#### TECHNICAL COMPLIANCE MATRIX

**IAEA RFQ 649603-AK - Freeze Dryer cGMP for Cuba (CUB6031)**

**IMPORTANT INSTRUCTIONS**

1. Responses should not be direct copies (copy and paste) of the provided IAEA specifications. Bidders are required to provide a detailed response/explanation for each specification line item. This response must include specific technical details of the offered solution. Any proposed deviations shall be clearly defined and justified.
2. If a bidder references a technical proposal, please indicate where the relevant information can be found.
3. Generic statements such as “we shall customize to your needs/requirements” are **NOT** acceptable.

| **Ref.** | **Specification Requirements** | **Compliance Yes/No** | **Bidder’s technical details and explanations (Expand rows as needed)** |
| --- | --- | --- | --- |
| **4.** | **Requirements** |  |  |
| **4.1** | **Functional and performance Requirements** | | |
|  | The system should be suitable for aseptic production of pharmaceutical products as per cGMP criteria providing minimum access control for building freeze drying cycle, visualization of process, batch report, data history.  The system should include complete units for automatic cleaning (Cleaning in Place, CIP), sterilization system (Sterilization in Place, SIP; based on VHP (H2O2 sterilization)) in addition to basic components such as vacuum pump, compressor and system for heat transfer. | Yes  No |  |
|  | **The system shall meet the following functional and performance requirements:** | | |
|  | **4.1.1** Shelf area 0.5 m²; | Yes  No |  |
|  | **4.1.2** Shelf dimensions (W x D) 380 x 450 mm; | Yes  No |  |
|  | **4.1.3** Nº of shelves 3 + 1; | Yes  No |  |
|  | **4.1.4** Shelves clearance: 90 mm; | Yes  No |  |
|  | **4.1.5** Chamber material: Stainless steel AISI 316L; | Yes  No |  |
|  | **4.1.6** Condenser capacity: 30 kg; | Yes  No |  |
|  | **4.1.7** Condenser temperature: -85 ºC; | Yes  No |  |
|  | **4.1.8** Shelves temperature range: from - 60 ºC to +85 ºC; | Yes  No |  |
|  | **4.1.9** CIP (Clean in Place) system: piping and nozzles system in chamber and condenser. External drying unit: with liquid ring pump, water tank and plate heat exchanger | Yes  No |  |
|  | **4.1.10** VHP disinfection (hydrogen peroxide vapor) – including piping and nozzles system, H2O2 hydrogen peroxide tank with heating resistance, temperature probe and valves necessary for correct operation | Yes  No |  |
|  | **4.1.11** Vial closing by pneumatic piston | Yes  No |  |
|  | **4.1.12** Sealing of vials should be carried out under two conditions: vacuum conditions or with inert gas prior venting. Chamber aeration by HEPA filter + inlet for N2 | Yes  No |  |
|  | **4.1.13** Overall dimensions (W x D x H): 1,600 x 1,300 x 1,800 mm; | Yes  No |  |
|  | **4.1.14** The equipment will be installed in a location with a controlled temperature ( 22ºC) and humidity < 60%, no condensation. | Yes  No |  |
|  | **4.1.15** Allow the use of 2R, 10R and 15R vials | Yes  No |  |
|  | **4.1.16** Break up the vacuum with filtered nitrogen and clean air. | Yes  No |  |
|  | **4.1.17** Dry Air Compressor 5-10 bar, 220 VAC, 60 Hz is needed to be procured to guarantee the sustainability of the use of the freeze dryer | Yes  No |  |
|  | **4.1.18** PC + external software control | Yes  No |  |
| **4.2**. | **Technical Requirements: The system shall meet the following technical requirements:** | | |
|  | **4.2.1** The equipment should work with a power supply of AC 380 VAC; 3 phases + neutral + earth, 60 Hz; | Yes  No |  |
|  | **4.2.2** Ports: USB, Ethernet 10/100/1000Mb, RS232, RS485 for communication and save tracing dates. | Yes  No |  |
| **5** | **Marking** |  |  |
|  | The System shall have all safety markings and user manual either in Spanish or in English language. | Yes  No |  |
| **6** | **Packing** |  |  |
|  | The System, for the shipment by air to the Isotopes Centre, Cuba, shall be packed in accordance with international standards that are applicable for the shipment by air of this kind of equipment. | Yes  No |  |
| **7** | **Quality Requirements** |  |  |
|  | 7.1. The System shall be manufactured, shipped and installed in accordance with the Contractor’s ISO quality assurance system or an equivalent quality assurance system.  7.2. The Contractor shall document the compliance with this quality assurance system. | Yes  No |  |
| **8** | **Testing and Acceptance** |  |  |
|  | 8.1. The System, prior to shipment, shall be tested for conformance of the System with manufacturer’s performance specifications (FAT) and the minimum requirements specified herein.  8.2. System, after installation, shall be tested by the Isotopes Centre (End-User) to demonstrate that the performance meets the manufacturer’s performance specifications (SAT, IQ and OQ) and the minimum requirements specified herein as determined by the IAEA and the Isotopes Centre.  8.3. A report will be written by the Isotopes Centre and sent to IAEA in case of any compliance about the specifications of the equipment. | Yes  No |  |
| **9** | **Installation and Training** |  |  |
|  | 9.1. The contractor shall Install the equipment at the end-user site.  9.2. The contractor shall provide three (days) local training course, for five (5) specialists. | Yes  No |  |
| **10** | **Deliverable Data Items** |  |  |
|  | The Contractor shall provide two complete sets of operation and servicing manuals and technical drawings in either Spanish or English language. | ☐ Yes  ☐ No |  |