

FILLING LINE ISOLATOR 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 Cosmetics
 Chemicals Paint
 Food Others, please specify:
 Soap and Detergents

13. Name of Project

14. Project Location*

15. Unit/s Required*

16. Deadline of submission for tender*

17. Timeline for Purchase

18. Timeline for Installation*

19. Application*

20. Product Nature/Type*

Product Nature

- Liquid Lyophilized Chemical
- Solution
- Suspension

Product Type

- Allogenic Cell Therapy Pharmaceuticals
- Autologous Cell Therapy Protein Production
- Biologics Vaccine Research
- Cellular Agriculture Virus Production
- Cell Banking Viral Vector Production
- Cell Therapy (ATMP) Phase III Clinical Trial Products
- Monoclonal Antibody Production
- Other/s:

21. Product Density/ Viscosity

22. Other Product Characteristics*

- Sterile**
- Hazardous
- Volatile Biosafety Levels 3 and 4 (BSL 3 or 4) Laboratory
- Non-Volatile
- Non - Hazardous
- Non-Sterile**
- Hazardous
- Volatile Biosafety Levels 3 and 4 (BSL 3 or 4) Laboratory
- Non-Volatile
- Non - Hazardous
- Others

23. Classification of External & Internal Areas*

- Safe internal
- ATEX internal
- ATEX Zone 0
- ATEX Zone 1
- ATEX Zone 2
- ATEX Zone 20
- ATEX Zone 21
- ATEX Zone 22

- Safe external (cleanroom)
- ATEX external (cleanroom)
- ATEX Zone 0
- ATEX Zone 1
- ATEX Zone 2
- ATEX Zone 20
- ATEX Zone 21
- ATEX Zone 22

More Information

24. Maximum Footprint Dimensions*

25. Room Height*

26. Space above ceiling for HVAC

- Yes, specify:
- No

27. Provide Site Plan/ Floor Layout showing delivery to final location path so Esco can verify clearance sufficiency for Installation/ Maintenance Access

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

28. Area Classification

- Class 1 (ISO Class 3)
- Class 10 (ISO Class 4)
- Class 100 (ISO Class 5 / Grade A)
- Class 1,000 (ISO Class 6 / Grade B)
- Class 10,000 (ISO Class 7 / Grade C)
- Class 100,000 (ISO Class 8 / Grade D)

29. Level of Need

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

III. SYSTEM REQUIREMENTS

*Fields required to be filled out

30. Average Batch Size (Liters)*

31. Container Type & Filling Machine Type*

A. Container Type

- ISO Vials Ampoules Bottles (Glass)
 Non-ISO Vials Cartridges Bottles (PTFE)
 Syringes Other/s:

B. Process Requirement

- Non-Sterilized
 Filling Line System (vial washers + sterilizing tunnels)
- Sterilized
 Ready-to-Use Filling Line System
- Single Format Multiple Format
- Non Robotic Non Robotic
 Robotic Robotic

32. Container Material*
(Multiple container material can be selected) *

- Glass
 Plastic

33. Barrier System*

- Restricted Access Barrier System
- Passive
 Active
 Airflow System
 Recirculating
 Total Exhaust
- Isolator
- Aseptic
 Containment
 OEB Level (1-7)

 Airflow System
 Recirculating
 Total Exhaust

34. Tub Debugging
(Only for RTU clients)

- Manual
 Automated

35. Lid & Liner Removal (tub opening)
(Only for RTU clients)

- Manual
 Automated

36. Types of Processing Machine Required*

Legend:

- Filling: liquids
- Micro-Dosing: powders
- ** N/A for RTUs

- Washing Machine**
- Sterilization Tunnel Machine**
- Safety Device Insertion Machine
- Filling/Micro-Dosing Machine
- Plunger Rod Insertion Machine (Only applicable for syringes: i.e. PFS)
- Stopper/Insertion Machine
- Lyophilizer (N/A for syringes & cartridges)
- Closing/Crimping
- Other/s:

37. Container Format(s)

(Multiple container formats can be selected) *

- Vial
 - ISO Vial/s (WDH):
 - NON-ISO Vial/s (WDH):
 - Vial Opening (diameter):
 - Vial Height:

*Please provide Vial drawing(s)/Image(s)

- Syringe
 - 0.5ml
 - 1ml long
 - 1-3ml
 - 5ml
 - 10ml
 - 20ml
 - Other/s:

- Cartridge
 - 3ml
 - 5ml
 - Other/s:

- Infusion Bag
 - 150ml
 - 250ml
 - 500ml
 - 750ml
 - 1000ml
 - 1500ml
 - Other/s:

- Other/s*:
- Supplier/s:
- Comment/s:

*Please provide with drawing and samples ASAP.

38. Volume/s, Output and Accuracy and Dimensions*

Legends:
Bpm: bottle per minute

Vol. 1: Output Reqd: pc/min Fill Accuracy: +/-
Dimensions: Ø x mm

Vol. 2: Output Reqd: pc/min Fill Accuracy: +/-
Dimensions: Ø x mm

Vol. 3: Output Reqd: pc/min Fill Accuracy: +/-
Dimensions: Ø x mm

Vol. 4: Output Reqd: pc/min Fill Accuracy: +/-
Dimensions: Ø x mm

Vol. 5: Output Reqd: pc/min Fill Accuracy: +/-
Dimensions: Ø x mm

Vol. 6: Output Reqd: pc/min Fill Accuracy: +/-
Dimensions: Ø x mm

Vol. 7: Output Reqd: pc/min Fill Accuracy: +/-
Dimensions: Ø x mm

Vol. 8: Output Reqd: pc/min Fill Accuracy: +/-
Dimensions: Ø x mm

Vol. 9: Output Reqd: pc/min Fill Accuracy: +/-
Dimensions: Ø x mm

Vol. 10: Output Reqd: pc/min Fill Accuracy: +/-
Dimensions: Ø x mm

Year Production: No. of shift/s per day:

