**Section I**

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| **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 II**

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| **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-Hazardous  Others: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 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 III**

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| **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\_\_\_\_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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 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 Automatic  Stoppering:  Auto-Stoppering  Others  Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Lyophilizer Door:  Pizza  Swing  Single Hinge  Gimble (Double Hinge)  Integration Flange- Lyophiliser condenser:  Forward Facing  Rear Facing  No. 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 \_\_\_\_\_\_\_\_\_\_\_\_\_\_Kilogram  Product 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-RABS  Sterilization:  Sterilization-in-Place Clean-in-Place Integrated H2O2  Biodecontamination  Redundant or Back-Up Systems:  Refrigeration Vacuum Shelf Fluid Pumps  Battery Others: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Chamber Vacuum Sensor:  Yes  Pirani  Capitance Manometer  Both  No  Unique 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 required  Overlay gas \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 43 | Integrated Weigh Check (IPC) | Required  Not Required |
| 44 | Listing Required | UL CE None  Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 45 | Control System | Allen Bradley  Siemens |

**Section IV**

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| **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 |