**重庆药友水土工厂202车间单抗项目**

**下游不锈钢配储液系统用户需求**

**URS for Downstream Preparation & Holding Tank 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生产线的下游配储液系统的用户需求。

The purpose of this document is to define the user requirements of down-stream preparation & holding SS tank system 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15,000L生产线的下游不锈钢配储液系统及其辅助系统（钢平台、取样口等）。

This document, together with all attachments, covers the scope of work and the minimum requirements of the design, fabrication, inspection, delivery, start-up, and performance testing. The plant consists of down-stream preparation & holding Stainless steel tank system and support system (SS Plate form and so on).

本项目包含以下部分：

The scope of supply includes:

* 1套500L缓冲液配制罐500L buffer preparation tank, 1 set
* 1套1500L缓冲液配制罐1500L buffer preparation tank, 1 set
* 1套4000L缓冲液配制罐4000L buffer preparation tank, 1 set
* 2套200L 缓冲液储罐 200L buffer holding tank,2 sets
* 3套500L 缓冲液储罐 500L buffer holding tank,3 sets
* 3套1000L 缓冲液储罐 2000L buffer holding tank, 3sets
* 1套1500L 缓冲液储罐 1500L buffer holding tank, 1 set
* 1套2000L 缓冲液储罐 2000L buffer holding tank, 1 set
* 1套2500L 缓冲液储罐 2500L buffer holding tank, 1 set
* 1套3000L PW储罐3000L PW tank, 1 set
* 3套4000L 缓冲液储罐 4000L buffer holding tank, 3 sets
* 3套15000L WFI储罐15000L WFI tank, 3 sets
* 所有缓冲液配制罐附属的取样口 Sampling ports for all media preparation tanks
* 所有罐各自附属的电控柜 Electrical and control Cabinet for all tanks
* 所有罐附属钢平台 Stainless-steel plate forms for all tanks
* 工艺料液输送系统 The process liquid transfer 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

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.

本系统内容包括：

The system includes:

* 缓冲液配制罐，用于下游纯化系统的清洗，平衡，洗脱。罐体，管架，取样，投料，呼吸器和液体过滤单元位于D级区。

Buffer preparation tank for cleaning, balancing and elution of downstream purification systems.  The tanks, frame, the sampling, feeding, vent filter and liquid filter are located in the D area.

* 缓冲液原物料经过称量后，量大的物料（大于40L）放置在IBC中，小于40L的物料放置在投料袋中。投料时，通过提升机将IBC提升至合适的高度后，由软连接将IBC口和罐体投料口连接后，进行投料。投料袋则直接由人工投料。IBC系统不在此URS范围内。
* After the raw materials of the media material are weighed, the large amount of material(more than 40L) is placed in the IBC, and material less than 40Lis placed in the feeding bag. When feeding, after the IBC is lifted to a suitable height by the hoist, the IBC port and the feeding port of the tank are connected by a soft connection, and then the feeding is carried out. The feeding bag is directly fed manually. IBC systems are not covered by this URS.
* 500L缓冲液配制罐、1500L缓冲液配制罐和4000L缓冲液配制罐，分别通过不锈钢管路和0.22um除菌过滤器过滤后输送到对应的储罐和纯化设备。物料的传输通过压缩空气实现。详见P&ID图纸。

500L buffer preparation tank, 1500L buffer preparation tank and 4000L buffer preparation tank are filtered through stainless steel pipes and 0.22um sterilizing filters and then transported to corresponding storage tanks and purification equipment. Material transfer is achieved by compressed air. See P&ID drawing for details.

* 缓冲液存储罐和PW储罐，WFI储罐位于缓冲液储存间。罐体，管架，呼吸器位于CNC区域。缓冲液存储罐通过不锈钢管路输送到在线配液系统和纯化设备，物料的传输通过压缩空气实现，详见P&ID图纸。

Buffer storage tanks, PW storage, WFI storage are located in the buffer storage room . Tanks, frame and vent filter are located in the CNC area. The buffer storage tank is delivered to the Inline conditioning system and purification devices via stainless steel pipes, and the material is delivered via compressed air. See P&ID drawing for details.

* 缓冲液配制罐只保留一个固体投料口和对应的软连接，用于与固体投料系统对接，具体接口尺寸详见P&ID图纸。

Only one solid feeding port and the corresponding soft connectionare reserved for the buffer preparation tank, which is used for docking with the solid feeding system. For the specific interface size, please refer to the P&ID drawings.

* 缓冲液配储系统以及分配管路可以实现CIP/SIP，总共3套CIP站服务于缓冲液配储系统。CIP站不在此文件范围内。

The buffer distribution system and distribution pipeline can realize CIP/SIP. A total of 3 CIP stations serves the buffer distribution and storage system. CIP stations are not covered by this document.

上述设备之间需要有联动功能。

Associated interconnection among above listed equipment.

具体的罐体分配情况详见PFD。

The specific tank allocations are detailed in the PFD.

* 1. 布局/安装条件 Layout/ Construction Conditions

供应商需根据业主的平面布局图进行不锈钢工艺系统以及辅助设备的设计。若设备有额外的高度要求，应告知业主并由业主批准。

Vendor should design the stainless steel process system and support system according to the owner's layout. Any additional height requirements for the equipment must be notified and approved by Owner.

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℃  CNC级区，18~30℃ |
|  | 房间湿度要求 Room Humidity Requirement | D级区，30~70%RH |
|  | 房间布局图 Room Layout | 参见布局图 See Layout |

1. 公用介质 Utility

业主负责提供以下公用工程。 The owner is responsible to provide the following utility.

|  |  |  |  |
| --- | --- | --- | --- |
| **序号 No.** | **公共设施 Utilities** | **用途 Function** | **范围/容量 Conditions** |
|  | 注射用水 WFI | 清洗 Washing | 压力 Pressure：0.3~0.3 5 MPa  温度 Temp. : 75℃左右 |
|  | 纯化水 PW | 清洗 Washing | 压力 Pressure：0.3~0.35 MPa  温度 Temp. : 20~25℃ |
|  | 电气 Electric | 供电 Power | 380V/50Hz  220V/50Hz |
|  | 压缩空气  Compressed air | 动力 Drive | 压力 Pressure：0.6 MPa |
|  | 压缩空气  Compressed air | 工艺 Process | 压力 Pressure：0.6 MPa |
|  | 洁净蒸汽  Clean steam | 灭菌 Sterilization | 压力 Pressure：0.3 MPa |
|  | 工业蒸汽  Plant steam | 加热 Heating | 压力 Pressure：0.6 MPa |
|  | 冷冻水  Chiller water | 冷却 Cooling | 压力 Pressure: ≥ 0.3 MPa  温度 Temperature: 7 - 12℃ |

1. 定义/缩略语DEFINITIONS AND ABBREVIATIONS
   1. DQ：设计确认 Design Qualification
   2. FAT：工厂验收测试 Factory Acceptance Test
   3. SAT：现场验收测试 Site Acceptance Test
   4. IQ：安装确认 Installation Qualification
   5. OQ：运行确认 Operational Qualification
   6. PQ：性能确认 Performance Qualification
   7. P&ID：管道和仪表流程图 Piping and Instrument Diagram
   8. PW：纯化水 Purified Water
   9. WFI：注射用水 Water for Injection
   10. MCC：马达控制中心 Motor Control Center
   11. PCS：工艺自控系统 Process Control System
   12. PD：工艺描述规程 Process description
   13. CU 洁净公用工程 Clean Utility
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 revision of the following documents.

