Offer for cleanroom system components and services

Ladies and Gentlemen

On behalf of [your company name], we would like to request a quote for the planning, supply, and installation of cleanroom system components and related services. Our goal is to meet the requirements according to the GMP room book and the specific URS (User Requirement Specifications ). Below you will find a detailed list of our requirements:

1. General requirements

* **Clean rooms** : Number and size according to GMP room book, including room labeling.
* **Zone status and transitions** : Specification of zone status for cleanrooms and material pass-throughs, including airlock systems.

2. Flows (material, personnel flow)

* **Separation of material and personnel flow** : Through material and personnel locks, as well as material pass-throughs.
* **Biological waste** : Disposal via autoclave.

3. Clean room conditions

* **Ambient conditions** : specifications for pressure, pressure difference, temperature, humidity and monitoring.

4. Maintenance/Repair

* **Accessibility** : Systems must be maintainable, including inspection hatches and replaceable wall modules.

5. Calibration

* **Sensors** : Must be calibrated and recalibratable .

6. Control panel

* **Monitoring** : Control panel for monitoring cleanroom parameters.

7. Environmental conditions/interfaces

* **Ventilation system** : Specifications for HEPA filters and connections to central extraction systems.

8. Media supply

* **Connections** : For compressed air, oxygen and purified Water in clean rooms.

9. Structural requirements

* **Building envelope** : specifications for double-shell and room-in-room systems.
* **Materials and surfaces** : requirements for hygienic design, floor coverings and interior material pass-throughs.

10. Performance data

* **Ventilation** : Specifications for supply air, extract air and air volumes.

11. Safety requirements

* **Locking system** : For locks and material hatches, as well as other specific safety requirements.

12. Process requirements

Material flow IN:

* **Storage and transport** : Solutions for storage in the central external warehouse, transport to the GMP-I building and introduction via material locks.
* **Outer packaging** : Use of stainless steel or plastic pallets, avoidance of cardboard boxes in the GMP-I building.

Material flow OUT:

* **Storage and dispensing** : Systems for the storage of material/product and dispensing via material locks after QC approval.

Persons:

* **Lock capacity** : According to GMP room book.
* **Clothing concept** : definition and implementation.

13. Functional requirements

* **Lock locking** : Automatic locking and display system.
* **Monitoring of room conditions** : alarm systems for monitoring.

14. Monitoring

* **Display of cleanroom conditions** : Implementation of a display system for important parameters.
* **Pressure difference monitoring** : Continuous monitoring and alarm.
* **Data integrity** : Protection and archiving of monitoring data.

15. Security and access controls

* **Software** : Protection through physical access controls and password rules.
* **Audit trail** : generation and reliability.

16. Backups and Recovery

* **Functionality** : Documentation of an emergency program.

17. Hardware and software requirements

* **Standard components** : Use of well-known manufacturers and compliance with GAMP requirements.

18. Documentation and training requirements

* **Documentation** : Provided in German, including all relevant lists and electrical documentation.
* **Training** : Conducting initial operator training.

Please include detailed information on the proposed solutions, cost estimates, implementation schedules, and references from similar projects in your offer. We attach great importance to compliance with GxP guidelines and meeting our specific requirements.

We are happy to answer any questions you may have. We look forward to receiving your offer and hope for a successful collaboration.

Best regards,

[Name] [Purchasing Department] [Name of your company]