Upstream BioProcessing Questionnaire

Please answer the following questions as completely as possible.

I. Customer Information

CONTACT PERSON

COMPANY NAME

DESIGNATION

CONTACT NUMBER

DEPARTMENT

EMAIL ADDRESS

II. General Details

1. Target Product

- ☐ Secreted Protein
- ☐ Non secreted protein
- ☐ Cell bank
- ☐ mAbs
- ☐ Cell Therapy
- ☐ Virus Production
  - ○ Human
  - ○ Veterinary
- ☐ Cultivated Meat
- ☐ _____

2. Cell Type

- ☐ Adherent cell (Proceed to Adherent Cell Questionnaire)
- ☐ Suspension cell (Proceed to Suspension Cell Questionnaire)

3. What process development (PD)/optimization do you require?

- ☐ Cell line development
- ☐ Upstream development
  e.g. bioreactor media optimization, harvest protocol
- ☐ Downstream development
  e.g. optimization of platform DS process
- ☐ No PD required. Process to be transferred at existing scale to manufacturing.

4. Do you require any of the following? Please attach an extra sheet if additional services are required.

- ☐ Analytical Method Validation
- ☐ cGMP manufacturing and lot release
- ☐ Stability testing
- ☐ Sterility testing of final product
- ☐ Adventitious virus testing
- ☐ _____

Adherent Cells Questionnaire

III. Experiment Details

a. General Details

1. Cell Line

- ☐ CHO
- ☐ Vero
- ☐ Hybridoma
- ☐ MDCK
- ☐ HEK 293
- ☐ SF-9
- ☐ _____

2. Any special features or peculiarities of the cell line or methods

3. Intended Use

- ☐ Human Use
- ☐ Animal Use

4. Current Culture System

- ☐ T-flask
- ☐ Cell stack
- ☐ Roller bottle
- ☐ Hyper flask
- ☐ Spinner flask
- ☐ Stirred Tank Bioreactor with Carriers
- ☐ Cell factory
- ☐ _____

Indicate Capacity in liters (L):

5. If carriers are used, please specify type and amount of carrier.

- ☐ Microbeads, Specify: _____
- ☐ Fibrous matrices, Specify: _____
- ☐ Others, Specify: _____

Amount of carriers: _____ grams

6. Culture condition for cell growth

- ☐ Media _____
- ☐ Serum _____
- ☐ Temperature _____

7. Currently using serum-free culture medium?

- ☐ Yes
- ☐ No

8. Concentration of additives

- ☐ Sodium Bicarbonate
- ☐ Others _____
- ☐ Hepes Buffer

9. Cell Harvesting Required

- ☐ Yes
- ☐ No

10. Use of trypsin during cell harvest

- ☐ Yes
- ☐ No
- ☐ Use others. Please specify: _____

11. Cell Quantification

- ☐ Manual counting
- ☐ Nuclei counting
- ☐ Auto-counter
- ☐ Others _____

12. Access to a bio-analyzer for measuring glucose, lactate, glutamine, etc.

- ☐ Yes
- ☐ No

13. System preference

- ☐ Single-Use Preference
- ☐ No Preference
- ☐ Multiple-Use Preference

14. Scale-up plan in terms of number of cells	☐ 10^9 ☐ 10^{10} ☐ 10^{11} ☐ 10^{12} ☐ $>10^{13}$
15. Scale-up plan in terms of volume	☐ 50L ☐ 100L ☐ 500L ☐ Others

b. Protein Production

1. Culture period prior to harvesting	☐ 3 Days ☐ 5 Days ☐ 7 Days ☐ Other (Please Specify): days
2. Protein extraction method	☐ By cell harvest ☐ By medium harvest ☐ Freeze/Thaw method ☐ Others

c. Cell Therapy

1. Target	☐ Autologous Cell Therapy ☐ Allogeneic Cell Therapy ☐ Research Use ☐ Others
2. Cell Source	☐ Bone Marrow ☐ Adipose-derived ☐ iPS ☐ Embryo ☐ Placenta ☐ Umbilical ☐ Dermal fibroblast ☐ Others

III. Experiment Details

d. Virus Production

1. Virus Type/Strain

☐ Secreted Virus ☐ Non-secreted Virus Virus

Strain:

