**重庆药友水土工厂202车间单抗项目**

**不锈钢工艺罐系统用户需求**

**URS for Process Tank 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生产线的不锈钢工艺罐系统的用户需求。

The purpose of this document is to define the user requirements of the SS process 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生产线的不锈钢工艺罐系统及其辅助系统（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 SS process 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2,000L 上清液中转罐 2,000L process tank, 1 set
* 1套18,000L收获罐 18,000L process tank, 1 set
* 3套1,500L 层析一收样灭活罐 1,500L chromatography A process tank, 3 sets
* 1套5,000L 层析二上样罐 5,000L chromatography B process tank, 1 set
* 2套4,000L 层析二收样罐 4,000L chromatography B process tank, 2 sets
* 1套15,000L层析三上样罐 15,000L chromatography C process tank, 1 set
* 1套15,000L层析三收样罐 15,000L chromatography C process tank, 1 set
* 1套15,000L除病毒收样罐 15,000L process t tank, 1 set
* 1套5,000L原液稀释罐 5,000L process tank, 1 set
* 所有不锈钢工艺罐附属的取样口 Sampling ports for all process tanks
* 18,000L离心收获罐配置底部通气装置 spargers for 18000L harvest tanks
* 灭活深滤过滤模块及夹具Depth filtration skid & holder
* 除病毒过滤模块及夹具Virus filtration skid & holder
* 4套除菌过滤模块Sterilizing filter module, 4 sets
* 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:

* 15,000L原液线不锈钢工艺罐系统

Stainless steel Process Tank system for 15,000L fermentation line

2,000L上清液中转罐\*1，18,000L收获罐\*1，1,500L层析一收样灭活罐\*4，5,000L层析二上样罐\*1，4,000L层析二收样罐\*2，15,000L层析三上样罐\*1，15,000L层析三收样罐\*1，15,000L除病毒收样罐\*1，2,000L原液稀释罐\*1，2,000L原液分装罐\*1，位于202生产楼。

2,000L process tank\*1, 18,000L process tank\*1, 1,500L chromatography A process tank\*4, 5,000L chromatography B process tank\*1, 1,500L chromatography B process tank \*4, 4,000L chromatography B process tank \*2, 15,000L chromatography C process tank\*1，15,000L chromatography C process tank\*1，15,000L process tank\*1, 2,000L process tank\*2 are located in the mechanical room of building 202#.

通过上游收获到的细胞培养液对其进行纯化技术，纯化步骤主要为3步层析，亲和层析，阴阳离子交换层析，除病毒过滤、超滤以及最终的原液配制。设备之间的工艺物料走向可参见下图：

The purification technology was carried out through the upstream harvested cell culture medium. The purification steps mainly included three steps of chromatography, pH virus inactivation, ion-exchange, virus removal filtration, ultrafiltration and final stock solution preparation. Downstream process equipment includes chromatography system, virus removal filtration system, ultrafiltration system, magnetic stirring system and freeze-thaw machine. See Figure below:







* 2000L上清液中转罐\*1，位于收获间，用于离心机产生上清液的收集缓冲，并持续将上清液传输至深层过滤模块；

2000L Supernatant buffer tank \* 1, located in the harvesting room, is used to buffering collect the supernatant produced by the centrifuge and continuously transfer the supernatant to the Depth Filtration Skid;

* 18000L收获罐\*1，位于机械间，用于深层过滤后的中间产品的收集、暂存和层析I的上样。

18000L harvest tank \* 1, located in the machine room, is used for collecting, temporary storage of intermediates after depth filtration and sample loading for chromatography I.

* 1500L层析I收集罐\*3，位于粗纯间，用于层析I中间产品分步收集、低pH灭活和调节。调节完成的中间产品会经过深层过滤和减菌过滤进入层析II上样罐。

1500L chromatography I collection tank \* 3, located in the Initial Purification room, is used for the step-by-step collection of chromatography I intermediate, low pH inactivation and regulation. The intermediates after adjustment will be filtered into chromatography II loading tank.

* 灭活深层过滤模块，位于粗纯间，用于过滤调节完成的中间产品并传输至层析II上样罐。灭活深层过滤膜包夹具需要包含在此文件范围内。

Inactivation Depth Filtration Skid \* 1, located in the Initial Purification room, is used to filter the supernatant and transmit it to the chromatography II loading tank. Inactivation depth filter membrane pack fixtures need to be included in this document scope.

