Offer for cleanroom system components and services

Ladies and gentlemen,

On behalf of [ Name of your company] we would like to ask you for an offer for the planning, delivery and installation of cleanroom system components and associated services. Our aim is to meet the requirements of the GMP Space Book and the specific URS (UserRequirementSpecifications==References== Below you will find a detailed list of our requirements:

1. General requirements

**Cleanrooms**: Number and size according to GMP-Roombook, including marking of the rooms.

**Zone status and transitions**: Specification of the zone status for clean rooms and material, including lock systems.

2. Rivers (material flow, personnel flow)

**Separation of material and personnel flow**: Through material and personnel locks, as well as material.

**Biological waste**: Disposal via autoclaves.

3. Cleanroom conditions

**Environmental conditions**: Specifications for pressure, pressure difference, temperature, humidity and monitoring.

4. Maintenance/maintenance

**Accessibility**: Systems must be maintainable, including revision flaps and interchangeable wall modules.

5. Calibration

**Sensors**: must be calibrated andRecalibratablebe.

6. Control panel

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

7. Environmental conditions/interfaces

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

8. Media coverage

**Connections**: For compressed air, oxygen andPurifiedWaterin cleanrooms.

9. Building requirements

**Building envelope**: Specifications for double shells and room-in-room systems.

**Materials and surfaces**: Requirements forHygienicDesign, floor covering and interior material throughout.

10. Performance data

**Ventilation**: Specifications for supply air, exhaust air and air quantities.

11. Safety requirements

**Lock lock**: For sluices and materials, as well as other specific safety requirements.

12. Process requirements

Material flow IN:

**Storage and transport**: Solutions for storage in the central outer warehouse, transport to the GMP-I building and transfer via material locks.

**Repackaging**: Use of stainless steel or plastic pallets, avoidance of cardboard boxes in the GMP-I building.

Material flow OUT:

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

Persons:

**Lock capacity**: According to GMP Room Book.

**Clothing concept**: Definition and implementation.

13. Functional requirements

**Lock lock**: Automatic locking and display system.

**Monitoring of spatial conditions**: Monitoring alarm systems.

14. Monitoring

**Display of cleanroom conditions**: Implementation of a display system for important parameters.

**Pressure differential monitoring**: Continuous monitoring and alarming.

**Data integrity**: Protection and archiving of monitoring data.

15. Security and access controls

**Software**: Protection by 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**: Provision in German, including all relevant lists and electrical documentation.

**Training**: carrying out initial operator training.

Please add detailed information to your offer on the proposed solutions, cost calculations, schedules for implementation and references of similar projects. We attach great importance to compliance with the GxP guidelines and to meeting our specific requirements.

For further questions we are at your disposal. We look forward to your offer and hope for a successful cooperation.

Yours sincerely,

[ Name] [Purchasing department] [ Name of your company]