**重庆药友水土工厂202车间单抗项目**

**在线配液系统用户需求**

**URS for Inline Conditioning System of 202 Project**

目录

[1. 目的PURPOSE 3](#_Toc107911751)

[2. 范围SCOPE 3](#_Toc107911752)

[3. 系统描述SYSTEM DESCRIPTION 4](#_Toc107911753)

[4. 定义/缩略语DEFINITIONS AND ABBREVIATIONS 6](#_Toc107911754)

[5. 参考资料及法规符合性 REFERENCES & REGULATIONS 6](#_Toc107911755)

[6. 需求REQUIREMENTS 6](#_Toc107911756)

[7. 版本历史REVISION HISTORY 32](#_Toc107911757)

[8. 附录APPENDIX 34](#_Toc107911758)

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生产线的在线配液系统的用户需求。

The purpose of this document is to define the user requirements of the Inline Conditioning

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生产线的在线配液系统及其附属的跟随罐和控制系统。

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 inline conditioning system and follow-up tanks, and control system.

本项目包含以下部分：

The scope of supply includes:

* 2套在线配液系统 Inline conditioning system, 2 sets
* 4套1500L 跟随罐 1500L follow-up tanks, 4 sets
* 2套3000L 跟随罐 3000L follow-up tanks, 2 sets
* 电控柜以及控制系统 Control Cabinet and Control system
* 在线配液系统到跟随罐的物料输送管道 The liquid transfer pipeline from inline conditioning system to follow-up tanks.

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:

 2套在线配液系统。6个跟随罐。

该系统主要用于生产过程中溶液配制，能够实现工艺所需的配方溶液的在线配液，达到较高的溶液配制精度及较少的废液排放，系统运行稳定且批次重复性高。系统包括，至少5台四元隔膜泵，至少5台流量计，压力传感器，在线混合器，PH传感器，电导率仪以及相应的管路和阀门。

2 sets inline condition system and 6 follow up tank. The system is mainly used for buffer preparation in production process. It can realize the inline preparation of formula solution required by the process, achieve higher buffer preparation accuracy and less waste liquid. The system operates stably and has high batch repeatability. The system includes at least five diaphragm pumps, at least five flow meters, pressure sensors, online mixers, PH sensors, conductivity meters and corresponding pipelines and valves.

在线配液系统供应商需要满足所给配方母液的配置要求，选择合适的泵来实现精准在线配液。

The supplier of the inline condition system needs to meet the configuration requirements of the mother liquor of the given formula, select the appropriate pump to achieve accurate online liquid preparation.

2套在线配液系统位于技术间，在线配液系统#1只服务于粗纯区，在线配液系统#2服务于粗纯区和精纯区。

Two sets of the inline condition systems are located in the technical room. The inline condition system #1 only serves the coarse purity zone, while the inline condition system #2 serves the coarse purity zone and the fine purity zone.

4套跟随罐分别给离心深层过滤模块，灭活深层过滤模块，除病毒过滤模块，亲和层析系统，阳离子层析系统，阴离子层析系统提供所需得buffer溶液。同时4套跟随罐还需要分别提供顶洗液到3套层析上样罐罐底物料管路。

4 sets of follow-tanks provide the required buffer solution for centrifugal depth filtration module, inactivated depth filtration module, virus filtration module, affinity chromatography system, cationic chromatography system and anionic chromatography system respectively. At the same time, the four sets of follow-tanks also need to provide the washing buffer solution to the bottom product pipe of the three sets of chromatographic sample tanks.

另外2套跟随罐分别给超滤模块提供所需得buffer溶液。

The other two sets of follow-tanks provide the required buffer solution to the ultrafiltration module.

