MOHW FDA No. 1091105341 Announcement dated August 31, 2020 "

Notices for the application of Plant master file" Form C-2 revised version

PMF Checklist **for Foreign Pharmaceutical Manufacturer**

Form C-2: Sterile Product (Simplified) (For the expansion of manufacturing site, the items which are marked with asterisk are required, and the relevant documents shall be enclosed.)

To which case be applied : Sterile medicinal products/ Biological medicinal products/Biological active substances (including the substance claimed non sterile or low bioburden level)/Blood products derived from human blood or human plasma

Applicant:	**Receipt No.**	**Case Number**
Item	Please complete the checklist item by item and indicate the attachment numbers or the page numbers of **submitted documents**.	reviewer comment
2.1 Pharmaceutical Quality System (Chapter 1 of Part I and Annex 2 and 3)		
2.1.1 Describe the product release procedure.	P.	
2.1.2 For product with short shelf-life (such as radiopharmaceuticals, advanced therapy medicinal products, etc.) and which is released before completion of all quality control, describe alternatives methods (such as rapid microbiological methods) of obtaining equivalent data to permit batch certification; procedures for different stages of release shall also be described.	P.	
2.2 Organization and Personnel (Chapter 2 of Part I and Annex 1)		
2.2.1 Describe the procedure of personnel qualification, including training programs for personnel employed in sterile product manufacturing areas, and qualification protocols for personnel gowning procedures relevant to aseptically prepared products	P.	
2.2.2 For sterile product manufacturer, describe in detail the requirement of clothing, the gowning procedure and the washing procedure of clothing for each grade of clean area.	P.	
2.3*. Premises, Facilities, Equipment, and Production (Chapters 3 and 5 of Part I and Annex 1)		

*2.3.1 Layouts showing the flow of personnel, materials, products, and waste.	P.	
*2.3.2 Heating, ventilation and air conditioning (HVAC) systems		
*2.3.2.1 Briefly describe the HVAC systems in production area.	P.	
*2.3.2.2 Layouts of clean room specified classification in production areas (such as A, B, C, D, CNC, etc.).	P.	
*2.3.2.3 Describe pressure differences between adjacent rooms and indicate-air-flow directions in the layout of production area.	P.	
*2.3.3 Water systems		
*2.3.3.1 Describe water treatment system (including the schematic drawings)	P.	
*2.3.3.2 Describe the disinfection of water treatment units and pipelines.	P.	
*2.3.3.3 Describe the monitoring program of the water (including sampling plans, frequency, test items and acceptance criteria).	P.	
*2.3.4 Describe the type(s) of gas(es) that come in contact with products during the manufacturing process and the monitoring program thereof.	P.	
*2.3.5 Environmental control in production area		
*2.3.5.1 Describe the environmental monitoring program in the production area, such as temperature/humidity, particles, microorganisms, and personnel.	P.	
*2.3.5.2 For sterile product manufacturer, describe the cleaning and disinfection procedure in the production area, and list the disinfectants used and the rotation frequency.	P.	
*2.3.6 List of major manufacturing equipments (including weighing, manufacturing processing, packaging, and storage)	P.	
*2.4 Flowchart of major manufacturing steps for the applied dosage form/product/manufacturing process in this case; and indicate the grades of the production area, major equipment, process parameters and in process control items.	P.	
	Signature (including date of signing)	