number	Version
	<input type="checkbox"/>	Management responsibility (Chapter 2)		
	<input type="checkbox"/>	Quality system (Chapter 3)		
	<input type="checkbox"/>	Contract review (Chapter 4)		
	<input type="checkbox"/>	Design control (Chapter 5)		
	<input type="checkbox"/>	Risk analysis (Chapter 5)		
	<input type="checkbox"/>	Document and data control (Chapter 6)		
	<input type="checkbox"/>	Procurement (Chapter 7)		

	<input type="checkbox"/>	Control of product supply from customers (Chapter 8)		
	<input type="checkbox"/>	Product identification and ascent (Chapter 9)		
	<input type="checkbox"/>	Control of manufacturing procedures (Chapter 10)		
	<input type="checkbox"/>	Examination and test (Chapter 11)		
	<input type="checkbox"/>	Control of facilities for examination and measurement (Chapter 12)		
	<input type="checkbox"/>	Labels for examination and test conditions (Chapter 13)		
	<input type="checkbox"/>	Unqualified product control (Chapter 14)		
	<input type="checkbox"/>	Correction and prevention measures (Chapter 15)		
	<input type="checkbox"/>	Monitoring and reporting back of products in the market (Chapter 15)		
	<input type="checkbox"/>	Procedures of product retrieval from the market (Chapter 15)		
	<input type="checkbox"/>	Reporting of injuries and accidents (Chapter 15)		
	<input type="checkbox"/>	Statement announcement (Chapter 15)		
	<input type="checkbox"/>	Transportation, storage, package protection and goods delivery (Chapter 16)		
	<input type="checkbox"/>	Quality record control (Chapter 17)		
	<input type="checkbox"/>	Internal quality auditing (Chapter 18)		
	<input type="checkbox"/>	Training (Chapter 19)		
	<input type="checkbox"/>	Services (Chapter 20)		
	<input type="checkbox"/>	Statistical technique (Chapter 21)		
<input type="checkbox"/>	5.3.3	Factory floor plan		
<input type="checkbox"/>	5.3.4	Manufacturing operational areas for various types of products (when it is essential, please also label the passageway for operators and goods delivery)		
<input type="checkbox"/>	5.3.5	Main facilities		

<input type="checkbox"/>	5.3.6	Product manufacturing procedures (if there are procedures contracted to other companies, please state the name of the contracted company in accordance with point 3.4)
<input type="checkbox"/>	5.3.7	The original copy of approved certificate (applicable for follow-up applications)

Appendix 4 Standard QSD mode 2: (For the application that the quality system of original factories was established according to CNS 15013(ISO 13485 : 2003 version)

<input type="checkbox"/>	5.4.1	The qualified certificate that is as valid as the GMP standard for medical devices		
<input type="checkbox"/>		Certificate citing standard:	<input type="checkbox"/> ISO13485 : 2003 <input type="checkbox"/> The certificate for manufacture and sale as provided by the highest health administration (applicable for the products made in the USA, and the certificate should clearly state that the manufacturer complies with Current Good Manufacturing Practice for medical devices in the USA)	
		Certificate issuing institution:		
		Date of factory investigation:		
<input type="checkbox"/>	5.4.2	Quality system documents		
<input type="checkbox"/>	A.	Quality handbook number:	Issuing date:	Version:
<input type="checkbox"/>	B.	Document catalogue		
<input type="checkbox"/>	C.	Quality system procedural document		
		Requirements (Chapter CNS 15013)	Procedural document number	Version
		Quality management system (Section 4)		
	<input type="checkbox"/>	General requirements (Section 4.1)		
	<input type="checkbox"/>	Document requirements (Sections 4.2.1~4.2.3)		
	<input type="checkbox"/>	Quality record requirements (Section 4.2.4)		
		Responsibility of management level (Section 5)		
	<input type="checkbox"/>	Commitment of management level (Section 5.1)		
	<input type="checkbox"/>	Customer priority (Section 5.2)		
	<input type="checkbox"/>	Quality policy (Section 5.3)		
	<input type="checkbox"/>	Planning (Section 5.4)		