* 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上游不锈钢配储液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 Media Preparation & Holding 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 | 18~28℃ |
|  | 房间湿度要求Room Humidity Requirement | 无 |
|  | 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 |
|  | 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 |

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
	14. DCS 分散控制系统 Decentralized control system
2. 参考资料及法规符合性 REFERENCES & REGULATIONS

在编写本URS的内容时已参考，且供应商需要满足下列文档的当前修订版：

The contents of this URS have been referenced and the supplier is required to meet the current 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要求，提交业主审核；若选型不一致，需提交业主批准后方可执行。The brand of system components and instruments shall refer to the owner's parts brand recommendation table. The selection of all parts should be submitted to the Client for review according to URS requirements; if the type selection is inconsistent, it should be submitted to the Client for approval before implementation. | 商务Commerce |
|  | 设备应贴有统一的设备铭牌，铭牌上应注明名称、产地、出厂日期、型号、重量及其他重要技术参数。The equipment should be attached with a unified nameplate. The equipment name, origin, date of manufacture, type, weight and other important technical parameters should be specified on the nameplate. | 质量Quality |
|  | 所有模块设计需满足客户的工艺功能要求。All the module design shall follow the process function requirement from the client.  | 质量Quality |
|  | 在线配液系统与缓冲液存储罐交接面：在线配液系统各个进出口预留一个阀门，此阀门和在线配液系统一起清洗。 预留的阀门和缓冲液存储罐之间的管路的连接和安装由缓冲液存储罐的供应商负责。缓冲液储存罐到预留的阀门之间的管路由清洗缓冲液储存罐的CIP站负责清洗。在线配液系统到跟随罐之间管路的连接和安装由在线配液系统的供应商负责。在线配液系统到跟随罐之间的管路由清洗在线配液系统的CIP站负责清洗。如下示意图：Interface between the inline conditioning system and buffer holding tank: one valve is reserved at each inlet and outlet of the inline conditioning system, which is cleaned together with the inline conditioning system. The connection and installation of the pipeline between the reserved valve and the buffer holding tank is the responsibility of the buffer holding tank’s supplier. The pipeline between the buffer holding tank and the reserved valve is cleaned by the CIP station that cleans the buffer holding tank. The connection and installation of the pipeline between the inline conditioning system and the follow-tank is the responsibility of the supplier of the inline conditioning system. The CIP station is responsible for cleaning the pipeline between the inline conditioning system and the follow-tank. The following diagram is shown: | 商务Commerce |
|  | 供应商的P&ID图需要根据业主要求进行更改和修正。The supplier P&ID drawing needs to be changed and corrected according to the owner's requirements. | 商务Commerce |

* 1. 工艺需求 Process Requirement

| **序号****ID No.** | **需求描述****Requirement Description** | **需求分类****Requirement Category** |
| --- | --- | --- |
|  | 跟随罐工作体积范围的需要满足以下要求：The follow-up tanks should be able to produce media every batch as below:* 4个1500L 跟随罐，工作体积为300L~1500L；

4set 1500L follow-up tank, working volume 300L~1500L* 2个3000L 跟随罐，工作体积为600L~3000L

