Customer Requirement Specification (CRS)

GBC is pleasure to discuss the CDMO/CMO requirement specification with you. We fully understand the cumbersome requirements of the MA/GMP regulations, and your concerns on technical/formulation, also understand that you have some undetermined points. However, we will work with you to complete this form. This will help GBC QMS (view point from QA) to provide you with the right advice quickly and correctly.

0.Contract Giver Information			
0.1 Company		0.2 Address	
0.3 Cell Phone		0.4 Telephone	
0.5 E-mail		0.6 Contact Person	

1. Basic Information			
1.1 Product name		1.2 Production line	
1.3 CAS No.		1.4 Chemical name	
1.5 Strength		1.6 Indication	
1.7 Physical and chemical properties			
1.8 The production and/or storage of technical poisons, such as pesticides (except where these are used for manufacture of medicinal products) and herbicides			☐Yes ☐No
1.9 Is it potential highly allergenic category		☐Yes ☐β-Lactams Antibacteria	

	☐Penicillins ☐Non-Penicillin ☐Cephalosporins ☐Carbapenems ☐Others ☐β-Lactams Non-Antibacteria ☐β-lactamase inhibitors ☐β-lactam intermediates and derivatives ☐Other products containing a β-lactam structure ☐No
1.10 Is it cytotoxicity category(Indications: for the treatment of cancer)	☐Yes (direct acting) ☐alkylating agents(8 subcategories) ☐antibiotics(5 subcategories) ☐anti-biometabolites(6 subcategories) ☐topoisomerase(3 subcategories) ☐antimicrotubules(3 subcategories) ☐No (indirect acting) ☐immuno-active ☐hormone agonist and antagonists(5 subcategories) ☐tyrosine and serine kinase inhibition ☐osteo-active ☐antisense oligonucleotide
1.11 Manufacture of ATMPs for Human Use (Annex 2A)	☐Yes ☐No
1.12 Manufacture of Biological Medicinal Substances and Products for Human Use (Annex 2B)	☐Yes ☐No

1.13 Manufacture of Radiopharmaceuticals (Annex 3)	☐Yes ☐No
1.14 Manufacture of Medicinal Gases (Annex 6)	☐Yes ☐No
1.15 Manufacture of Pressurised Metered Dose Aerosol Preparations for Inhalation (Annex 10)	☐Yes ☐No
1.16 Manufacture of IMPs (Annex 13)	☐Yes ☐No
1.17 Manufacture of Medicinal Products Derived from Human Blood or Plasma (Annex 14)	☐Yes ☐No
1.18 Provide BSE/TSE legality statement (or management process)	☐Yes ☐No
1.19 Provide Nitrosamines legality statement (or management process)	☐Yes ☐No
1.20 Manufacture of MP/DP or API/DS	☐Yes, ☐MP/DP☐API/DS ☐No, ☐Medical Device☐Veterinary☐Standard☐Others
1.21 Evaluate Potency and Toxicological	☐Genotoxicant ☐Reproductive developmental toxicant ☐Carcinogen ☐Highly sensitizing potential ☐OEL：_____ug/m^3 ☐OEB：_____(1~5) ☐ADE/PDE：_____ug/day ☐NOAEL：_____mg/day
1.22 Others/Summary	☐CDMO ☐CMO

	Summary ☐ For worker safety ☐ Elimination ☐ Substitution ☐ Modification ☐ Containment ☐ Ventilation ☐ Work practice ☐ Personal protection ☐ For patient safety ☐ Can be accommodated in multi-product facility with dedicated equipment or units (Options) ☐ Disposable equipment for a given process step ☐ Dedicated equipment for a given process step ☐ Dedicated unit (in a multi-product facility) ☐ Can be accommodated in multi-product facility with no restrictions

2. Customer Requirements		
Aspect	Factor	Element
1. Operator	☐ 1.1 GBC ☐ 1.2 Customer ☐ 1.3 Is education and training required?	☐ Operated by qualified GMP operators in the production line (or laboratory), the number of people? ☐ Based on MAH QMS, customer needs to participate in the on-site guidance of the operation, the number of people? ☐ What are the educational and training needs and content of GBC and

	☐ 1.4 Others	customer? ☐ Please detail it：
2. Machine	☐ 2.1 GBC established machine ☐ 2.2 Customer machine ☐ 2.3 Others	☐ Using GMP qualified machine, and do I need to retrofit or add modules? ☐ Features and quantity? Space required? ☐ Please detail it：
3. Material	☐ 3.1 GBC established materials ☐ 3.2 Customer materials ☐ 3.3 Others	☐ Type? Quantity (related batch size)? Sterile/non-Sterile? Aseptic filling/Terminal sterilization? ☐ Type? Quantity (related batch size)? Sterile/non-Sterile? Aseptic filling/Terminal sterilization? ☐ Please detail it：
4. Regulation	☐ 4.1 GMP regulations ☐ 4.2 GMP licensing ☐ 4.3 MA ☐ 4.4 Objective purpose ☐ 4.5 MAA ☐ 4.6 Others	☐ PIC/S GMP? EU GMP? cGMP? or others? ☐ PAI that related with 4.3 ☐ IND (Phase I, II, III)/ANDA/NDA/Biosimilar/BLA? ☐ API/DS (or Intermediate), MP/DP (or semi-MP/DP), package? ☐ EMA/MHRA/PMDA/TFDA/US FDA/SFDA/Others? ☐ Please detail it：
5. Environment	☐ 5.1 Grade A ☐ 5.2 Grade C ☐ 5.3 Others	☐ DP: Lyo/Solution vial/PFS/Cartridge ☐ DS: Peptide/Biological/Oncology ☐ Please detail it：
6. Test	☐ 6.1 Physical-chemical ☐ 6.2 Microbial	☐ Specification and methodology of Raw materials (or Intermediate), MP/DP (or semi-MP/DP)? ☐ Specification and methodology of Raw materials (or Intermediate),

	☐ 6.3 Others	MP/DP (or semi-MP/DP)? ☐ Please detail it：

3. CDMO Module		
Aspect	Factor	Element
1. Module	☐ 1.1 Established module ☐ 1.2 Not yet established	☐ Module：_____ ☐ Need to be established ☐ Not required

4. Conclusion		
Aspect	Factor	Element
1. Does GBC accept the contract?	☐ Yes ☐ No	☐ CDMO/ CMO ☐ Conclusion of accepting the contract： ☐ Conclusion of unaccepted the contract：
Evaluator/ Date		

Remark 1：Module is presented on GBC Official website/QMS/MAH/CDMO (https://tw.genovior.com.tw/quality_19.htm)

Remark 2：CRS helps GBC QA to complete ”Questionnaires for Contract Manufacture(A1)” and ” Feasibility assessment of new product conducting (A2)”。