Contract Giver

(**MAH**)

Step0 Inform manufacture plan

1

2

(Contract Acceptor: **GBC** CMO)

Step1 Manufacture: Sterile AMP
Step2 Before Packaging: Income Materials (Carton Label/Carton)
Step3 Test 1: Income Test (Original Spec.)
Step4 GMP Package (Package vials into Carton/ Labelling Carton) (Include IPC*)
Step5 Test 2: Income QC (Customer Spec.*)
Step6 After Packaging: Income AMP

"*": Depend on customer requirements

Base on Annex **16** Certification by the AP and Batch Release

Contract Manufacture without labelling AMP Vial(for Commercial) of TQA (Demo)

- ☐ Contract Giver (MAH) and Contract Acceptor (GBC) follow the regulations of PIC/S GMP Annex 16 Certification by The AP and Batch Release to ensure Contract Giver performs "vial labelling", in order to safeguard the safety of patients.
- ☐ Batch Release is followed the arrangement and the MA Definitions.
- ☐ The contract content is followed as the diagram and performed by the responsibilities as the table.
- ☐ TQA scope involves the relationship between MAH and GBC, and follows the MAH QMS (MAH plans and determines the solutions of contract deviations). It does not only involve the regulation of Annex 16 for AMP without Labelling, but also needs to consider PIC/S GMP Part I and Annex 1.

1 (MAH to GBC)		**MAH**	**GBC**
1.1	Supply the basic information, e.g. name, lot no, batch size, unit operation, package unit…etc.	O	
1.2	Supply the Market Authorized File (MAF) for manufacture AMP requirements. ☐ Supply ADE/PDE (e.g. API CAS No.、OEL Monograph) for evaluating to avoid cross contamination. ☐ Supply information follows the content of MAF to satisfy the requirements to perform the contract that includes package vials into carton and labelling carton.	O	
1.3	Is the Carton and Label supplier qualified by MAH (e.g. supply the Qualified Statement of the supplier)?	O	
1.4	Performs Step 0：Inform manufacture plan to GBC (includes the related information).	O	
1.5	Others???		
1.6	Others???		
2 (GBC to MAH)		**MAH**	**GBC**
2.1	Establish the quality documents following no.1.2.		O
2.2	Perform Step1 to manufacture sterile AMP.		O
2.3	Before Packaging, perform Step2 to income materials (Carton Label/Carton (with ATD))		
2.4	Perform sampling and income test following Step3 (Original spec.)(include reference sample).		O
2.5	Inform Step4 packaging result with fill vials into carton and labelling carton (include IPC data*) (Data should supply to help deviation investigation, e.g. OOS, OOT).		O
2.6	Inform Step5 test result of finished product with labelling carton (Customer spec.*) (include reference sample).		O
2.7	Perform Step6 income warehouse.		O
2.8	Assist to investigate deviation (MAH plans and determines).	O	O
2.9	Others???		
2.10	Others???		
The certification of the AMP with labelling carton			
[LETTER HEAD OF THE BATCH CERTIFYING AND RELEASING MANUFACTURER] 1. Name, strength/potency, dosage form and package size (identical to the text on the finished product			

package).
2. Batch number of the finished product.
3. Name of the destination country/countries of the batch.

4. Certification statement.
I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements of the [insert jurisdiction] and [as applicable] with the requirements of the IND or IRB of the destination country/countries.

5. Name of the Authorised Person certifying the batch.
6. Signature of the Authorised Person certifying the batch.
Date of signature.