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

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. Intended Application of Bioreactor/Fermenter** | | | |
| 1. | Application | □ | Microbial Culture |
| □ | Suspension Cell Culture |
| □ | others |
| 2. | Type of microorganism/cells | □ | Bacteria |
| □ | Yeast |
| □ | Fungi |
| □ | Cell Line: |
| □ | Other: |
|  | \*Please indicate organism or cell line to be cultured |  |  |
| 3. | Product | □ | Secreted Protein |
| □ | Non-Secreted /Inclusion body (IB) Protein |
| □ | Biomass |
| □ | Secreted Virus |
| □ | Non-Secreted Virus |
| □ | Others: |
| 4. | a. Current Culture System | □ | Spinner Flask (\_\_\_ mL x \_\_\_\_) |
| □ | Stirred Tank Bioreactor ( \_\_\_\_\_\_ mL or L) |
| □ | Other: |
|  | b. Current Culture Scale in liters (L): |  |  |

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| * **III. Bioprocess Parameters** | | | |
| 1. | Current Process Mode | □ Batch  □ Fed-Batch  □ Continuous  □ Repeated Batch  □ Other: | |
| 2. | Reactor Size | □ Minimum working volume: \_\_\_\_\_\_\_ L  □ Maximum working volume: \_\_\_\_\_\_\_ L  □ Working volume: \_\_\_\_\_\_\_\_ L | |
| 3. | Agitation Speed | Range: rpm | |
| 4. | Measurements Required | □ Temperature | oC to oC |
| □ pH | to |
| □ DO | % to % |
| □ Redox | mV to mV |
| □ Turbidity | |
| □ Foaming | |
| □ Level | |
| □ pCO2 | |
| □ O2/CO2 in Exhaust Gas | |
| □ Others | |

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| * **IV. Bioprocess Controls** | | |
| 1. | Sterilization | Temperature: oC to oC Period: |
| 2. | Temperature Control | * Double wall vessel * Heating Jacket * Heating Pad * Heating/Cooling Pad * Other: |
| 3. | pH Control | * Addition of Base * Addition of Acid * Addition of CO2 * Others: |
| 4. | Dissolved Oxygen Control | * Impeller Speed * Addition of O2 * Gas Flow Rate * Others: |
| 5. | Mixing Impeller | * Ruston Impeller * Marine blade impeller * Pitched blade impeller * Others: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 6. | Foaming | * High * Low * Not yet determined |
| 7. | Applied Gases for Aeration | * Air * Air + O2 * Air + O2 + N2 * Air + O2 + N2 + CO2 * Gas Mixing System   + Yes   + No |
| 8. | Airflow | Range: vvm to vvm Control:   * Regulator/ Rotameter (manual) * Mass Flow Controller (Automatic) * Others |
| 9. | Aeration Delivery | * Overlay * Sparger,   + Sparger type:     - Ring Sparger     - Micro-sparger * Overlay and Sparger * Others |
| 10. | Pressure Control Requirements | * Manual Control * Automatic Control |
| 11. | Other Special Requirements |  |

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| **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-   * 0 * 1 * 2 * 3 * 4 * 5 * 6 | |
| 4. | Number of sampling port | Number of ports-   * 0 * 1 * 2 | |
| 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 | |

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| **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   ----------------------------------- |