Questionnaire: Bioreactor/Fermenter for Microbial and Mammalian (suspension) Cell Culture

Please answer the following questions as completely as possible.

I. Customer Information

CONTACT PERSON

COMPANY NAME

DESIGNATION

CONTACT NUMBER

DEPARTMENT

EMAIL ADDRESS

II. Intended Application of Bioreactor/Fermenter

1. Application

- ☐ Microbial Culture
- ☐ Suspension Cell Culture
- ☐ _____

2. Type of microorganism/cells

*** Please indicate organism or cell line to be cultured**

- ☐ Yeast
- ☐ Bacteria _____
- ☐ Fungi _____
- ☐ Cell Line _____
- ☐ Others _____

3. Product

- ☐ Secreted Protein
- ☐ Non-Secreted /Inclusion body (IB) Protein
- ☐ Biomass
- ☐ Secreted Virus
- ☐ Non-Secreted Virus
- ☐ _____

4a. Current Culture System	☐ Spinner Flask: _____ ml x _____ Pcs ☐ Stirred-tank Bioreactor: _____ ml or L ☐ _____
4b. Current Culture Scale in liters (L):	_____

III. Bioprocess Parameters

1. Current Process Mode	☐ Batch ☐ Continuous ☐ Fed-Batch ☐ Repeated Batch ☐ _____
2. Reactor Size	☐ Minimum working volume: _____ L ☐ Maximum working volume: _____ L ☐ Working volume: _____ L
3. Agitation Speed	Range: _____ rpm
4. Measurements Required	☐ Temperature _____ °C to _____ °C ☐ pH _____ to _____ ☐ DO _____ % to _____ % ☐ Redox _____ mV to _____ mV ☐ Turbidity ☐ pCO_2 ☐ Foaming ☐ O_2/CO_2 in Exhaust Gas ☐ Level ☐ Others _____

IV. Bioprocess Controls

1. Sterilization

Temperature: _____ °C to _____ °C

Period: _____

2. Temperature Control

- ☐ Double wall vessel
- ☐ Heating Pad
- ☐ Heating Jacket
- ☐ Heating/Cooling Pad
- ☐ Others _____

3. pH Control

- ☐ Addition of Base
- ☐ Addition of CO_2
- ☐ Addition of Acid
- ☐ Others _____

4. Dissolved Oxygen Control

- ☐ Impeller Speed
- ☐ Gas Flow Rate
- ☐ Addition of O_2
- ☐ Others _____

5. Mixing Impeller

- ☐ Rushton Impeller
- ☐ Pitched blade impeller
- ☐ Marine blade impeller
- ☐ Others _____

6. Foaming

- ☐ High
- ☐ Not yet determined
- ☐ Low

7. Applied Gases for Aeration

- ☐ Air
- ☐ Air + O_2
- ☐ Air + O_2 + N_2
- ☐ Air + O_2 + N_2 + CO_2
- ☐ Others _____

Gas Mixing System:

☐ Yes ☐ No

8. Airflow

Range: _____ vvm to _____ vvm

Control:

- ☐ Regulator/ Rotameter (manual)
- ☐ _____
- ☐ Mass Flow Controller (Automatic)

9. Aeration Delivery	☐ Sparger, Type: ◯ Ring Sparger ◯ Microsparger ☐ _____ ☐ Overlay ☐ Overlay and Sparger
10. Pressure Control Requirements	☐ Manual Control ☐ Automatic Control
11. Other Special Requirements	_____

V. Bioreactor/Fermenter Hardware Requirement

1. Vessel Material	☐ Borosilicate Glass ☐ SS 316L ☐ Others _____
2. Seeding/Inoculation	☐ Needleless Seeding Port ☐ Needle Injection Inoculation Port ☐ Others _____
3. Fluid Addition Number of Ports	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
4. Number of sampling port	Number of ports- ☐ 1 ☐ 2 ☐ 3
5. Air Filter Housing	Filter Size: ☐ 0.2µm ☐ Others _____ Integrity Test Port: ☐ Yes ☐ No

6. Exhaust Filter Housing	Filter Size: ☐ 0.2μm ☐ Others	Integrity Test Port: ☐ Yes ☐ No

VI. Software Requirement

1. Software compatibility	☐ Non-GMP ☐ GMP (21 CFR Part 11)	☐ Others
2. Other requirements	☐ Data-log ☐ Real-time trend	☐ Remote control ☐ Others

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