

Upstream BioProcessing Questionnaire

Please answer the following questions as completely as possible.

I. Customer Information	
Contact Person	
Designation	
Department	
Company Name	
Contact Number	
Email Address	

II. General Details		
1.	Target Product	<input type="checkbox"/> Secreted Protein <input type="checkbox"/> Non-secreted protein <input type="checkbox"/> Cell bank <input type="checkbox"/> mAbs <input type="checkbox"/> Virus production <ul style="list-style-type: none"> ○ Human ○ Veterinary <input type="checkbox"/> Cell therapy <input type="checkbox"/> Artificial Meats <input type="checkbox"/> Others:
2.	Cell Type	<input type="checkbox"/> Adherent cell (Proceed to Adherent Cell Questionnaire) <input type="checkbox"/> Suspension cell (Proceed to Suspension Cell Questionnaire)
3.	What process development (PD)/optimization do you require?	<input type="checkbox"/> Cell line development <input type="checkbox"/> Upstream development, e.g. bioreactor media optimization, harvest protocol <input type="checkbox"/> Downstream development, e.g. optimization of platform DS process <input type="checkbox"/> 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 required.	<input type="checkbox"/> Analytical Method Validation <input type="checkbox"/> cGMP manufacturing and lot release <input type="checkbox"/> Stability testing <input type="checkbox"/> Sterility testing of final product <input type="checkbox"/> Adventitious virus testing <input type="checkbox"/> Other: _____
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Adherent Cells Questionnaire

I. Experiment Details		
<i>a. General Details</i>		
1.	Cell Line	<input type="checkbox"/> CHO <input type="checkbox"/> MDCK <input type="checkbox"/> Vero <input type="checkbox"/> HEK 293 <input type="checkbox"/> Hybridoma <input type="checkbox"/> Sf 9 <input type="checkbox"/> Others:
2.	Any special features or peculiarities of the cell line or methods	
3.	Intended Use	<input type="checkbox"/> Human Use <input type="checkbox"/> Animal Use
4.	Current Culture System	<input type="checkbox"/> T-flask <input type="checkbox"/> Roller bottle <input type="checkbox"/> Spinner flask <input type="checkbox"/> Cell factory <input type="checkbox"/> Cell stack <input type="checkbox"/> Hyper flask <input type="checkbox"/> Stirred Tank Bioreactor with Carriers <input type="checkbox"/> Others: Indicate Capacity in liters (L):
5.	If carriers are used, please specify type and amount of carrier.	<input type="checkbox"/> Microbeads, Specify: <input type="checkbox"/> Fibers, Specify: <input type="checkbox"/> Others, Specify: Amount of carrier:

6.	Culture condition for cell growth	<input type="checkbox"/> Media: <input type="checkbox"/> Serum: <input type="checkbox"/> Temp.:
7.	Currently using serum-free culture medium?	<input type="checkbox"/> Yes <input type="checkbox"/> No
8.	Concentration of additives	<input type="checkbox"/> Sodium bicarbonate: <input type="checkbox"/> Hepes buffer: <input type="checkbox"/> Others:
9.	Cell Harvesting Required	<input type="checkbox"/> Yes <input type="checkbox"/> No
10.	Use of trypsin during cell harvest	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Use others. Please specify:
11.	Cell Quantification	<input type="checkbox"/> Manual counting <input type="checkbox"/> Auto-counter <input type="checkbox"/> Nuclei counting <input type="checkbox"/> Others:
12.	Access to a bio-analyzer for measuring glucose, lactate, glutamine, etc.	<input type="checkbox"/> Yes <input type="checkbox"/> No
13.	System preference	<input type="checkbox"/> Single-Use Preference <input type="checkbox"/> Multiple-Use Preference <input type="checkbox"/> No Preference
14.	Scale-up plan in terms of number of cells	<input type="checkbox"/> 10^9 <input type="checkbox"/> 10^{10} <input type="checkbox"/> 10^{11} <input type="checkbox"/> 10^{12} <input type="checkbox"/> $>10^{13}$
	Scale-up plan in terms of volume	<input type="checkbox"/> 50L <input type="checkbox"/> 100L <input type="checkbox"/> 500L <input type="checkbox"/> Others:

b. Protein Production

1.	Culture period prior to harvesting	<input type="checkbox"/> 3 days <input type="checkbox"/> 5 days <input type="checkbox"/> 7 days <input type="checkbox"/> Other (Please Specify): _____ days
2.	Protein extraction method	<input type="checkbox"/> By cell harvest <input type="checkbox"/> By medium harvest <input type="checkbox"/> Freeze/Thaw method <input type="checkbox"/> Others:

<i>c. Cell Therapy</i>		
1.	Target	<input type="checkbox"/> Autologous Cell Therapy <input type="checkbox"/> Allogeneic Cell Therapy <input type="checkbox"/> Research Use <input type="checkbox"/> Others:
2.	Cell Source	<input type="checkbox"/> Bone Marrow <input type="checkbox"/> Adipose-derived <input type="checkbox"/> iPS <input type="checkbox"/> Embryo <input type="checkbox"/> Placenta <input type="checkbox"/> Umbilical <input type="checkbox"/> Dermal fibroblast <input type="checkbox"/> Others: <input type="checkbox"/> Bone Marrow
<i>d. Virus Production</i>		
1.	Virus Type/Strain	<input type="checkbox"/> Secreted Virus <input type="checkbox"/> Non-secreted 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	<input type="checkbox"/> Media: <input type="checkbox"/> Serum: <input type="checkbox"/> Temperature:
7.	Best phase for infection	<input type="checkbox"/> Right after seeding <input type="checkbox"/> Exponential phase <input type="checkbox"/> Plateau 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?	<input type="checkbox"/> Yes _____ hours / days later <input type="checkbox"/> No
12.	What kind of CPE is formed (e.g. syncytium, destruction, etc.)	<input type="checkbox"/>
13.	Cell lysis post infection	<input type="checkbox"/> Yes _____ hours / days later <input type="checkbox"/> No
14.	Number of harvests that could be done during post-infection period	<input type="checkbox"/> Single Harvest <input type="checkbox"/> Multi-harvest for _____ times <input type="checkbox"/> Continuous Harvest for _____ days
15.	Do cells keep propagation after virus infection?	<input type="checkbox"/> No <input type="checkbox"/> Yes, Indicate fold increase post infection:
16.	For virus production, annual manufactured dose	

