Protein 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  |   |
| Designation  |   |
| Department  |   |
| Company Name  |   |
| Contact Number  |   |
| Email Address  |   |

|  |  |
| --- | --- |
| **I. General Details**  |  |
| 1.  | Target Product  | [ ]  Secreted Protein[ ]  Non-secreted Protein[ ]  Monoclonal Antibody[ ]  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. Experiment Details**  |  |
| 1. Cell Culture
 |
| 1.  | Cell Line  | [ ]  CHO[ ]  HEK 293[ ]  Hybridoma for IVD (In-Vitro Diagnostics)[ ]  Hybridoma for Therapeutics[ ]  Others: |
| 2. | Any Special features or peculiarities of the cell line or culture methods? |  |
| 3.  | Intended Use | [ ]  Human Use (Production)[ ]  Animal Use (Production)[ ]  Human Use (Research)[ ]  Animal Use (Research) |
| 4. | Current Culture System | [ ]  T-flask cm2 x Pcs [ ]  Petri dish mm x Pcs[ ]  Roller Bottle cm2 x Btls[ ]  Spinner flask ml x Btls Carriers: ( )[ ]  Cell Factory / Cell Stack (Multi-layer) cm2 x Pcs (total surface area)[ ]  Stirred-tank Bioreactor ml x Vessel Carriers: ( )[ ]  Others:  |
| 5. | Media Volume Capacity | * Working Volume Capacity

 mL / Pc (or /Btl) * Total Volume Capacity

 mL / Batch |
| 6. | If carriers are used, please specify type and amount of carrier. | [ ]  Microbeads. Specify:[ ]  Fibrous matrixes Specify:[ ]  Others Specify:[ ]  Amount of carriers:  |
| 7. | Medium exchange frequency for current system * During Cell Culture
 | [ ]  24 hours (1 day)[ ]  48 hours (2 days)[ ]  72 hours (3 days)[ ]  Other: hours ( days)[ ]  Media volume per change: ml |
| 8. | Medium exchange frequency and volume for current system* Post Infection
 | [ ]  24 hours (1 day)[ ]  48 hours (2 days)[ ]  72 hours (3 days)[ ]  Other: hours ( days)[ ]  Media volume per change: ml |
| 9. | Culture condition during cell culture | [ ]  Media: [ ]  Serum: [ ]  Temperature: [ ]  CO2 concentration of incubator |
| 10. | Other additives (eg., sodium bicarbonate,Hepes buffer etc) |  |
| 11. | Glucose Concentration in initial culture medium |  g/L |
| 12. | Cell Harvesting (Cell dissociation) required | [ ]  Yes [ ]  No  |
| 13. | Cell Harvest (Cell Dissociation) method if have | [ ]  Trypsin[ ]  Enzymatic Dissociation Reagents (Specify: )[ ]  Non-Enzymatic Dissociation Reagents (Specify: )[ ]  Others: |
| 14. | Cell Quantification (Cell Counting) | [ ]  Manual Counting[ ]  Auto-counter[ ]  Nuclei counting[ ]  Others: |
| 15. | Access to bio-analyzer for measuring glucose, lactate, glutamine, etc | [ ]  Yes [ ]  No |
| 16.  | System Preference | [ ]  Prefer Single-Use[ ]  Prefer Multiple-Use[ ]  No preference |
| 17. | Current System Annual dose (product quantity) |  |
| 18. | Current System average total cell density (per single system eg., per 1 roller bottle) | * Seeding Cell Density:
* Harvesting End Cell Density:
 |
| 19. | Do you have scale up plan? | [ ]  Yes [ ]  No |
| 20. | Expected Scale when scaled up(Cell Density, Doses etc) |  |
| 1. Protein Production
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| 21. | Protein extraction method | [ ]  Cell Harvest[ ]  Medium Harvest[ ]  Freeze/Thaw[ ]  Lysis Buffer[ ]  Others: |
| 22. | For medium harvest extraction method, what is the harvest process? | [ ]  Single Harvest[ ]  Multiple Harvest Interval time hrs for days[ ]  Other |
| 1. CelCradleTM System
 |
| 23. | Seeding 1 – 3 x 108 cells be difficult? | [ ]  Yes [ ]  NoIf yes, how many cells do you plan to seed? |
| 24. | CO2 incubator is exclusively used for the CelCradleTM System? | [ ]  Yes [ ]  No |
| 25. | Can you adjust the CO2 concentration of incubator for CelCradleTM System? | [ ]  Yes [ ]  No |
| 26. | What are the challenges / limitations you experience with your current system? |  |
| 27. | What is your expectation using CelCradleTM System? |  |
| 28. | Is there any changes required from your existing process protocol? | [ ]  Yes [ ]  No |
| 29. | With Tide-motion bioreactor, is it okay to change the process protocol? | [ ]  Yes [ ]  No |