Offer for the supply and installation of a process control system

Ladies and Gentlemen

We, [your company name], are looking for a reliable partner to design, supply, and install a state-of-the-art process control system that meets our specific requirements. After carefully reviewing your expertise and experience in this field, we would like to offer you the opportunity to submit a proposal for our project.

1. General requirements

* **Batch size** : Up to approx. 30 kg.
* **Ex version** : Suitable for flammable liquids group IIA and IIB.
* **HWS operation** : Suitable for operation with highly effective substances.
* **Compliance** : Fulfillment of all relevant ISO, GMP, FDA requirements including CFR 21 Part 11.

2. Design and technical implementation

* **Direct current spraying principle** : With perforated drum and interchangeable drums for different product shapes.
* **Cleaning** : Easy to clean and clear labeling of all media inlets and outlets.
* **Temperature and pressure control** : supply air temperature up to min. 90°C, material temperature up to approx. 70°C, including pressure concept for HWS operation.
* **Filtration** : Exhaust air filtration with F6, F9 and H14 filters as well as a 2-stage safety filter.

3. Operation, control and data acquisition

* **Data recording** : Comprehensive logging of all relevant process parameters according to 21 CFR 11.
* **Control** : Siemens PLC, preferably Simatic S7, with audit trail functionality and backup function.
* **Operating system** : Microsoft Windows 10 with user-friendly interface.

4. Occupational safety

* **Safety devices** : Including emergency stop switches and protective devices.

5. Documentation

* **CE certificate** , **risk analysis** , **operating and maintenance instructions** in German, **spare/wear parts list** , **specifications/system specifications** , **circuit diagrams** , **technical data of the machine** and **installation plan/layout** .

6. Requirements for computerized systems

* **User management** : Role-based authorization concept, multi-level user classes, audit trail, data integrity and security, automatic log-out and data backup concept.

7. Hardware and software requirements

* **Hardware** : specifications and connection, **software** : automatic start, admin rights, storage paths, backup creation, database use preferably Microsoft SQL Server.
  + 1. **Language** : All technical documents, visualizations, user interfaces, labels and warnings must be in German.

9. Content of the technical documentation:

* + Operating instructions
  + Plant description
  + Functional description
  + EMC test report
  + Parts list (spare/wear parts list)
  + Technical data sheets
  + Alarm and fault report list including fault rectification
  + Electrical circuit diagram
  + Software description and program
  + Backup software (PLC + HMI)
  + Disaster and System Recovery Guide
  1. Format:

The documents must be created in one of the following formats: Microsoft Office, E-Plan, AutoCAD as DWG or DXF, PDF.

**11.. Lock-Out/Tag-Out concept** :

The operating instructions include a written concept for lock-out/tag-out protection during maintenance, cleaning and setup work as well as during troubleshooting.

* 1. **MSR safety devices** :

If MSR safety devices are present to reduce risks, they must be evaluated or their suitability confirmed in accordance with IEC 61508/IEC 61511. Proof of the evaluation is part of the contract and must be submitted to the customer. The resulting recurring tests to ensure proper maintenance of the safety function must be documented in the operating instructions.

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]