**重庆药友水土工厂202车间单抗项目**

**层析柱及装柱系统用户需求**

**URS for Chromatography Column and Packing Column System of 202 Project**

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1. 目的PURPOSE

本文件目的是定义重庆药友水土工厂202车间单抗项目15,000L生产线的层析柱及其相关设备的用户需求。

The purpose of this document is to define the user requirements for chromatography column with associated devices of 15,000L fermentation line of 202 project.

1. 范围SCOPE

本文连同其所有附件，涵盖了所有工作范围以及设计、制造、检查、交付、调试和性能测试的最低要求。本项目包括了层析柱以及辅助设备（例如装柱站等）。

This document, together with all attachments to it, covers the scope of work and the minimum requirements for the design, fabrication, inspection, delivery, start-up, and performance testing. The plant consists of chromatography column and support system (the stand of packing column and so on).

本项目包含1根1800mm亲和层析柱，1根1600mm阳离子层析柱，1根1000mm阴离子层析柱，层析柱由以下部分组成：

The scope of supply includes one 1600mm affinity column, one 1600mm cation chromatography column, one 1200mm anion chromatography column，which consist of the following parts:

* 柱头 Column head
* 分配板 Distribution board
* 进胶口 Into the gate
* 筛板 Sieve plate
* 柱管 Column jacket
* 其他支撑附件 Other supporting accessories

装柱系统至少包括以下几个部分：

The stand of packing column system at least consist of the following parts:

* 输送泵 Transfer pump
* 匀浆罐 Slurry tank
* 柱效测试单元 Column efficiency test unit
* 气动阀 [Pneumatic](javascript:;) [valve](javascript:;)
* 流量计 Flowmeter
* 压力表 Pressure gage

一套用于监视和控制装柱操作的控制模块，包括可与上位控制系统连接的SCADA/PLC控制系统。

A set of control modules for monitoring and controlling column mounting operations, including the SCADA/PLC control system that can be connected to the upper control system.

本系统服务于202生产楼15,000L生产线。

The system service for production building 202# of 15,000L fermentation line.

需要提供的范围包括：

The scope of supply shall include:

* 详细设计Detail Design
* 设计确认 Design Qualification
* 建造 Fabrication
* 工厂接收测试 FAT
* 交付 Delivery
* 调试以及现场接收测试 Commissioning & SAT
* 安装确认和运行确认 IQ & OQ
* 性能确认协助 PQ Assistance
* 操作人员的培训 Operation Personnel Training
* 文件 Documentation
* 移交 Handover

1. 系统描述SYSTEM DESCRIPTION
   1. 设施/设备/仪器/系统描述 Facility/ Equipment/ Instrument/ System Description

层析柱位于202生产楼15,000L生产线粗纯间，将用于15,000 L原液生产规模中的粗纯工序。

The chromatography columns are located on the 15,000L fermentation Line of production building 202# and will be used for purification of 15,000 L bulk production.

本系统应满足每天24小时连续工作，并且连续时间不少于每周7\*24小时。

The system should work continuously 24 hours a day, and the continuous time should not be less than 7\*24 hours per week.

* 1. 布局/安装要求 Layout/ Construction Requirement

供应商需根据业主的平面布局进行层析柱以及辅助设备的设计。若设备有额外的布局要求，应告知业主并由业主批准。

Vendor should design the chromatography columns and support system according to the owner's layout. Any additional layout requirements for the system must be notified and approved by Client.

* + 1. 布局 Layout

|  |  |  |
| --- | --- | --- |
| **序号No.** | **描述Description** | **信息Information** |
|  | 房间温度要求 Room Temp. Requirement | D级区，18~25℃  Grade D Area, 18~25℃ |
|  | 房间湿度要求 Room Humidity Requirement | 30~70%rh |
|  | 房间布局图 Room Layout | 参见平面布局图 See layout |

* + 1. 公用介质 Utility

|  |  |  |  |
| --- | --- | --- | --- |
| **序号 No.** | **公共设施 Utilities** | **用途 Function** | **范围/容量 Conditions** |
|  | 电气  Electric | 供电  Power | 380V±10V，50Hz±10%  220V±10V，50Hz±10% |
|  | 洁净压缩空气  Clean Compressed air | 动力  Drive | 压力 Pressure：0.6 MPa |

1. 定义/缩略语DEFINITIONS AND ABBREVIATIONS
   1. GMP：药品生产质量管理规范 Good Manufacturing Practices
   2. EU GMP：欧盟药品质量管理规范 European Good Manufacturing Practice
   3. GAMP：良好的自动生产规范 Good Automated Manufacturing Practices
   4. ASME：美国机械工程师学会 American Society of Mechanical Engineers
   5. BPE：生物加工设备 Bioprocessing Equipment
   6. ICE：国际电工技术委员会 International Electrotechnical Commission
   7. CFR：联邦法规法典 Code of Federal Regulations
   8. DQ：设计确认 Design Qualification
   9. FAT：工厂验收测试 Factory Acceptance Test
   10. SAT：现场验收测试 Site Acceptance Test
   11. IQ：安装确认 Installation Qualification
   12. OQ：运行确认 Operational Qualification
   13. PQ：性能确认 Performance Qualification
   14. SOP：标准操作规程 Standard Operation Procedure
   15. PLC：可编程逻辑控制器 Programmable logic controller
   16. WFI：注射用水 Water for injection
   17. HEPA：高效空气过滤器 High Efficiency Air Filter
   18. HMI：人机界面 Human Machine Interface
   19. P&ID：管道和仪表流程图 Pipe & Install Diagram
   20. SCADA：数据采集与监控系统 Supervisory Control and Data Acquisition
   21. PCV：压力调节阀 Pressure Control Valve
   22. PCS：工艺控制系统 Process Control System
   23. DCS：分散控制系统 Decentralized control system
2. 参考资料及法规符合性 REFERENCES & REGULATIONS

在编写本URS的内容时已参考，且供应商需要满足下列文档的当前修订版：

The contents of this URS have been referenced and the supplier is required to meet the current revisions of the following documents.

* 2010中国GMP

NMPA: Good Manufacturing Practice for Drugs (2010 Version)

* US FDA: 21 CFR Parts 210 and 211
* US FDA: 21 CFR Part 11
* EU GMP Volume Ⅳ
* ASME BPE
* GAMP 5
* GB 150 (2011版)

1. 需求REQUIREMENTS

URS的每条要求可按如下分类为：

Each requirement in the URS can be classified as following:

* 质量需求: 质量需求是具有法规或合规相关影响的可测量需求，需在确认阶段进行测试，质量需求可能是以下之一：

Quality Requirements are measurable requirements that have a regulatory or compliance related impact and will be tested during qualification. A quality requirement may be one of the following:

* 关键质量属性 (CQA)
* 关键工艺参数 (CPP)
* 关键操作参数（KOP）
* 关键方面 (CA)
* 其他需求如GMP法规及组织质量要求等

Other requirement such as GMP regulatory, organization quality requirement, etc.

* 商业需求：不影响产品质量的商业需求

Business: Business requirements that do not impact product quality

* 安全需求：EHS
* 商务需求：与商务合同相关的非技术性需求，不影响产品质量，无需在DQ和RTM中追溯

Commerce requirements: non-technical requirements related to business contracts that do not affect product quality, do not need to be traded in DQ or RTM.

* 1. 通用要求 General Requirement

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 供应商需提供设备的三维图纸，配合业主完成厂房立体布局图。  The supplier shall provide the 3D drawings of the equipment and cooperate with the owner to complete the 3D layout of the plant. | 质量  Quality |
|  | 系统部件及仪器仪表的品牌参考业主的零部件品牌推荐表。所有零部件选型应依据URS要求，提交业主审核；若选型不一致，需提交业主批准后方可执行。  The brand of system components and instruments shall refer to the owner's parts brand recommendation table. The selection of all parts should be submitted to the Client for review according to URS requirements; if the type selection is inconsistent, it should be submitted to the Client for approval before implementation. | 商务  Commerce |
|  | 设备应贴有统一的设备铭牌，铭牌上应注明名称、产地、出厂日期、型号、重量及其他重要技术参数。  The equipment should be attached with a unified nameplate. The equipment name, origin, date of manufacture, type, weight and other important technical parameters should be specified on the nameplate. | 质量  Quality |
|  | 供应商的P&ID图需要根据业主要求进行更改和修正。  The supplier P&ID drawing needs to be changed and corrected according to the owner's requirements. | 商务  Commerce |

* 1. 工艺需求 Process Requirement

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 所有设备应设计确保设备能够自排尽。  All equipment shall be designed to ensure that the equipment can be self-drained. | 质量  Quality |
|  | 所有走液体管道均需要自排空。最低点的排空坡度考虑至少1%。例如物料输送管路，冷凝水排水管路，CIP清洗管路，排污管路。  All liquid pipelines need to be self-emptying. The lowest point of the drainage slope should be considered at least 1%. Such as product delivery pipelines, condensate drainage pipelines, CIP cleaning lines, sewage pipelines. | 质量  Quality |
|  | 系统模块设计以及物料输送管路设计应尽可能减少死体积，死管段接受标准需满足现行ASME BPE的L/d对不同管径的对应要求。  System module design and product transfer pipelines design shall minimize dead volume, and the acceptance standards for dead pipe sections shall meet the corresponding requirements of the current ASME BPE L/d for different pipe sizes. | 质量  Quality |
|  | 对于每台设备，每种公用工程管路（包括进/出）只提供一个确定位置的出入接口。公用工程接口至设备之间的连接（包括材料和安装）属于供应商的范围。若有必要，供应商应在公用工程管道上安装必要减压阀和安全阀。  Only one utility connection will be foreseen for each fluid (including in and out) at agreed position for each equipment. Connections between utility interfaces and equipment (including materials and installation) fall within the scope of suppliers. If needed, Vendor will insert on the utilities lines the necessary pressure-reducing valves and safety devices. | 商业  Business |
|  | 所有可拆连管道和仪表接均为快卡连接。  All detachable pipe and instruments connections are clamps. | 商业  Business |
|  | 管路内容物和流向应在管路上标明，不同内容物采用不同颜色区分。  The contents and direction of the pipeline should be marked, and different contents should be distinguished by different colors. | 商业  Business |
|  | 机械部件和管路的标识样式由业主提供，供应商设计交业主确认。  例如阀门，传感器，泵等。  The identification pattern of mechanical parts and piping shall be provided by the owner, and the supplier's design shall be submitted to the Owner for approval. Such as valves, sensors, pumps, etc. | 商务  Commerce |