* 5000L层析II上样罐\*1，位于机械间，用于灭活后中间产品的收集、混合和层析II的上样。

5000L chromatography II loading tank \* 1, located in the machine room, is used for collecting, mixing of intermediates after low pH inactivation and sample loading for chromatography II.

* 4000L层析II收集罐\*2，位于机械间，用于层析II中间产品收集、调节和层析III的上样。

4000L chromatography II collection tank \* 2, located in the Machine room, is used for the collection of chromatography II intermediate, regulation and sample loading for chromatography III.

* 18000L层析III上样罐\*1，位于机械间，用于层析II后中间产品的收集、混合和层析III的上样。

18000L chromatography III loading tank \* 1, located in the machine room, is used for collecting, mixing of intermediates after low pH inactivation and sample loading for chromatography III.

* 18000L层析III收集罐\*1，位于机械间，用于层析III中间产品收集和纳滤系统的进料。

18000L chromatography III collection tank \* 1, located in the Machine room, is used for the collection of chromatography III intermediate and feed of nanofiltration system.

* 除病毒过滤模块\*1，位于粗纯间，用于中间产品的过滤处理，并传输至纳滤收集罐。除病毒过滤膜包夹具需要包含在此文件范围内。

Nanofiltration Skid \* 1, located in the Initial Purification room, is used to filter the intermediate and transmit it to the nanofiltration collection tank. Virus filtration membrane pack fixtures need to be included in this document scope.

* 18000L纳滤收集罐\*1，位于精纯间，用于纳滤后中间产品收集。纳滤后的中间产品会进入超滤系统。

18000L nanofiltration collection tank \* 1, located in the Final Purification room, is used for the collection of intermediate after nanofiltration and the intermediate will be fed to Ultrafiltration system.

* 2000L原液稀释罐\*1，2000L原液分装罐\*1位于机械间，用于原液的配制和分装。

5000L bulk tank \* 2 is located in the machine room, used for preparation and sub-packaging of stock solution.

* 4套除菌过滤模块，2套分别用于层析三上样罐前，层析三收样罐前，位于粗纯间；2套分别用于原液稀释前，原液稀释后，位于精纯间。具体尺寸要求见条款6.4.5.7。

4 sets of sterilizing filter modules, 2 sets were used respectively before the sample loading tank of chromatography#3 and before the adoption tank of chromatography#3, located in the coarse room; 2 sets are respectively used before and after the dilution of the stock solution, located in the purity room. See Article 6.4.5.7 for specific size requirements.

上述设备之间需要有联动功能。

Associated interconnection among above listed equipment.

* 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管罐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 tank 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 | 18~30℃ |
|  | 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：0.3~0.35 MPa温度 Temp. : 80~85℃ |
|  | 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/50Hz220V/50Hz |
|  | 压缩空气 Compressed air | 动力 Drive | 压力 Pressure：0.6 MPa |
|  | 洁净压缩空气Clean 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 |
|  | 乙二醇Glycol solution | 降温Cooling | 压力 Pressure：0.3~0.35 MPa温度 Temp. : -5~0℃ |

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 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** |
| --- | --- | --- |
|  | 不锈钢工艺罐每批次工作体积范围的需要满足以下要求：The process tanks should be able to produce media every batch as below:* 1,500L 不锈钢工艺罐工作体积为300L~1,500L;

300L~1,500L working volume for 1,500L process tank;* 2,000L 不锈钢工艺罐工作体积为400L~2,000L；

400L~2,000L working volume for 2,000L process tank;* 3,000L 不锈钢工艺罐工作体积为600L~3000L；

600L~3,000L working volume for 3,000L process tank;* 5,000L不锈钢工艺罐工作体积为1,000L~5,000L；

1,000L~5,000L working volume for 5,000L process tank;* 8,000L不锈钢工艺罐工作体积为1,600L~8,000L；

1,600L~8,000L working volume for 8,000L process tank.* 10,000L不锈钢工艺罐工作体积为2,000L~10,000L；

2,000L~10,000L working volume for 10,000L process tank.* 18,000L不锈钢工艺罐工作体积为3,600L~18,000L；

