

ISOLATOR GENERAL QUESTIONNAIRE



DATE:

I. ABOUT YOUR COMPANY

**Fields required to be filled out*

1. NAME*

2. COMPANY*

3. ADDRESS*

4. EMAIL*

5. WEBSITE

6. PHONE NUMBER AND EXTENSION*

7. FAX

8. YOU WORK FOR*

(Please Tick)

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

9. EXISTING ESCO EQUIPMENT*

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*

16. Deadline of submission for Tender*

17. Timeline of Purchase

18. Timeline of Installation*

19. Level of Need

- ☐ Have an approved budget (indicate:)
- ☐ Preparing to submit a budget for approval
- ☐ Gathering information for future reference

20. Application/s*
(Please tick)

Note: Respond only to fields that are applicable to your products, processes, or application details.

- ☐ Pharmacy Compounding
- ☐ Radiopharmaceutical Compounding
- ☐ Sterility Testing
- ☐ Aseptic Production
- ☐ Research and Development
- ☐ Potent Material Handling
- ☐ Cell Processing
- ☐ Biosafety Levels 3 and 4 (BSL 3 or 4) Laboratory
- ☐ Others:

21. Type of Protection
(Please tick one)

- ☐ Operator protection
- ☐ Product protection
- ☐ Operator and product protection

22. Occupational Exposure Band (Occupational Exposure Limit)

*For more info, please check:
<http://www.escopharma.com/hazard-sub-page.php?hazardId=53&pg=hzd>*

- ☐ OEB 1 (>1000 – 5000 $\mu\text{g}/\text{m}^3$)
- ☐ OEB 2 (>100 - ≤ 1000 $\mu\text{g}/\text{m}^3$)
- ☐ OEB 3 (>10 - ≤ 100 $\mu\text{g}/\text{m}^3$)
- ☐ OEB 4 (>1 - ≤ 10 $\mu\text{g}/\text{m}^3$)
- ☐ OEB 5 (<1.0 $\mu\text{g}/\text{m}^3$ - 0.01 $\mu\text{g}/\text{m}^3$ or 10 ng/ m^3)
- ☐ OEB 6 (0.01 $\mu\text{g}/\text{m}^3$ - 0.001 $\mu\text{g}/\text{m}^3$ or >10 ng/ m^3 - 1 ng/ m^3)
- ☐ OEB 7 (<0.001 $\mu\text{g}/\text{m}^3$ - <1 ng/ m^3)

23. For API/HPAPI with OEB 4 to 7, please state:

- Amount of powder being handled per batch:
Please specify:
- What is the type and size of the container that the powder enters the isolator?
Please specify:
- ☐ Open transfer: Is it through double-interlocked doors in a transfer chamber/transfer hatch?
☐ Yes ☐ No
- ☐ Open transfer: Is it via drum loading system?
☐ Yes ☐ No

☐ Closed transfer (If closed transfer, RTP will be required)

☐ Yes

☐ No

- What type of weighing scale will be used? Please define the range and resolution needed, or the brand and model of scale to be used.

Please specify:

- What is the OHC, category of powder, and mechanism of action?

- What is the major route of exposure for these powders and can these powders be absorbed through the skin?

- Are the powders hazardous?

☐ Yes

☐ No

- If Yes, are they volatile?

☐ Yes

☐ No

Volatile or chemicals being handled will need a negative pressure isolator with 100% exhaust

- Other production machine needed, please state type, brand, and model:

Please provide drawings/brochures of these machines and equipment.

24. For Sterility Testing Applications, please state:

- Particle Counter Integration:

Viable - Brand/Model:

Non-viable - Brand/Model:

- Sterility Test Pump Integration:

Brand/Model:

- Batch Size (or attach the document detailing out the Batch Size)

25. For Aseptic Production, please state:

For Filling Line Isolators, please refer to the "Filling Line Questionnaire".

- Particle Counters Needed

Viable - Brand/Model:

Non-viable - Brand/Model:

- List of Needed Equipment Integration, please specify:

Please provide drawings/brochures of these machines and equipment.

- Filling Line Integration:

Manual, specify brand/model:

Automated, specify brand/model:

- Other details needed:

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:

- Target Product:
 - ☐ 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:
 - ☐ CO₂ Incubator:
 - ☐ Centrifuge:
 - ☐ Microscope:
- Others, please specify brand/model:

Please provide drawings/brochures of these machines and equipment.

28. 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. Monitoring 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
☐ Humidity
☐ Pressure in isolator
☐ 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
☐ Other:

42. Area Classification*

For more info, please check:
<http://www.escopharma.com/hazard-sub-page.php?hazardId=105&pg=hzd>

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

43. Options*

- ☐ Electrical outlets, indicate the Type Code and Power/Current Rating Required:
- ☐ Equipment services:
 - ☐ N2 ☐ Compressed Air
 - ☐ Drain Connection ☐ Exhaust Duct Connection
 - ☐ WFI/PW ☐ 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 Ball
- ☐ Spray Gun
- ☐ Others, Specify:

44. Validation Documentation*

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

45. Site Service*

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

(If required, we will provide a proposal for travel cost and daily rate)

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