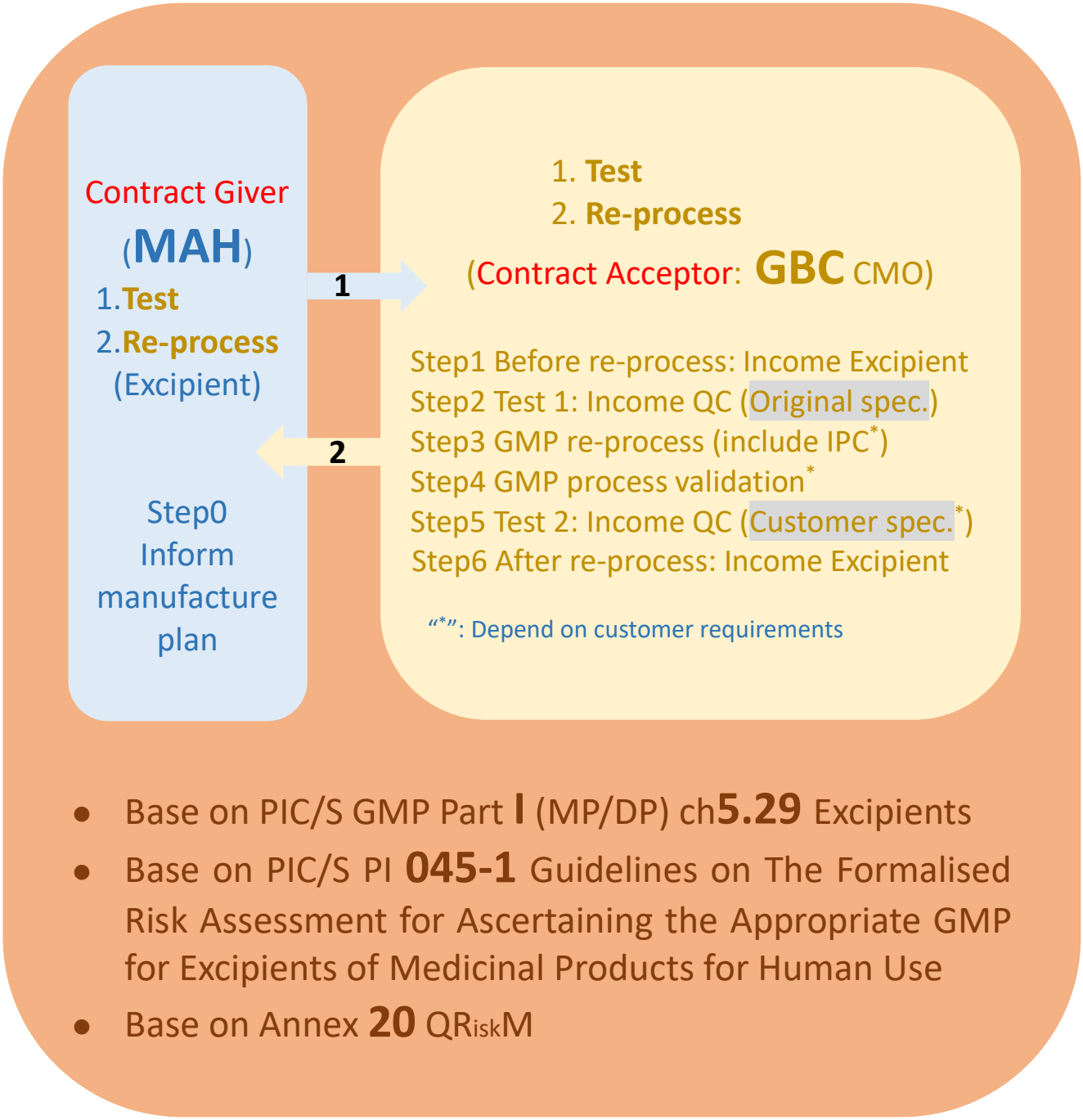

- Base on PIC/S GMP Part **I** (MP/DP) ch**5.29** Excipients
- Base on PIC/S PI **045-1** Guidelines on The Formalised Risk Assessment for Ascertaining the Appropriate GMP for Excipients of Medicinal Products for Human Use
- Base on Annex **20** QRiskM

Test& Re-process Excipients (Used in Sterile MPs) of TQA (Demo)

- ☐ Contract Giver(MAH) and Contract Acceptor(GBC) follow the regulations as below to ensure the quality in order to safeguard the safety of patients and the reliability and the robustness of re-process.
  - PIC/S GMP Part I Ch5.29 Excipients
  - PIC/S GMP Annex 20 Quality Risk Management
  - PIC/S PI 045-1 Guidelines on The Formalised Risk Assessment for Ascertaining the Appropriate GMP for Excipients of Medicinal Products for Human Use
- ☐ MAH and GBC follow the 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 and GBC, and follows the MAH QMS (MAH plans and determines the solutions of contract deviations). It, excipients are used in sterile MPs, not only involves the regulation of PIC/S GMP Part I Ch5.29 Excipients, but also needs to consider PIC/S GMP Part I Ch5.29 Active substances and Part II (API/DS).

1 (MAH to GBC)		**MAH**	**GBC**
1.1	Supply the excipient's basic information, e.g. name, lot no, batch size, unit operation, package unit…etc.	O	
1.2	Supply the excipient's Product Specification File (PSF) for the re-processing requirements. ☐ 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	Is the Excipient supplier qualified by MAH (e.g. supply the Qualified Statement of the Excipient 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 re-processing, perform Step1 income the Excipient 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 re-process result (include IPC data*) (Data should supply to help deviation investigation, e.g. OOS, OOT).		O
2.5	Inform Step4 process validation* result (Data should supply to help deviation investigation, e.g. OOS, OOT).		O
2.6	Inform Step5 test result of finished re-processing product (Customer spec.*) (include reference sample).		O
2.7	After re-processing, perform Step6 income the Excipient.		O
2.8	Assist to investigate deviation (MAH plans and determines).	O	O
2.9	Others???		
2.10	Others???		