2set 3000L follow-up tank, working volume 600L~3000L | 质量Quality |
|  | 在线配液模块接触高盐母液的部件需要满足特殊缓冲液母液特性，最少需要耐受4mol/L NaCl。The parts of the inline conditioning module which receiving high salt liquid should meet the characteristics of the special buffer mother liquid and be able to tolerate at least 4mol/L NaCl. | 质量Quality |
|  | 所有溶液配制合格(pH电导达到目标值)时间应控制在2min以内。All the buffer need to complete preparation（pH and conductivity achieve target range） in 2 minutes. | 质量Quality |
|  | 在线配液系统能够和母液罐，下游的纯化设备连接，实现在线配液。It can be connected with mother liquor tank and downstream purification equipment to realize inline conditioning. | 质量Quality |
|  | 在不同配方溶液间切换时，系统可自动进行清洗。When switching between different formulations, the system can clean automatical. | 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 |
|  | 在线配液系统在每步CIP的结束步骤，可以实现吹扫。The inline conditioning system 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。所有管道均需要自排空。最低点的排空坡度考虑至少1%。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.Self-emptying should be considered in all pipelines. The lowest discharge slope should be considered at least 1%. | 质量Quality |
|  | 系统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。The design shall aim at including as few dead leg as possible. The dead leg L/d qualification standard shall meet the corresponding requirements of current ASME BPE for different pipe diameters. | 质量Quality |
|  | 对于每台设备，每种公用工程管路（包括进/出）只提供一个确定位置的出入接口。公用工程接口至设备之间的连接（包括材料和安装）属于供应商的范围。若有必要，供应商应在公用工程管道上安装必要减压阀和安全阀。Only one utility connection will be foreseen for each fluid (including in and out) at agreed position for each equipment. Connections between utility interfaces and equipment (including materials and installation) fall within the scope of suppliers. If needed, Vendor will insert on the utilities lines the necessary pressure-reducing valves and safety devices. | 商业Business |
|  | 管路上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.标识的样式需由业主确认。The style of the mark should be confirmed by the owner. | 商务Commerce |
|  | 需要考虑CU如何取样，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。The vendor shall simulate the CU sampling to ensure the adequate space, safety, and ergonomics. Sampling requires installation of a water tray. | 商务Commerce |
|  | 系统具有流速配比配制缓冲液功能，即设备通过设定总流量和每个泵的流量比例自动运行。System shall have flow ratio control mode to prepare buffers. System runs automatically according to setting total flow rate and each pump flow rate percentage. | 质量Quality |
|  | pH和电导检测合格作为放行条件。pH and conductance test qualified as the release conditions. | 质量Quality |
|  | 系统稳定后，应当在线检测缓冲液的pH 和/或电导，当缓冲液偏离设定规格时，自动从排废口排废。当恢复到设定范围内时，自动切换回去。In steady state，System monitor final buffer pH and or Conductivity，if outside of spec, system will drain it from waste port automatically. When re fall into spec range. Switch online automatically. | 质量Quality |
|  | 在线配液系统#1配置一套PH计，电导率仪，取样阀，用于粗纯区的放行检测。在线配液系统#2配置2套PH计，电 导率仪，取样阀（1套用于粗纯区的放行检测，1套用于精纯区的放行检测）。所有的PH计，电导率仪，取样阀必须位于洁净区（粗纯区或者精纯区）。The inline condition system #1 is equipped with one set of PH meter, conductivity meter and sampling valve, which are used for the release detection of coarse purity area. The inline condition system #2 is equipped with 2 sets of PH meter, conductivity meter and sampling valve (one set is used for the release detection of coarse pure area and another set is used for the release detection of fine purity area). All PH meters, conductivity meters, and sampling valves must be located in the clean zone (coarse purity zone or fine purity zone). | 质量Quality |

* 1. 关键参数 Critical Parameter

| **序号****ID No.** | **参数 Parameter** | **要求 Requirement** | **需求分类****Requirement Category** |
| --- | --- | --- | --- |
|  | 控制模式Control mode | 流速控制模式flow rate control mode | 质量Quality |
|  | 系统流速Flow rate | 1000~12000L/h | 质量Quality |
|  | 隔膜泵精度Accuracy Diagram pump | 流速范围内精确度：≤±1%Accuracy within flow rate range: ± 2L/h | 质量Quality |
|  | 进口管路Inlet pipe | 不少于5个≥5pcs | 质量Quality |
|  | 出口管路Outlet pipe | 不少于2个≥2pcs | 质量Quality |
|  | pH误差精度pHError precision | pH误差≤±0.1pH,error ≤±0.1 | 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 -500 mS/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: 0.01-500mS /cm;Accuracy within the range≤ current test value ±5%;Low Conductivity detection range: 0-1000μS/cm;Accuracy within the range ≤current test value±1%; | 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 |
|  | pH测量范围PH measurement range | 2~12 | 质量Quality |
|  | pH测量精度PH measurement accuracy | ±0.01 | 质量Quality |
|  | 电导率值在线与离线检测差值Conductivity difference between online & offline | 高电导 ±1 mS /cm/低电导±0.1μS/cmHigh Conductivity: ±1 mS /cm Low Conductivity: ±0.1μS/cm | 质量Quality |
|  | 液位计测量精度Measuring accuracy of liquid level gauge | ±5% | 质量Quality |
|  | 流量传感器精度Flow rate accuracy | ±2% | 质量Quality |
|  | 管道耐压Piping withstand pressure | 不小于5bar | 质量Quality |

