

Plant Registration for importing medical device into Taiwan

Standard QSD mode

Required documents:

(1) Factory Information:

- 1. Fill in the Basic Information of Factory from 2.1- 3.9 on GMP application form.**
- 2. Provide actual documents for the Basic Information of Factory from 3.1-3.9 on GMP application form.**
- 3. Issue the statement letter from original factory to declare/demonstrate Basic Information of Factory from 3.1-3.9 on GMP application form is effective and true.**

(2) Product list: All products listing in whole plant (including all the products needed to do product registration for importing later)

(3) Plant Layout

- 1. Factory floor plan**
- 2. Manufacturing operational areas for various types of products (when it is essential, please also label the passageway for operations and goods delivery)**
- 3. Main facilities**
- 4. 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 on GMP application form)**

(4) ISO 13485 certificate

(5) QSD (Quality System Document) *Accord With Good Manufacturing Practice (GMP) which including **three parts:***

- 1. Quality Manual/handbook**

2. Quality Document Index/Catalogue (Master List of the whole Quality System)

3. Quality system procedural document, choose one of the following GMP standard:

- **25 SOPs** according to ISO 13485:1996 (please see attachment 20070530_GMP application form: Appendix 3)

OR

- **41 SOPs** according to ISO 13485:2003 (please see attachment 20070530_GMP application form: Appendix 4)