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

Notices for the application of Plant master file" **Form C-3**

PMF Checklist for Foreign Pharmaceutical Manufacturer

Form C-3: Full review (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 :All products

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
3.1 Pharmaceutical Quality System (Chapter 1 and 9 of Part I and Annex 2, 3 and 15)		
3.1.1 Product release procedure		
3.1.1.1 Describe the product release procedure.	P.	
3.1.1.2 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 alternative 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.	
3.1.2 Describe the procedure for product quality review.	P.	
3.1.3 Describe the procedure for quality assessment and management of supplier.	P.	
3.1.4 Describe the management of deviations and non-conformity, their related investigations, as well as the resultant corrective and preventive actions	P.	
3.1.5 Describe the change control procedure regarding to change in premises, equipment, facilities, products and validations.	P.	
3.1.6 Describe the self-inspection and/or quality inspection procedures.	P.	
3.2 Organization and Personnel (Chapter 2 of Part I and Annex 1)		
3.2.1 Responsibilities of senior managers and key personnel (the head of production, the head of quality control, the head of quality assurance, and the authorized person for release)	P.	

3.2.2 Employee training		
3.2.2.1 Basic training on theory and practice for personnel, which shall include orientation and on-the-job training programs; describe the GMP-related training and the way of training. Describe also how the training program is established in accordance with personnel needs, the approval of the training program , the assessment of the training effectiveness, and the maintenance of the training records	P.	
3.2.2.2 For sterile product manufacturer, 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.	
3.2.3 Personnel hygiene requirements		
3.2.3.1 Describe medical examination for new employees, routine medical examinations, disease reporting system for operators in the production area, and additional health examinations for operators working in clean areas.	P.	
3.2.3.2 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.	
3.3. Premises, Facilities, Equipment (Chapters 3 and 5 of Part I, and Annex 1, 9, and 10)		
3.3.1* Premises design		
*3.3.1.1 Layouts of personnel, materials, products, and waste flow.	P.	
3.3.1.2 Describe the storage and control for printed packaging materials.	P.	
*3.3.2 Heating, ventilation and air conditioning (HVAC) systems		
*3.3.2.1 Briefly describe the HVAC systems in production area.	P.	
*3.3.2.2. Layouts of clean room classification in production area (such as A, B, C, D, CNC, etc.).	P.	
*3.3.2.3 Describe pressure differences between adjacent rooms and indicate air-flow directions in the layout of production area.	P.	

*3.3.3 Water treatment systems		
*3.3.3.1 Schematic drawings of water system (including each treatment unit and circulation pipeline).	P.	
*3.3.3.2 Describe the process water treatment system.	P.	
*3.3. 3.3 Describe the disinfection of water treatment units and pipelines.	P.	
*3.3.3.4 Describe the quality monitoring program of the water (including sampling plans, frequency, test items and acceptance criteria).	P.	
*3.3.4 Describe the type(s) of gas(es) that come in contact with products during the manufacturing process and the monitoring program thereof.	P.	
*3.3.5 Environmental control in production areas		
*3.3.5.1 Describe the environmental monitoring program in the production area, such as temperature/humidity, particles, microorganisms, and personnel.	P.	
*3.3.5.2 For sterile product manufacturer, describe the cleaning and disinfection procedure in the production area, and list the disinfectants used and the rotation frequency.	P.	
*3.3.5.3 For manufacturer for liquid, cream, ointment, or aerosol, please describe the design and measures to prevent microbial and other contamination.	P.	
*3.3.6 Manufacturing/testing equipment		
*3.3.6.1 List of major manufacturing (including weighing, processing, packaging, and storage) equipment.	P.	
*3.3.6.2 List of in- process control (IPC) instruments and QC lab equipment.	P.	
3.4. Documentation (Chapter 4 of Part I)		
3.4.1 Describe the procedures of documents preparation, review, approval, distribution, and superseded, and controls for records retention.	P.	
3.4.2 Describe procedures for periodical review of documents.	P.	
3.5 In-Process Control (Chapter 5 of Part I, Annexes 1 and 8)		
3.5.1 For manufacturer of drug product, describe the amount of samples taken from the received starting materials for the identification test(s). Describe the procedures or measures to assure the identity of the contents of each container.	P.	

*3.5.2 Flowchart of major manufacturing steps for the applied dosage form/product/process in this case; and indicate the grades of the production area, major equipment, process parameters and in process control items.	P.	
3.5.3 Describe the measures to reduce the risk of cross contamination and mix-ups when different products are packaged in close proximity.	P.	
3.5.4 Describe the management of rejected projects; in cases of additional handling, such as rework or reprocess, the relevant SOP should be provided.	P.	
3.5.5 For sterile product manufacturer, describe the procedure for container integrity test (including the sampling plan, frequency, and test methods).	P.	
3.6 Quality Control (Chapter 6 of Part I, Annexes 3 and 19)		
3.6.1 Describe the ongoing stability program after the product is introduced to the market.	P.	
3.6.2 Reference sample and retention sample: For manufacturer of drug product, describe the sampling, storage conditions, and-shelf-life period of reference samples (including starting materials, packaging materials, or finished products) and retention samples (finished products).	P.	
3.7. Complaints, Returned Products, and Recalls (Chapters 5 and 8 of Part I and Annex 3)		
3.7.1 Describe the procedures of handling complaints.	P.	
3.7.2 Describe the procedures of handling returned products.	P.	
3.7.3 Describe the procedures of product recall, and the evaluation of the effectiveness of the arrangements for recalls.	P.	
3.8 Storage and Transportation (Chapter 3 of Part I and Annex 15)		
3.8.1 Describe the storage conditions of dosage form applied.	P.	
3.8.2 Describe procedures to ensure the products were transported in accordance with the pre-defined conditions.	P.	
	Signature (including date of signing)	