* 1. mk缓冲液母液配方表Buffer mother liquor formula table

| **序号****ID No.** | **需求描述****Requirement Description** | **需求分类****Requirement Category** |
| --- | --- | --- |
|  | 表格  描述已自动生成 | 质量Quality |

* 1. 部件要求 Components Requirement
		1. 跟随罐 Stainless steel follow-up tanks

| **序号****ID No.** | **需求描述****Requirement Description** | **需求分类****Requirement Category** |
| --- | --- | --- |
|  | 跟随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、进液口、一次性取样器、pH探头、电导率探头、液位计，罐底阀。The follow-up tanks shall be equipped with light mirror, rupture disk, tank pressure sensor, diaphragm pressure gauge, air filter, manhole / hand hole, inlet port, disposable sampler, pH probe, conductivity probe, tank bottom valve, level sensor. | 质量Quality |
|  | 跟随罐不需要带夹套需带保温。The follow up tanks without the jacket but need insulation. | 质量Quality |
|  | 服务于精纯间的跟随罐采用泵来送液，其他跟随罐使用压缩空气压料。The follow-tank serving the purity room uses the pump to deliver the liquid, and the other follow-tank uses compressed air to transfer the liquid. | 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 |
|  | 罐底阀采用隔膜式罐底阀。The follow-up 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 |
|  | 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. 四元隔膜泵 Four element diaphragm pump

| **序号****ID No.** | **需求描述****Requirement Description** | **需求分类****Requirement Category** |
| --- | --- | --- |
|  | 根据buffer配方情况，匹配足够数量的四元隔膜泵。According to the formulation of buffer , adequate amount of four element diaphragm pump need to be equipped . | 质量Quality |
|  | 每台泵后应当配备背压阀，可以抵消进口带来的正压，防止穿透。允许进口压力0-1 barg。Each pump has back pressure control valve（PCV） to compensation of inlet pressure avoiding of penetration. Working inlet pressure 0-1 barg. | 质量Quality |
|  | 膜片材质应采用EPDM膜片，材质符合FDA和NMPA的要求，附相关材质证书The diaphragm materials should be EPDM, the material should meet the requirements of FDA and NMPA, and the relevant material certificate should be attached. | 质量Quality |
|  | 每个泵后应当配备压力传感器。A pressure sensor shall be installed post each pump. | 质量Quality |
|  | 每个泵入口前应当配备气泡感应器，当母液耗尽，进口空管时，自动报警，关闭泵。Air sensor shall be installed pre each pump, when the stock solutions ran out, it detect air directly and stop the pump. | 质量Quality |
|  | 每个泵后应当配备质量流量计。Mass flow meter shall be installed post each pump. | 质量Quality |

* + 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 |
|  | 转子泵流量需至少满足36t/h，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 rotor pump should meet at least 50t/h, 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 |

* + 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。To prevent cross contamination, 0.22 μm Gas filter in/out shall be provided for compounding vessel, and the filter material should be PTFE.  | 质量Quality |
|  | 供应商每个过滤器需要配备滤芯以满足PQ之前（不包括PQ）的检测使用，直到验证通过为止。Each filter shall be equipped with a filter element to meet the requirements of PQ prior (excluding PQ) test use until the 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 |
|  | 呼吸器安装位置应便于维修拆卸和操作。The gas filter in/out should be installed in a position that is easy to service, remove and operate.  | 商业Business |