3,600L~18,000L working volume for 18,000L process tank. | 质量Quality |
|  | 2000L以下的不锈钢工艺罐应至少在30min内完成物料的完全溶解且混合均匀。5000L至18000L的不锈钢工艺罐则需要至少在1小时内达到上述要求。The process tank below 2000L should complete dissolution of the material and mix it evenly within 30min at least. The 5000L 18,000L process tank needs to meet the above requirements within at least 1h. | 质量Quality |
|  | 根据厂房布局部分不锈钢工艺罐有单独的取样口连接洁净间。该取样口与洁净室墙板和罐体都需要密闭衔接，以保证C级/D级洁净室与机械间无连通。According to the layout of the plant, some intermediate tanks have separate sampling ports connected to clean rooms. The sampling port and the clean room wall panel and tank should be closed to ensure that there is no communication between grade C /D clean room and machinery. | 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，最终淋洗将使用热注射用水。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 hot 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 |
|  | 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 |
|  | 所有接触产品、物料或清洗水的设备应设计确保设备能够自排尽。All equipment in contact with product materials 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 |
|  | 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 |
|  | 夹套控温精度Jacket temperature control accuracy | ±0.5℃ | 质量Quality |
|  | 搅拌速度Agitation speed | 建议50~350rpm，具体数值根据搅拌选型50-350rpm is recommended, depends on the mixing model selection | 质量Quality |
|  | 搅拌速度控制精度Agitation speed control accuracy | ±2% | 质量Quality |
|  | pH测量范围及精度PH measurement range & accuracy | 范围/Range：2~12精度/Accuracy：±0.01 | 质量Quality |
|  | pH值在线检测与离线检测差值pH difference between online & offline | ±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 |
|  | 电导率值在线与离线检测差值Conductivity difference between online & offline | 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%; | 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 |
|  | 过滤压力传感器Filter pressure sensor | 精度≤0.1barAccuracy ≤ 0.1bar | 质量Quality |
|  | 深层过滤动力泵Power pump of deep filtration  | 泵的压力：3.5bar，流速不低于10000 L/hPressure: 3.5bar, Flow rate not less than 10000 L/h流速范围内精确度：≤±2%Accuracy within flow rate range: ≤± 2%  | 质量Quality |
|  | 灭活深层过滤动力泵Power pump of (Inactivated deep filtration) | 泵的压力：3.5bar，流速不低于10000 L/hPressure: 3.5bar, Flow rate not less than 10000 L/h流速范围内精确度：≤±2%或Accuracy within flow rate range: ≤±2% | 质量Quality |
|  | 除病毒过滤动力泵Power pump of virus filtration  | 泵的压力：3.5bar，流速不低于6000 L/hPressure: 3.5bar, Flow rate not less than 6000 L/h流速范围内精确度：≤±2%或±Accuracy within flow rate range: ≤± 2%  | 质量Quality |
|  | 动力泵运行时最低转速Power pump minimum speed in operation | 能满足至少10%的额定功率运行Meet at least 10% of the rated power operation | 质量Quality |
|  | 灭活深层过滤面积Fixture volume of inactivation depth filtration  | 预过滤 Pre-filtration：15 m2深层过滤 Depth filtration：10 m2 | 质量Quality |
|  | 除病毒过滤面积Fixture volume of virus filtration | 预过滤 Pre-filtration：20 m2除病毒过滤 virus filtration：15 m2 | 质量Quality |

