

Virus Production Questionnaire

Please answer the following questions as completely as possible. The information here will be kept with utmost confidentiality and will only be used to generate a customized protocol for your facility.

I. Customer Information			
С	ontact Person		
D	esignation		
Department			
Company Name			
Contact Number			
Email Address			
I. General Details			
1.	Target Product		Secreted Protein Non-secreted Protein Cell Bank Monoclonal Antibody Secreted Virus Non-secreted Virus Autologous Cell Therapy Allogeneic Cell Therapy Others:
2.	Cell Type		Adherent Cell Suspension Cell Microbial Stem Cell



(Different cell line, different application has to be filled in separate questionnaire).

Adherent Cells Questionnaire

II. Ex	periment Details				
A.	Cell Culture				
1.	Cell Line		CHO MDCK Vero HEK 293 Hybridoma Sf 9		
			Others:		
2.	Any Special features or peculiarities of the cell line or culture methods?				
3.	Intended Use		Human Use Animal Use		
4.	Target Product		Secreted Protein Non-secreted Pr Cell Bank Monoclonal Antil Secreted Virus Non-secreted Virus Others:	otein	
5.	Current Culture System		T-flask		
			Roller Bottle Spinner flask Carriers: (Cell Factory / Cell (total surface and Stirred-tank Biores)		Btls _Btls) Pcs
6.	Media Volume Capacity	□ • W	Carriers: (Others: /orking Volume Ca	apacity)
		_	r otal Volume Capa	nL / Pc (or /Btl)	



		Please specify if media volume is different after virus	
		infection	
7.	If carriers are used, please	☐ Microbeads. Specify:	
	specify type and amount of	☐ Fibers Specify:	
	carrier.	☐ Others Specify:	
		☐ Amount of carriers:	
8.	Medium exchange	□ 24 hours (1 day)	
	frequency for current	□ 48 hours (2 days)	
	system - During Cell Culture	□ 72 hours (3 days)	
		□ Other:hours (days)	
	NA diama and an are	☐ Media volume per change: ml	
9.	Medium exchange frequency and volume for	☐ 24 hours (1 day)	
	current system	☐ 48 hours (2 days)	
	- Post Infection	□ 72 hours (3 days)	
	. cot illicotion	□ Other:hours (days)	
		☐ Media volume per change: ml	
10.	Culture condition during	□ Media:	
	cell culture	□ Serum:	
		☐ Temperature:	
		☐ CO₂ concentration of incubator	
11.	Concentration of additives	□ Sodium Bicarbonate:	
		☐ Hepes buffer:	
		□ Others:	
12.	Glucose Concentration in		
	initial culture medium	g/L	
13.	Cell Harvesting (Cell	□ Yes	
	dissociation) required	□ No	
14.	Cell Harvest (Cell	☐ Trypsin	
	Dissociation) method if	☐ Enzymatic Dissociation Reagents	
	have	(Specify:	
		☐ Non-Enzymatic Dissociation Reagents	
		(Specify:	
		☐ Others:	
15.	Cell Quantification (Cell	☐ Manual Counting	
	Counting)	☐ Auto-counter	
		☐ Nuclei counting	
		☐ Others:	
16.	Access to bio-analyzer for	☐ Yes	
	measuring glucose, lactate, glutamine, etc	□ No	
17.	System Preference	□ Prefer Single-Use	
'''		□ Prefer Single-Ose □ Prefer Multiple-Use	



		☐ No preference
18.	Current System Annual dose (product quantity)	
19.	Current System average total cell density (per single system eg., per 1 roller bottle)	 Seeding Cell Density: Harvesting End Cell Density: Cell Density before virus infection:
20.	Do you have scale up plan?	☐ Yes ☐ No
21.	Expected Scale when scaled up (Cell Density, Doses etc)	
B.	Virus production	
22.	Virus Strain	
23.	Please describe the virus strain. (ds/ss DNA, ds/ss,+/- RNA, temperature sensitivity etc)	
24.	Cell Stability during post infection	 ☐ Yes, grow and attach same as before infection ☐ A little less stable than before infection ☐ No, cells tend to detach post infection period inhours ☐ Others
25.	Do cells propagate after virus infection?	☐ YesFold increase post infection:☐ No☐ Not sure
26.	What is the temperature of virus be active?	
27.	Is the virus stable during post infection?	
28.	Culture Condition during post infection	☐ Media☐ Serum☐ Temperature☐ Others:
29.	Glucose concentration in post infection culture medium	g/L
30.	Does virus MOI sensitive of temperature difference?	☐ Yes☐ No☐ Not sure☐ Others:



31.	Cell density prior to infection in current culture	
32.	system Multiplicity of infection (MOI)	
33.	Virus titer in current culture system	pfu/ml dose/ml
34.	Best phase for infection	 □ Seed cells with virus □ Right after seeding □ Exponential phase □ Plateau phase □ Not sure (hours after cell culture)
35.	Cell lysis occur after infection?	☐ Yes☐ No☐ Not sure☐ Others:
36.	If yes, period of time for cell lysis in current culture system	hours post infection
37.	Best time to harvest the virus	hours post infection
38.	Is there CPE (Cytopathic effect) after infection? When?	☐ Yes hours post infection☐ No☐ Not sure
39.	What kind of CPE (cytopathic effect) is formed?	 ☐ Monolayer Destruction ☐ Swelling ☐ Clumping ☐ Vacuolization ☐ Inclusion bodies ☐ Others:
40.	Number of harvest that is done during post infection period	□ Single harvest □ Multiple harvest □ times withinterval hours □ Harvest volume in each time:mL □ Continuous harvest □ days with total volume ofmL □ Others:
41.	After cell harvest, is any post process is required?	☐ Yes Method:(eg., centrifugation) ☐ No ☐ Not sure



42.	Downstream process	☐ Yes
	required	Specify: ()
		□ No
43.	Can you provide general virus production profile in existing system?	
C.		
44.	Seeding 1 – 3 x 10 ⁸ cells	☐ Yes
	be difficult?	□ No
		If yes, how many cells do you plan to seed?
45.	CO2 incubator be	☐ Yes
	exclusively used for the CelCradle™ System?	□ No
46.	Can you adjust the CO2	☐ Yes
	concentration of incubator?	□ No
47.	What are the challenges / limitations you experience with your current system?	
48.	What is your expectation using our system?	
49.	Is there any changes	☐ Yes
	required from your existing process protocol?	□ No
50.	With Tide-motion	☐ Yes
	bioreactor, is it okay to	□ No
	change the process	
	protocol?	