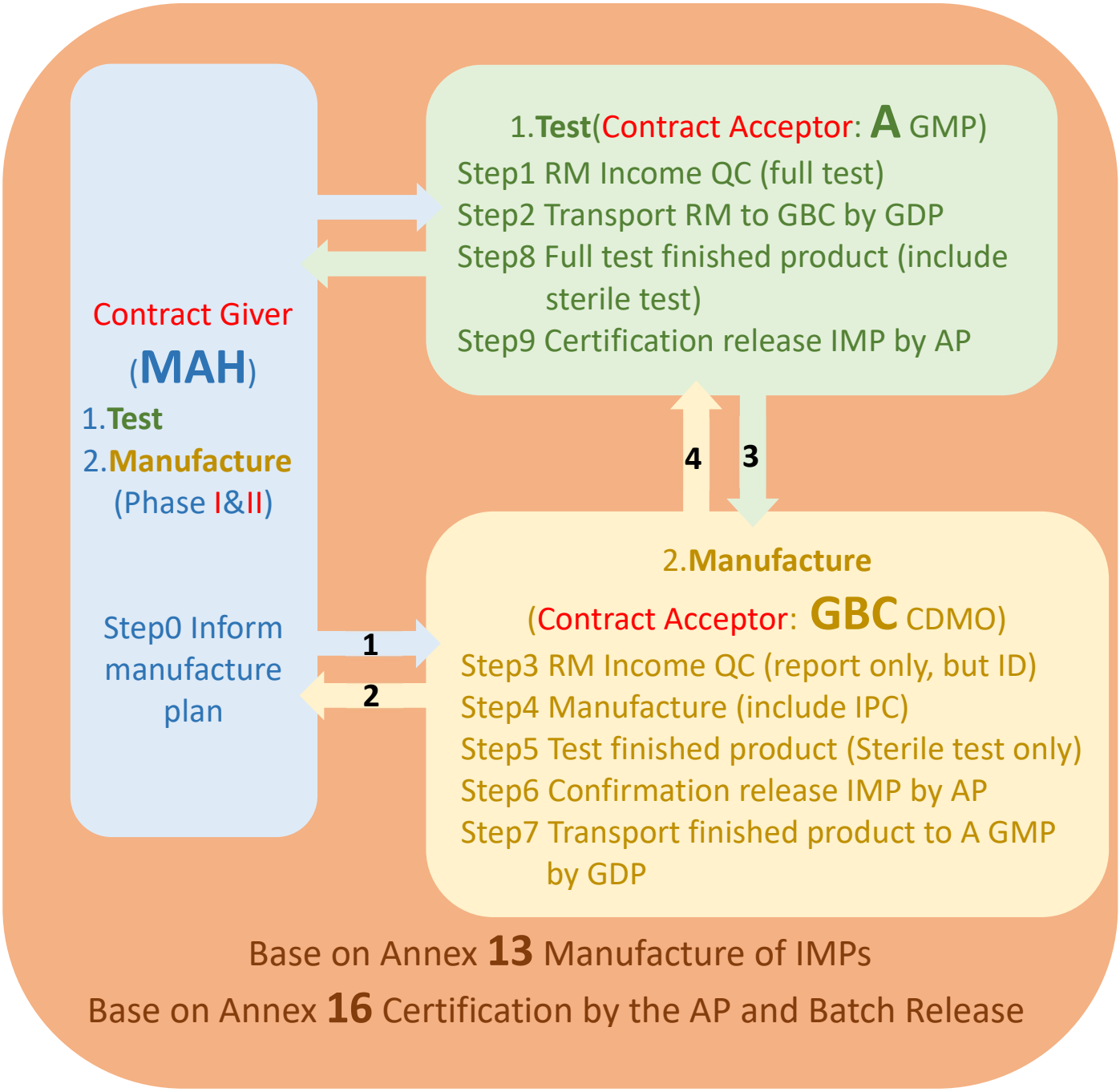

Contract Giver
(MAH)
1.Test
2.Manufacture
(Phase I&II)
Step0 Inform manufacture plan
1
2
1.Test(Contract Acceptor: A GMP)
Step1 RM Income QC (full test)
Step2 Transport RM to GBC by GDP
Step8 Full test finished product (include sterile test)
Step9 Certification release IMP by AP
4
3
2.Manufacture
(Contract Acceptor: GBC CDMO)
Step3 RM Income QC (report only, but ID)
Step4 Manufacture (include IPC)
Step5 Test finished product (Sterile test only)
Step6 Confirmation release IMP by AP
Step7 Transport finished product to A GMP by GDP
Base on Annex 13 Manufacture of IMPs
Base on Annex 16 Certification by the AP and Batch Release

