Offer for the delivery and installation of a process control system

Ladies and gentlemen,

we, [ Name of your company], are looking for a reliable partner for the planning, delivery and installation of a state-of-the-art process control system that meets our specific requirements. After careful examination of your expertise and experience in this area, we would like to give you the opportunity to make an offer for our project.

1. General requirements

**Batch size**: Up to about 30 kg.

**Ex-execution**: Suitable for combustible liquids group IIA and IIB.

**HWS holding**: Suitable for operation with highly effective substances.

**Compliance**: Compliance with all relevant ISO, GMP, FDA requirements incl. CFR 21 Part 11.

2. Design and technical design

**DC spraying principle**: With perforated drum and interchangeable drums for different product shapes.

**Cleaning**: LightCleanabilityand clear labelling of all media inflows and outflows.

**Temperature and pressure control**: Supply air temperature up to min. 90°C, good temperature up to approx. 70°C, including pressure concept for HWS operation.

**Filtration**: Exhaust air filtration with F6, F9 and H14 filters and a 2-stage safety filter.

3. Operation, control and data collection

**Data recording**: Comprehensive logging of all relevant process parameters according to 21 CFR 11.

**Control**: Siemens SPS/PLC, preferably Simatic S7, with audit trail functionality and backup function.

**Operating system**: Microsoft Windows 10 with user-friendly user interface.

Safety at work

**Safety equipment**: Including emergency-off switches and protective devices.

Documentation

**CE certificate**,**Hazard analysis**,**Operating and maintenance instructions**in German,**Replacement/wear list**,**Compulsory specification/system specification**,**Schematics**,**technical data of the machine**and**Plan of preparation/layout**.

6. Requirements for computerised systems

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

7.Requirements for hardware and software

**Hardware**: specifications and connection;**Software**: Automatic start, admin rights, storage paths, back-up creation, database use preferably Microsoft SQL server.

**Language**:All technical documents, visualizations, user interfaces, markings and warnings must be carried out in German.

9.Content of the technical documentation:

Operating instructions

Appendix description

Function description

EMC test protocol

Parts list (replacement/wear list)

Technical data sheets

Alarm and troubleshooting list including troubleshooting

Electrical circuit diagram

Software description and program

Backup Software (SPS + HMI)

Disaster and System Recovery Instructions

Format:

The documents shall be drawn up in one of the following formats: MicrosoftOffice, 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 for maintenance, cleaning and set-up work as well as troubleshooting.

**MSR security devices**:

If MSR safety devices are available for risk reduction, they shall be assessed or confirmed in accordance with IEC61508/IEC61511. The proof of the evaluation is part of the order and must be handed over to the customer. The resulting recurring tests for the correct maintenance of the safety function shall be recorded in the operating instructions.

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]