* 中国GMP (2010版)

NMPA: Good Manufacturing Practice for Drugs (2010 Version)

* US FDA: 21 CFR Part 210 and 211
* US FDA: 21 CFR Part 11
* EU GMP Volume Ⅳ
* ASME BPE
* GB150 (2011版)
* GB50017-2003 钢结构设计规范

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 EHS (Environment, Health & Safety)
* 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

Commercial requirements: non-technical requirements related to commercial contracts that do not affect product quality, do not need to be traced in DQ and RTM.

* 1. 通用要求 General Requirements

| **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及P&ID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 and P&ID 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 |
|  | 所有模块设计需满足附录8.3中工艺仪表流程图的逻辑功能要求。  All the module design shall follow the logical function requirement from the P&ID attached in Appendix 8.3. | 质量  Quality |
|  | 供应商应在业主提供的P&ID基础上深化设计，并提交业主审核，批准后负责执行。  The supplier shall deepen the design based on the P&ID provided by the Client, submit the design to the owner for review, and be responsible for implementation after approval. | 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** |
| --- | --- | --- |
|  | 配制罐每批次配液量的需要满足以下要求：  The preparation tanks should be able to produce media every batch as below:   * 500L 配制罐的工作体积为100L~500L；   100L~500L working volume for 500L Buffer preparation tank;   * 1500L配制罐的工作体积为300L~1500L；   300L~1500L working volume for 1500L Buffer preparation tank;   * 4000L配制罐的工作体积为800L~4000L；   800L~4000L working volume for 4000L Buffer preparation tank. | 质量  Quality |
|  | 缓冲液配制罐应至少在30min内完成物料的完全溶解且混合均匀。  The buffer preparation tank should complete dissolution of the material and mix it evenly within 30min at least. | 质量  Quality |
|  | 应使用CIP循环清洗来去除罐体和管道内的颗粒、污迹和残余溶液。冲洗将使用纯化水，最终淋洗将使用注射用水。  CIP cycle cleaning should be used to remove particles, stains and residual solution in the tank and piping. Purified water will be used for flushing and WFI will be used for final rinsing. | 质量  Quality |
|  | 必须使用核黄素做罐体以及所有关联部件的覆盖检测，包括呼吸器底部，罐顶预留口背面，上封头喷淋测试和罐体全覆盖喷淋测试等。  Riboflavin must be used to perform coverage tests for tanks and all associated components, including the bottom of the vent filter, the back of the tank top reserve, spray tests for the upper head and full coverage spray tests for tanks. | 质量  Quality |
|  | CIP 过程中底部磁力搅拌需要被浸没。  Bottom magnetic stirrer may be submerged during CIP. | 质量  Quality |
|  | 罐和管道在每步CIP的结束步骤，可以实现吹扫。  The tank and pipe should be able to blow dry at the per CIP end step. | 质量  Quality |
|  | 系统的SIP应设计为121℃以上纯蒸汽灭菌。  Sip of the system shall be designed for clean steam sterilization above 121 ℃. | 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版本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 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。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. 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 |
|  | 软管应尽量做到自排尽。  Hose should be self-draining as far as possible | 质量  Quality |
|  | 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 |
|  | 需要考虑CU如何取样，且产品取样，检修，滤器的拆装，管道的连接都要保证有足够的操作空间，安全和人体工程学。取样需要安装接水盘。  It is necessary to consider how to sample CU, and to ensure sufficient operating space, safety and ergonomics for product sampling, maintenance, filter disassembly, and pipeline connection. Sampling requires installation of a water tray. | 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** |
| --- | --- | --- | --- |
|  | 罐体设计温度  Tank design temperature | -10~150℃ | 质量  Quality |
|  | 罐体设计压力  Tank design pressure | -1~3 bar | 质量  Quality |
|  | 高径比  Height diameter ratio | 1.1~1.3 | 商业  Business |
|  | 夹套设计温度  Jacket design temperature | -10~150℃ | 商业  Business |
|  | 夹套设计压力  Jacket design pressure | -1~5 bar | 商业  Business |
|  | 搅拌速度  Agitation speed | 建议50~1000rpm，具体数值根据搅拌选型，需满足最小混合时间要求（最小混合时间参见6.2.2）  50-1000rpm is recommended, depends on the mixing model selection, and the minimum mixing time should be met (see item 6.2.2) | 质量  Quality |
|  | 搅拌速度控制精度 Agitation speed control accuracy | ±2% | 质量  Quality |
|  | pH测量范围和测量精度  PH measurement range and measurement accuracy | 2~12 /±0.01 | 质量  Quality |
|  | pH测量精度  PH measurement accuracy | ±0.01 | 质量  Quality |
|  | 工艺电导率测量范围和测量精度  Conductivity measurement range and measurement accuracy for process | 高电导率检测范围：0.1 mS/cm -500mS/cm；  范围内精确度: ≤当前测试值±5%  低电导率检测范围：0.1μS/cm ~1000μS/cm  范围内精确度≤当前测试值±1%。  High conductivity detection range: 0.1 mS/cm -500mS/cm; accuracy in range: ≤±5% of current test value.  Low conductivity detection range: 0.1μS/cm ~1000μS/cm; accuracy in range: ≤±1% of current test value. | 质量  Quality |
|  | 工艺电导率离线和在线差值  Process conductivity difference between off-line and on-line | 高电导范围/High conductivity range：±1 mS/cm  低电导范围/Low conductivity range：±0.1μS/cm | 质量  Quality |
|  | 称重系统精度  Weighing system accuracy | 系统精度：最小工作体积的0.3%;（最小工作体积参见6.2.1条款）;  System accuracy: 0.3% of the minimum working volume (the minimum working volume see item 6.2.1); | 质量  Quality |
|  | 液位计测量精度  Measuring accuracy of liquid level gauge | ±5% | 质量  Quality |
|  | 管道耐压  Piping withstand pressure | 不小于5bar | 质量  Quality |
|  | 压力传感器  Pressure sensor | 精度≤0.1bar  Accuracy ≤ 0.1bar | 质量  Quality |