Partial Manufacture IMP (Phase I&II) of TQA (Demo)

- ☐ Contract Giver(MAH) and Contract Acceptor(GBC) follow the regulation of PIC/S GMP Annex 13：Manufacture of IMPs to ensure the quality in order to safeguard the safety of the subject and the reliability and the robustness of clinic data generated in the clinic trial.
- ☐ MAH and GBC follow PIC/S GMP Annex 16：Certification by the AP and Batch Release, and the basic arrangements for batch release for IMP are defined by its MA 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/GBC and GBC/A GMP, and follows the MAH QMS (MAH plans and determines the solutions of contract deviations). It, sterile IMP, not only involves the regulation of Annex 13&16, but also needs to comply with PIC/S GMP Part I and Annex 1.

1 (MAH to GBC)		**MAH**	**GBC**
1.1	Supply the IMP's basic information, e.g. name, lot no, strength, batch size, filling qty, unit operation, package unit…etc.	O	
1.2	Supply the IMP's Product Specification File (PSF) for the manufacturing 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) IND.	O	
1.4	Supply the contact information of A GMP.	O	
1.5	Is A GMP supplier qualified by MAH (e.g. supply the Qualified Statement of A GMP supplier)?	O	
1.6	Performs Step 0：Inform manufacture plan to GBC/A GMP (includes the related information).	O	
1.7	Others???		
1.8	Others???		
2 (GBC to MAH)		**MAH**	**GBC**
2.1	Establish the quality documents following no.1.2.		O
2.2	Perform sampling and income test following Step3 (report only, but ID) (include retention sample).		O
2.3	Inform Step4 manufacture result (include IPC data) (Data should supply to help deviation investigation, e.g. OOS, OOT).		O
2.4	Inform Step5 test result of finished product (Sterile test only).		O
2.5	Perform Step6 IMP Confirmation release by AP and generate the statement of "**The confirmation of the partial manufacturing of an IMP**" (include retention sample).		O
2.6	Confirm Step7 GDP transportation date.	O	O
2.7	Assist to investigate deviation (MAH plans and determines).	O	O
2.8	Others???		
2.9	Others???		
3 (A GMP to GBC)		**A GMP**	**GBC**
3.1	Confirm Step2 GDP transportation date (include test report).	O	O
3.2	Assist to investigate deviation (MAH plans and determines).	O	O

3.3	Others???		
3.4	Others???		
4 (GBC to A GMP)		**A GMP**	**GBC**
4.1	Attach Step3 income test report (report only, but ID).		O
4.2	Attach Step4 manufacture result (include IPC data).		O
4.3	Attach Step5 test result of finished product (Sterile test only).		O
4.4	Perform Step6 IMP Confirmation release by AP and generate the statement of "**The confirmation of the partial manufacturing of an IMP**" (include retention sample).		O
4.5	Confirm Step7 GDP transportation date.	O	O
4.6	Attach the statement of "**The confirmation of the partial manufacturing of an IMP**" following no.4.5.		O
4.7	Assist to investigate deviation (MAH plans and determines).	O	O
4.8	Others???		
4.9	Others???		