* 1. 关键参数 Critical Parameter

| **序号**  **ID No.** | **参数 Parameter** | **要求 Requirement** | **需求分类**  **Requirement Category** |
| --- | --- | --- | --- |
|  | 柱高  Bed height | 100mm~600mm | 质量  Quality |
|  | 在30℃下的耐受压力  Withstand pressure at 30℃ | 4 bar | 质量  Quality |
|  | 操作温度范围  Operating Temperature | 2-30 ℃ | 质量  Quality |
|  | 电机控制高度精度  Motor control height accuracy | 1mm | 质量  Quality |

* 1. 部件要求 Components Requirement
     1. 层析柱 Chromatography columns

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 供应商需提供设备的三维图纸，配合业主完成厂房立体布局图。  The supplier shall provide the 3D drawings of the equipment and cooperate with the owner to complete the layout of the plant. | 质量  Quality |
|  | 层析柱设计：全自动智能装柱，装柱程序可预置在自动装柱工作站。  层析柱可实现自动排气。  The packing mode shall be preprogrammed, axial compression to achieve accurate and reproducible result. The chromatography column can realize automatic exhaust. | 质量  Quality |
|  | 层析柱柱头移动实现方式：电机驱动。驱动电机应采用西门子或同等质量著名品牌。  The movement of adaptor shall be with power such as stepper motor actuators control, not by manual. The motor should adopt Siemens or famous brand of the same quality. | 质量  Quality |
|  | 装柱时采用轴向压缩方式，使层析介质压紧。柱头上下移动时不应刮磨到柱体。  Axial compression method is used to compress the chromatography medium.  When the stigma moves up and down, it should not be scraped to the cylinder | 质量  Quality |
|  | 筛板要求耐压耐用，可实现10-20 μm规格筛网更换使用。  The screen plate is required to be pressure-resistant and durable. The preferred polymer can be replaced. Porosity of bed support: 10-20μm | 质量  Quality |
|  | 柱管需具备高度指示装置。具备有水平显示和调节。  Need Physical bed height indicator which can show the real time of height.  It is better to have horizontal display and adjustment. | 质量  Quality |
|  | 层析柱及附属配件无卫生死角，可进行在位清洗。  Column and accessories should be cleaned in place without dead end. | 质量  Quality |
|  | 层析柱的装柱和拆柱过程，可以在自动装柱站中运行方法运行完成，不需要人员过多干预，保证不同操作人员装柱结果的一致性。  The column installation and removal process of the tomographic column can be completed automatically in the automatic column installation station without too much human intervention, so as to ensure the consistency of column installation results of different operators. | 质量  Quality |
|  | 层析柱应该有合适的机制来实现自动探测柱床，保证整个装柱过程中不需要人工判断，确保柱效的可重复性，同时也能避免柱床探测错误带来的过压缩。  客户输入压缩比后，层析柱可自动压缩至所需高度/体积。  The column should have mechanism of auto-detecting the bed height to avoid the errors caused by manual judgement of bed height detecting.  After the customer enters the compression ratio, the column can be automatically compressed to the required height/volume. | 质量  Quality |
|  | 装卸填料时柱头可以与柱管分离，易于装卸填料和清洗柱管。  筛板应方便拆卸，易于维护/更换。  When loading and unloading packing column head can be separated from the column tube, easy loading and unloading packing and cleaning column tube.  The screen plate should be easy to disassemble and easy to maintain/replace. | 质量  Quality |
|  | 柱子进出口尺寸：柱子进出口是1.5”，供应商可根据具体流量要求核算选择合适的进出口尺寸。  The inlet and outlet size of the column: the inlet size of the column is 1.5 ". The supplier can select the appropriate inlet and outlet size according to the specific flow requirements. | 质量  Quality |

* + 1. 全自动装柱工作站 Automatic packing system

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 全自动设计，有灵活装柱程序方法的可编辑功能，可以通过自动程序完成装柱、卸柱。  Automated design with intelligent packing and unpacking wizard. | 质量  Quality |
|  | 装柱方法要求：装柱工作站可编辑、保存不同层析介质的装柱方法。  Packing System can edit and save different packing methods. | 质量  Quality |
|  | 装柱控件模式：向导模式，并在装柱工作站显示所需操作的步骤以及图像显示操作的部件。  Packing procedure shall be guided with wizard and show the current step with image during packing. | 质量  Quality |
|  | 柱效测定：可配合全自动层析系统完成柱效的自动检测及计算。  Column effiency test can be performed with purification systems. | 质量  Quality |
|  | 需能够显示安全报警（例如：高、低压，高温，泵过载）。  Be able to display safety alarms (e.g. high, low pressure, high temperature, pump overload). | 质量  Quality |
|  | 全自动装柱工作站可适用不同层析介质完成设置压缩比。根据不同的填料、不同的压缩比，可实现自动装柱。  Packing System is compatible with different media. According to different packing and compression ratio, automatic column loading can be realized. | 质量  Quality |
|  | 全自动装柱工作站可适用于层析柱柱高度：100mm-600mm；直径：1200mm-2000mm。  Packing System is compatible with different columns height (100-600mm)；Diameter: 1200 mm - 2000 mm. | 质量  Quality |
|  | 界面：全自动装柱工作站具有人机对话操作界面系统，包括装柱、卸柱以及层析柱维护。有向导以及图像显示操作位置便于操作。  Packing System should have touch-screen interface and incorporate packing and unpacking wizard, also maintenance wizard. | 质量  Quality |
|  | 装柱工作站同时配备压力传感器，能够实时装柱过程中监控层析柱内的压力变化。压力检测范围-0.5 - 4 bar，精度±0.1 bar。  Have a pressure transmitter to pause packing procedure during overpressure or vacuum. Pressure transmitter range: -0.5 - 4 bar and accuracy ±0.1 bar. | 质量  Quality |
|  | 紧急停机：应具有紧急停机按钮，且可以让操作者在正常的操作位置触摸到。  Emergency stop button easy to touch. | 质量  Quality |
|  | 电磁干扰和无线电波干扰：装柱工作站应抗电磁干扰和无线电波干扰。应符合CE认证电磁干扰和排放的要求。  Electromagnetic interference and radio wave interference: the column mount station should resist electromagnetic interference and radio wave interference.  Comply with CE - certified emi and emission requirements. | 质量  Quality |

* + 1. 匀浆罐 Slurry tank

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 匀浆罐容积2000L，采用抬升式机械搅拌  Slurry tank volume is 2000L, machinal agitator need to be equipped. | 质量  Quality |
|  | 匀浆罐均应配有带灯视镜、爆破片、罐体压力传感器、隔膜压力表、呼吸器、人孔/手孔、罐体温度探头、罐底阀等必要部件。  The process tanks shall be equipped with light mirror, rupture disk, tank pressure sensor, diaphragm pressure gauge, air filter, manhole / hand hole, tank temperature probe, and tank bottom valve and other necessary parts. | 质量  Quality |
|  | 爆破片的规格应与容器尺寸相适应，并配有信号反馈。  Specification of rupture disk shall be suitable to vessel size and equipped with signal feedback. | 质量  Quality |
|  | 机械搅拌可调速，可显示实际转速，同时CIP过程中100%覆盖，无清洁死角。  The magnetic stirring and mechanical stirring can adjust the speed, display the actual speed, and have the self-cleaning function. It shall be covered 100% in CIP process without cleaning dead angle. | 质量  Quality |
|  | 供应商需要结合搅拌桨叶的清洗要求设置喷淋球的位置和数量，罐体/管道清洁无死角。喷淋球为固定式，清洗压力在1.5~2 bar范围内。  The system supplier shall set the position and number of spray balls according to the cleaning requirements of the stirring blades, and the tank / pipeline shall be clean without dead angle. The spray ball is fix-type. The clean pressure is within 1.5~2 bar. | 质量  Quality |
|  | 匀浆罐至少同时具有液位探测报警、压力报警、换液功能。  The homogenizer at least equipped has the functions of liquid level detection and alarm, pressure alarm, liquid change and linkage with the column loading station. | 质量  Quality |
|  | 匀浆罐筛板孔径为10μm。筛板要易于拆卸更换。罐底筛板优先考虑整块底部筛板。  The sieve plate diameter of homogenizer is 10μm. The sieve plate should be easily removed and replaced. The bottom sieve plate of the pot gives priority to the whole bottom sieve plate. | 质量  Quality |
|  | 匀浆罐罐底阀设计要求无混匀死角，排放无残留填料。  The design of the bottom valve of homogenizing tank requires no mixing dead Angle and discharge of residual packing. | 质量  Quality |
|  | 匀浆罐需具备满载可移动功能。  The homogenizer shall be movable when it’s fully loaded. | 商业  Business |