* 1. 部件要求 Components Requirement

1. 罐体 Tank

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 缓冲液配制罐配有带灯视镜、爆破片、罐体压力传感器、呼吸器、人孔、固体投料口、进液口、清洗口、罐顶预留口、隔膜压力表、一次性取样器、pH探头、电导率探头、罐侧壁预留口、罐体温度探头、罐底阀、称重模块、底部磁力搅拌。  Buffer preparation tank with sight glass with light, rupture disk, pressure sensor, vent filter, manhole, solid feeding port, liquid inlet, spray ball port, spare port, pressure gauge, disposable sampler, pH probe, electrical conductivity probe, tank wall spare port, temperature probe, tank bottom valve, weighing module, magnetic stirring. | 质量  Quality |
|  | 缓冲液存储罐配有带灯视镜、爆破片、罐体压力传感器、呼吸器、人孔、固体投料口、进液口、清洗口、罐顶预留口、隔膜压力表、一次性取样器、pH口、电导率口、罐侧壁预留口、罐体温度探头、罐底阀、差压液位计。  Buffer holding tank with sight glass with light, rupture disk, pressure sensor, vent filter, manhole, solid feeding port, liquid inlet, spray ball port, spare port, pressure gauge, disposable sampler, pH port, electrical conductivity port, tank wall spare port, temperature probe, tank bottom valve, differential pressure levelmeter. | 质量  Quality |
|  | WFI储罐配有带灯视镜、爆破片、罐体压力传感器、呼吸器、人孔/手孔、进液口、清洗口、罐顶预留口、压力表、一次性取样器、罐侧壁预留口、罐体温度探头、罐底阀、差压液位计。  WFI tank with sight glass with light, rupture disk, pressure sensor, vent filter, manhole/hand hole, liquid inlet, spray ball port, spare port, pressure gauge, disposable sampler, tank wall spare port, temperature probe, tank bottom valve, differential pressure levelmeter. | 质量  Quality |
|  | 对于500L和1500L缓冲液配制罐，原辅料通过人孔或者固体投料口人工加料。对于4000L配制罐是通过IBC 提升加料，罐体需要配合设置加料口，具体界面参见相关的工艺仪表流程图。  For 500Land 400L buffer preparation tanks, the raw material will be charged through manhole or solid feeding port by manual. For 4,000L buffer preparation tank, the raw material will be charged through IBC, the tank should set a charge port. The interface refer to P&ID. | 质量  Quality |
|  | 系统供应商需提供4000L配制罐加料口尺寸相对应的软连接，加料口尺寸建议为DN250，系统供应商需提供连接面的具体规格尺寸。  The system supplier shall provide the soft connection corresponding to the feeding port size of 4000L toppings tank. The feeding port size is suggested to be DN250. The system supplier shall provide the specific specification and size of the connecting surface. | 商务  Commence |
|  | 配液罐需要带夹套控温单元，用于罐内液体温度控制。夹套形式由供应商提交业主审批确认。储存罐只预留夹套，不带控温单元。  The preparation tanks shall be equipped with a jacket temperature control unit for liquid temperature control in the tank. The jacket form shall be submitted by the supplier to the owner for approval. Storage tanks only reserved jacket, without temperature control unit. | 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 |
|  | 人孔盖应配制人孔助力器和有限位设施，方便开闭。且开闭不会对操作人员或设备造成损害。  The cover of manhole should be equipped with a manhole booster and a limited bit facility to facilitate opening and closing. And the opening and closing will not cause damage to the operator or equipment. | 商业  Business |
|  | 配制罐采用柱塞式罐底阀。存储罐使用隔膜式罐底阀。  The preparation tanks adopts plunger type tank bottom valve. The holding tank adopts a diaphragm tank bottom valve. | 质量  Quality |
|  | 罐底阀的最低点和洁净室地面之间的距离至少为800mm。  The distance between tank bottom lowest point and cleanroom floor shall be at least 800mm. | 商业  Business |
|  | pH探头：罐体采用N.A.连接形式，管道上采用卫生型连接（卡箍），应考虑CIP时，探头的取出和保护，并对探头孔密封，CIP无死角。  PH probe: The tank use the N.A. connection form, the pipe use the sanitary connection (clamp). During CIP, the probe shall be taken out and protected, and the probe hole shall be sealed, and CIP shall have no dead angle. | 质量  Quality |
|  | 电导率探头：罐体采用NA法兰接口形式，管道上采用卫生型连接（卡箍）。根据不同工艺要求选择相对应的电导率探头。  Conductivity probe: The tank use the NA flange connection form, Sanitary connection (clamp). Select corresponding conductivity probe according to different process requirements. | 质量  Quality |
|  | 罐体温度探头应能够连续显示温度，采用套筒形式，可与罐体拆卸方便校验。  The tank temperature probe shall be able to continuously display the temperature, sleeve form, which can be easily separated from the tank for calibration. | 质量  Quality |
|  | 供应商需要结合搅拌，罐顶管口布局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 supplier needs to set the position and number of spray balls according to the requirements of mixing and cleaning of tank top nozzle layout, 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 |
|  | 所有喷淋球和内伸管需要设置定位销。  Spray balls and inlet pipe all require directional pins. | 质量  Quality |
|  | 用于进气/出气的0.22μm的呼吸器应与罐体一同进行CIP/SIP。  A 0.22 μm filter for air in / out shall be CIP/SIP with the tank together. | 质量  Quality |
|  | 需要配制灭菌所需的装置，例如蒸汽疏水装置，温度传感器等。  Instrument required for sterilization to be provided, example steam traps, temperature sensor etc.. | 质量  Quality |

1. 搅拌 Stirrer

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 配液罐还需要配备磁力搅拌器，储存罐无需配备磁力搅拌，搅拌由供应商选型，经业主审核后提供。  The buffer preparation tank also needs to be equipped with a magnetic stirrer. The storage tank does not need to be equipped with a magnetic stirrer. The mixing is selected by the supplier and approval by client. | 质量  Quality |
|  | 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 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 |
|  | 搅拌器应易于拆卸，需配置至少一套拆装工具，且可以适用于不同型号搅拌器型号，可实现CIP和SIP，不会造成产品残留。  The agitator should be easy to disassemble and equipped with at least one set of disassembly tools. It can be applied to different types of agitators and can realize CIP and SIP without causing product residue. | 质量  Quality |
|  | 搅拌器的位置应与人孔/手孔相匹配，方便后期维护将搅拌桨取出。  The position of the stirrer shall match the manhole / handhole to facilitate the later maintenance and take out the stirrer. | 商业  Business |