* + 1. 阀门、排水 Valves/Draining

| **序号****ID No.** | **需求描述****Requirement Description** | **需求分类****Requirement Category** |
| --- | --- | --- |
|  | 关键部位阀门需配置单反馈装置，使用感应式反馈装置，反馈装置需要配置LED灯。反馈装置和阀门应采用同一品牌。没有反馈装置的阀门需要配置可视化装置用于现场观察阀门状态。Valves at key parts shall be equipped with single feedback device, and it should use inductive feedback unit. The feedback device needs to be equipped with LED lights. Feedback device and valves should use the same brand. And the valves without feedback device need to be equipped with visualization device to observe the valve status on site. | 质量Quality |
|  | 与物料和洁净介质接触的阀门采用隔膜阀，隔膜阀的安装角度须与隔膜阀供应商的要求一致，膜片材质应采用EPDM/PTFE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相对应的材质证明。All valves in contact with materials and clean utility should be provided with material certification corresponding to the valve body. | 质量Quality |
|  | 所有与物料、纯蒸汽或清洗用水接触的阀门采用锻造隔膜阀；若采用其他形式阀门须经过业主同意。Forged diaphragm valves should be equipped in contact with product, pure steam or cleaning water; If other forms of valves are used, they must be approved by the owner. | 质量Quality |
|  | 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 |
|  | 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 |
|  | 所有疏水管路温度探头前端就近预留TC接口（50.5mm卡盘），用于布置验证探头。供应商给出接口位置的建议。TC interface(50.5mm) 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 |
|  | 管道温度传感器优先采用卫生型卡箍连接，与介质直接接触的部分采用316L材质，带4-20mA或RTD信号输出。若采用其他连接形式须经过业主同意。The sanitary tri-clamp connection is preferred for the temperature sensor of pipe, 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 |
|  | 罐体温度传感器采用套管式设计， ingold连接形式，温度传感器探头不与介质直接接触，带4-20mA或RTD信号输出。连接形式须经过业主同意。Tank temperature sensor adopts casing design, ingold connection form, the temperature sensor probe is not in direct contact with the medium, with 4-20mA or RTD signal output. The connection form must 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Ingold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 Ingold 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 |
|  | 流量计具有累计功能，并能清零。Flow meter has totalizer functionality, with re zero functionality. | 质量Quality |
|  | 所有仪表配备有流通池，以减少死角，短径三通插入式连接不被接受。To reduce dead leg, all the sensors elements fit into process line through flow cell, short T insertion format adaptor is not accepted. | 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应至少为316L，或满足特殊工艺需求，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 316L at least, or it should meet the special process requirement. 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. | 商业Business |
|  | 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，提供照片，且必需刻制成光盘。
2. 必须显示完整的焊道。
3. 必须可以看到氧化区的颜色。

Borescope video requirements.(1) Must be a live color video clip, supply photos and must be burned to CD.(2) The complete weld path must be visible.(3) The color of the oxide area must be visible. | 质量Quality |
|  | 焊点验收：1. 所有焊接质量应至少应达氧含量小于100 ppm，目测内表面显淡黄色。
2. 所有手动氩弧焊必需100%做彩色内窥镜检测，并留有记录。
3. 所有自动氩弧焊，最少随机抽取焊缝总量的20%要做彩色内窥镜摄影，并留有记录。
4. 焊接标准应参照现行版ASME BPE的标准。

焊接位置应该在焊接图上有文件记录可以追溯到焊缝施工人员，焊接记录上要有焊接两侧的材料的炉号。Welded joint acceptance:(1) All welding quality should be at least up to oxygen content less than 100 ppm, visual inspection of the inner surface shows light yellow.(2) All manual argon arc welding must do 100% color borescope inspection and keep records.(3) All automatic argon arc welding, at least 20% of the total number of randomly selected welds to do color borescope video, and keep records.(4) Welding standards should refer to the current version of the ASME BPE standards.Welding position should be documented on the welding diagram and can be traced back to the welder, welding log should indicate the heat number of the material on both sides of the weld. | 质量Quality |