* + 1. 阀门、排水 Valves/draining

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 关键部位阀门需配置单反馈装置，使用感应式反馈装置，反馈装置需要配置LED灯。反馈装置和阀门应采用同一品牌。没有反馈装置的阀门需要配置可视化装置用于现场观察阀门状态。  Valves at key parts shall be equipped with single feedback device, and it should use inductive feedback unit. The feedback device needs to be equipped with LED lights. Feedback device and valves should use the same brand. And the valves without feedback device need to be equipped with visualization device to observe the valve status on site. | 质量  Quality |
|  | 与物料和洁净介质接触的阀门采用隔膜阀，隔膜阀的安装角度须与隔膜阀供应商的要求一致，膜片材质应采用EPDM/PTFE双膜片，材质符合FDA和NMPA的要求，附相关材质证书；  Valves in contact with materials and clean utility are diaphragm valves. The installation angle of diaphragm valves should be in accordance with the requirements of valves suppliers. The diaphragm materials should be EPDM/PTFE double diaphragm, the material should meet the requirements of FDA and NMPA, and the relevant material certificate should be attached. | 质量  Quality |
|  | 所有与物料和洁净介质接触的阀门须提供与阀体相对应的材质证明。  All valves in contact with materials and clean utility should be provided with material certification corresponding to the valve body. | 质量  Quality |
|  | 所有与物料、纯蒸汽或清洗用水接触的隔膜阀采用锻造隔膜阀；采用其他形式阀门须经过业主同意。  Forged diaphragm valves should be equipped in contact with product, pure steam or cleaning water; If other forms of valves are used, they must be approved by the owner. | 质量  Quality |
|  | 所有与产品和物料接触的阀门金属材质均应最低为AISI 316L不锈钢，电抛光粗糙度不大于0.4μm，并钝化处理。  All metal in contact with product and buffer shall be stainless steel AISI 316L as a minimum, electro polishing to a roughness of less than 0.4 um and passivation treatment. | 质量  Quality |

* + 1. 仪表 Instruments

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 仪器仪表应提供由第三方校验机构出具的检验合格证。检验有效期需覆盖至PQ完成。  Certificates for instruments issued by third-party verification agency should be provided. The validity period of instruments should be covered until PQ is completed. | 商业  Business |
|  | 温度传感器优先采用卫生型卡箍连接，与介质直接接触的部分采用316L材质，带4-20mA或RTD信号输出。若采用其他连接形式须经过业主同意。  The sanitary tri-clamp connection is preferred for the temperature sensor, and the part in direct contact with the medium is made of 316L, with 4-20mA signal output or RTD signal output. Any other connection forms shall be approved by the owner. | 质量  Quality |
|  | 系统应配备探头/传感器，监测以下内容，包括但不限于：  The system shall be equipped with probes/sensors to monitor the following, including but not limited to:   * 压力传感器 Pressure sensor | 质量  Quality |
|  | 管路中的压力仪表及模拟输入信号的校准和自行调节功能需可在就地控制单元上进行操作。  The calibration and self-adjusting functions of the pressure instruments and analog input signals in the pipeline need to be operable on the local control unit. | 商业  Business |
|  | 过压保护。  Overpressure protection. | EHS |
|  | 装柱工作站同时配备压力传感器，能够实时装柱过程中监控层析柱内的压力变化。压力检测范围-0.5 - 4 bar，精度±0.1 bar。  Have a pressure transmitter to pause packing procedure during overpressure or vacuum. Pressure transmitter range: -0.5 - 4 bar and accuracy ±0.1 bar. | 质量  Quality |

* 1. 机械要求Mechanical Requirement
     1. 材质及表面处理 Material & Surface Finish

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 所有与产品和溶液接触的金属材质均应为不锈钢SS316L，内表面电抛光至粗糙度不大于0.4μm并钝化处理；  All metal in contact with product or buffer shall be stainless steel SS 316L. The inner surface should be electropolished to a roughness of no more than 0.4 μm and passivated. | 质量  Quality |
|  | 筛板要求耐压耐用，材质为316 L不锈钢，方便更换。  The screen plate is required to be pressure-resistant and durable. The material is 316 L stainless steel. | 质量  Quality |
|  | 压力探头应采用316L不锈钢，Ra ≤0.4 μm。  Pressure contact should be made of 316L stainless steel, Ra ≤0.4 μm. | 质量  Quality |
|  | 层析柱管材质为硼化玻璃或亚克力，有刻度显示。不易因碰撞损伤。  Chromatographic column tube material is boride glass or acrylic, with scale display.  Not susceptible to collision damage. | 质量  Quality |
|  | 所有不接触产品及所有介质的金属材质均应为不锈钢SS304材质（包括所有支腿、框架、外罩、取样口和钢平台等），表面无毛刺。  All metal materials which is not touch the product and all media should be stainless steel SS304 (including all legs, frames, enclosures, sampling ports and steel platforms, etc.) without burrs on the surface. | 质量  Quality |
|  | 设备外表面应易于清洁。不允许出现尖角、锐边、突出物等导致设备难以清洁或清洁用具破损的异常状况。  Equipment external surface shall be easy to clean. No sharp corners, sharp edges or protrusions are allowed, which leads to some abnormal situation, such as difficult to thoroughly clean or easy to break the cleaning tools. | 商业  Business |
|  | 与产品接触的非金属材质（如软管、波纹管、垫圈）表面应符合FDA和NMPA的要求，并提供材质证明（FDA或USP ClassVI）。  The surface of non-metallic materials (such as hoses, bellows, washers) in contact with the product shall meet FDA and NMPA requirements and provide material certification (FDA or USP ClassVI). | 质量  Quality |
|  | 与产品接触或洁净室内的表面不允许进行表面喷涂（电机外壳除外）。  There shall be no painted surfaces local to product or in cleanroom (except motor housing). | 质量  Quality |
|  | 所有设备与产品接触的不锈钢原材料均须追溯至炉批号。  Raw material traceability must be maintained for all materials of construction used to manufacture the equipment. | 质量  Quality |
|  | 制造材料不得释放颗粒物（不脱落、无添加、不反应、不会因清洗或湿热灭菌而降解）。  Materials of construction shall not release particles. (MOC’s shall be non-shedding, non-additive, non-reactive and will not degrade due to cleaning or autoclaving). | 质量  Quality |
|  | 所有需高温灭菌的设备/部件材质应能够耐受135℃高温，持续时间至少30分钟。  All equipment/components requiring high temperature sterilization should be material to withstand temperatures up to 135°C for at least 30 minutes. | 质量  Quality |
|  | 非产品接触的表面应能经受消毒剂The surface of non-product contact parts shall be resistant to the sanitizing agents:  - 30%的双氧水 30% H2O2  - 70%酒精 70% alcohol  - 4.5%的过氧乙酸4.5% peracetic acid  - 杀孢子剂 Sporicide  - 甲醛 Formaldehyde  - 异丙醇 IPA | 商业  Business |
|  | 所有运动部件均应经过润滑。有润滑的设备需保证润滑剂不会泄漏到工艺系统和公用工程中也不会泄漏到洁净室环境中。  All moving parts shall be lubricated. The design of the lubrication equipment shall ensure that the lubricant cannot leak into the process, direct utilities or into the cGMP area. | 商业  Business |
|  | 如使用润滑剂，应使用易于清洗的食品级润滑剂。供应商应提供所有润滑剂的相关证明文件。  Food grade lubricants that are easy to clean using WFI, shall be used for all locations where mechanical failure of lubricant seals would allow the lubricant to leak into areas where it may come into contact with the vials. The Vendor shall provide supporting documentation for each lubricant. | 质量  Quality |