<input type="checkbox"/>	Duty, limits of authority and communication (Section 5.5)		
<input type="checkbox"/>	Examination of management level (Section 5.6)		
	Resource management (Section 6)		
<input type="checkbox"/>	Resource supply (Section 6.1)		
<input type="checkbox"/>	Human resources (Section 6.2)		
<input type="checkbox"/>	Fundamental facilities (Section 6.3)		
<input type="checkbox"/>	Work environment (Section 6.4)		
	Product accomplishment (Section 7)		
<input type="checkbox"/>	Planning for product accomplishment (Section 7.1)		
<input type="checkbox"/>	Risk management (Section 7.1)		
<input type="checkbox"/>	Customer related procedures (Section 7.2)		
<input type="checkbox"/>	Design and development (Section 7.3)		
<input type="checkbox"/>	Procurement (Section 7.4)		
<input type="checkbox"/>	Control of production and services (Section 7.5.1)		
<input type="checkbox"/>	Product cleaning and contamination control (Section 7.5.1.2.1)		
<input type="checkbox"/>	Installation activities (Section 7.5.1.2.2)		
<input type="checkbox"/>	Services (Section 7.5.1.2.3)		
<input type="checkbox"/>	Special requirements for sterile medical appliances (Section 7.5.1.3)		
<input type="checkbox"/>	Confirmation of manufacturing and service providing procedures (Section 7.5.2)		
<input type="checkbox"/>	Efficiency confirmation of sterilization (Section 7.5.2.2)		
<input type="checkbox"/>	Identification and ascent (Section 7.5.3)		
<input type="checkbox"/>	Customers' property (Section 7.5.4)		

	<input type="checkbox"/>	Product protection (Section 7.5.5)		
	<input type="checkbox"/>	Control of monitoring and measuring devices (Section 7.6)		
		Measurement, analysis and improvement (Section 8)		
	<input type="checkbox"/>	Feedback (Section 8.2.1)		
	<input type="checkbox"/>	Internal auditing (Section 8.2.2)		
	<input type="checkbox"/>	Procedure monitoring, control and measurement (Section 8.2.3)		
	<input type="checkbox"/>	monitoring, control and measurement (Section 8.2.4)		
	<input type="checkbox"/>	Unqualified product control (Section 8.3)		
	<input type="checkbox"/>	Data analysis (Section 8.4)		
	<input type="checkbox"/>	Improvement (Section 8.5)		
	<input type="checkbox"/>	Reporting of injuries and accidents (Section 8.5.1)		
	<input type="checkbox"/>	Procedures of product retrieval from the market (Section 8.5.1)		
	<input type="checkbox"/>	Statement announcement (Section 8.5.1)		
	<input type="checkbox"/>	Correction measures (Section 8.5.2)		
	<input type="checkbox"/>	Prevention measures (Section 8.5.3)		
<input type="checkbox"/>	5.4.3	Factory floor plan		
<input type="checkbox"/>	5.4.4	Manufacturing operational areas for various types of products (when it is essential, please also label the passageway for operators and goods delivery)		
<input type="checkbox"/>	5.4.5	Main facilities		
<input type="checkbox"/>	5.4.6	Product manufacturing procedures (if there are procedures contracted to other companies, please state the name of the contracted company in accordance with point 20)		
<input type="checkbox"/>	5.4.7	The original copy of approved certificate (applicable for follow-up applications)		

Appendix 5 Overseas factory investigation mode

<input type="checkbox"/>	5.5.1	Factory quality handbook:			
		Number:	Issuing date:		Version:
<input type="checkbox"/>	5.5.2	Factory floor plan			
<input type="checkbox"/>	5.5.3.	Manufacturing operational areas for various types of products (when it is essential, please also label the passageway for operators and goods delivery)			
<input type="checkbox"/>	5.5.4	Main facilities			
<input type="checkbox"/>	5.5.5	Product manufacturing procedures (if there are procedures contracted to other companies, please state the name of the contracted company in accordance with point 3.4)			
<input type="checkbox"/>	5.5.6	The document stating the legal status of the factory			
<input type="checkbox"/>	5.5.7	A letter of authorization from the original factory (clearly states that the original factory authorizes the pharmaceutical manufacturers in Taiwan to submit an application for oversea factory investigation to the Department of Health)			
<input type="checkbox"/>	5.5.8	Are the medical devices to be imported manufactured at the same factory? <input type="checkbox"/> Yes <input type="checkbox"/> No (Please describe about other factories)			
<input type="checkbox"/>	5.5.9	The original copy of approved certificate (applicable for follow-up applications)			