Stem Cell Culture Questionnaire

Please answer the following questions as completely as possible.

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| --- |
| **I. Customer Information**  |
| Contact Person  |   |
| Designation  |   |
| Department  |   |
| Company Name  |   |
| Contact Number  |   |
| Email Address  |   |

|  |  |
| --- | --- |
| **II. Experiment Details**  |  |
|  *a. General Details* |  |
|  | Target  | [ ]  Autologous Cell Therapy  |
|  | [ ]  Allogeneic Cell Therapy  |
|  | [ ]  Subsidiary Products (Specify: ) |
|  | [ ]  Research  |
|  | [ ]  Others:  |
|  | Cell Source  | [ ]  Bone Marrow-derived |
|  | [ ]  Adipose-derived |
|  | [ ]  Umbilical Cord-derived  |
|  | [ ]  Embryo  |
|  | [ ]  Placenta  |
|  | [ ]  iPSC |
|  | [ ]  Amniotic fluid  |
|  | [ ]  Others:  |
|  *b. Current Cell Culture*  |
|  | Cell Line description (Any special features regarding the cell line or culture methods?) |  |
|  | Intended Use | [ ]  Human Use (Production)[ ]  Animal Use (Production) [x]  Human Use (Research)[ ]  Animal Use (Research)[ ]  Others |
|  | Current Culture System (Device used per production batch) | [ ]  T-flask cm2 x Pcs [ ]  Petri dish mm x Pcs[ ]  Roller Bottle cm2 x Btls[ ]  Spinner flask ml x Btls Carrier Type: ( )[ ]  Cell Factory / Cell Stack (Multi-layer) cm2 x Pcs (total surface area)[ ]  Stirred-tank Bioreactor ml x Vessel Carrier Type: ( )[ ]  Others:  |
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|  | Average Cell Densities from current system(per culture using a single system e.g. per 1 roller bottle) | [ ]  Seeding Cell Density \_\_\_\_\_\_\_\_\_\_\_\_\_ cells/cm2 or  \_\_\_\_\_\_\_\_\_\_\_\_\_ cells/ml[ ]  Harvesting End Cell Density: \_\_\_\_\_\_\_\_\_\_\_\_\_ cells/cm2 or  \_\_\_\_\_\_\_\_\_\_\_\_\_ cells/ml[ ]  Average culture duration: \_\_\_\_\_\_\_\_\_ days  |
|  | If carriers are used, please specify type and amount of carrier. | [ ]  Microbeads. Specify:[ ]  Fibrous matrices Specify:[ ]  Others Specify:[ ]  Amount of carriers: |
| 1.
 | Additional coating reagent for current system? | [ ]  None[ ]  Fibronectin[ ]  Gelatin[ ]  Collagen[ ]  Others |
|  | Media Volume Capacity | [ ]  Working Volume Capacity mL / Pc (or /Btl) [ ]  Total Media Volume (start to end of culture) mL / Pc (or /Btl) |
|  | Medium exchange frequency for current system  | [ ]  24 hours (1 day)[ ]  48 hours (2 days)[ ]  72 hours (3 days)[ ]  Others: hours ( days)[ ]  Media volume per change: ml |
|  | Culture condition during cell culture | [ ]  Basal Media: [ ]  Serum (type and %): [ ]  Temperature:[ ]  CO2 concentration of incubator: |
|  | Oxygen Control | [ ]  Normoxia: % O2[ ]  Hypoxia: % O2[ ]  No Specific control[ ]  Others: |
|  | Concentration of additives  | [ ]  Sodium Bicarbonate:[ ]  HEPES buffer: [ ]  Others: |
|  |
|  |
|  | Glucose Concentration in initial culture medium  |  g/L  |
|  | Cell Harvesting (Cell dissociation) required | [ ]  Yes [ ]  No |
|  | Cell Harvest (Cell Dissociation) method if any | [ ]  Trypsin[ ]  TrypLE Express[ ]  TrypLE Select[ ]  Accumax[ ]  Accutase[ ]  Collagenase: Type ( )[ ]  Others: |
|  | Access to bio-analyzer for measuring glucose, lactate, glutamine, etc | [ ]  Yes [ ]  No |
|  *c. Process Plan*  |
|  | Scale up plan  | [ ]  Yes [ ]  No  |
|  | Scale up size in terms of cell numbers (per production batch) | [ ]  109 [ ]  1010 [ ]  1011 [ ]  1012 [ ]  >1013  |
|  | In scaled-up system  | [ ]  Single-Use [ ]  Multiple-Use [ ]  Hybrid (both single- and multiple- use components in 1 culture system) [ ]  No preference  |
|  | Cell culture mode  | [ ]  Batch [ ]  Fed-batch [ ]  Recirculation [ ]  No preference [ ]  Others:  |
|  | Cell Quantification  | [ ]  Manual Counting [ ]  Auto-counter [ ]  Nuclei Counting [ ]  Others:  |
|  | Do you prefer aseptic cell culture process? (System inside isolator)  | [ ]  Yes [ ]  No  |
|  *d. CelCradle™ System*  |
|  | Would seeding of 2 x 107 cells be difficult?  | [ ]  Yes [ ]  No  |
|  | Will the CO2 incubator be exclusively used for the CelCradle™ system?  | [ ]  Yes [ ]  No Is the CO concentration adjustable? [ ]  Yes [ ]  No  |