* + 1. 焊接要求 Welding

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 所有洁净管路应尽可能采用符合现行ASME BPE要求的自动焊接。  All clean tubing will be orbital welded as per requirement of current ASME BPE. | 质量  Quality |
|  | 所有的人工焊接，包括焊工和焊接信息均应记录在供应商焊接记录中。  All manual welding, including welder and welding information, should be recorded in the supplier's welding record. | 质量  Quality |
|  | 所有焊缝均应正确标识，标识号应刻印在管道上且与文件中的记录保持一致。  All weld beams shall be correctly tagged and tag number shall be permanently marked on pipe in correspondence with that in documents. | 质量  Quality |
|  | 供应商应根据交付文件列表中的要求交付焊接相关文件。  Supplier shall deliver the welding documents according to the requirements of the delivery documents list. | 质量  Quality |
|  | 洁净管道需充氩保护焊接，避免内部氧化，接用惰性保护气体纯度必须达到99.999%，需要提供正式的报告。  Hygienic pipes need to be filled with argon protection welding to avoid internal oxidation, and the purity of the inert shielding gas used must reach 99.999%, and an official report needs to be provided. | 质量  Quality |
|  | 自动焊接和手动焊接都必需提供焊接工艺评定。  WPS must be provided for both automatic and manual welding. | 质量  Quality |
|  | 焊样留取的要求：   1. 焊样应保留原色，不得处理。 2. 在更换参数时必需提供焊样。（管道尺寸或焊接参数） 3. 焊样必需是对焊，不得假焊。 4. 焊样的记录必需递交，并对每个焊样进行编号。   焊样应作为竣工资料的一部分保存备查，不得丢弃。  Requirements for the retention of weld samples.   1. The weld sample shall be retained in its original color and shall not be processed. 2. Weld samples must be provided when changing parameters. (pipe size or welding parameters) 3. welding samples must be butt weld, no false welding. 4. Records of weld samples must be submitted and each weld sample must be numbered.   Weld samples shall be kept as part of the as-built data and shall not be discarded. | 质量  Quality |
|  | 内窥镜摄像要求：   1. 须为实时彩色摄像片段，提供照片，且必需刻制成光盘。 2. 必须显示完整的焊道。 3. 必须可以看到氧化区的颜色。   Borescope video requirements.   1. Must be a live color video clip, supply photos and must be burned to CD. 2. The complete weld path must be visible. 3. The color of the oxide area must be visible. | 质量  Quality |
|  | 焊点验收：   1. 所有焊接质量应至少应达氧含量小于100 ppm，目测内表面显淡黄色。 2. 所有手动氩弧焊必需100%做彩色内窥镜检测，并留有记录。 3. 所有自动氩弧焊，最少随机抽取焊缝总量的20%要做彩色内窥镜摄影，并留有记录。 4. 焊接标准应参照现行版ASME BPE的标准。   焊接位置应该在焊接图上有文件记录可以追溯到焊缝施工人员，焊接记录上要有焊接两侧的材料的炉号。  Welded joint acceptance:   1. All welding quality should be at least up to oxygen content less than 100 ppm, visual inspection of the inner surface shows light yellow. 2. All manual argon arc welding must do 100% color borescope inspection and keep records. 3. All automatic argon arc welding, at least 20% of the total number of randomly selected welds to do color borescope video, and keep records. 4. Welding standards should refer to the current version of the ASME BPE standards.   Welding position should be documented on the welding diagram and can be traced back to the welder, welding log should indicate the heat number of the material on both sides of the weld. | 质量  Quality |

* 1. 自控系统-硬件部分 Control system – Hardware part
     1. 操作面板 Operation Panel

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 装柱站和匀浆罐配置一套PLC控制系统，安装于匀浆罐模块上，不在单独配置装柱操作站，层析柱信号采用航空快接头接入控制系统电控柜。在匀浆罐CIP过程时，由于未接入层析柱信号，系统配置自动屏蔽该部分信号报警功能。  The PLC control system is configured for the chromatography column loading station and the slurry tank, which is installed on the module of the slurry tank. The chromatography column loading operation station is not configured separately, and the chromatography column signal is connected to the electric control cabinet of the control system by the aviation quick connector. In the CIP process of slurry tank, the system is equipped with automatic shielding function of this part of signal alarm because no chromatography column signal is connected. | 质量  Quality |
|  | 现场控制模块应采用图形界面带彩屏显示，带触摸屏功能。操作面板不小于14”。  The local control module shall have a graphical user interface with color display and touch screen display. Operating panel shall be not less than 14". | 商务  Commerce |
|  | 操作面板附近应配置声光报警器。  Combined aural and visual alarm should be included and be located near the operator panel. | 质量  Quality |
|  | 全自动装柱站控制电脑可实现所有生产和操作数据的显示、生产配方的存储和调用、生产参数和生产追溯记录等，且不会影响正在运行的程序。  The control PC displays all production and operation data, store and invoke production formula, record production parameters and production traceability, etc., and does not affect the running program. | 质量  Quality |
|  | 自控系统预留至少10% 的PLC输入/输出接点。  The automatic control system reserves at least 10% of PLC input/output contacts. | 商业  Business |
|  | 在合适的位置安装操作面板，面板采用图形界面。操作面板可实现所有生产和操作数据的显示、生产配方的存储和调用、生产参数和生产追溯记录等，且不会影响正在运行的程序。  Install the operation panel in the right place, and the panel adopts the graphical interface. The operation panel can display all production and operation data, store and invoke production formula, record production parameters and production traceability, etc., and does not affect the running program. | 商业  Business |
|  | 电控柜面板的设计和安装需符合所在区域的环境级别要求。面板的设计和安装应符合当地标准或IEC等效条款。  The design and installation of the electronic control cabinet panel shall meet the specified area classification. Design and construction of panels shall be in accordance with Local Standards or IEC equivalent code. | 商业  Business |
|  | 若无特殊说明，所有电控柜和面板应为IP54或更佳；  Unless otherwise specified all electrical cabinets and panels shall be IP54 or better. | EHS |

* + 1. 电缆和接线 Cables and wiring

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 电控柜内电线整齐一致，线号朝正面，柜内无杂物，线槽内走线整齐，扎带头剪掉，线槽盖盖好。  The wires in the electric control cabinet are neat and tidy, the wire number is facing the front, there is no debris in the cabinet, the wiring is neat in the cable trough, the cable tie head is cut off, and the cable trough cover is covered. | 商业  Business |
|  | 系统内所有的信号电缆要求为阻燃屏蔽或以上线缆，4~20mA线径≥1.0 mm2。  The signal cable within system shall be anti-flaming and shield cable, the cable diameter shall be more than 1.0 mm2. | 商业  Business |
|  | 每个接线端子接线不得超过2根，接线牢固。  Each wiring terminal must not have more than 2 wires, and the wiring is firm. | 商业  Business |
|  | 电气标识要清楚、可靠，和电气原理图一致。  The electrical marking should be clear, reliable, and consistent with the electrical schematic. | 商业  Business |
|  | 匀浆罐控制系统内部或与外部设备信号电缆进线及气管应采用电控柜底部进线方式。  The signal cables inside the slurry tank control system or between external devices and the gas pipe should be fed into the bottom of the electric control cabinet. | 质量  Quality |
|  | 匀浆罐控制系统电控柜至PCS系统夹层分支桥架线槽穿线管由在线系统供应商负责完成安装，从并完成匀浆罐系统侧线缆接线。  The wiring pipe between the electric control cabinet of the slurry control system and the bridge cable trough of the sandwich branch of the PCS system shall be installed by the supplier of the inline conditioning system, and the cable connection from the side of the slurry control system shall be completed. | 商业  Business |

* 1. 自控系统-软件部分 Control system – Software part
     1. 数据记录Data records

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 所有的报警、设备启停、设备运行参数的变更和事件信息都应被记录。  All alarms, machine start-up and shut-down, changes in machine operating parameters setting and events information shall be recorded. | 质量  Quality |
|  | 匀浆罐系统需配置柱效分析软件，完成柱效分析、生产分析报告并记录结果。  The slurry tank system should be equipped with column efficiency analysis software to complete column efficiency analysis, production analysis report and record the results. | 质量  Quality |
|  | 在完成一个批次的生产后，需要自动生成一个批报告  The system must be able to create a batch report after each batch production is completed. | 质量  Quality |
|  | 批报告至少包括以下内容The batch report must at least contain the following information:   * 所有的关键程序参数 All critical recipe values * 所有的关键执行参数 All critical executed values * 参与执行的操作人员 Operators involved in implementation * 所有的事件 All events * 所有的监控统计汇总 Summary of all monitoring statistics * 所有的报警 All alarms   批报告的具体形式将由供应商提供，由业主确认。  The form of the batch report will be provided by the supplier and confirmed by the owner | 质量  Quality |
|  | 数据可以打印，或上传至中央服务器。  Data can be printed or uploaded to central server. | 商业  Business |
|  | 实时数据采集频率：至少每秒一次。数据打印频率：至少每分钟一次。系统至少可存储一年生产数据。  Real-time data acquisition frequency: at least once per second. Printing data frequency: at least once per minute. The system can store production data for at least one year. | 商业  Business |

* + 1. 网络要求Network

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 控制系统需为如下网络需配备独立的网口并设置独立的网段：   * 控制系统的内部控制网络； * 用于与第三方系统（如MES、SCADA）通讯的网络。 * 用于NTP时钟同步的网络.   The following network shall be equipped with dedicated Ethernet port and shall be configured with isolated network segments:   * Control network of control system. * The network for communication with 3rd party system (such as MES, SCADA).   The network for NTP synchronization. | 质量  Quality |
|  | 控制系统需支持OPC UA通讯协议，控制系统作为OPC UA服务器将设备的关键工艺参数及报警通讯至第三方系统（例如MES、SCADA）。层析柱供应商需提供详细的通讯IO表，IO表中必须包含参数位号、数据地址、参数描述、量程、单位、小数点位数以及批号、批次状态等与生产批次相关的信息。控制系统需为OPC UA通讯网络配置独立的网络接口，IP地址可由用户自定义。OPC UA的RJ45接口需安装在装柱站及匀浆罐的控制柜上，并配备保护套。供应商需完成在DCS系统完成匀浆罐系统的数据采集相关设计工作。  The control system shall have support OPC UA communication protocol. The control system, which shall be OPC UA server, communicate the critical process parameter and alarm to 3rd party system(such as MES、SCADA). The chromatography column supplier shall provide the communication IO list, in which the tag, data address, parameter description, scale, unit, decimal point and batch ID, batch status shall be listed. A dedicated Ethernet port shall be equipped for OPC UA, and the IP address can be defined by customer. The RJ45 port with protective jacket of OPC UA shall be installed on the control cabinet. The supplier shall complete the design work related to data acquisition of the homogenate tank system in the DCS system. | 质量  Quality |
|  | 控制系统需支持NTP协议，实现控制系统内部时钟服务器与工厂主时钟服务器的时间同步功能。装柱站及匀浆罐内部触摸屏、PLC控制器、计算机等设备均需与其内部时钟服务器时间同步。控制系统需为NTP网络配置独立的网络接口，IP地址可由用户自定义。NTP的RJ45接口需安装在装柱站及匀浆罐的控制柜上，并配备保护套。  The control system shall support NTP protocol, which is used to synchronize the time of chromatography to the time of plant master time server. The HMI，PLC controller and computer, which belong to the control system of column installation station and slurry tank respectively, shall synchronize their time to the mater time server of column installation station and slurry tank. A dedicated Ethernet port shall be equipped for NTP, and the IP address can be defined by customer. The RJ45 port with protective jacket of NTP shall be installed on the control cabinet. | 质量  Quality |
|  | 控制系统需支持Profibus DP通讯，用于与PCS进行数据交互通讯以实现工艺过程控制。控制系统作为DP从站，PCS作为DP主站。层析柱供应商需提供Profibus DP通讯IO表、GSD文件、信号交互的逻辑图。通讯IO表中必须包含参数位号、数据地址、参数描述、量程、单位、小数点位数等信息。层析柱供应商需为匀浆罐提供两对M12 DP接头，其中1公1母接头安装在控制柜上，另外1公1母接头用于外部线缆连接。  The control system shall support Profibus DP protocol, which is used for communication with PCS for process control. The control system shall be DP slave and PCS shall be DP Master. The chromatography column supplier shall provide the communication IO list, GSD file and logic flow chart for data communication. The communication IO list shall list the data tag, data address, parameter description, scale, unit, decimal point, etc. information. The chromatography column supplier shall support two pairs of M12 DP connector for slurry tank. One male connector and one female connector shall be installed on the control cabinet, and another fame and female connector will be used for connecting DP cable from PCS. | 质量  Quality |