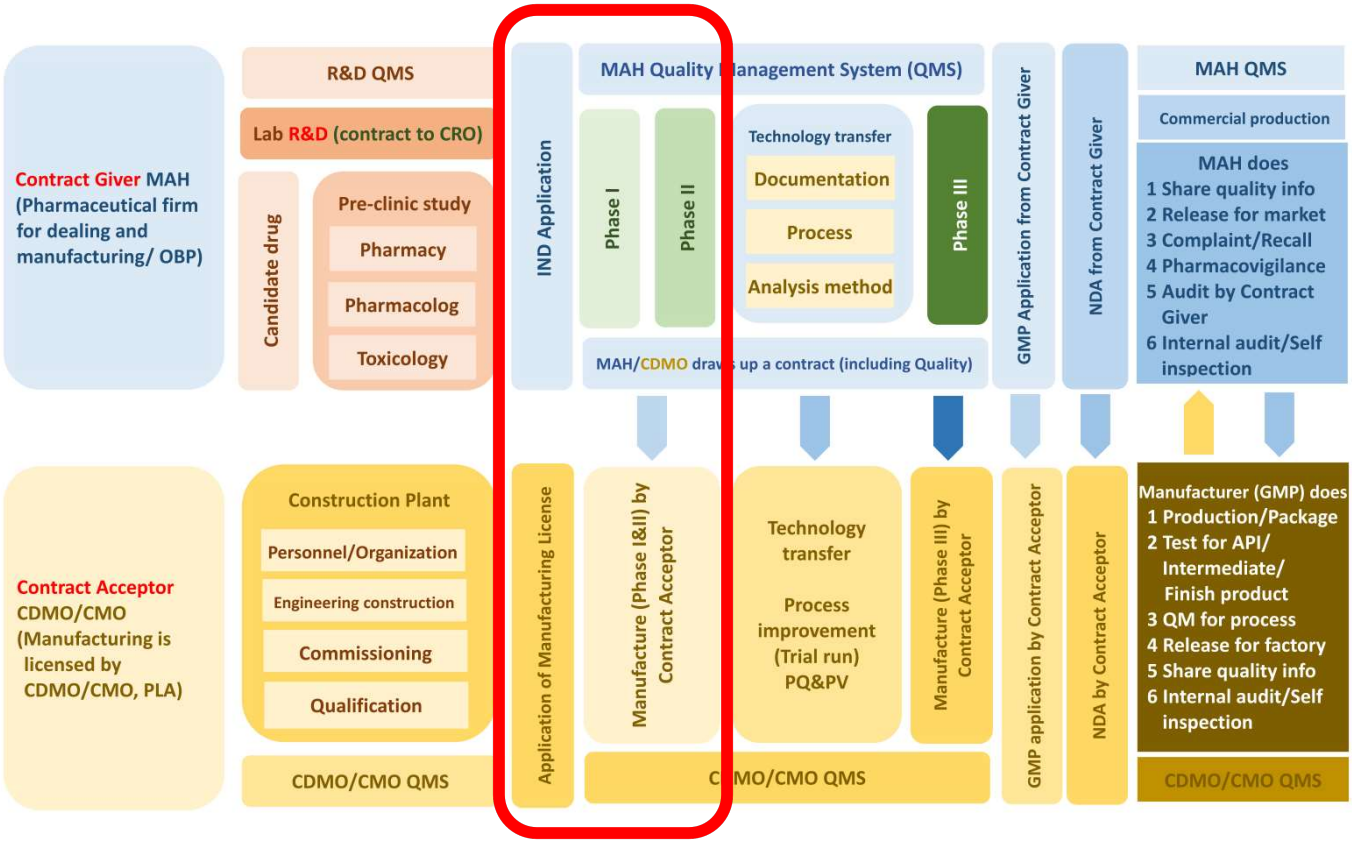
The confirmation of the partial manufacturing of an IMP

[LETTER HEAD OF MANUFACTURER WHO CARRIED OUT THE MANUFACTURING ACTIVITY]

1. Name of the product and description of the manufacturing stage (e.g. paracetamol 500 mg tablets, primary packaging into blister packs).
2. Batch number.
3. Name and address of the site carrying out the partial manufacturing.
4. Reference to the Technical Quality Agreement/ TQA (in accordance with Chapter 7 of the PIC/S GMP Guide).

5. Confirmation statement.
   I hereby confirm that the manufacturing stages referred to in the Technical Quality Agreement have been carried out in full compliance with the GMP requirements of the [insert jurisdiction] and the terms described in the Agreement for ensuring compliance with the requirements of the Marketing Authorisation(s) as provided by [Contract Giver/ manufacturer certifying and releasing the batch].

Name of the Authorised Person confirming the partial manufacturing.
Signature of Authorised Person confirming the partial manufacturing.
Date of signature.


Contract Giver MAH (Pharmaceutical firm for dealing and manufacturing/ OBP)
R&D QMS
Lab R&D (contract to CRO)
Candidate drug
Pre-clinic study
Pharmacy
Pharmacolog
Toxicology
IND Application
MAH Quality Management System (QMS)
Phase I
Phase II
Technology transfer
Documentation
Process
Analysis method
Phase III
MAH/CDMO draws up a contract (including Quality)
GMP Application from Contract Giver
NDA from Contract Giver
MAH QMS
Commercial production
MAH does
1 Share quality info
2 Release for market
3 Complaint/Recall
4 Pharmacovigilance
5 Audit by Contract Giver
6 Internal audit/Self inspection
Contract Acceptor CDMO/CMO (Manufacturing is licensed by CDMO/CMO, PLA)
Construction Plant
Personnel/Organization
Engineering construction
Commissioning
Qualification
CDMO/CMO QMS
Application of Manufacturing License
Manufacture (Phase I&II) by Contract Acceptor
Technology transfer
Process improvement (Trial run) PQ&PV
Manufacture (Phase III) by Contract Acceptor
CDMO/CMO QMS
GMP application by Contract Acceptor
NDA by Contract Acceptor
Manufacturer (GMP) does
1 Production/Package
2 Test for API/ Intermediate/ Finish product
3 QM for process
4 Release for factory
5 Share quality info
6 Internal audit/Self inspection
CDMO/CMO QMS