Fermentation/Suspension Cells

I. Experimental Details

a. General Details

1.	Application	<input type="checkbox"/> Microbial Culture <input type="checkbox"/> Suspension Cell Culture <input type="checkbox"/> Adherent Cell Culture
2.	Cells Culture	<input type="checkbox"/> Bacteria <input type="checkbox"/> Yeast <input type="checkbox"/> Fungi <input type="checkbox"/> Cell Line: <input type="checkbox"/> Other:
3.	a. For adherent cells, specify type and amount of carrier used	<input type="checkbox"/> Microbeads, Specify: <input type="checkbox"/> Fibers, Specify: <input type="checkbox"/> Others, Specify:
	b. Amount of carrier	
4.	Product	<input type="checkbox"/> Secreted Protein <input type="checkbox"/> Non-Secreted Protein <input type="checkbox"/> Fermentation <input type="checkbox"/> Cell Banking <input type="checkbox"/> Secreted Virus <input type="checkbox"/> Non-Secreted Virus <input type="checkbox"/> Others:
5.	a. Current Culture System	<input type="checkbox"/> Spinner Flask

		<input type="checkbox"/> Stirred Tank Bioreactor <input type="checkbox"/> Other:
	b. Current Culture Scale in liters (L):	
6.	Current Process Mode	<input type="checkbox"/> Batch <input type="checkbox"/> Fed-Batch <input type="checkbox"/> Continuous <input type="checkbox"/> Other:
7.	Culture condition for cell growth	<input type="checkbox"/> Media: <input type="checkbox"/> Serum: <input type="checkbox"/> Temp.:
8.	Currently using serum-free culture medium?	<input type="checkbox"/> Yes <input type="checkbox"/> No
9.	Concentration of additives	<input type="checkbox"/> Sodium bicarbonate: <input type="checkbox"/> Hepes buffer: <input type="checkbox"/> Others:
10.	Cooling system required?	<input type="checkbox"/> Yes <input type="checkbox"/> No
11.	Temperature sensitive?	<input type="checkbox"/> Yes <input type="checkbox"/> No
12.	pH Sensitive?	<input type="checkbox"/> Yes <input type="checkbox"/> No
13.	a. Shear Stress Tolerance	<input type="checkbox"/> High Sensitivity <input type="checkbox"/> Medium Sensitivity <input type="checkbox"/> High tolerance to shear stress
	b. Preferred Impeller Type	
14.	Scale up plan in terms of volume	_____ L
b. Process Control		
1.	Reactor Size	Minimum working volume: Maximum working volume:
2.	Agitation Speed	Range: ____ rpm to ____ rpm
3.	Measurements Required	<input type="checkbox"/> Temperature ____ °C to ____ °C
		<input type="checkbox"/> pH ____ to ____
		<input type="checkbox"/> DO ____ % to ____ %
		<input type="checkbox"/> Redox ____ mV to ____ mV

		<input type="checkbox"/> Turbidity <input type="checkbox"/> Foaming <input type="checkbox"/> Level <input type="checkbox"/> pCO ₂ <input type="checkbox"/> O ₂ /CO ₂ in Exhaust Gas <input type="checkbox"/> Others
4.	Temperature Control	<input type="checkbox"/> Double wall vessel <input type="checkbox"/> Heating Jacket <input type="checkbox"/> Heating Pad <input type="checkbox"/> Heating/Cooling Pad <input type="checkbox"/> Other:
5.	pH Control	<input type="checkbox"/> Addition of Base <input type="checkbox"/> Addition of Acid <input type="checkbox"/> Addition of CO ₂ <input type="checkbox"/> Others:
6.	Dissolved Oxygen Control	<input type="checkbox"/> Impeller Speed <input type="checkbox"/> Addition of O ₂ <input type="checkbox"/> Gas Flow Rate <input type="checkbox"/> Others:
7.	Foaming	<input type="checkbox"/> High <input type="checkbox"/> Low <input type="checkbox"/> Not yet determined
8.	Applied Gases for Aeration	<input type="checkbox"/> Air <input type="checkbox"/> Air + O ₂ <input type="checkbox"/> Air + O ₂ + N ₂ <input type="checkbox"/> Air + O ₂ + N ₂ + CO ₂ <input type="checkbox"/> Others Mixing System: <input type="checkbox"/> Yes <input type="checkbox"/> No
9.	Airflow	Range: ___ vvm to ___ vvm Control: <input type="checkbox"/> Regulator (manual) <input type="checkbox"/> Mass Flow Controller <input type="checkbox"/> Others:
10.	Aeration Delivery	<input type="checkbox"/> Overlay <input type="checkbox"/> Sparger, Type: <input type="radio"/> Ring Sparger <input type="radio"/> Microsparger <input type="radio"/> Others: <input type="checkbox"/> Both

11.	Pressure Control Requirements	
12.	Other Special Requirements	