Comment/s:

39. Dispense System(s) (Multiple systems can be selected)*

Nb:

- **Peristaltic pump:** N/A cleaning validation (w/ Single-Use tubes)
 - o Normally has load cell
- **Piston pump:** requires cleaning validation (Multiple-Use SS)
- **Gear pump:** for high viscosity products

Peristaltic Pump

Piston Pump

Gear Pump

Other:

40. Lyophiliser*
(part 1)

Loading / Unloading Requirements

Manual

Semi- Automatic

Fully Automatic

Stoppering:

Auto-Stoppering

No Stoppering, Specify:

Lyophilizer Door:

Pizza (slide door up/down)

Swing (left to right or vice-versa)

Single Hinge (push/pull, single door: front)

Gimble (Double Hinge) (push/pull, two doors: front/rear)

Integration Flange- Lyophiliser condenser:

Forward Facing

Side Facing

Rear Facing

No. of Shelves:

Please do NOT include the auto-stoppering shelf at the top when counting the lyophilizer shelves.

Percentage (%) of Solvents Present in the product:

Percentage of Liquid in the Product prior to drying:

Type of Thermal Analysis to Characterize the Product:

Product Cycle Time:

Vial Height with Partially Inserted Stopper:

No. of Vials per Batch:

Vial Type: R

Other/s:

Vial Opening (diameter):

Vial Height:

Amount of material to be processed per batch:

Liters

Kilogram

40. Lyophiliser*
(part 2)

Tray Size (WxL):

Shelf Temperature Required:

Condenser Size Required: L

Need for Nitrogen (N2) environment:

Yes No

Requirement for Isolation valve between chamber and condenser:

Yes No

Voltage and Frequency Available:

Hz

Ph

Unit will be installed in:

Isolator o-RABS
 c-RABS

Sterilization:

Sterilization-in-Place (*steam*) Clean-in-Place (*WFI-spray gun*)
 Built-In Integrated H₂O₂ Biodecontamination
 Supplied by client facility
 Wash-in-Place (*WFI-spray gun*)

Redundant or Back-Up Systems:

Refrigeration Shelf Fluid Pumps
 Battery Others:
 Vacuum

Chamber Vacuum Sensor:

Yes No

Unique User Security Log-in ID:

Yes No
 21 CFR 11 Compliant
 Others:

41. Air Handling Units (AHU)

On-Board
 Remote

<p>42. Main Control Panel (MCP)</p>	<p><input type="checkbox"/> On-Board</p> <p><input type="checkbox"/> Remote</p>
<p>43. System Decontamination*</p>	<p><input type="checkbox"/> Manual</p> <p><input type="checkbox"/> Automated</p> <p><input type="radio"/> Vapor Phase Hydrogen Peroxide (VPH), 1 PPM</p> <p><input type="checkbox"/> VPHP < 1 PPM, Specify <input type="text"/></p> <p>Dedicated Exhaust Duct for H₂O₂ or Catalytic converter required:</p> <p><input type="checkbox"/> Yes; Specify: <input type="text"/></p> <p><input type="checkbox"/> No</p>
<p>44. Compressed Air Utilities Available*</p>	<p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p>
<p>45. Environmental Enclosure Controls*</p>	<p><input type="checkbox"/> Temperature</p> <p><input type="radio"/> Yes; Specify levels to control: <input type="text"/></p> <p><input type="radio"/> No (Monitoring only)</p> <p><input type="checkbox"/> Relative Humidity</p> <p><input type="radio"/> Yes; Specify levels to control: <input type="text"/></p> <p><input type="radio"/> No (Monitoring only)</p> <p><input type="checkbox"/> Others: <input type="text"/></p>
<p>46. Environmental Monitoring</p>	<p><input type="checkbox"/> Non-viable Particle Counter</p> <p><input type="checkbox"/> Viable Sampler</p>
<p>47. Nitrogen Gas Overlay for Filling Line Chambers*</p>	<p><input type="checkbox"/> Pre and/or Post Fill Gassing</p> <p><input type="radio"/> Required</p> <p><input type="radio"/> Not required</p>
<p>48. Integrated Weigh Check (IPC)*</p>	<p><input type="checkbox"/> Required; If yes: <input type="text"/> %</p> <p><input type="checkbox"/> Not Required</p>
<p>49. Listing Required</p>	<p><input type="checkbox"/> UL <input type="checkbox"/> None</p> <p><input type="checkbox"/> CE <input type="checkbox"/> Other: <input type="text"/></p>

50. Control System for Filling Line Chambers*

Nb: Filling Line Isolators are always required to comply with 21 CFR Pt 11 guidelines

- Allen Bradley
- Siemens

51. SCADA/BMS Integration & Connection Protocol

- Yes No
- OPC-UA
- Profibus
- Other/s:

III. INSTALLATION SITE REQUIREMENTS

**Fields required to be filled out*

52. Power Utilities*

53. Cleanroom Dimensions

- (L) x (W) x (H)
- Not Defined

54. Validation Documentation

- FAT protocols
- SAT protocols
- IQ/OQ Protocols
- Surrogate Powder Test as per ISPE

55. Site Services

- Full Installation
- Installation Supervisor
- Commissioning

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