* + 1. 系统界面 System interface

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 人机界面采用中英文双语。  The HMI language shall be preferable in bilingual. | 商业  Business |
|  | 系统应配置至少2种运行模式：  The system is able to work in three function modes at least:   * 手动模式Manual Mode * 自动模式Automatic Mode * 维护模式 Maintenance Mode | 商业  Business |
|  | PLC直接控制所有系统功能。根据存储器中预存的数据和程序运行系统。  The PLC directly controls all the system functions. According to the data acquired and the loaded program in its memory, it activates the outputs to properly operate the systems | 商业  Business |
|  | 上位机软件必须允许: Upper computer software must be allowed:  - 使用用户名和密码进行用户登录User logon with username and password.  - 设置不同的用户访问等级 Different user level of access.  - 批次生产过程中对配方进行编辑和保存Recipe editing/saving after batch start.  - 查看和确认报警 Viewing and acknowledgment of alarms.  - 操作人员对事件进行确认以及文本输入User answer to events, text input  - 查看趋势图 Visualization of trends.  - 操作模式的切换（自动、维护、手动模式） Changing modes of operation (auto, maintenance, manual).  - 执行下载 Initiation of Download | 商业  Business |
|  | 操作者应能在系统操作界面上输入或直接显示以下信息：  The machine control system shall prompt the operator to enter or display the following alphanumeric data:   * 操作者名称Operator identity * 产品名称或项目号Product name or project number * 批号Batch number * 日期 Date   以上信息应作为保存的批生产记录的开头。  The above information shall be saved at the beginning of the batch record. | 质量  Quality |
|  | 参数查看和历史数据查阅应不会干扰或暂停当前设备运行。  Parameter viewing and historical data access should not interfere with or suspend device operation. | 商业  Business |
|  | 屏幕显示的参数单位应是公制标准单位。  Display parameter units shall be metric standard units. | 商业  Business |
|  | 全自动设计，有灵活装柱程序方法的可编辑功能，可以通过自动程序完成装柱、卸柱。  Automated design with intelligent packing and unpacking wizard. | 质量  Quality |
|  | 装柱方法要求：装柱工作站可编辑、保存不同层析介质的装柱方法。  Packing System can edit and save different packing methods. | 质量  Quality |
|  | 装柱控件模式：向导模式，并在装柱工作站显示所需操作的步骤以及图像显示操作的部件。  Packing procedure shall be guided with wizard and show the current step with image during packing. | 质量  Quality |
|  | 柱效测定：可配合全自动层析系统完成柱效的自动检测及计算。  Column effiency test can be performed with purification systems. | 质量  Quality |
|  | 需能够显示安全报警（例如：高、低压，高温，泵过载）。  Be able to display safety alarms (e.g. high, low pressure, high temperature, pump overload). | 质量  Quality |
|  | 全自动装柱工作站可适用不同层析介质完成设置压缩比。根据不同的填料、不同的压缩比，可实现自动装柱。  Packing System is compatible with different media. According to different packing and compression ratio, automatic column loading can be realized. | 质量  Quality |
|  | 全自动装柱工作站可适用于层析柱柱高度：100mm-600mm；直径：1200mm-2000mm。  Packing System is compatible with different columns height (100-600mm)；Diameter: 1200 mm - 2000 mm. | 质量  Quality |
|  | 界面：全自动装柱工作站具有人机对话操作界面系统，包括装柱、卸柱以及层析柱维护。有向导以及图像显示操作位置便于操作。  Packing System should have touch-screen interface and incorporate packing and unpacking wizard, also maintenance wizard. | 质量  Quality |

* + 1. 数据管理要求 Data Management

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 作为审计追踪的一部分，所有关键操作、报警和参数设置均应被记录（包括时间、操作人员、操作内容、原设定值、现设定值等）。  As part of the audit trail, all crucial operations, alarm and parameter settings should be recorded (including time, operator, operation content, original set value, current set value, etc.). | 质量  Quality |
|  | 审计追踪记录不能被修改、删除，审计追踪功能不能被关闭。  Audit trail records cannot be modified or deleted, and audit trail function cannot be closed. | 质量  Quality |
|  | 所有生成的记录无法被修改，批记录导出的文件格式应是不可修改的。  All the records cannot be modified, and the file format of the exported records should be non- modifiable type. | 质量  Quality |
|  | 设备应能够备份和灾难恢复。  The equipment shall be capable of backup and disaster recovery. | 质量  Quality |
|  | 供应商提供系统数据存储容量及数据转移方式的建议；  The supplier provides suggestions on system data storage capacity and data transfer mode. | 商务  Commerce |
|  | 需有电子签名功能。  Electronic signature functions should be included. | 质量  Quality |

* + 1. 计算机化系统安全要求 Computerized System Safety

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 控制系统设计应采用GAMP或相应欧盟标准中定义的方法和程序进行编程。所有系统均应满足FDA 21CFR Part 11的要求。  The control system design shall be organized and programmed utilizing the methods and procedures defined in the Good Automated Manufacturing Practice (GAMP) document or equivalent European standard. All systems shall meet the FDA requirements as specified in the FDA document 21CFR Part 11. | 质量  Quality |
|  | 软件的开发应遵从质量计划（例如ISO9000-3）。  Software is to be developed in accordance with a quality plan (e.g. ISO 9000-3). | 质量  Quality |
|  | 供应商应确保所有的控制组件的兼容性，在正常运行的情况下不会引起系统故障。  The vendor shall ensure that all control equipment is compatible and will not cause system failure during its normal operation. | 商务  Commerce |

* + 1. 权限要求 Security

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 操作人员可设置专用的账户，并通过账户和密码登录系统。系统账户设置数量不少于99个。  The operator can set up a special account and login the system through the account and password. The number of system accounts is not less than 99 | 质量  Quality |
|  | 密码有效期90天（或者可配置），第一次登录时强制用户修改或者重置密码，基于密码有效期自动提醒用户修改密码，最短密码长度8位字符，至少包括大写字母、小写字母、数字及特殊字符其中的三种，当输入密码时系统不允许显示或者打印密码，系统不允许存储或者转移密码。  Password is valid for 90 days (or configurable), login for the first time force the user to change or reset the password, the password based validity automatically reminds the user to change password, minimum password length of eight characters, including at least uppercase and lowercase letters, numbers and special characters of the three, when the input password system are not allowed to display or print the password, system does not allow storage or transfer the password. | 质量  Quality |
|  | 密码应采用不固定的期限有效期；  The password shall be valid for an unset period of time. | 质量  Quality |
|  | 在一定次数的失败登录尝试之后系统能够锁定该账户，只有授权的用户才能解锁用户账户。  After a certain number of failed login attempts, the system can lock the account, and only authorized users can unlock the user account. | 质量  Quality |
|  | 日期和时间应被保护，未经授权的人不得修改。  The date and time should be protected from unauthorized modification. | 质量  Quality |
|  | 系统权限至少分为以下5级：The system permissions should at least 5 levels:   * 系统管理员，有操作系统的权限，但不可具有操作的权限，防止使用最高权限操作时，误操作。应有备份权限。 Administrator, operating system permissions, but can not have the right to operate, to prevent the use of the highest authority operation, disoperation. There should be backup privileges. * 主管，能修改系统配方或工艺参数。 Supervisor, can modify recipe or process parameters * 维护人员，可执行仪表的校准、设备维护、组件动作控制。 Maintenance, calibration of instruments, equipment maintenance and action control. * 操作员，可调用配方，读取数据，查阅记录。 operator, recipes calling, data reading and records checking. * 访客，仅可观察。 visitor, only observable. | 质量  Quality |
|  | 供应商提供详细的权限分级，由业主确认。  The detailed security list should be provided by the vendor and approved by client. | 商务  Commerce |
|  | 不同组别的账户，系统界面功能相应有所不同。  The accounts of different groups have different interfaces function. | 商业  Business |
|  | 业主具有设施、设备、仪器或系统所附带的软件的永久使用权。  The Owner has the permanent right to use the software attached to the facilities, equipment, instruments or systems. | 商务  Commerce |