* 1. 自控系统 Control system
		1. 控制系统供货范围及责任 Scope of supply of control system and responsibilities

| **序号****ID No.** | **需求描述****Requirement Description** | **需求分类****Requirement Category** |
| --- | --- | --- |
|  | 该项目将采用DCS一体化集中控制方式，控制系统将由甲方负责统一采购，不在在线配液系统供应商供货范围。The project will adopt DCS integrated centralized control mode, and the control system will be uniformly purchased by Henlius, which is not within the supply scope of the inline conditioning system supplier. | 商务Commerce |
|  | 在线配液系统供应商需提供所需DCS控制器硬件的数量及详细的技术要求，所配控制器负荷率≤60%。The supplier of the inline conditioning system shall provide the quantity and detailed technical requirements of the required DCS controller hardware, and the conformity rate of the equipped controller shall be less than 60%. | 质量Quality |
|  | 在线配液系统供应商系统集成需确保所有IO信号在DCS控制器冗余切换过程中无任何扰动。The system integration of the inline conditioning system supplier ensures that all IO signals are not disturbed during redundancy switching of DCS controllers. | 质量Quality |
|  | 在线配液系统电控柜内需预留DCS系统硬件安装位置。The DCS hardware installation position must be reserved in the electronic control cabinet of the inline conditioning system. | 商业Business |
|  | 在线配液系统供应商需提供详细的DCS系统详细的授权数量要求，授权应包括系统IO点、Unit单元、历史收集点数量及报表软件配置要求等。The inline conditioning system supplier shall provide detailed authorization quantity requirements for the DCS system, including system IO points, Unit units, historical collection points, report software ,etc. | 商业Business |
|  | 在线配液系统供应商需完成系统流程画面及程序组态设计工作，系统画面及编程软件版本及数据库需同甲方系统保持一致，不得擅自更改。The supplier of the inline conditioning system shall complete the system process picture and program configuration design. The system picture, programming software version and database shall be consistent with Henlius system, and shall not be changed without authorization. | 质量Quality |
|  | 在线配液系统供应商需严格按照S88标准完成系统控制程序、流程画面的设计及组态工作， 需完成OP及以下层程序设计工作，并协助甲方完成Procedure层程序设计工作。The inline conditioning system supplier shall complete the design and configuration of the system control program and process screen in strict accordance with the S88 standard, complete the program design of OP and the following layers, and assist Henlius to complete the program design of the procedure layer. | 商业Business |
|  | 在线配液系统供应商需协助甲方完成DCS系统数据库合并工作，并协同甲方一起完成对合库过程中产生的技术问题进行记录、分析处理及测试等工作，一旦数据库合并完成，数据库产权将归甲方所有，在线配液系统供应商不得拷贝DCS系统完整的数据库。The inline conditioning system supplier shall assist Henlius to complete the database integration of DCS system, and cooperate with Henlius to complete the recording, analysis and testing of technical problems arising in the process of database integration. Once the database integration is completed, the property right of the database shall belong to Henlius, and the Inline conditioning system supplier shall not copy the complete database of DCS system. | 商业Business |
|  | 在线配液系统供应商按照要求完成责任范围内的PD、FS、工程及相应的验证文件的编写工作和执行工作。The inline conditioning system supplier shall complete the preparation and execution of PD, FS, engineering and corresponding verification documents within the scope of responsibility as required. | 商业Business |
|  | 在线配液系统及其辅助设备的所需的pH、电导、温度、液位传感器及变送器均由在线配液系统供应商提供。The required pH, conductivity, temperature, level and transmitter of Inline condition system and its auxiliary equipment shall be provided by the supplier of Inline condition system. | 商务Commerce |

* + 1. 操作面板 Operation Panel

| **序号****ID No.** | **需求描述****Requirement Description** | **需求分类****Requirement Category** |
| --- | --- | --- |
|  | 现场操作HMI及键盘不在线配液系统供应商供货范围，将由甲方统一配置和安装，若需安装在层析系统模块上，在线配液系统供应商应负责设计安装位置。主控制屏应可以转动。The field operation HMI and keyboard of the inline conditioning system is no longer within the scope of the supply of the inline conditioning system supplier, and shall be uniformly configured and installed by Henlius. If it needs to be installed on the chromatography system module, the inline conditioning system supplier shall be responsible for designing the installation position. | 商务Commerce |
|  | 操作面板附近应配置声光报警器。Combined aural and visual alarm should be included and be located near the operator panel. | 质量Quality |

