

## ISOLATOR GENERAL QUESTIONNAIRE



DATE:

### I. ABOUT YOUR COMPANY

\*Fields required to be filled out

1. NAME\*

7. FAX\*

2. COMPANY\*

8. YOU WORK FOR\*

(Please Tick)

- End User/Facility Owner
- Cleanroom Builder/Contractor
- Lab Builder/Contractor
- Distributor

3. ADDRESS\*

4. EMAIL\*

5. WEBSITE

9. EXISTING ESCO EQUIPMENT\*

6. PHONE NUMBER AND EXTENSION\*

10. REPEATED ORDER\*

Yes, SN:

No

### II. PROJECT INFORMATION

\*Fields required to be filled out

11. URS Available\*

Yes (please attach document)

No

12. Industry\*

- Pharmaceutical/Biotech
- Chemicals
- Food and Beverage
- Soap/Detergents
- Cosmetics
- Paint
- Others, please specify:

13. Name of Project

14. Project Location\*

15. Unit/s Required\*





**26. For Biosafety Level Facility Protection, please state:**

- Biosafety Level, Specify:
- Risk Group of Microorganisms Handled, Specify:
- List of Equipment Integration, please specify:

*Please provide drawings/brochures of these machines and equipment.*

**27. For Cell Processing Applications, please state:**

- Biosafety Level, Specify:
  - Secreted Protein
  - Non-secreted Protein
  - Cell Bank
  - Monoclonal Antibodies (mAbs)
  - Virus Production (Human/Veterinary)
  - Cell Therapy (Autologous/Allogenic)
- Intended Use
  - Human Use
  - Animal Use
- Environment Needed for the Application:
  - ISO Class/Grade of Environment:
  - Temperature:
  - Relative Humidity:
  - Pressure:
  - Oxygen Control:
  - Others, please specify:
- List of Equipment Integration, please specify brand/model:
  - Bioreactor:
  - CO<sub>2</sub> Incubator:
  - Centrifuge:
  - Microscope:
- Others, please specify brand/model:

*Please provide drawings/brochures of these machines and equipment.*

**27. Brief description of process inclusive of the following points:**

- A.) Quantity and type of material brought into isolator:
- B.) Manner in which material is brought into the isolator:
- C.) Process carried out within the isolator:
- D.) Instrument/s used to carry out the process:
- E.) Quantity and type of material brought out of the isolator after process:
- F.) Is the process generating high amounts of dust or particulates inside the isolator?

**29. Other Machinery Details:**

- Will production machinery be used?
- i. Width, height, and depth of production machinery
  
  - ii. Amps to operate the machine
  
  - iii. Position of charge and discharge points
  
  - iv. Range of thermostatic control on machinery
  
  - v. Dust generating or heat zones within the machinery
  
  - vi. Number of personnel required to operate machinery

**III. ISOLATOR SPECIFICATIONS INFORMATION**

*\*Fields required to be filled out*

**30. Internal Width\***

**31. Internal Height\***

**32. Internal Depth\***

**33. Provide Site Plan/  
Floor Layout so that  
Esco can verify clearances  
are Sufficient for  
Installation/Maintenance  
Access**

*Please attach the site plan/floor layout together with  
this questionnaire*

**34. Pressure Mode\***

- Positive Pressure
- Negative Pressure
- Required Pressure, please specify per chamber:

**35. Airflow Circulation\***

- Recirculating
- Total Exhaust

**36. Airflow Pattern\***

- Unidirectional
- Turbulent

**37. Construction Material\***

Specify chosen material from below options:

Internal:

External:

- Antimicrobial Powder-Coated ElectroGalvanized Steel
- Stainless Steel 304
- Stainless Steel 316L
- Others, Specify:

**38. Control System**

- Standard Esco Sentinel Microprocessor
- Industry Grade HMI/PLC

**39. Control System**

- Continuous monitoring with digital display at the HMI screen, audible alarms, and alarm messages
- Other options:
  - Magnehelic® Gauges (visual only)
  - Magnehelic® Gauges (visual only) + audible alarms and lamp indication

**40. Parameters to Monitor**  
(Tick All That Apply)\*

- Velocity
- Pressure across filters
- Temperature
- Pressure in isolator
- Paint
- Others, Specify:

**41. Utility Requirement\***

- 100 VAC 50/60 Hz 1 Ph
- 115 VAC 50/60 Hz 1 Ph
- 230 VAC 50/60 Hz 1 Ph
- 380 – 400 VAC 50/60 Hz 3 Ph
- 480 VAC 60 Hz 3 Ph
- Others:

**42. Area Classification\***

- Safe Area (non-hazardous)
- Zone 0
- Zone 1
- Zone 2
- Zone 20
- Zone 21
- Zone 22
- Others:

**43. Control System**

- Electrical outlets, indicate the Type Code and Power/Current Rating Required:
- Equipment services:
  - N2
  - Drain Connection
  - WFI/PW
  - Compressed Air
  - Exhaust Duct Connection
  - Other:
- Network connections
- Adjustable Hydraulic Stand
- BioVap™ Bio-decontamination System
- Continuous Liner System
- Drain Valve
- Drum lifter
- Double-sided Access
- Particle Counter (Viable/Non-viable)
- RTPØ Alpha - mm
- RTPØ Beta Canister - mm
- RTPØ Beta Liner - mm
- Split Butterfly Valve
- Spray Bal
- Spray Gun
- Others, Specify:

**42. Validation Documentation\***

- FAT Protocols
- SAT Protocols
- IQ/OQ Protocol
- Surrogate Powder Test as per ISPE
- Biodecon Cycle Development
- Cleaning Coverage Validation
- Others, Specify:

**42. Validation Documentation\***

- Full Installation
- Commissioning
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Site Acceptance Test (SAT)
- User and Service Training
- Preventive Maintenance (PM)

**Important: Save the completed PDF form (use menu File - Save).**