Contract Giver

(**MAH**)

Labelling (RLD)

Step0 Inform manufacture plan

1

2

Labelling RLD

(Contract Acceptor: **GBC** CDMO)

Step1 Before Labelling: Income Label/RLD
Step2 Test 1: Income Test (Original Spec.)
Step3 GMP Labelling Process (Include IPC*)
Step4 Test 2: Income QC (Customer Spec.*)
Step5 After Labelling: Income RLD

"*": Depend on customer requirements

Base on Annex **13** Manufacture of IMPs

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

Labelling RLD of IMP (for Clinic Trial) of TQA (Demo)

- ☐ Contract Giver (MAH) and Contract Acceptor (GBC) follow the regulations of PIC/S GMP Annex 13 Manufacture of IMPs to ensure the quality in order to safeguard the safety of patients and the reliability and the robustness of Labelling.
- ☐ MAH and GBC follow the defined by its IRB or IND.
- ☐ 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, labels are used in Clinic Trial, not only involves the regulation of Annex 13 for Labelling RLD of IMP, but also needs to consider PIC/S GMP Annex 16.

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 Product Specification File (PSF) for the labelling requirements. ☐ Supply ADE/PDE (e.g. API CAS No.、OEL Monograph) for evaluating to avoid cross contamination. ☐ Supply information follows the content of Annex 13 Ch2.1 PSF to satisfy the requirements to perform the contract.	O	
1.3	MAH has followed no.1.1 and 1.2 that will to get (or application) IRB or IND.	O	
1.4	Is the Label supplier qualified by MAH (e.g. supply the Qualified Statement of the Label supplier)?	O	
1.5	Performs Step 0：Inform manufacture plan to GBC (includes the related information).	O	
1.6	Others???		
1.7	Others???		
2 (GBC to MAH)		**MAH**	**GBC**
2.1	Establish the quality documents following no.1.2.		O
2.2	Before labelling, perform Step1 income the label/RLD and open the test requirement.		O
2.3	Perform sampling and income test following Step2 (Original spec.)(include reference sample).		O
2.4	Inform Step3 labelling result (include IPC data*) (Data should supply to help deviation investigation, e.g. OOS, OOT).		O
2.5	Inform Step4 test result of finished labelling product (Customer spec.*) (include reference sample).		O
2.6	After labelling, perform Step5 income the RLD.		O
2.7	Assist to investigate deviation (MAH plans and determines).	O	O
2.8	Others???		
2.9	Others???		

The certification of the labelling of the RLD

[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.