1. 钢平台 Stainless Steel Platform

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 钢平台应符合人体工程学，方便操作人员投放物料、处理滤器等。  The steel platform shall conform to the ergonomics, which is convenient for the operator to put materials and handle the filter, etc. | 商务  Commerce |
|  | 工艺罐钢平台底部需预留足够的空间用于维护。  Sufficient space should be reserved at the bottom of the steel platform for process tank for maintenance. | 商务  Commence |
|  | 钢平台需在合适位置预留电源插座，供辅助设备使用。（如蠕动泵等）  Power socket shall be reserved in proper position on the steel platform for auxiliary equipment. (such as peristaltic pump, etc.) | 商务  Commence |
|  | 钢平台应考虑对空间气流组织的影响，应安全、坚固、耐用。钢平台上表面/底面均应方便清洁，不得有死角。钢平台下表面用钢板封闭平整，接缝满焊。  The steel platform shall consider the impact on the air distribution of the space, and shall be safe, solid and durable. The upper surface / bottom surface of the steel platform shall be easy to clean without dead angle. | 商业  Business |
|  | 不锈钢平台下方需要考虑300LX的照度，设置开关  Under the stainless steel platform, the minimum 300LX illumination is required. And it should set the switch. | 商务  Commence |
|  | 在设计上需要考虑EHS的要求，如坡度较陡（40°以上）的钢梯尽量避免使用。  EHS should be considered in design, for example, the steep ladder shall avoid to be used. | EHS |
|  | 钢平台与设备模块，支架，管道没有空间上的干涉，人员在平台上行动操作没有阻碍。  There is no space interference between the steel platform and the equipment modules, supports and pipes, and there is no obstacle for personnel to move and operate on the platform. | 商业  Business |

1. 蠕动泵 Peristaltic pump

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 对于小体积液体料液，配制罐共用蠕动泵来补入称重过的料液。供应商应考虑提供摆放蠕动泵和补料瓶的平台，以及就近的公用介质接口。  For small volume liquid addition, preparation tank will be equipped with a shared peristaltic pump to transfer the liquid from bottles. The liquid materials will be weighted. The supplier shall provide a platform with adequate space and utilities connection ports nearby for the peristaltic pumps and bottles. | 商业  Business |
|  | 蠕动泵流量需满足按照具体P&ID要求，需配置远程/就地控制功能，并支持Profibus-DP协议接入PCS系统，可实现蠕动泵的远程/就地切换、转速设定/实际值、启动/停止指令、运行状态反馈及故障等信号与PCS系统交互。  The flow rate of peristaltic pump should meet the requirement of 2L/min, and the remote/local control function should be configured. Profibus-DP protocol should be supported to access the PCS system, which can realize the remote/local switch of peristaltic pump, speed setting/actual value, start/stop command, running status feedback and fault signal interaction with PCS system. | 质量  Quality |
|  | 蠕动泵的流量精度要应小于或达到±1%。  The flow accuracy of peristaltic pump should be less than or reach to ±1%. | 质量  Quality |

1. 过滤器 Filter

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 为防止交叉污染，应为罐体提供滤芯材质为PTFE的0.22μm呼吸器，带适配电加热套。呼吸器具体尺寸见P&ID。  To prevent cross contamination, 0.22 μm Gas filter in/out shall be provided for compounding vessel, and the filter material should be PTFE. The dimension of gas filter refer to P&ID. | 质量  Quality |
|  | 供应商每个过滤器需要配备符合工艺条件的滤芯以满足PQ之前（不包括PQ）的检测使用，直到验证通过为止。  Each filter of supplier should be equipped with filter elements that meet the process conditions to meet the test use before PQ (excluding PQ) until verification is passed. | 商务  Commerce |
|  | 需要为罐体空气滤器配置CIP专用替换件，保证系统整体清洗效果。  CIP special replacement parts for air filter are required to ensure the cleaning effect of the system. | 质量  Quality |
|  | 管道液体过滤器采用在线清洗的方式，需要配制专用的滤壳清洗喷淋球及相关设施。喷淋球的安装设计成可拆卸形式。  The pipeline liquid filter is cleaned online, and special filter shell cleaning spray ball and related facilities need to be prepared. The spray ball is mounted in a detachable form. | 质量  Quality |
|  | 呼吸器和液体过滤器安装位置应便于维修拆卸和操作。对于过滤器滤壳拆装需要提供移动拆装设备。  The liquid filter and gas filter in/out should be installed in a position that is easy to service, remove and operate. For filter shell disassembly, mobile disassembly and disassembly equipment shall be provided. | 商业  Business |
|  | 滤芯和滤壳之间的接口应采用Code 7-226型式。  The interface between filter element and filter shell should be Code 7-226. | 质量  Quality |

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复合膜片，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 composite 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一一对应的材质证明。  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阀门采用锻造隔膜阀。  Forged diaphragm valves should be equipped in contact with product, pure steam or cleaning water. | 质量  Quality |
|  | 纯蒸汽通过PID调节阀和压力传感器联锁实现调压的目的，调节阀采用洁净卫生型阀门。工业蒸汽减压阀采用直接作用式减压阀。压缩空气减压阀采用有过滤减压功能。  Pure steam through P&ID control valve and pressure sensor interlock to achieve the purpose of regulating pressure. The P&ID control valve used clean and hygienic type. The industrial steam pressure reducing valve uses the direct action type pressure reducing valve. The compressed air pressure reducing valve has the function of filtration and decompression. | 质量  Quality |
|  | 无菌取样阀门采用无菌取样袋的形式（5孔），选型为2mm取样针，供应商需要提供Holder 堵头，无菌取样袋不在供应商范围内。  Aseptic device (5 holes) shall be used for all tank sampling, choose 2mm sampling needle. The vendor shall provide holder and cap, but the sampling bags are not in vendor’s scope. | 商务  Commerce |
|  | 纯蒸汽疏水阀应使用的可自调节洁净型热静力平衡型疏水阀。需根据罐体积匹配合适的疏水量。疏水阀选用快装卡箍连接。  Provide self-adjusting balanced thermostatic type steam trap designed for clean steam sanitary operation. Suitable water retention should be matched according to the tank volume. The type of trap is tri-clamp. | 质量  Quality |
|  | 模块内纯蒸汽总管末端需配备洁净型热静力平衡型疏水阀。  The end of the pure steam main in the module shall be equipped with thermostatic type steam trap. | 质量  Quality |
|  | 每根排放总管应设置空气隔断。空气隔断的位置建议设置在模块内部，便于维护。  Each discharge main should be provided with an air breaking. It is recommended that the air breaking should be installed inside the module for easy maintenance. | 质量  Quality |