* + 1. 电缆和接线 Cables and wiring

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

* + 1. 数据记录Data records

| **序号****ID No.** | **需求描述****Requirement Description** | **需求分类****Requirement Category** |
| --- | --- | --- |
|  | 所有的报警、设备启停、设备运行参数的变更和事件信息都应被记录。All alarms, machine start-up and shut-down, changes in machine operating parameters setting and events information shall be recorded. | 质量Quality |
|  | 在线配液系统应至少连续记录以下批次数据：The inline condition system shall continuously record the following date as minimum during the batch run:- 泵流速 Flow velocity of pump- 进口端累计流量 Cumulative flow of Inlet - 跟随罐液位 level of process tank- pH pH- 电导 Conductivity  | 质量Quality |
|  | 在完成一个批次的生产后，需要自动生成一个批报告The system must be able to create a batch report after each batch production is completed. | 质量Quality |
|  | 批报告至少包括以下内容The batch report must at least contain the following information:* 所有的关键程序参数 All critical recipe values
* 所有的关键执行参数 All critical executed values
* 参与执行的操作人员 Operators involved in implementation
* 所有的事件 All events
* 所有的监控统计汇总 Summary of all monitoring statistics
* 所有的报警 All alarms

批报告的具体形式将由供应商提供，由业主确认。The form of the batch report will be provided by the supplier and confirmed by the owner | 质量Quality |
|  | 所有的数据将由在线配液系统的控制电脑进行存储和输出。All data will be stored and output by the control PC of the inline condition system. | 商业Business |
|  | 数据可以打印，或上传至中央服务器。Data can be printed or uploaded to central server. | 商业Business |
|  | 实时数据采集频率：至少每秒一次。数据打印频率：至少每分钟一次。系统至少可存储一年生产数据。Real-time data acquisition frequency: at least once per second. Printing data frequency: at least once per minute. The system can store production data for at least one year. | 商业Business |

* + 1. 系统界面 System interface

| **序号****ID No.** | **需求描述****Requirement Description** | **需求分类****Requirement Category** |
| --- | --- | --- |
|  | 人机界面采用中英文双语。The HMI language shall be preferable in bilingual. | 商业Business |
|  | 系统应配置至少2种运行模式：The system is able to work in three function modes at least:- 手动模式Manual Mode- 自动模式Automatic Mode | 商业Business |
|  | DCS直接控制所有系统功能。根据存储器中预存的数据和程序运行系统。The DCS directly controls all the system functions. According to the data acquired and the loaded program in its memory, it activates the outputs to properly operate the systems | 商业Business |
|  | 上位机软件必须允许：Upper computer software must be allowed:* 使用用户名和密码进行用户登录； User logon with username and password;
* 设置不同的用户访问等级；Different user level of access;
* 批次生产过程中对配方进行编辑和保存；recipe editing/saving after batch start.
* 查看和确认报警；Viewing and acknowledgment of alarms;
* 操作人员对事件进行确认以及文本输入；User answer to event, text input;
* 查看趋势图；Visualization of trends;
* 操作模式的切换（自动、维护和手动模式）；Changing modes of operation (auto, maintenance & manual);
* 执行下载。Initiation of Download.
 | 质量Quality |
|  | 操作者应能在系统操作界面上输入或直接显示以下信息：The machine control system shall prompt the operator to enter or display the following alphanumeric data:* 操作者名称Operator identity
* 产品名称或项目号Product name or project number
* 批号Batch number
* 日期 Date

以上信息应作为保存的批生产记录的开头。The above information shall be saved at the beginning of the batch record. | 质量Quality |
|  | 参数查看和历史数据查阅应不会干扰或暂停当前设备运行。Parameter viewing and historical data access should not interfere with or suspend device operation. | 商业Business |
|  | 屏幕显示的参数单位应是公制标准单位。Display parameter units shall be metric standard units. | 商业Business |