* + 1. 故障和报警 Fault/alarm

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 故障和报警应有声光报警指示。  Fault and alarm should be able to trigger audible and visual alarm. | 质量  Quality |
|  | 以下情况应设为最基本的关键报警并能够导致层析柱停机。停机的原因应被记录并在操作面板上有报警信息：  As a minimum, the following events are regarded as ‘critical’ and shall trigger the ultrafiltration system to stop. The reason for the stop shall be recorded and displayed alarm on the operator panel:  - 设定压力超标 Out of specification pressure set points | 质量  Quality |
|  | 一旦电源故障，UPS应自动启动为PLC、图表记录器、传感器等供电。  UPS shall be auto-started to supply energy to the PLC, chart recorder, sensors, etc. once the power failure | 质量  Quality |
|  | 至少应在每个单独房间的操作面板上设置一个蘑菇型、带保护的紧急停止按钮。紧急停止按钮可以切断所有控制动作的接触器的电源。  Provide at least one mushroom-type, latching, emergency-stop buttons on the panel which is set in each individual room. The emergency stop removes power from all contactors, which control stored kinetic energy and potential energy.  紧急停止状态下数据记录功能仍然保持运行。  The Data recording function shall be maintained in that status.  急停按钮复原后，需人工确认后，设备方能进入运行状态。  After the emergency stop button is restored, the device can enter the running state only after manually confirmation. | 质量  Quality |
|  | 应对所有报警进行分类，不同类别的报警有不同的提示形式和对应动作。供应商提供报警分类列表，由业主确认。  All alarms should be classified. Different types of alarms have different prompting forms and corresponding actions. The supplier provides the alarm classification list and is confirmed by the owner. | 质量  Quality |
|  | 报警的设定值应可以调整。  Alarm set points shall be adjustable. | 质量  Quality |
|  | 系统应有日志文件追踪所有报警，以便在偏差调查或设备维护时进行分析。日志数据必须无法修改且能够导出或复制供离线分析。(可包含在审计追踪列表中)  A log file shall keep track of all alarms in order to do an analysis in case of investigations or maintenance. The log data must be unmodifiable and be able to be exported or copied for offline analysis.（can be included in the audit trail） | 质量  Quality |

* 1. 安全要求 Safety Requirement

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 设备应贴有统一的设备铭牌，铭牌上应注明名称、产地、出厂日期、型号、重量及其他重要技术参数。  The equipment should be attached with a unified nameplate. The equipment name, origin, date of manufacture, type, weight and other important technical parameters should be specified on the nameplate. | 商业  Business |
|  | 如果设备功能失调或失控的情况下，应该按照以下优先级别保护:人员→设备→产品  If the device is out of control or functioning, it should be protected according to the following priority: personnel > equipment > products. | EHS |
|  | 软件系统如果有可替换的高版本操作系统，厂家须提供升级服务，升级后满足工艺和使用要求。  If there is a replacement version of the operating system, the manufacturer must provide upgrade services, upgrade to meet the requirements of the process and use. | 商务  Commerce |
|  | 控制系统应与公用工程互锁，以防止在公用工程不足时运行程序。  The control system should be interlocked with the utility to prevent the program from running when there are insufficient utilities. | 质量  Quality |
|  | 系统突然断电时，机器逐渐停稳，以保护操作工、设备和产品。恢复供电后设备不能自动开机，必须人工启动。  When the system suddenly loses power, the machine gradually stops to protect operators, equipment and products. The equipment cannot be started automatically after power supply is restored, but must be started manually. | 质量  Quality |
|  | 设备应配置有防电涌装置。  Surge protection devices should be equipped. | EHS |
|  | 设备框架和钢平台需充分考虑人员的安全防护（如护栏、台阶宽度和防滑）。  标识和铭牌等任何部位不应有锋利的边缘和尖角。  The safety protection of personnel should be fully considered in the design of system frame and steel platform. (e.g. Guardrails, wide steps and anti-skidding).  There shall be no sharp edge and sharp angle at any part of logo, nameplate, etc. | 安全  EHS |
|  | 所有设备应满足在最大负荷和运行速度的情况下，距设备任何方向1m处的噪音不超过80dBA。  All equipment shall conform to peak noise of 80 dBA measured at 1 meter in any direction from the equipment when operating at all maximum loads and speeds. | 安全  EHS |
|  | 设备的安全阀、爆破片的出口管应导向地面，防止喷溅到人员。  The outlet pipe of the safety valves and the rupture discs of the equipment should be directed to the ground to prevent splashing to the personnel. | 安全  EHS |
|  | 供应商应在冷、热或高压工况管道，以及超重设备/部件的周边设置明显的标识和保护措施。  The supplier shall provide evident identification and protection measures in the vicinity of the cold, hot or high pressure utility pipeline and superheavy equipment/components. | 安全  EHS |
|  | 热点周边应有标识和保护措施。  Hot spots access shall be signaled and protected. | 安全  EHS |
|  | 层析柱在意外断电情况下自动进入保护状态，避免设备内部环境遭到破坏。供应商应详细说明，断电后层析柱的保护状态及持续时间。  The Column automatically enters the protection state under the condition of accidental power failure, avoiding the internal environment of the equipment being polluted. The supplier shall specify the protection state and duration time of the Column after power failure. | 安全  EHS |
|  | 电磁干扰和无线电波干扰：装柱工作站应抗电磁干扰和无线电波干扰。应符合CE认证电磁干扰和排放的要求。  Electromagnetic interference and radio wave interference: the column mount station should resist electromagnetic interference and radio wave interference.  Comply with CE - certified emi and emission requirements. | 质量  Quality |

* 1. 验证要求 Validation Requirement

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 供应商应提供一份质量计划，由业主审核批准。  The supplier shall develop a Quality Plan for owner’s review and approval. | 商务  Commerce |
|  | 供应商需要完成的质量工作须包括，但不限于：  The quality work required by the supplier shall include, but not limited to:   * 验证计划 Verification Plan * 风险评估 Risk assessment * 设计确认 DQ * 预FAT(工厂内部测试) Pre-FAT(VIT) * 工厂验收测试 FAT * 现场验收测试 SAT * 调试 Commissioning * 安装/运行确认 I/OQ * 协助性能确认 PQ assistance | 商务  Commerce |
|  | DQ工作应在设备开始制造前完成，避免DQ结果对设备制造过程造成影响。  It is recommended to complete DQ before equipment manufacturing to avoid DQ results affecting equipment manufacturing process. | 商务  Commerce |
|  | 在进行正式的工厂验收测试之前，供应商必须完成以下测试项目。测试项目的相关文件需在FAT时可以查阅。  Prior to the performance of the main Factory Acceptance test, the supplier must complete the items listed below. Documentation of these activities will be available for review at the FAT.   * 100%图纸检查(机械和电气) 100% Drawings checks (Mechanical & Electrical) * PID一致性检查 P&ID compliance check * 布局图一致性检查 GA compliance check * 制造材质确认 Material of construction verification. * 100%表面抛光度确认   100% Surface finish verification   * 坡度确认 Slope verification. * 电气检查，包括接线、终端等 Electrical verification including wiring, terminations etc. * 绝缘检查 Insulation inspection * 控制面板检查、设备盘点及实物检查 Control panel visual inspection, equipment inventory & physical checks * 标签标牌检查 All items tagged and labelled as per specification * 100%文件检查 Documentation check; all documents * 容器、管道压力测试 Pneumatic/vacuum testing of vessels & pipe works. | 商务  Commerce |
|  | 只有在所有FAT文件经业主验收关闭后设备方可打包运输以交付。  The system will only be released for delivery when all FAT documents are closed out by the owner | 商务  Commerce |
|  | 在FAT期间，须编制故障日志以及偏差/备注日志，记录每天FAT中发现的问题。  During FAT, the fault log and deviation/comment log should be compiled to record the problems found in FAT every day. | 商务  Commerce |
|  | 在FAT前，供应商应对温度、压力和流量仪表进行校准。  Primary calibration will be carried out by the Vendor, prior to FAT, on temperature, pressure and flow instruments. | 商务  Commerce |
|  | FAT测试应包括，但不限于：  The FAT tests shall include, but not be limited to, the following tests:   * 设备尺寸检查Dimensional Check * 与房顶/墙壁/地面的界面检查Interface with Ceiling / Walls / Floor * 公用工程连接位置检查 Utilities Connection Location x, y and z * PID检查 P&ID Check * 核黄素和全排放测试Riboflavin and Full Discharge Test * 坡度检查 Slopes * 排水检查 Drainability * 组件安装及方向检查 Component installation and orientation Check * 仪器仪表安装检查 Instrument Installation * 保温检查 Insulation inspection * 标签检查 Labeling inspection * 材质证书检查 Material Certificates * 焊接检查 Welding Certificates * 100%内窥镜检查 100%Endoscope Welding Shots * 焊工资质检查 Welders Certification * 压力容器报告检查 Pressure Vessel Certificates * 压力测试报告检查 Pressure Test Reports * 管道清洁报告检查 Welding and Piping Cleaning Reports * 管道钝化报告检查 Welding and Piping Passivation Reports | 商务  Commerce |
|  | FAT电气测试应包括，但不限于：  The FAT electrical tests shall include, but not be limited to, the following tests:   * 安装检查 Installation Check * 电控柜布局检查 Control Cabinets Layout * GMP关键仪器校验证书确认   Verify Calibration Certificates of GMP Critical Instruments   * GMP关键仪器回路检查及功能测试   Loop Check of GMP Critical Instruments and Functional Testing   * 接线标签和颜色检查 Labelling and color * 硬件及PLC配置检查 Hardware and PLC Configuration * SCADA PC配置检查 SCADA PC Configuration | 商务  Commerce |
|  | FAT系统功能测试应包括，但不限于：  The FAT control system functional tests shall include, but not be limited to, the following tests:   * 屏幕菜单、图形测试 Menus and Mimics Check * 100%输入输出测试 100% Input/output test * 参数/配方测试 Parameter/ recipe test * 报警测试 Alarm test * 趋势记录测试 Trend test * 权限测试 Security test * 备份/恢复测试 Back-up/ restore test * 审计追踪测试 Audit trail test | 商务  Commerce |
|  | FAT性能测试应包括，但不限于：  The FAT performance tests shall include, but not be limited to, the following tests:   * 流速测试 Flow rate test * 参数反馈调节测试 Parameter feedback adjustment test * 仪器仪表校准调节测试 Instrument calibration adjustment test * 设计功能测试 Design function test | 商务  Commerce |
|  | 工厂验收测试的内容应在现场验收测试中重复执行，但根据项目质量计划和验证计划中关于测试引用的描述，部分的测试可以引用FAT的结果或进行抽样检查。  In general FAT tests shall be repeated in SAT. According to the description of test references in Project Quality Plan and Validation Plan, part of the tests can refer to the results of FAT or be confirmed by spot check. | 商务  Commerce |
|  | SAT的方案由供应商起草，业主审核批准。  Protocols for the site acceptance test (SAT) shall be produced by the Vendor and approved by Owner. | 商务  Commerce |
|  | IQ方案由供应商起草并在IQ执行前由业主批准。IQ测试将在业主现场进行，业主将见证所有的测试执行。  IQ protocols are to be prepared by the supplier and approved by owner prior to the IQ. The supplier shall execute tests on the owner’s site and owner will witness all the tests. | 商务  Commerce |
|  | 供应商需协助业主进行PQ方案的起草和执行。  The supplier shall assist the owner in the drafting and implementation of PQ scheme. | 商务  Commerce |
|  | 调试阶段包括校准、回路调整和确保设备运行满足需求说明的所有调整。  The commissioning stage shall include calibration, loop tuning and all other adjustments required to ensure the equipment performs as specified in the Requisition. | 商务  Commerce |
|  | 供应商应对整个调试阶段负责，包括配合现场施工团队。供应商应估计完成调试所需的天数，并给出每日工作安排。  The supplier shall be responsible for the entire commissioning phase, including cooperation with the site construction team. Vendor shall estimate the number of days required to complete the commissioning and quote a daily rate for Site attendance. | 商务  Commerce |
|  | 供应商应配备足够的备件和材料以确保调试过程能够顺利完成。调试用的备件和材料应与设备一同运至业主现场。  The Vendor shall include for adequate spares and materials to ensure that the commissioning process can be successfully carried out. These shall be delivered to Site in the same shipment as the equipment. | 商务  Commerce |