1. 验证口 Port for Validation

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 所有罐体侧面预留至少1个1.5” NA接口和1个2”的NA接口用于验证取样。  At least one 1.5 " NA interface and one 2" NA interface for verification sampling on the side of all tanks. | 质量  Quality |
|  | 工艺系统清洗水排水口需安装取样阀；取样阀设置位置需便于操作，不易污染。  Sampling valves should be installed in the water drain of Stainless steel Process System. The setting position of sampling valve shall be easy to operate and not easy to pollute. | 质量  Quality |
|  | 所有疏水管路温度探头前端就近预留TC接口（卡盘50.5mm），用于布置验证探头。供应商给出接口位置的建议。  TC (50.5mm)interface shall be reserved nearby in front of temperature probes of all drain pipes for arrangement of verification probes. The supplier gives advice on the location of the interface. | 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 shall be provided. The validity period of verification agency should be covered until PQ is completed. | 质量  Quality |
|  | 温度传感器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 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 |
|  | 现场压力表采用卫生级隔膜式压力表，与介质直接接触的部分采用316L材质。油表油质选用食品级润滑油。  The on-site pressure gauge adopts sanitary diaphragm pressure gauge, and the part directly contacting with the medium adopts 316L material. Food grade lubricating oil is selected as the oil quality. | 质量  Quality |
|  | 液位计：采用卫生级差压式液位计，与介质直接接触的部分采用316L材质，带4~20mA信号输出，带高低液位和密度输入、现场显示和“零点复位”功能。  Liquid level gauge: sanitary differential pressure type liquid level gauge is used, 316L material is used for the part directly contacting with the medium, with 4 ~ 20mA signal output, high and low liquid level and density input, field display and "zero point reset" function. | 质量  Quality |
|  | 液位计的测量结果应不受液体温度变化的影响。  The measurement results of the liquid level gauge should not be affected by the change of liquid temperature. | 质量  Quality |
|  | pH探头：采用卫生型连接（卡箍）。应考虑CIP时，探头的取出和保护，并对探头孔密封，CIP无死角。  PH probe: Sanitary connection (NA or clamp). During CIP, the probe shall be taken out and protected, and the probe hole shall be sealed, and CIP shall have no dead angle. | 质量  Quality |
|  | 电导率探头：采用卫生型连接（卡箍）。根据不同工艺要求选择相对应的电导率探头。  Conductivity probe: Sanitary connection (NA or clamp). Select corresponding conductivity probe according to different process requirements. | 质量  Quality |
|  | 每个疏水阀（除蒸汽供应管路前端疏水阀以外）上端均应配置温度探头（距离疏水阀至少300mm），用于监控和记录灭菌温度，最冷点的温度探头用于控制。  The front of each steam trap (except the steam supply pipeline trap) should be equipped with a temperature probe (the distance to steam trap at least 300mm) for monitoring and recording the sterilization temperature, the cold point probe for control. | 质量  Quality |
|  | 配制罐应采用称重传感器。重量变送器包括重量值的数字传输、并支持PCS系统远程清零、去皮、清除去皮等控制功能。  The preparation tanks shall include load cells. The weight transmitter includes digital transmission of weight values, and supports remote zeroing, , clearing and peeling of PCS system | 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** |
| --- | --- | --- |
|  | 500L，1500L，4000L缓冲配制罐采用特材制造，2个4000L和1个500L缓冲液储存罐采用特材制造。特材材质最高可耐受5 mol氯离子。  500L, 1500L and 4000L buffer preparation tanks are made of special materials, and two 5000L and one 500L buffer solution storage tank are made with special materials. The special material can tolerate up to 5 mol CL¯. | 质量  Quality |
|  | 所有罐体内表面电抛光至粗糙度不大于0.4μm并钝化处理。  The inner surface should be electropolished to a roughness of no more than 0.4 μm and passivated. | 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 |
|  | 所有罐体外表面抛光处理，管件外表面应抛光，光滑无毛刺。外表面应抛光至粗糙度不大于1.0μm。  The external surfaces of all tanks shall be polished and pipe fittings shall be smooth without burrs. The outer surface should be polished to a roughness of no more than 1.0 μm. | 商业  Business |
|  | 搅拌器的搅拌头和焊接盘材质需要和罐体材质一致，定子和转子采用碳化硅材质，密封圈采用EPDM材质，需满足FDA卫生要求。  The stirring head and welding plate of the agitator should be made of the same material as the tank, the stator and rotor should be made of silicon carbide, and the sealing ring should be made of EPDM, which should meet the sanitary requirements of FDA. | 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。The selected material should be able to withstand high temperature sterilization and can be cleaned by hot (80 °C) or cold WFI. | 质量  Quality |
|  | 洁净室内设备/部件的外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. 保温 Insulation

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 保温材料不得含有氯离子和石棉。  The insulation should be made of high quality insulation material (not including chloride ion and asbestos). | 商业  Business |
|  | 操作员易接触到的设备/部件外表面温度在任何时候都应低于45°C，并且不能表面结霜滴水（特殊位置，如疏水阀以上500mm和罐顶等，除外）。  The external surface temperature of the equipment/parts accessible to the operator should be less than 45°C at all times and no frosting and dripping (except in special locations such as 500mm above the trap and tank roof). | 商务  Commerce |

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, asupply 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

1. 通用 General

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | PCS系统服务器、工程师站、批量服务器、历史服务器、杀毒服务器、OPC服务器等功能站、系统网络交换机及控制器、AI、AO卡件不包含在系统供应商合同范围内。  The PCS system server, engineer station, batch server, history server, antivirus server, OPC server and other functional stations, system network switches and controllers, AI, AO cards are not included in the contract scope of this system vender. | 商务  Commerce |
|  | 以下下游不锈钢配储液系统的电气元器件需支持支持Profibus-DP协议或经甲方许可的通讯协议总线：  The following stainless steel system electrical components shall support Profibus-DP protocol or communication protocol bus approved by Owner:   * 称重仪表；   Weighting system;  - 阀岛模块；  Valve island module; | 商务  Commerce |
|  | pH、电导率等电极的仪表变送器需支持带hart协议的4~20mA信号输出.  The instrument transmitter with pH, conductivity and other electrodes should support 4~20mA signal output with hart protocol. | 商务  Commerce |
|  | 系统模块上或系统所在房间需安装声光报警灯，报警灯至少包括3种颜色显示。  The audible and visual alarm shall be install on stainless steel system module or in process room where the stainless steel system is located. The alarm lights shall have three colors at least. | 商业  Business |

