**Virus Production Questionnaire**

**病毒包装服务 （问答卷）**

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| **I. Customer Information**  |
| Contact Person 联络人 |   |
| Designation 职位 |   |
| Department 部门 |   |
| Company Name 公司名称 |   |
| Contact Number 连络电话 |   |
| Email Address 电邮网址 |   |

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|  **II. General Details**  |  |
| 1.  | Target Product 所需要的最终产物 | [ ]  Secreted Virus 分泌型病毒[ ]  Non-secreted Virus 非分泌型病毒[ ]  Others其他: |
| 2.  | Cell Type 细胞株 （种类） | [ ]  Adherent Cell 贴壁[ ]  Suspension Cell 悬浮 |
| 3. |  What is the intended use for the product? e.g. animal vaccine, clinical phase, raw material for clinical trials 产品的用途是什么？例如 、动物疫苗，临床期，临床试验原料 |
| 4. |  What is the analytical technique for measuring viral titer? 测量病毒滴度的分析技术是什么？ |
| 5. | Target viral titer, volume and yield目标病毒滴度、体积和产量 | Titer滴度 (pfu/mL):Volume体积数量 (L):Yield病毒产量 (pfu): |
| 6. | Current titer, volume and yield 目前的滴度，体积和产量 | Titer滴度 (pfu/mL):Volume体积数量 (L):Yield病毒产量 (pfu): |
| 7. | What is process development (PD) and optimization step required? 需要哪些流程开发和优化？ | [ ]  Cell line development, e.g. vector engineering, transfection protocol 细胞珠开发[ ]  Upstream development, e.g. bioreactor media optimization, harvest protocol 上游工艺开发[ ]  Downstream development, e.g. optimization of platform process, resin/ media screening 下游工艺开发[ ]  Analytical development/characterization, e.g. analysis of virus titer, residual host cell protein/ DNA, nanoparticle analysis or imaging 分析流程[ ]  No PD required. Process to be transferred at existing scale to manufacturing 无需流程开发 |
| 8. | Any Master Viral Banking and Characterization required? 否需要病毒保藏库和分析档案？ | [ ]  Master Viral Bank 病毒保藏库[ ]  Master Viral Banking Characterization 分析档案 |
| 9. | Any additional services required? 需要任何项目? | [ ]  Analytical Method Validation分析方法验证[ ]  cGMP manufacturing and lot release cGMP制造和批次管理[ ]  Stability testing稳定性测试[ ]  Sterility testing of final product产品的无菌测试[ ]  Adventitious virus testing 病毒测试[ ]  Other 其他: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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|  **III. Experiment Details**  |  |
| 1.  | Cell Line 细胞株 |  [ ]  HEK 293人胚胎肾细胞293 Subtype, e.g. HEK293T:\_\_\_\_\_\_\_\_\_\_\_[ ]  CHO中国黄金鼠卵巢细胞[ ]  MDCK犬肾细胞[ ]  Vero非洲绿猴肾细胞[ ]  HEK 293人胚胎肾细胞293[ ]  Hybridoma融合 (杂种) 瘤细胞[ ]  Sf 9昆虫细胞[ ]  Others其他: |
| 2. | Describe current cell culture and virus production protocols, including transfection/virus infection steps.请描述当前的病毒包装、转染步骤。 |
| 3. | Describe harvest protocol, e.g. lysis or clarification steps.请描述病毒收获，例如裂解或澄清步骤。Number of harvests x volume of each harvest: \_\_\_\_\_\_ x \_\_\_\_\_mL 收获数量 × 每次收获量：: \_\_\_\_\_\_ x \_\_\_\_\_mL |
| 4. | Describe current downstream processing/ post-harvest processing, e.g. ultracentrifugation, filtration, chromatography, etc.请描述下游工艺/ 收获后加工，例如：超速离心，过滤，色谱等。 |
| 5. | Any animal serum at any point in the process? 步骤里有用上血精成分？ | [ ]  Yes, what percentage? 有血精，% 数？[ ]  No 无血精 |
| 6. | Is the media a chemically defined formula? 培养基是否是化学限定、无动物源以及动物源添加物和补料产品? | [ ]  Yes, chemically defined 化学限定[ ]  No, contains animal derived products 动物源性 Media description 请注明:  |
| 7. | What is the cell density?细胞密度是多少？ | * Seeding Cell Density:

种细胞密度：* Cell Density at first harvest:

第一次收获时的细胞密度：* Cell Density at last harvest:

最后收获时的细胞密度： |
| 8. | Virus name and strain 病毒和菌株 |  |
| 9. | Please describe the virus strain morphology, e.g. ds/ss DNA, ds/ss, +/- RNA, any lipid envelope, temperature sensitivity, surface proteins, etc 病毒株的形态，例如： ds / ss DNA，ds / ss，+ / - RNA，任何脂质包膜，温度敏感性，表面蛋白、等 |
| 10. | Cell health and stability post infection 感染后细胞健康和稳定 | [ ]  Yes, no significant differences observed 没有观察到差异[ ]  Somewhat stable, differences observed for cell health  有些[ ]  No, cells tend to detach post infection period in  Hours  细胞倾向于在感染后分离 |
| 11. | Do cells propagate after virus infection? 病毒感染后细胞会繁殖吗？ | [ ]  Yes 有：Fold increase post infection: [ ]  No 没有[ ]  Not sure 不清楚 |
| 12. | Is the virus stable during post infection?转染后病毒是否稳定？ | [ ]  Yes, virus does not degrade until harvest 是，病毒直到收获不会降解、甚微[ ]  No, virus starts to degrade as soon as it is produced  不是，病毒直到收获会降解、甚微 |
| 13. | Best phase for infection 转染时最佳阶段 | [ ]  Cells seeded with virus infected already 接种病毒的细胞已经感染[ ]  Right after seeding接种后立即[ ]  Exponential phase指数阶段[ ]  Plateau phase 阶段高原细胞[ ]  Not sure不清楚( hours after cell culture 细胞种植之后小时) |
| 14. | Does cell lysis occur after infection? 转染会发生细胞裂解？ | [ ]  Yes, it occurs \_\_\_\_\_\_ hours after infection 有，转染后数小时[ ]  No 没有[ ]  Not sure 不清楚[ ]  Others: 其他 |
| 15. | Best time to harvest the virus 收获病毒的最佳时间？ |  hours post infection转染后数小时 |
| 16. | Is there CPE (Cytopathic effect) after infection? When? 转染后有CPE（细胞病变效应） | [ ]  Yes hours post infection有，转染后数小时 Describe the CPE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  No没有[ ]  Not sure不清楚 |