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

CONTACT PERSON

COMPANY NAME

DESIGNATION

CONTACT NUMBER

DEPARTMENT

EMAIL ADDRESS

II. General Details

1. Target Product

- ☐ Secreted Virus
- ☐ Non-secreted Virus
- ☐ Others

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

4. What is the analytical technique for measuring viral titer?

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

1. Cell Line

- ☐ CHO
- ☐ HEK 293
- ☐ MDCK
- ☐ Hybridoma
- ☐ Vero
- ☐ Sf 9
- ☐ HEK 293 Subtype, e.g. HEK293T: _____
- ☐ Others _____

2. Describe current cell culture and virus production protocols, including transfection/ virus infection steps.

_____

3. Describe harvest protocol, e.g. lysis or clarification steps.

Number of harvests x volume of each harvest:

- ☐ _____ x _____ mL
- ☐ _____ x _____ mL

4. Describe current downstream processing/ post-harvest processing, e.g. ultracentrifugation, filtration, chromatography, etc.

_____

5. Any animal serum at any point in the process?

- ☐ Yes, what percentage? _____
- ☐ No

6. Is the media a chemically defined formula?

- ☐ Yes, chemically defined
- ☐ No, contains animal derived products
  Media description: _____

7. What is the cell density?

- ☐ Seeding 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 infection: _____
- ☐ No
- ☐ 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 infected already
- ☐ Right after seeding
- ☐ Plateau phase
- ☐ Exponential phase
- ☐ Not sure

_____ (hours after cell culture)

14. Does cell lysis occur after infection?

- ☐ Yes, it occurs _____ hours after infection
- ☐ No
- ☐ Not Sure
- ☐ Others _____

15. Best time to harvest the virus	hours post infection
16. Is there CPE (Cytopathic effect) after infection? When?	☐ Yes; hours post infection Describe the CPE: ☐ No ☐ Not Sure

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