2. Please describe the Virus Strain? (ds, ssDNA,ds,+/- ssRNA, enveloped, nonenveloped, temperature sensitivity, etc.)

3. Cell density prior to infection in current culture system

4. Multiplicity of Infection (MOI)

5. Period of time for cell lysis to occur after infection in current culture system

6. Culture condition post infection

☐ Media

☐ Serum

☐ Temperature

7. Best phase for infection

☐ Right after seeding ☐ Plateau phase

☐ Exponential phase

8. Is the virus stable during post infection?

9. Virus titer in current culture system (dose/ml)

10. Best time to harvest the virus	
11. Is there CPE (cytopathic effect) after infection? When?	☐ Yes; ☐ No
12. What kind of CPE is formed (e.g. syncytium, destruction, etc.)	
13. Cell lysis post infection	☐ Yes; ☐ No
14. Number of harvests that could be done during post infection period	☐ Single Harvest ☐ Multi-harvest for ____ times ☐ Continuous Harvest for ____ days
15. Do cells keep propagating after virus infection?	☐ Yes. Indicate fold increase post infection: ____ ☐ No
16. For virus production, annual manufactured dose	

Fermentation/Suspension Cells

III. Experiment Details

a. General Details

1. Application

- ☐ Microbial Culture
- ☐ Adherent Cell Culture
- ☐ Suspension Mammalian Culture

2. Cells Culture

- ☐ Bacteria
- ☐ Cell Line: _____
- ☐ Yeast
- ☐ Others _____
- ☐ Fungi

3. For mammalian cells, specify type and amount of carrier used

- ☐ Microbeads, Specify: _____
- ☐ Fibers, Specify: _____
- ☐ Others, Specify: _____

Amount of carrier: _____

4. Product

- ☐ Secreted Protein
- ☐ Secreted Virus
- ☐ Non-Secreted Protein
- ☐ Non-Secreted Virus
- ☐ Fermentation
- ☐ Cell Banking
- ☐ Others _____

5a. Current Culture System

- ☐ Spinner Flask
- ☐ Others _____
- ☐ Stirred Tank Bioreactor

5b. Current Culture Scale in liters (L): _____

6. Current Process Mode

- ☐ Batch
- ☐ Continuous
- ☐ Fed-Batch
- ☐ Others _____

7. Culture condition for cell growth	☐ Media ☐ Serum ☐ Temperature
8. Currently using serum-free culture medium?	☐ Yes ☐ No
9. Concentration of additives	☐ Sodium Bicarbonate: ☐ HEPES Buffer: ☐ Others
10. Cooling system required?	☐ Yes ☐ No
11. Temperature sensitive?	☐ Yes ☐ No
12. pH Sensitive?	☐ Yes ☐ No
13a. Shear Stress Tolerance	☐ High Sensitivity ☐ Medium Sensitivity ☐ High tolerance to shear stress
13b. Preferred Impeller Type	
14. Scale up plan in terms of volume in liters	

III. Experiment Details

b. Process Control

1. Reactor Size

Minimum working volume: _____

Maximum working volume: _____

2. Agitation Speed

Range: _____ rpm to _____ rpm

3. Measurements Required

- ☐ Temperature _____ °C to _____ °C
- ☐ pH _____ to _____
- ☐ DO _____ % to _____ %
- ☐ Redox _____ mV to _____ mV
- ☐ Turbidity
- ☐ pCO$_2$
- ☐ Foaming
- ☐ O_2/CO_2 in Exhaust Gas
- ☐ Level
- ☐ Others _____

4. Temperature Control

- ☐ Double wall vessel
- ☐ Heating Pad
- ☐ Heating Jacket
- ☐ Heating/Cooling Pad
- ☐ Others _____

5. pH Control

- ☐ Addition of Base
- ☐ Addition of CO_2
- ☐ Addition of Acid
- ☐ Others _____

6. Dissolved Oxygen Control

- ☐ Impeller Speed
- ☐ Gas Flow Rate
- ☐ Addition of O_2
- ☐ Others _____

7. Foaming

- ☐ High
- ☐ Not yet determined
- ☐ Low

8. Applied Gases for Aeration

- ☐ Air
- ☐ Air + O_2
- ☐ Air + O_2 + N_2
- ☐ Air + O_2 + N_2 + CO_2
- ☐ Others

Mixing System:

☐ Yes ☐ No

9. Airflow

Range: _____ vvm to _____ vvm

Control:

☐ Regulator (manual) ☐ Mass Flow Controller

☐ Others _____

10. Aeration Delivery

☐ Sparger, Type:
- ○ Ring Sparger
- ○ Microsparger
- ○ _____

☐ Overlay

☐ Both

11. Pressure Control Requirements

12. Other Special Requirements

Important: *Save the completed PDF form (use menu File - Save).*