SECTION I:

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| **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:

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| **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) Laboratory  Others:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 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:

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| **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)* |