**Section 1**

|  |
| --- |
| **ABOUT YOUR COMPANY** |
| 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 |  |

**Section 2**

|  |
| --- |
| **PROJECT INFORMATION** |
| 10 | Industry |  Pharmaceutical/Biotech Chemicals Food Soap and Detergents Cosmetics Paint Others, please specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 11 | Name of Project |  |
| 12 | Project Location |  |
| 13 | Deadline of submission for tender |  |
| 14 | Timeline for Purchase |  |
| 15 | Timeline for Installation |  |
| 16 | Application |  |
| 17 | Product Type |  Liquid Suspension Chemical Lyophilized Multi-product |
| 18 | Product Density/ Viscosity |  |
| 19 | Other Product Characteristics |  Sterile Hazardous Volatile Non-Volatile Non-Hazardous Non-Sterile Hazardous Volatile Non-Volatile Non-HazardousOthers: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 20 | Maximum Footprint Dimensions |  |
| 21 | Room Height |  |
| 22 | Space above ceiling for HVAC |  Yes Specify: \_\_\_\_\_\_\_\_\_\_ No |
| 23 | 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* |
| 24 | 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) |
| 25 | Level of Need |  Have an approved budget (indicate\_\_\_\_\_\_\_\_\_\_) Preparing to submit a budget for approval Gathering information for future reference |