* 1. 部件要求 Components Requirement
		1. 不锈钢工艺罐Process tanks

| **序号****ID No.** | **需求描述****Requirement Description** | **需求分类****Requirement Category** |
| --- | --- | --- |
|  | 工艺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、物料添加口、一次性取样器、pH探头、电导率探头、罐体温度探头、罐底阀。工艺罐采用称重模块和磁力搅拌。The process tanks shall be equipped with light mirror, rupture disk, tank pressure sensor, diaphragm pressure gauge, air filter, manhole / hand hole, material delivery port, disposable sampler, pH probe, conductivity probe, tank temperature probe, and tank bottom valve. The process tanks should use weighing module and magnetic stirring.  | 质量Quality |
|  | 亲和层析系统的上样罐控温要求：产品通过夹套低温保存在2~8℃，在进样到层析系统前需要回温至18~22℃。热媒介质温度不超过35℃，回温可通过管道换热（管中管）实现，罐体控温需要在3小时内完成。换热器不得采用无法排尽的形式，比如毛细管形式的换热器。The sample tank temperature control requirements of affinity chromatography system: the product is kept at 2~8℃ through the jacket and needs to be warmed back to 18~22℃ before the sample is injected into the chromatography system. The temperature of heat water does not exceed 35℃, The return temperature can be achieved through the pipeline heat exchange (tube in tube),tank temperature control needs to be completed within 3 hours. The heat exchanger shall not be in a form that cannot be drained, such as the capillary tube heat exchanger. | 质量Quality |
|  | 不锈钢工艺罐都需要带夹套，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。The process tanks needs jacket for liquid temperature control. And the style of jacket should be submitted by vender to owner for approval.  | 质量Quality |
|  | 深层过滤收获罐需要安装通气Sparger（采用直管式，通气孔直径3mm），通气管路需要配置质量流量计，空气过滤器。The harvest tank of Depth filtration system needs to be fitted with aerated Sparger (straight pipe type, with air hole diameter of 3mm), and the ventilation line needs to be equipped with mass flowmeter and air filter. | 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 |
|  | 人孔盖应配置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 |
|  | 不锈钢工艺罐采用柱塞式罐底阀。The process tank adopts plunger type 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电极能够连续显示，具有在线校正功能，且带3点校准功能。能够启用/禁用温度补偿功能。PH electrode can be displayed continuously, with online correction function, and with 3 point calibration function. and can be capable to use or not to use temperature compensate function. | 质量Quality |
|  | 电导率电极能够连续显示，能够启用/禁用温度补偿功能。The conductivity electrode can display continuously, and can be capable to use or not to use temperature compensate function. | 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 fixed with a pressure of 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 |
|  | 需要配置灭菌所需的装置，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** |
| --- | --- | --- |
|  | 工艺罐需要配备低剪切力磁力搅拌器，搅拌由供应商选型，经业主审核后提供。The process tanks needs to be equipped with a low shear force magnetic stirrer. The stirrer 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. 转子泵 Rotor pump

| **序号****ID No.** | **需求描述****Requirement Description** | **需求分类****Requirement Category** |
| --- | --- | --- |
|  | 转子泵符合卫生型设计要求，与产品接触部件材质SS316L，单机械密封Sic/Sic/EPDM(FDA)，内表面电解抛光处理，可以满足CIP/SIP工况。The rotor pump meets the sanitary design requirements. The product contact parts are made of SS316L, single mechanical seal Sic/Sic/EPDM(FDA), and the inner surface is electrolytically polished, which can meet CIP/SIP conditions. | 质量Quality |
|  | 转子泵流量需按照具体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 the rotor pump shall meet the P&ID requirements, 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 pump, speed setting/actual value, start/stop command, running status feedback and fault signal interaction with PCS system. | 质量Quality |

* + 1. 灭活深层过滤模块和除病毒过滤模块

Inactivated depth filtration skid and Virus filtration skid

| **序号****ID No.** | **需求描述****Requirement Description** | **需求分类****Requirement Category** |
| --- | --- | --- |
|  | 系统组成：动力泵模块、过滤器安装模块、管道、传感器等；System composition: power pump, filter installation module, pipeline, sensor, electric control cabinet, etc. | 质量Quality |
|  | 灭活深层过滤模块和除病毒过滤模块须配置有动力泵，用于上清液和中间产品的传输。The inactivated depth filtration skid and nanofiltration skid shall be equipped with a pump for the transmission of supernatant and intermediate. | 质量Quality |
|  | 泵后应配备质量流量计，反馈调节流速，实时记录通过流量。质量流量计的量程范围大于转子泵的流量量程范围。A mass flow meter shall be equipped behind the pump to feed back and adjust the flow rate and record the passing flow in real time. The range of the mass flowmeter should be larger than the flow range of the rotor pump. | 质量Quality |
|  | 灭活深层过滤膜包、除病毒预过滤滤器和除病毒过滤器的前后端须配有压力传感器，用于监控过滤压力。The front and rear ends of the inactivated depth filtration membrane package, nanofiltration pre-filter and main filter must be equipped with pressure sensors to monitor the filtration pressure. | 质量Quality |
|  | 过滤压力传感器精度≤0.1barFilter pressure sensor accuracy ≤ 0.1bar | 质量Quality |
|  | 须配有CIP短接管道，用于短接膜包/过滤器组对模块进行自动CIP/SIP。CIP stub pipe shall be provided for automatic CIP / SIP of module by short circuiting membrane package / filter group. | 质量Quality |
|  | 过滤器安装模块可适配多种品牌、滤器、膜包或夹具。同时应满足一级过滤&二级过滤的安装方式。The filter installation module can be adapted to various brands of filters, membrane packs or fixtures. At the same time, it shall meet the installation mode of primary filtration & secondary filtration. | 商业Business |