* 1. 培训要求 Training

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 供应商负责所有技术指导和人员培训，包括：图纸、工艺、操作、设备维护、设备性能及问题解答等。  Supplier is responsible for all technical guidance and personnel training, including drawings, processes, operations, equipment maintenance, equipment performance and problem solving. | 商务  Commerce |
|  | 供应商应派遣经验丰富的培训师，并明确培训的内容、时间、人员等。  Suppliers should send experienced trainers and clarify the contents, time and personnel of the training. | 商务  Commerce |
|  | 提供每台设备不少于10个名额的培训，培训内容应包括设备基本原理和操作技能培训，应确保培训的系统全面。  The provision of not less than 10 training places for each equipment should include training in basic principles and operational skills of the equipment and ensure that the training system is comprehensive. | 商务  Commerce |

* 1. 维护保养 Maintenance

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 设备所有部件必须便于维护、维修和清洗。供应商应提供常规维护中必须拆卸部分的吊装点。供应商应告知设备维护中哪些部分需要提吊。  All parts of the equipment must be readily accessible for maintenance, servicing and cleaning. The Vendor shall provide lifting points for equipment that must be removed for routine maintenance. The Vendor shall advise where lifting aids are required to maintain equipment. | 商务  Commerce |
|  | 设备周围应留有足够的维护空间，开门方向应满足车间布局和维修要求；  There should be enough maintenance space around the equipment.. The opening direction should meet the layout and maintenance requirements of the workshop. | 商务  Commerce |
|  | 供应商的维护手册中应包含一个预防性修护计划，其中包含了各种维护活动的次数、频率和成本。  The Vendor’s maintenance manual shall include a preventive maintenance plan with times, frequencies and costs for each activity. | 商务  Commerce |
|  | 设备保修期自设备最终移交后算起24个月。  24 months warrant period from final hand-over of all systems in scope of work. | 商务  Commerce |
|  | 维修响应时间不超过48小时。  Maintenance response time is less than 48 hours. | 商务  Commerce |

* 1. 后期服务 Service

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 保修期内免费更换和重新安装任何因制造原因出现的问题零件。保修期外，长期提供优惠的维修服务及零部件。  During the warranty period, replace any parts found defective due to manufacture and reinstall new ones at no cost to owner.  Over the warranty period, provide long-term preferential maintenance services and spare parts. | 商务  Commerce |

* 1. 备品备件 Spares

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 提供可满足两年设备运行需要的易损零部件，以及详细的零部件清单（零件编号、数量、价格和交货期）。  Provide vulnerable parts to meet the requirements of two-year equipment operation, and a detailed list of parts (part number, quantity, price and delivery date). | 商务  Commerce |
|  | 提供必要的设备维修专用工具及相应的工具清单表。  Provide necessary special tools for equipment maintenance with tool list. | 商务  Commerce |
|  | 设备的主要部件必须进行编号且记入说明书，提供一份部件清单。同时注明主要零部件的建议更换周期。  The main parts of the equipment must be numbered in a parts list in the specification. The recommended replacement cycle for major components should be indicated in the parts list. | 商务  Commerce |

* 1. 包装运输要求 Packing and Transportation

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 设备需经过业主工作人员到供应商处进行FAT，确认合格后方能打包发货  The equipment can be packed and shipped only after the FAT is confirmed by owner’s staff. | 商务  Commerce |
|  | 货物包装的形式应考虑运输的形式和运输、装卸和储存过程中将要遇到的环境条件。  The type of packing to be used shall be selected with due regard to the chosen shipping media to be used and the environmental conditions to be encountered during shipping, handling and storage. | 商务  Commerce |
|  | 设备在运输至现场的过程中应受到足够的保护，所有松动的部件都应装箱或装袋。  Equipment shall be adequately protected during shipping to site. All loose parts shall be adequately boxed crated or bagged. | 商务  Commerce |
|  | 类似螺栓、螺母垫圈、垫片、封隔器等设备小部件应保存在防水无尘的容器中。  Small items such as bolts, nuts washers, shims, packers and small items of equipment shall be provided in waterproof grit free containers. | 商务  Commerce |
|  | 所有旋转设备，如电机、风扇等，其中活动的部件可能由于运输震动而损坏，必须根据制造商的建议进行保护。  All rotating equipment such as motors, fans etc., in which moving parts could be damaged due to shipping vibration must be secured per the manufacturer’s recommendations. | 商务  Commerce |
|  | 管道、软管及其他敞口部件都应封口，防止湿气、灰尘和其他可能污染工艺流体任何外来物质的侵入。与工艺流体接触的管件和设备应装袋并标记防止与湿气和灰尘接触。  Pipe, tubing and all openings shall be end capped to prevent the ingress of moisture, dust and any foreign matter that may contaminate the process fluid. Pipe fittings and equipment which contacts the process fluid shall be bagged and tagged to prevent contact with moisture and dust. | 商务  Commerce |
|  | 暴露在外的机加工表面或抛光表面应用可剥离膜进行保护或涂覆合适的保护剂，保护剂要求能在不使用溶剂的情况下轻松去除。  Exposed machined and/or polished surfaces shall be protected with a strippable membrane or coated with a suitable protective compound that shall be easily removable without the use of solvents. | 商务  Commerce |
|  | 供货商应承担由于包装、运输不妥引起的货物锈蚀、损伤和丢失的责任。  The supplier shall bear the responsibility of rust, damage and loss caused by improper packing and transportation. | 商务  Commerce |
|  | 从设备合同签订到设备抵达业主指定场地，时间不超过8个月。  It is not more than 8 months from the signing of the equipment contract to the equipment to the owner's designated site. | 商务  Commerce |

* 1. 文件要求 Documentation

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 需提供1份纸质以及一份电子版的“竣工版”文件。图纸应使用AUTOCAD绘制，文件使用Microsoft Office编写。  One (1) hard copy as “AS BUILT” documentation plus electronic form. Drawings and documents shall be made in AUTOCAD and Microsoft Office. | 商务  Commerce |
|  | 需提供三份纸质以及一份电子版的安装、维护手册。  Three (3) hard copies of Installation and Maintenance Manuals plus electronic form | 商务  Commerce |
|  | 供应商文件应以中英文双语形式编写（在设计文件中另有说明的除外），所有计量单位均为公制单位。  The Vendor documents shall be written in bilingual (unless otherwise specified in design documents) and all units of measurement shall be metric units. | 商务  Commerce |
|  | 供应商需采用业主的图纸、管道和部件编号系统。  The supplier shall use the owner's drawing, piping and part numbering system. | 商务  Commerce |

