

Virus Production Questionnaire

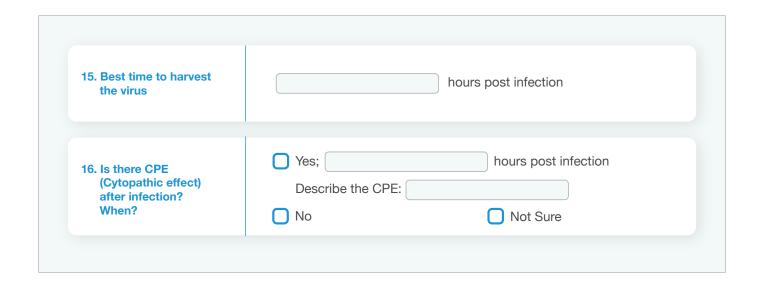
Please answer the following questions as completely as possible. The information here will be kept with utmost confidentiality and will only be used to generate a customized protocol for your facility.

Customer Information		
CONTACT PERSON		COMPANY NAME
DESIGNATION		CONTACT NUMBER
DEPARTMENT		EMAIL ADDRESS
II. General Details		
1. Target Product	Secreted Virus Others	Non-secreted Virus
2. Cell Type	Adherent cell Suspension cell	
3. What is the intended use for the product? e.g. animal vaccine, clinical phase, raw material for clinical trials		

5. Target viral titer, volume and yield	Titer (pfu/mL): Volume (L): Yield (pfu):		
6. Current titer, volume and yield	Titer (pfu/mL): Volume (L): Yield (pfu):		
7. What is process development (PD) and optimization step required?	 Cell line development, e.g. vector engineering, transfection protocol Upstream development, e.g. bioreactor media optimization, harvest protocol Downstream development, e.g. optimization of platform process, resin/ media screening Analytical development/characterization, e.g. analysis of virus titer, residual host cell protein/ DNA, nanoparticle analysis or imaging No PD required. Process to be transferred at existing scale to manufacturing 		
8. Any Master Viral Banking and Characterization required?	Master Viral Bank Master Viral Banking Characterization		
9. Any additional services required?	 Analytical Method Validation cGMP manufacturing and lot release cGMP Stability testing Sterility testing of final product Adventitious virus testing Others 		

III. Experiment Details CHO HEK 293 MDCK **H**ybridoma Vero Sf 9 1. Cell Line HEK 293 Subtype, e.g. HEK293T: Others 2. Describe current cell culture and virus production protocols, including transfection/ virus infection steps. Number of harvests x volume of each harvest: 3. Describe harvest mL protocol, e.g. lysis or clarification steps. mL 4. Describe current downstream processing/ post-harvest processing, e.g. ultracentrifugation, filtration, chromatography, etc. 5. Any animal serum at Yes, what percentage? any point in the ■ No process? Yes, chemically defined 6. Is the media a chemically defined No, contains animal derived products formula? Media description: Seeding Cell Density: 7. What is the cell density? Cell Density at first harvest: Cell Density at last harvest:

8. Virus name and strain		
9. Please describe the virus strain morphology, e.g. ds/ss DNA, ds/ss, +/- RNA, any lipid envelope, temperature sensitivity, surface proteins, etc: ds / ss DNA, ds / ss, +/- RNA		
10. Cell health and stability post infection	Yes, no significant differences observed Somewhat stable, differences observed for cell health No, cells tend to detach post infection period in hours	
11. Do cells propagate after virus infection?	Yes; Fold increase post in	nfection: Not Sure
12. Is the virus stable during post infection?	Yes, virus does not degrade until harvest No, virus starts to degrade as soon as it is produced	
13. Best phase for infection	Cells seeded with virus in Right after seeding Exponential phase	fected already Plateau phase Not sure (hours after cell culture)
14. Does cell lysis occur after infection?	Yes, it occurs No Not Sure Others	hours after infection



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