

# 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
- Chemicals
- Food
- Soap and 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 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
- Others:

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 H<sub>2</sub>O<sub>2</sub> 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><b>42. Main Control Panel (MCP)</b></p>	<p><input type="checkbox"/> On-Board</p> <p><input type="checkbox"/> Remote</p>
<p><b>43. System Decontamination*</b></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 &lt; 1 PPM, Specify <input type="text"/></p> <p><b>Dedicated Exhaust Duct for H<sub>2</sub>O<sub>2</sub> or Catalytic converter required:</b></p> <p><input type="checkbox"/> Yes; Specify: <input type="text"/></p> <p><input type="checkbox"/> No</p>
<p><b>44. Compressed Air Utilities Available*</b></p>	<p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p>
<p><b>45. Environmental Enclosure Controls*</b></p>	<p><input type="checkbox"/> <b>Temperature</b></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"/> <b>Relative Humidity</b></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"/> <b>Others:</b> <input type="text"/></p>
<p><b>46. Environmental Monitoring</b></p>	<p><input type="checkbox"/> Non-viable Particle Counter</p> <p><input type="checkbox"/> Viable Sampler</p>
<p><b>47. Nitrogen Gas Overlay for Filling Line Chambers*</b></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><b>48. Integrated Weigh Check (IPC)*</b></p>	<p><input type="checkbox"/> Required; If yes: <input type="text"/> %</p> <p><input type="checkbox"/> Not Required</p>
<p><b>49. Listing Required</b></p>	<p><input type="checkbox"/> UL <span style="margin-left: 200px;"><input type="checkbox"/> None</span></p> <p><input type="checkbox"/> CE <span style="margin-left: 200px;"><input type="checkbox"/> Other: <input type="text"/></span></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).