SECTION I:

|  |
| --- |
| **ABOUT YOUR COMPANY** |
| 1 | Name: |  |
| 2 |  Company: |  |
| 3 |  Facility Address: |  |
| 4 | Email Address: |  |
| 5 | Website: |  |
| 6 | Phone Number and Extension: |  |
| 7 | Fax: |  |
| 8 | Existing Esco Equipment: |  |
| 9 | You Work For:*(Please tick)* |  End User/Facility Owner Cleanroom Builder/Contractor Lab Builder/Contractor Distributor |

SECTION II:

|  |
| --- |
| **PROJECT INFORMATION** |
| 10 | URS Available: | * Yes (please attach document)
* No
 |
| 11 | Industry:*(Please tick)* |  Pharmaceutical/Biotech Chemicals Food and Beverage Soap/Detergents Cosmetics Paint Others, please specify:  |
| 12 | Name of Project: |  |
| 13 | Location of Project (City, Country): |   |
| 14 |  Deadline of Submission  of Quotations: |  |
| 15 | Delivery Date Required: |  |
| 16 | Application:*(Please tick)*Application: |  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) LaboratoryOthers: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 17 | Protection:*(Please tick one)* | * Operator protection
* Product protection
* Operator and product protection
 |
| 18 | Occupational Exposure Band (Occupational Exposure Limit):*For more info, please check:*[*http://www.escopharma.com/hazard-sub-page.php?hazardId=53&pg=hzd*](http://www.escopharma.com/hazard-sub-page.php?hazardId=53&pg=hzd) | * OEB 1 (>1000 – 5000 µg/m3)
* OEB 2 (>100 - ≤1000 µg/m3)
* OEB 3 (>10 - ≤100 µg/m3)
* OEB 4 (>1 - ≤10 µg/m3)
* OEB 5 (<1.0 µg/m3 - 0.01 µg/m3 or 10 ng/ m3)
* OEB 6 (0.01 µg/m3 - 0.001 µg/m3 or >10 ng/m3 - 1 ng/m3)
* OEB 7 (<0.001 µg/m3 - <1 ng/m3)
 |
| 19 | Level of Need: | * Have an approved budget
* Preparing to submit a budget for approval
* Gathering information for future reference
 |
| 20 | 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?

Please specify: *\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** What is the OHC, category of powder, mechanism of action?
* What is the major route of exposure for these powders and can these powders be absorbed through skin?
* Are the powders hazardous?

 [ ] No [ ] Yes If Yes, are they volatile? [ ] No [ ] Yes*Volatile or chemicals being handled will need 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.*  |
| 21 | For **Sterility Testing Applications**, please state: | * Particle Counter Integration:

Viable - Brand/Model: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Non-viable - Brand/Model: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* Sterility Test Pump Integration:

Brand/Model: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* Batch Size:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 22 | 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:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 23 | 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.* |
| 24 | 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.* |
| 25 | 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 isolator: C.) Process carried out within the isolator:D.) Instrument/s used to carry out 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? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  | G.) Will production machinery be used?i. Width, height and depth of production machinery \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ii. Amps to operate machine \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_iii. Position of charge and discharge points \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_iv. Range of thermostatic control on machinery \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_v. Dust generating or heat zones within machinery \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_H.) Number of personnel required to operate machinery \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

SECTION III:

|  |
| --- |
| **ISOLATOR SPECIFICATIONS INFORMATION** |
| 26 | Internal Width: |  |
| 27 | Internal Height: |  |
| 28 | Internal Depth: |  |
| 29 | Provide Site Plan/Floor Layout so that Esco can verify clearances are Sufficient for Installation/Maintenance Access | *Please attach site plan/floor layout together with this questionnaire* |
| 30 | Pressure Mode: | * Positive Pressure
* Negative Pressure
* Required Pressure, please specify per chamber:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 31 | Airflow Circulation | * Recirculating
* Total Exhaust
 |
| 32 | Airflow Pattern: |  Unidirectional Turbulent |
| 33 | Construction Material: | Specify chosen material from below options:Internal: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_External: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Antimicrobial Powder-Coated Electrogalvanized Steel Stainless Steel 304 Stainless Steel 304L* Stainless Steel 316L
* Hastelloy
* Coated stainless steel e.g PTFE-PFA Coated Stainless Steel

(Please specify coating: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)* Others, Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 |
| 34 | Control System: | * Standard Esco Sentinel Microprocessor
* Industry Grade HMI/PLC

  |
| 35 | 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 |
| 36 | Parameters to Monitor*(Tick All That Apply)* |  Velocity Pressure across filters Temperature Humidity* Pressure in isolator
* Others, Specify:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 37 | 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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 |
| 38 | Area Classification:*For more info, please check:*[*http://www.escopharma.com/hazard-sub-page.php?hazardId=105&pg=hzd*](http://www.escopharma.com/hazard-sub-page.php?hazardId=105&pg=hzd) |  Safe Area (non-hazardous) Zone 20 Zone 21* Zone 22
* Zone 0/20
* Zone 1/21
* Zone 2/22
* Class I Div. 1
* Class II Div. 2

 Class II Div. 1* Class II Div. 2
* Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 |
| 39 | Options: | * Electrical outlets, indicate the Type Code and Power/Current Rating Required:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* Equipment services:

[ ] N2 [ ] WFI/PW [ ] Compressed Air[ ] Drain Connection [ ] Exhaust Duct Connection[ ] Others, specify:* 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 Butterlfy Valve
* Spray Ball
* Spray Gun
* Others, Specify:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 40 | Validation Documentation: |  FAT Protocols SAT Protocols IQ/OQ Protocol* Surrogate Powder Test as per ISPE
* Biodecon Cycle Development
* Cleaning Coverage Validation
* Others, Specify:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 41 | Site Services: | * Full Installation
* Commissioning
* Installation Qualification (IQ)
* Operational Qualification (OQ)
* Site Acceptance Test (SAT)
* User and Service Training
* Preventive Maintenane (PM)

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