* + 1. 离心后深层过滤模块The depth filtration skid after the centrifuge

| **序号****ID No.** | **需求描述****Requirement Description** | **需求分类****Requirement Category** |
| --- | --- | --- |
|  | 系统组成：动力泵模块、大滤筒过滤器、管道、传感器等。System composition: power pump, large filter housing, pipeline, sensor, electric control cabinet, etc. | 质量Quality |
|  | 整个过滤面积不能低于120m2。The whole filtration area shall not be less than 120m2. | 质量Quality |
|  | 滤壳配备相应的清洗球，可以CIP/SIP功能。SIP需要整体进行，CIP分段进行，但需要在一个清洗程序中。Filter shell equipped with corresponding cleaning ball, can be CIP/SIP function. SIP needs to be done as a whole and CIP in sections, but in a cleaning program. | 质量Quality |
|  | 泵后应配备质量流量计，反馈调节流速，实时记录通过流量。A mass flow meter shall be equipped behind the pump to feed back and adjust the flow rate and record the passing flow in real time. | 质量Quality |
|  | 每个滤壳的前后均需要单独的压力监测，配备足够的压力传感器。Separate pressure monitoring at the front and back of each filter shell with adequate pressure sensors is required. | 质量Quality |
|  | 过滤压力传感器精度≤0.1barFilter pressure sensor accuracy ≤ 0.1bar | 质量Quality |
|  | 深层过滤膜包后端还需要配有浊度探头。浊度计的测量范围是0~200 NTUA turbidity probe is also required at the back end of the rear ends of the depth filtration membrane package. The measuring range of the turbidimeter is 0~200 NTU. | 质量Quality |
|  | 泵前配备液位计。The front of the pump is equipped with a level gauge | 质量Quality |
|  | 过滤器模块设计应便于维修拆卸和操作。对于过滤器滤壳提升和拆装需要提供移动提升拆装设备。 The filter module should be designed to facilitate maintenance, disassembly and operation. For the disassembly and assembly of the filter shell, Mobile disassembly equipment is required for lifting and disassembly of filter shell. | 商业Business |
|  | 所有滤壳顶部都配备吊耳。All filter shells are provided with lifting lugs at the top. | 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。呼吸器须位于洁净区，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 vent filters are installed in the clean area, 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，需要配置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液压提升拆装设备。 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, hydraulic lifting equipment should 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 |
|  | 在层析三上样罐前，层析三收样罐前，原液稀释罐前分别安装一个5芯30英寸的液体过滤器，为了方便后期工艺变更，要求供应商在设计时需要预留可以安装9芯30英寸的液体过滤器空间位置。A 5 core\*30” liquid filter should be installed respectively before the sample loading tank of chromatography#3, the sample collection tank of chromatography#3 and stock solution dilution. In order to facilitate later process changes, the supplier is required to reserve a space for the installation of 9 core 30” liquid filter during the design. | 质量Quality |
|  | 层析二上样前，除病毒收样罐前也分别安装一个5芯30英寸的液体过滤器，为了方便后期工艺变更，要求供应商在设计时需要预留可以安装9芯30英寸的液体过滤器空间位置。此处的过滤器模块可以分别对应集成到灭活深层过滤模块和除病毒过滤器模块内。A 5 core\*30” liquid filter should be installed respectively before the sample loading tank of chromatography#2, the sample collection tank of virus filtration and stock solution dilution. In order to facilitate later process changes, the supplier is required to reserve a space for the installation of 9 core 30” liquid filter during the design. The filter module here can be integrated into the inactivated depth filter module and the virus filtration module respectively. | 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 |
|  | 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 |
|  | 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 |
|  | 不锈钢工艺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 process 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** |
| --- | --- | --- |
|  | 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 |
|  | 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。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 |
|  | 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300mm和罐顶等，除外）。External surface temperature during all phases shall be lower than 45°C (Except CIP tanks cover which shall be lower than 60°C). | 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，另有照片更佳，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, additional photos are preferred 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 |
|  | 以下不锈钢工艺管罐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** |
| --- | --- | --- |
|  | 不锈钢工艺罐不锈钢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 process 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，用于集成不锈钢工艺罐不锈钢系统所有阀门反馈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 |
|  | 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 |
|  | 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 |
|  | 不锈钢工艺罐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 process 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 |
|  | 供应商应提供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 |
|  | 系统模块与PCS控制系统联合FAT调试期间的临时线缆由系统模块供应商提供，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 |
|  | 不锈钢工艺罐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 process 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, 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 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 |
|  | 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 |
|  | 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** |
| --- | --- | --- | --- | --- | --- | --- |
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|  | 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 |
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