**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 | |