1. 远程IO柜及仪表 Remote IO Cabinet and instruments

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 不锈钢配储液系统的供应商需配置远程IO控制柜，用于集成和安装系统远程IO模块、阀岛、仪表、开关电源等电气元件。远程IO柜需安装在不锈钢模块上。  The SS preparation & holding system supplier shall provide remote IO control cabinet to integrate and install the system remote IO module, valve island, instrument, power supply and required electrical components. | 商务  Commerce |
|  | 远程IO柜材质采用SS304不锈钢。  The remote IO cabinet shall be ss304 stainless steel. | 商业  Business |
|  | 远程IO柜需配置远程IO模块。远程IO模块支持Profibus-DP协议总线或经甲方许可的通讯协议总线，用于集成不锈钢配储液系统所有所有阀门反馈DI信号，DI卡件需预留10%的备用通道。  The remote IO cabinet shall install remote IO module which shall support Profibus-DP protocol bus or communication protocol bus approved by Owner. The remote IO module will be used to integrate all valve feedback DI signals of the stainless steel system. The remote IO module shall reserve 10% spare channels for DI signals respectively. | 商业  Business |
|  | 远程IO柜需配置单层信号端子用于4-20mA信号线缆接线，4~20mA模拟量传感器及仪表需支持HART协议。  The remote IO cabinet shall install single-layer terminal which is used for connecting 4-20mA signal cable, HART protocol shall be supported for 4~20mA analog sensor and instrument. | 商业  Business |
|  | 远程IO柜需配置阀岛，采用Profibus-DP通讯协议与PCS通讯。每个远程IO柜中阀岛需预留10%的电磁阀片备用量。  The remote IO cabinet shall install Valve Island which will communicate with PCS via Profibus-DP protocol. The valve island shall reserve 10% spare valve blocks in each remote IO cabinet. | 商业  Business |
|  | 远程IO柜需配置磁力搅拌转速信号转换器，转速信号采用4-20mA信号类型接入PCS系统监测磁力搅拌器实际转速。  The remote IO cabinet shall install magnetic stirring speed signal converter. The speed signal, which is 4-20 mA signal, shall be connect to PCS for monitoring the actual speed. | 商业  Business |
|  | 远程IO柜需配置冗余24VDC开关电源。开关电源报警信号需接入PCS。  The remote I/O cabinet shall be equipped with redundant 24VDC power supply. The alarm of 24VDC power supply shall be connected to PCS. | 质量  Quality |
|  | 远程IO柜需配置仪表屏蔽层接线铜条，该铜条需与机柜绝缘。  The remote IO cabinet shall be equipped with shield bar for instrument wiring, the shield bar shall be insulated from the cabinet. | 质量  Quality |
|  | 远程IO柜需配置就地急停旋钮和安全继电器。  The remote I/O cabinet must be equipped with local emergency stop and safety relay. | 安全  EHS |
|  | 远程IO柜需配置过滤减压阀，用以过滤及调节压缩空气。并将压力低报警信号需接入PCS。  The remote I/O cabinet shall be equipped with filter relief-pressure valve to filtrate the compressed air and adjust the pressure of compressed air. The pressure low alarm shall be connected to PCS. | 质量  Quality |
|  | 传感器及变送器由不锈钢工艺系统供应商负责安装。  The installation and wiring of sensor, instrument and transmitter shall be done by stainless steel system supplier. | 商务  Commerce |
|  | 需在合同签署后1个月，提供仪表及变送器信号分配表（I/O 清单）。  Instrument and transmitter signal distribution form shall be provided one month after signing the contract (I/O list). | 商务  Commerce |
|  | IO柜接线与接管的工作应尽可能在系统供应商工厂内完成，系统供应商应根据模块设计设置IO柜数量。  IO cabinet wiring and take-over should be completed in the factory of the system supplier as far as possible. The system supplier should set the number of IO cabinets according to the module design. | 商务  Commerce |
|  | 远程IO柜与外部设备及系统连接的气管及线缆均需采用下进线方式。  The gas pipes and cables must be underwired for the remote I/O cabinet to external devices and systems. | 商务  Commerce |

1. 马达控制中心（Motor control center, MCC）

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | MCC柜不在此次招标范围内，由整厂PCS系统供应商供货。  MCC cabinet is not included in the bidding scope and is supplied by PCS system supplier. | 商务  Commerce |
|  | 不锈钢配储液系统供应商需提供系统中的电机的详细电气参数。系统供应商需配合完成变频器参数设置。  The supplier of system shall provide detailed electrical parameters of the motor used in the process equipment. The vender should cooperate to complete the parameter setting of frequency converter. | 商务  Commerce |
|  | 不锈钢配储液系统供应商需设计和安装电机紧急停止，远程/就地切换按钮、运行和故障状态指示灯。  The supplier of Stainless steel preparation & holding tanks system shall design and install the motor emergency stop, remote/local switch button, run and fault status indicator lamp. | 商业  Business |

1. 现场操作员站 Field operator station

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 现场操作员站HMI将采用悬臂或立柱式安装于模块上，不锈钢供应商需设计HMI的安装位置并安装悬臂或立柱，并在模块上预留安装接口。  The onsite operator station HMI, which will be mounted via cantilever or vertical column, to be installed on the stainless steel system module. The stainless steel system supplier shall design the installation location of HMI and reserve the installation interface on the stainless steel system module. | 商务  Commerce |
|  | 现场操作员站HMI及其悬臂或立柱不在此次招标范围内。现场操作员站的HMI及悬臂或立柱由PCS系统供应商设计、供货。  The onsite operator station HMI and its cantilever and column is not included in the bidding scope of stainless steel system supplier. And the onsite operator station is designed, supplied and installed by the PCS system supplier. | 商务  Commerce |

