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 |  |

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| --- | --- | --- |
| **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)  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: |
|  | 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: |
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|  |
|  | 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 |