When finished, please email reply to: Brian Dattilo

Email: [bdattilo@waisman.wisc.edu](mailto:bdattilo@waisman.wisc.edu)

|  |  |
| --- | --- |
| Today’s Date |  |
| Principal Investigator or Client |  |
| Company or Institution |  |
| Product Name |  |
| Services Requested | Assay Development  Cell Banking  cGMP Manufacture  Aseptic Fill |
| Quantity of cells desired (cell count or manufacturing scale) |  |
| What agency will this product be regulated by? | FDA  EMEA  Other |
| Date Desired |  |

# How did you hear about Waisman Biomanufacturing?

# Product and Intended Use

## Please briefly describe the identity of your cell product.

## This product is intended for use in (check all that apply):

Research only and not for use in animals or humans

Animal /tox studies

Human clinical trials:

Phase I

Phase II

Phase III

## What indication is this product for?

# Manufacturing Information

## Product format -

### Total final cell count required:

### Final formulation of product (cell count, media, cryopreservation solution, etc.):

### Vial format if known (glass vial, cryovials, bags, other):

### Fill volume, accuracy:

### Number of containers of material:

## Cell Bank Testing - if you will be creating a Master Cell Bank and/or Working Cell Bank, do you want Waisman Biomanufacturing to perform required adventitious agent testing? If so, should the testing meet FDA, EU, or ICH guidelines as applicable?

## How many cell banks do you need? What size? Do you need single tier (MCB) or two tiered (MCB/WCB)?

## If applicable, will any intermediate samples be cryopreserved or banked?

## Product Quality - please indicate specific target specifications where known and describe anticipated Quality Control testing:

**Table 1**

|  |  |  |  |
| --- | --- | --- | --- |
| **Test** | **Methods / Comments** | **Desired** | **Requested Specification** |
| Identity Assay (STR, HLA) |  |  |  |
| Cell Count  Viability | Trypan blue exclusion |  |  |
| Karyotype | G-band |  |  |
| Sterility | USP Sterility test |  |  |
| Endotoxin | LAL |  |  |
| *Flow Cytometry* |  |  |  |
| *Specific Adventitious Agents* |  |  |  |
| *Other impurities (e.g. feeder cells)* |  |  |  |
| *Potency* |  |  |  |

*Describe activity assay or any other assays that need development here, if necessary. Will these be performed by Customer or transferred to Waisman?*

# Starting Material -

## Are the cells autologous or allogeneic?

Allogeneic

Have you created a Master Cell Bank that has undergone adventitious agent testing? If so, please provide information on test results for the cell line.

What is the starting source material for the cell bank? Did the donor undergo medical history and donor testing (21 CFR 1271) with informed consent?

Autologous

What testing will be conducted on the donor prior to cell processing?

Note: The Waisman Biomanufacturing will only accept cell lines that have undergone a minimum level of adventitious agent testing including mycoplasma and specific viral pathogens as appropriate.

# Cell Culture Conditions:

## Describe your current method of production & purification of your cell therapeutic. Be as detailed as possible based on the following suggestions. Publications describing the procedure can be cited if available.

### Media:

### Special growth factors (and vendor):

### Incubator Conditions:

### Type of bioreactor (T-flasks, Cell Factory/Cell Stack, Cell Cube, Wave Bioreactor):

### Cell Growth Characteristics:

#### Seeding density (cells/area, cells/vol):

#### Lag phase:

#### Typical doubling time for your cells:

#### Density/percent confluence at harvest:

#### Number of passages and days in culture required to achieve targeted expansion:

## Does your cell line require a feeder cell layer?

Yes

No

### If yes, describe the feeder cells. Has a MCB created for the feeder cells?

### Describe growth characteristics of feeder cells. Note: Please fill out a separate copy of this form for the feeder cells if used in your process.

#### Describe treatment of feeder cells (e.g. gamma irradiation, mitomycin C treatment):

#### Required seeding density of feeder cells:

## Cell Passaging -

### How are cells harvested for passaging?

### What is the maximum number of passages allowed for your cell line?

## Harvest -

### Will pooling and centrifugation of multiple plates/bottles be required to prepare the cell preparation?

### Describe any other requirements for cell harvest.

## In-Process Testing -

### Is any special QC testing required on critical raw materials?

### Apart from media sterility and microscopic examination, are there any other in-process tests or measurements (e.g. cell counts, FACS)?

# Cryopreservation (if applicable) -

## Describe the cryopreservation and final formulation solution that you would like to use:

## What is the volume, cell number, and container (e.g. vial, bag) required for the final product?

## A controlled-rate freezer is available for freezing cell banks. Is a desired freezing profile available for this cell line? If not, what freezing techniques have been used in the past?

## How many doses per lot and for the entire project?

# Transfection/Transduction Information (if applicable) -

## Please describe your vector including overall size of plasmid, identity and size of gene, source of gene, promoters, enhancers, selection marker, etc. Attach a copy of the vector map if available. Has the vector been sequenced (GLP/GMP -grade?)?

## Describe how your vector will be provided (concentration, solution, storage conditions).

## Described the procedure for transfection/transduction.

# Pluripotent Cell Derivation/Differentiation (if applicable) -

# If deriving induced pluripotent stem cells, please describe your derivation process including critical reprogramming reagents. If plasmids are used, attach a copy of the vector map and describe the production and testing of the plasmids.

# If differentiating pluripotent stem cells (e.g. iPS, ES) please provide details on your differentiation process including cell culture media/matrices, cytokines and their source, process scale, and timing of differentiation steps. Also note any critical QC tests used for monitoring the differentiation process and for measuring residual undifferentiated cells.