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** |
| --- | --- | --- |
|  | 模块内电缆桥架设计及安装由系统供应商完成。罐体和模块应配有合理的管槽用于电缆走线，管槽应美观、坚固。罐体和模块适当位置需有用于固定电缆/电线的支架。电缆的铺设由供应商负责。  Tanks and modules shall be equipped with reasonable wire casing for cable routing, and the wire casing shall be beautiful and solid. Tanks and modules shall be provided with brackets for fixing cables / wires in place. The design and installation of cable tray in the module shall be completed by the stainless steel system supplier. | 商务  Commerce |
|  | 系统至PCS控制系统主桥架的辅助桥架或线缆管，由不锈钢配储液系统供应商负责设计及安装。  The cable tray or cable pipe from stainless steel system to PCS main cable tray shall be designed and install by supplier. | 商务  Commerce |
|  | 系统内部电源、仪表、阀门反馈、各类传感器至远程IO柜内线缆由系统供应商提供并完成接线。  The cabling and wiring from power supply, instrument, valve feedback and other device within stainless steel system module to remote IO cabinet shall be done by stainless steel system supplier. | 商务  Commerce |
|  | 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 |
|  | 系统内的Profibus-DP链路线缆敷设、接线由系统供应商完成。所有采用Profibus-DP的电气元件必须支持DP V0协议，必须与甲供PCS系统兼容。系统供应商需提供DP通讯设备的GSD文件及数据交互表。  The system supplier shall be in charge of cabling and wiring of Profibus-DP segment within stainless steel system. All Profibus-DP device must support DP V0 protocol and must be compatible with the PCS, and supplier shall provide the GSD files and data exchange list. | 商务  Commerce |
|  | 系统供应商需为其提供Profibus-DP设备配备Profibus-DP通讯接头，该通讯接头具备ON/OFF选择终端电阻的功能。  The system supplier shall provide the Poribus-DP connecter for Porfibus DP device, the DP comment shall have terminal resistance ON/OFF switch. | 商业  Business |
|  | 远程IO柜至PCS的信号线缆及网线由PCS供应商提供，本系统侧信号接线和线缆连接由系统供应商负责完成。  The signal cable and network cable from PCS cabinet to remote IO cabinet shall be provided by PCS supplier. The cable wiring on this system side shall be done by system supplier. | 商务  Commerce |
|  | 远程IO柜及下游不锈钢配储液模块至接地箱之间的接地线缆，由系统供应商提供和敷设。  The grounding cable from remote IO cabinet and system to grounding box shall be laid and wired by system supplier. | 商务  Commerce |
|  | 远程IO柜、仪表接线箱等柜内及接线端子电缆线号标识清晰。  The cable numbers in the valve terminal cabinet, instrument junction box and terminal block shall be clearly marked. | 商务  Commerce |
|  | 不锈钢配储液供应商应提供下游不锈钢配储液模块系统信号接线图，并配合完成系统至PCS的信号接线图。  The system supplier shall provide the wiring diagram of system, and support to design wiring diagram of wiring from the system to PCS. | 商务  Commerce |
|  | MCC柜到配储液系统及其辅助设备电机电缆由PCS供应商提供，PCS供应商完成MCC柜侧接线，系统供应商完成配储液系统设备侧接线。  The cable of motor from MCC cable to US preparation and holding system shall be provided by PCS supplier, the PCS supplier shall be responsible for wiring the motor cables on MCC cabinet side and the system supplier shall be responsible for wiring the motor cable on motor side. | 商务  Commerce |
|  | 每一根电缆需配置电缆标签，模块内电缆标签由配储液系统供应商提供，与PCS系统连接电缆标签由PCS供应商提供，电缆标签规则需协商一致。  Each cable shall be equipped with cable label. The label of the cable in the module shall be provided by the system supplier. The label of the cable connected with the PCS system shall be provided by the PCS supplier. The cable label rules shall be agreed by consensus. | 质量  Quality |
|  | 配储液模块与PCS控制系统联合FAT调试期间的临时线缆由配储液模块供应商提供，并负责完成PCS控制系统侧接线和测试后线缆的拆除工作。联合测试期间的线缆走线需采用桥架或穿线管，线缆不可以直接敷设在地面上。  The cable used for integrated test shall be provided by system supplier, and the cable connection and disconnection on PCS side shall be done by system supplier as well. The cable shall be laid within cable tray or cable pipe, it is not allowed to lay cable on the ground directly. | 商务  Commerce |
|  | 配储液系统供应商需为联合FAT期间的PCS系统提供UPS电源，并确保PCS系统在联合测试期间的环境满足如下需求：  The preparation & holding system supplier shall provide the UPS for the PCS during integrated FAT, and ensure the environment for PCS system as follow:   * 温度在10-35℃之间；   Temperature within 10-35℃   * 湿度在20-80%之间；   Humidity within 20-80%; | 商务  Commerce |

* 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、钢平台、标识和铭牌等任何部位不应有锋利的边缘和尖角。  There shall be no sharp edge and sharp angle at any part of equipment, steel platform, 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 |
|  | 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）。  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) | 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 |
|  | 系统供应商应负责设备模块和建筑接地装置的接线工作。  The system supplier shall be responsible for the wiring of equipment modules and building grounding devices. | 安全  EHS |

* 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 |
|  | 出厂前不锈钢系统供应商需与PCS系统供应商配合完成联合FAT，所有的设备须接受工厂验收测试（FAT）确认。  Before delivery, stainless steel system supplier shall cooperate with PCS system supplier to complete joint FAT, and all equipment shall be subject to factory acceptance test (FAT). | 商务  Commerce |
|  | FAT方案由系统供应商和PCS系统供应商共同起草并在FAT执行前由业主批准。联合FAT测试将在系统供应商工厂进行，业主将见证所有的测试执行。  Fat protocol shall be drafted jointly by system supplier and PCS system supplier and approved by the owner before FAT execution. The joint FAT will be carried out at the system supplier's factory, and the owner will witness the execution of all tests. | 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 Drain ability  - 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 |
|  | 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 |
|  | OQ方案由供应商起草，必要时方案中应包含程序运行时的功能检查，最终OQ方案由业主审核批准。  OQ protocol should be drafted by the supplier. If necessary, the plan shall include the functional inspection during the operation of the program. The final OQ protocol should be reviewed an approved by Client. | 商务  Commerce |
|  | 不锈钢系统供应商应与自控系统供应商积极配合，共同完成设备运行/系统功能方面的测试，业主将见证所有的测试执行。  The stainless steel system supplier shall actively cooperate with the automatic control system supplier to complete the equipment operation / system function test together, and the owner will witness the implementation of all 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 |
|  | 供应商应给出培训计划，并在计划内明确培训内容和时长。  The supplier should provide the training plan, and specify the training content and duration in the plan. | 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. 最终设备的成品保护 Finished product protection of equipment