**Section 3**

|  |
| --- |
| **SYSTEM REQUIREMENTS** |
| 26 | Average Batch Size (Liters) |  |
| 27 | Filling Line Type |  Traditional Filling Line System (inclusive of vial washers and sterilizing tunnels) Non-Robotic Robotic  Ready-to-Use Filling Line System  Single Format Non-Robotic Robotic Multiple Format Non-Robotic Robotic |
| 28 | 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 |
| 29 | Tub Debagging |  Manual Semi-automated Automated |
| 30 | Tyvek Lid & Liner Removal (tub opening) |  Manual Automated |
| 31 | Types of Processing Machine Required |  Washing Machine Filling / Dosing Lyophilisation Sterilization Tunnel Closing Labeling Safety Device Plunger Rod Bag Making Insertion Insertion |
| 32 | Container Format(s)(Multiple container formats can be selected) |  Vial 2ml 4ml 5ml 6ml 8ml 10ml 15ml 20ml 30ml Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Syringe 0.5ml 1ml long 1-3ml 5ml 10ml 20ml  Cartridge 3ml 5ml Infusion Bag 150ml 250ml 500ml 750 ml 1000ml 1500ml Other/s\*: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Supplier/s: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Comment/s: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*\*Please provide with drawing and samples ASAP.* |
| 33 | Container Material (Multiple container material types can be selected) |  Glass Plastic |
| 34 | Volume/s, Output and Accuracy and Dimensions | Vol. 1: \_\_\_\_ Output Reqd: \_\_\_\_pc/min Fill Accuracy: +/-\_\_\_\_ Dimensions: Ø\_\_\_\_x\_\_\_\_mmVol. 2: \_\_\_\_ Output Reqd: \_\_\_\_pc/min Fill Accuracy: +/-\_\_\_\_ Dimensions: Ø\_\_\_\_x\_\_\_\_mmVol. 3: \_\_\_\_ Output Reqd: \_\_\_\_pc/min Fill Accuracy: +/-\_\_\_\_ Dimensions: Ø\_\_\_\_x\_\_\_\_mmVol. 4: \_\_\_\_ Output Reqd: \_\_\_\_pc/min Fill Accuracy: +/-\_\_\_\_ Dimensions: Ø\_\_\_\_x\_\_\_\_mmVol. 5: \_\_\_\_ Output Reqd: \_\_\_\_pc/min Fill Accuracy: +/-\_\_\_\_ Dimensions: Ø\_\_\_\_x\_\_\_\_mmVol. 6: \_\_\_\_ Output Reqd: \_\_\_\_pc/min Fill Accuracy: +/-\_\_\_\_ Dimensions: Ø\_\_\_\_x\_\_\_\_mmVol. 7: \_\_\_\_ Output Reqd: \_\_\_\_pc/min Fill Accuracy: +/-\_\_\_\_ Dimensions: Ø\_\_\_\_x\_\_\_\_mmVol. 8: \_\_\_\_ Output Reqd: \_\_\_\_pc/min Fill Accuracy: +/-\_\_\_\_ Dimensions: Ø\_\_\_\_x\_\_\_\_mmVol. 9: \_\_\_\_ Output Reqd: \_\_\_\_pc/min Fill Accuracy: +/-\_\_\_\_ Dimensions: Ø\_\_\_\_x\_\_\_\_mmVol. 10: \_\_\_\_ Output Reqd: \_\_\_\_pc/min Fill Accuracy: +/-\_\_\_\_ Dimensions: Ø\_\_\_\_x\_\_\_\_mmYear Production: \_\_\_\_\_\_\_\_\_\_\_\_ No. of shift/s per day: \_\_\_\_\_\_\_\_\_\_\_\_Comment/s: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 35 | Dispense System(s)(Multiple systems can be selected) |  Peristaltic Rotary Piston Pump Time Pressure Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 36 | Lyophiliser |  Loading / Unloading Requirements Manual Semi- Automatic Fully AutomaticStoppering: Auto-Stoppering Others Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Lyophilizer Door: Pizza Swing Single Hinge Gimble (Double Hinge)Integration Flange- Lyophiliser condenser: Forward Facing Rear FacingNo. of 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:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Amount of material to be processed per batch: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Liters \_\_\_\_\_\_\_\_\_\_\_\_\_\_KilogramProduct Depth in Trays: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Type of Trays: Stainless Steel Plastic Others: \_\_\_\_\_\_\_\_\_\_\_Maximum Low Shelf Temperature Required: Yes No Maximum Low Condenser Required: Yes No Requirement for Isolation valve between chamber and condenser: Yes No Voltage and Frequency Available:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Unit will be installed in: Isolator c-RABS o-RABSSterilization: Sterilization-in-Place Clean-in-Place Integrated H2O2  BiodecontaminationRedundant or Back-Up Systems: Refrigeration Vacuum Shelf Fluid Pumps Battery Others: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Chamber Vacuum Sensor: Yes Pirani Capitance Manometer Both NoUnique User Security Log-in ID: Yes 21 CFR 11 Compliant Others: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  No |
| 37 | Air Handling Units and Main Control Panel |  On-Board Remote |
| 38 | System Decontamination |  Manual Vapor Phase Hydrogen Peroxide (VPHP), 1 PPM VPHP < 1 PPM, Specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Dedicated Exhaust Duct for H2O2 or Catalytic converter required: Yes Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ No |
| 39 | Compressed Air Utilities Available |  Yes No |
| 40 | Environmental Enclosure Controls |  Oxygen Yes Specify levels to control: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ No Temperature Yes Specify levels to control: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ No Relative Humidity Yes Specify levels to control: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ No |
| 41 | Environmental Monitoring |  Non-viable Viable Active air sampling Passive sampling |
| 42 | Gas Overlay |  Pre and/or Post Fill Gassing Required Not requiredOverlay gas \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 43 | Integrated Weigh Check (IPC) |  Required Not Required |
| 44 | Listing Required |  UL CE None Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 45 | Control System |  Allen Bradley Siemens |

**Section 4**

|  |
| --- |
| **INSTALLATION SITE REQUIREMENTS** |
| 46 | Power Utilities |  |
| 47 | Cleanroom Dimensions |  \_\_\_\_\_\_\_\_\_\_\_\_\_ (L) x \_\_\_\_\_\_\_\_\_\_\_\_\_(W) x \_\_\_\_\_\_\_\_\_\_\_\_\_ (H) Not defined |
| 48 | Validation Documentation |  FAT protocols SAT protocols IQ/OQ Protocols Surrogate Powder Test as per ISPE |
| 49 | Site Services |  Full Installation Installation Supervisor Commissioning |