1. 版本历史REVISION HISTORY

| 版本 Version | 修订内容 Change Content | 备注Note |
| --- | --- | --- |
| 01 | 新建文件 New document | N/A |

1. 附录APPENDIX
   1. 供应商提供文件的要求 Vendor Documents Requirements

供应商提供的文件要求属于商业约定，需要在文件交付过程检查，但无需在RTM中追溯。

The document requirements provided by the vendor are commercial agreements and need to be checked during the document delivery process, but there is no need to trace back in the RTM.

| **序号**  **No.** | **文件名称**  **Document Name** | **语言**  **Language** | **纸质版/电子版**  **Hard copy**  **/Electronic** | **电子版格式(Word, Excel, PDF. Etc.)** | **纸版份数**  **Num of Hard copy** | **文件提供时间**  **Doc Provide Time** |
| --- | --- | --- | --- | --- | --- | --- |
|  | URS响应表  Compliance to URS | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | DQ 开始前  Before DQ |
|  | 项目质量计划  Project Quality Plan | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | DQ 开始前  Before DQ |
|  | 图纸清单  Drawing list | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | DQ 开始前  Before DQ |
|  | 竣工PID图  As-built P&ID | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | 系统交付时  System Handover |
|  | 装配图  General assembly drawing | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | 系统交付前  Before System Handover |
|  | ISO证书  ISO certificate | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | DQ 开始前  Before DQ |
|  | 文件递交日期 Document delivery date | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | DQ 开始前  Before DQ |
|  | 设备重量信息  Weight information of equipment | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | FAT开始2周前  2 weeks before the start of FAT |
|  | 变更控制规程  Change Order Procedure | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | DQ 开始前  Before DQ |
|  | 项目及建设进度表 Project and production schedule | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | DQ 开始前  Before DQ |
|  | 仪表标签列表 Instrument Label Schedule | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | FAT开始2周前  2 weeks before the start of FAT |
|  | 公用介质消耗列表 Utilities consumption schedule | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | DQ 开始前  Before DQ |
|  | 供应商文件列表  Vendor document schedule | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | DQ 开始前  Before DQ |
|  | 铭牌信息  Nameplate data's | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | FAT开始2周前  2 weeks before the start of FAT |
|  | 货运文件  Shipping documentation | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | 系统交付前  Before System Handover |
|  | 钝化规程  Passivation procedure | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | 系统交付前  Before System Handover |
|  | 校准规程  SOP for Calibrations | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | FAT开始2周前  2 weeks before the start of FAT |
|  | 焊接规程  Welding procedure | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | FAT开始2周前  2 weeks before the start of FAT |
|  | 液压/气动测试规程 Hydrostatic & Pneumatic test procedure | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | FAT开始2周前  2 weeks before the start of FAT |
|  | 机抛光规程 Mechanical polishing procedure | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | FAT开始2周前  2 weeks before the start of FAT |
|  | 维护手册  Maintenance manual | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 2 | 系统交付时  System Handover |
|  | 安装手册  Installation manual | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 2 | 系统交付时  System Handover |
|  | 操作手册  Operation manual | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 2 | 系统交付时  System Handover |
|  | 控制系统手册  Control system manual | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 2 | 系统交付时  System Handover |
|  | 消耗品及耐耗品/配件清单  List of consumables and wear/spare parts | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | SAT开始4周前  4 weeks before the start of SAT |
|  | 设备数据表 Equipment data sheets | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | SAT开始4周前  4 weeks before the start of SAT |
|  | 电子数据表  Electrical data sheets | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | SAT开始4周前  4 weeks before the start of SAT |
|  | 仪器数据表 Instrument data sheets | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | SAT开始4周前  4 weeks before the start of SAT |
|  | 标签清单  Tag list | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | FAT开始2周前  2 weeks before the start of FAT |
|  | 组件清单  Components list | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | FAT开始2周前  2 weeks before the start of FAT |
|  | 部件数据表 Component datasheet | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | DQ 开始前  Before DQ |
|  | PID图  P&IDs | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | DQ 开始前  Before DQ |
|  | 容器图及接口清单 Vessel drawings & Nozzle list | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | DQ 开始前  Before DQ |
|  | 布局图  Layout | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | DQ 开始前  Before DQ |
|  | 电气部件列表 Electrical part list | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | DQ 开始前  Before DQ |
|  | 电气图  Electrical diagrams | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | DQ 开始前  Before DQ |
|  | 电气负荷  Electrical load (kW, V, Phase, Frequency) | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | DQ 开始前  Before DQ |
|  | I/O列表及地址列表  I/O List and address table | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | DQ 开始前  Before DQ |
|  | 参数设定值  Parameter settings | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | DQ 开始前  Before DQ |
|  | 控制系统功能主文件  FDS main document incl. controller | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | DQ 开始前  Before DQ |
|  | 运行描述  Operation Description | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | DQ 开始前  Before DQ |
|  | 互锁列表  interlock list | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | DQ 开始前  Before DQ |
|  | 仪器列表  Instrument list | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | DQ 开始前  Before DQ |
|  | 报警列表  Alarm list | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | DQ 开始前  Before DQ |
|  | 信号交换列表  Signal exchange list | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | DQ 开始前  Before DQ |
|  | 硬件设计说明 Hardware Design Specification | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | DQ 开始前  Before DQ |
|  | 软件设计说明 Software Design Specification | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | DQ 开始前  Before DQ |
|  | 功能说明  Functional specification | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | DQ 开始前  Before DQ |
|  | 灾难恢复计划 Disaster recovery plan | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | DQ 开始前  Before DQ |
|  | 数据备份规程  Date backup procedure | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | 主体设计完成2周以内 Within 2 weeks after subject design |
|  | 焊接设备及参数  Welding equipments and parameters | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | FAT开始2周前  2 weeks before the start of FAT |
|  | 焊接规程  Welding procedure | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | FAT开始2周前  2 weeks before the start of FAT |
|  | 焊点总表  Weld summary | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | FAT开始2周前  2 weeks before the start of FAT |
|  | 焊接记录及检查记录  Welding and inspection log | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | FAT开始2周前  2 weeks before the start of FAT |
|  | 20%焊缝照片  20% Weld seam pictures | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | FAT开始2周前  2 weeks before the start of FAT |
|  | 焊接样品（每个程序及每个工人）  Weld samples(per program and per manual welder) | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | FAT开始2周前  2 weeks before the start of FAT |
|  | 其他测试的报告（内窥镜，X光，铁素体）  Test result of other tests (borescope, x-ray, ferrite) | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | FAT开始2周前  2 weeks before the start of FAT |
|  | 脱脂证明  Degreasing certification | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | FAT开始2周前  2 weeks before the start of FAT |
|  | 校验证书  Calibration certificate | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | FAT开始2周前  2 weeks before the start of FAT |
|  | 接地检查记录  Earthing continuity check records | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | FAT开始2周前  2 weeks before the start of FAT |
|  | 钝化证明  Passivation certification | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | FAT开始2周前  2 weeks before the start of FAT |
|  | 焊工及检查员资质证明  Welder &Inspector Certificates | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | FAT开始2周前  2 weeks before the start of FAT |
|  | CE认证证书  CE conformity declarations | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | FAT开始2周前  2 weeks before the start of FAT |
|  | 测试仪器设备校验证书 Certificates for test instruments/equipments | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | FAT开始2周前  2 weeks before the start of FAT |
|  | 液压/气动测试证明  Hydrostatic & Pneumatic certificate | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | FAT开始2周前  2 weeks before the start of FAT |
|  | 电抛光证明  Electro polishing certification | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | FAT开始2周前  2 weeks before the start of FAT |
|  | 清洁证明  Certificate about cleaning and rinsing | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | FAT开始2周前  2 weeks before the start of FAT |
|  | 金属部件的材质证明  Material certificates for metallic parts | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | FAT开始2周前  2 weeks before the start of FAT |
|  | 非金属部件的材质证明 Material certificates for non-metallic parts | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | FAT开始2周前  2 weeks before the start of FAT |
|  | 表面抛光度证书  Surface finishing certificates | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | FAT开始2周前  2 weeks before the start of FAT |
|  | 验证计划  Validation Plan | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | Word | 1 | DQ 开始前  Before DQ |
|  | 风险评估及报告  Risk Assessment and Report | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | Word | 1 | DQ 开始前  Before DQ |
|  | DQ方案/报告  DQ protocol /report | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | Word | 1 | DQ 开始前  Before DQ |
|  | 需求追溯矩阵  RTM | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | Excel | 1 | DQ 开始前  Before DQ |
|  | FAT方案/报告  FAT protocol/report | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | Word | 1 | FAT开始2周前  2 weeks before the start of FAT |
|  | SAT方案/报告  SAT protocol/report | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | Word | 1 | SAT开始4周前  4 weeks before the start of SAT |
|  | IQ方案/报告  IQ protocol/report | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | Word | 1 | IQ开始4周前  4 weeks before the start of IQ |
|  | OQ方案/报告  OQ protocol/report | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | Word | 1 | IOQ开始4周前  4 weeks before the start of IOQ |
|  | 备品清单  Spares part list | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | Word | 1 | SAT开始4周前  4 weeks before the start of SAT |
|  | 特殊工具清单  Special tools list | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | Word | 1 | SAT开始4周前  4 weeks before the start of SAT |

* 1. 相关区域布局图 Relevant Layout
  2. 零部件品牌推荐表 Component brand recommendation list