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 供应商应负责罐体及焊接前后的洁净管道进场后的保护，保护措施需能防止长时间土建或净化施工过程中对罐体的损伤及污染。  The supplier should be responsible for the protection of the tank body and clean pipes before and after welding after entering the site, and the protection measures should be able to prevent the damage and pollution of the tank body in the process of long time civil construction or purification construction. | 商务  Commerce |
|  | 供应商应负责最终设备的成品保护，防止土建或净化施工过程中对系统的损伤及污染。  The supplier should be responsible for the protection of the finished product of the final equipment to prevent the damage and pollution of the system during the construction of civil engineering or purification. | 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 | 中文或英文  Chinese or English | 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 | 中文或英文  Chinese or English | 纸质和电子版  Hard copy &Elec | PDF | 1 | DQ 开始前  Before DQ |
|  | 项目执行计划  Project Execution Plan | 中文或英文  Chinese or English | 纸质和电子版  Hard copy &Elec | PDF | 1 | DQ 开始前  Before DQ |
|  | 图纸清单  Drawing list | 中文或英文  Chinese or English | 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 | 中文或英文  Chinese or English | 纸质和电子版  Hard copy &Elec | PDF | 3 | 系统交付时  System Handover |
|  | 组织结构图  Project Organization Chart | 中文或英文  Chinese or English | 纸质和电子版  Hard copy &Elec | PDF | 1 | DQ 开始前  Before DQ |
|  | 3D模型图  3D GA | 中文或英文  Chinese or English | 纸质和电子版  Hard copy &Elec | PDF | 1 | DQ 开始前  Before DQ |
|  | 容器机械图  Vessel mechanical drawings | 中文或英文  Chinese or English | 纸质和电子版  Hard copy &Elec | PDF | 1 | DQ 开始前  Before DQ |
|  | 装配图  General assembly drawing | 中文或英文  Chinese or English | 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 | 中文或英文  Chinese or English | 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 | 中文或英文  Chinese or English | 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 | 中文或英文  Chinese or English | 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 | 中文或英文  Chinese or English | 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 | 中文或英文  Chinese or English | 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 | 中文或英文  Chinese or English | 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 | 中文或英文  Chinese or English | 纸质和电子版  Hard copy &Elec | PDF | 1 | DQ 开始前  Before DQ |
|  | 子供应商容器文件  Vessel documentation of sub-supplier | 中文或英文Chinese or English | 纸质和电子版  Hard copy &Elec | PDF | 1 | DQ 开始前  Before DQ |
|  | 铭牌信息  Nameplate data's | 中文或英文Chinese or English | 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 | 中文或英文Chinese or English | 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 | 中文或英文Chinese or English | 纸质和电子版  Hard copy &Elec | PDF | 1 | FAT开始2周前  2 weeks before the start of FAT |
|  | 校准规程  SOP for Calibrations | 中文或英文Chinese or English | 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 | 中文或英文Chinese or English | 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 | 中文或英文Chinese or English | 纸质和电子版  Hard copy &Elec | PDF | 1 | FAT开始2周前  2 weeks before the start of FAT |
|  | 电抛光规程  Electro polishing procedure | 中文或英文Chinese or English | 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 | 中文或英文Chinese or English | 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 | 中文或英文Chinese or English | 纸质和电子版  Hard copy &Elec | PDF | 3 | 系统交付时  System Handover |
|  | 安装手册  Installation manual | 中文或英文Chinese or English | 纸质和电子版  Hard copy &Elec | PDF | 3 | 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 | 中文或英文Chinese or English | 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 | 中文或英文Chinese or English | 纸质和电子版  Hard copy &Elec | PDF | 1 | SAT开始4周前  4 weeks before the start of SAT |
|  | 仪表数据表  Instrument data sheets | 中文或英文Chinese or English | 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 | 中文或英文Chinese or English | 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 | 中文或英文Chinese or English | 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 | 中文或英文Chinese or English | 纸质和电子版  Hard copy &Elec | PDF | 1 | DQ 开始前  Before DQ |
|  | PID图  P&IDs | 中文或英文Chinese or English | 纸质和电子版  Hard copy &Elec | CAD | 1 | DQ 开始前  Before DQ |
|  | 容器图及接口清单 Vessel drawings & Nozzle list | 中文或英文Chinese or English | 纸质和电子版  Hard copy &Elec | PDF | 1 | DQ 开始前  Before DQ |
|  | 布局图  Layout | 中文或英文Chinese or English | 纸质和电子版  Hard copy &Elec | CAD | 1 | DQ 开始前  Before DQ |
|  | 运行描述  Operation Description | 中文或英文Chinese or English | 纸质和电子版  Hard copy &Elec | Word | 1 | DQ 开始前  Before DQ |
|  | I/O列表  I/O list （中英文 bilingual） | 中文或英文Chinese or English | 纸质和电子版  Hard copy &Elec | Excel | 1 | DQ 开始前  Before DQ |
|  | 功能说明  Functional specification | 中文或英文Chinese or English | 纸质和电子版  Hard copy &Elec | Word | 1 | DQ 开始前  Before DQ |
|  | 焊接设备及参数 Welding equipment and parameters | 中文或英文Chinese or English | 纸质和电子版  Hard copy &Elec | PDF | 1 | FAT开始2周前  2 weeks before the start of FAT |
|  | 偏差规程  Deviation procedure | 中文或英文Chinese or English | 纸质和电子版  Hard copy &Elec | PDF | 1 | DQ 开始前  Before DQ |
|  | 焊点总表  Weld summary | 中文或英文Chinese or English | 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 | 中文或英文Chinese or English | 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 | 中文或英文Chinese or English | 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) | 中文或英文Chinese or English | 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) | 中文或英文Chinese or English | 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 | 中文或英文Chinese or English | 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 | 中文或英文Chinese or English | 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 | 中文或英文Chinese or English | 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 | 中文或英文Chinese or English | 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 | 中文或英文Chinese or English | 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 | 中文或英文Chinese or English | 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 | 中文或英文Chinese or English | 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 | 中文或英文Chinese or English | 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 | 中文或英文Chinese or English | 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 | 中文或英文Chinese or English | 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 | 中文或英文Chinese or English | 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 | 中文或英文Chinese or English | 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 | 中文或英文Chinese or English | 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 | 中文或英文Chinese or English | 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 | 中文或英文Chinese or English | 纸质和电子版  Hard copy &Elec | Word | 1 | DQ 开始前  Before DQ |
|  | 需求追溯矩阵  RTM | 中文或英文Chinese or English | 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 | 中文或英文Chinese or English | 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 | 中文或英文Chinese or English | 纸质和电子版  Hard copy &Elec | Word | 1 | SAT开始4周前  4 weeks before the start of SAT |
|  | IOQ方案/报告  IOQ protocol/report | 中文或英文Chinese or English | 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 | 中文或英文Chinese or English | 纸质和电子版  Hard copy &Elec | PDF | 1 | SAT开始4周前  4 weeks before the start of SAT |
|  | 特殊工具清单  Special tools list | 中文或英文Chinese or English | 纸质和电子版  Hard copy &Elec | PDF | 1 | SAT开始4周前  4 weeks before the start of SAT |

\* 默认为报告批准后，于系统交付前统一交付 After the report is approved, it will be delivered before the delivery of the system.

* 1. 相关区域布局图 Relevant Layout
  2. 相关工艺仪表流程图 Relevant P&ID
  3. 零部件品牌推荐表 Component brand recommendation list
  4. 管道等级表 Piping Class Index