* + 1. 数据管理要求 Data Management

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

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

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

* + 1. 权限要求 Security

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

* + 1. 故障和报警 Fault/alarm

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

* 1. 安全要求 Safety Requirement

| **序号****ID No.** | **需求描述****Requirement Description** | **需求分类****Requirement Category** |
| --- | --- | --- |
|  | 设备、钢平台、标识和铭牌等任何部位不应有锋利的边缘和尖角。钢平台底面需包覆完整。There shall be no sharp edge and sharp angle at any part of equipment, steel platform, logo, nameplate, etc. The bottom side of steel platform needs to be covered completely. | 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 |

* 1. 验证要求 Validation Requirement

| **序号****ID No.** | **需求描述****Requirement Description** | **需求分类****Requirement Category** |
| --- | --- | --- |
|  | 供应商应提供一份质量计划，由业主审核批准。The supplier shall develop a Quality Plan for owner’s review and approval. | 商务Commerce |
|  | 供应商需要完成的质量工作须包括，但不限于：The quality work required by the supplier shall include, but not limited to:* 验证计划 Verification Plan
* 风险评估 Risk assessment
* 设计确认 DQ
* 预FAT(工厂内部测试) Pre-FAT(VIT)
* 工厂验收测试 FAT
* 现场验收测试 SAT
* 调试 Commissioning
* 安装/运行确认 I/OQ
* 协助性能确认 PQ assistance
 | 商务Commerce |
|  | DQ工作应在设备开始制造前完成，避免DQ结果对设备制造过程造成影响。It is recommended to complete DQ before equipment manufacturing to avoid DQ results affecting equipment manufacturing process. | 商务Commerce |
|  | 在进行正式的工厂验收测试之前，供应商必须完成以下测试项目。测试项目的相关文件需在FAT时可以查阅。Prior to the performance of the main Factory Acceptance test, the supplier must complete the items listed below. Documentation of these activities will be available for review at the FAT.* 100%图纸检查(机械和电气) 100% Drawings checks (Mechanical & Electrical)
* PID一致性检查 P&ID compliance check
* 布局图一致性检查 GA compliance check
* 制造材质确认 Material of construction verification.
* 100%表面抛光度确认

100% Surface finish verification * 坡度确认 Slope verification.
* 电气检查，包括接线、终端等 Electrical verification including wiring, terminations etc.
* 绝缘检查 Insulation inspection
* 控制面板检查、设备盘点及实物检查 Control panel visual inspection, equipment inventory & physical checks
* 标签标牌检查 All items tagged and labelled as per specification
* 100%文件检查 Documentation check; all documents
* 容器、管道压力测试 Pneumatic/vacuum testing of vessels & pipe works.
 | 商务Commerce |
|  | 只有在所有FAT文件经业主验收关闭后设备方可打包运输以交付。The system will only be released for delivery when all FAT documents are closed out by the owner | 商务Commerce |
|  | 在FAT期间，须编制故障日志以及偏差/备注日志，记录每天FAT中发现的问题。During FAT, the fault log and deviation/comment log should be compiled to record the problems found in FAT every day. | 商务Commerce |
|  | 在FAT前，供应商应对温度、压力和流量仪表进行校准。Primary calibration will be carried out by the Vendor, prior to FAT, on temperature, pressure and flow instruments. | 商务Commerce |
|  | FAT测试应包括，但不限于：The FAT tests shall include, but not be limited to, the following tests:- 设备尺寸检查Dimensional Check- 与房顶/墙壁/地面的界面检查Interface with Ceiling / Walls / Floor- 公用工程连接位置检查 Utilities Connection Location x, y and z- PID检查 P&ID Check- 核黄素和全排放测试Riboflavin and Full Discharge Test- 坡度检查 Slopes- 排水检查 Drainability- 组件安装及方向检查 Component installation and orientation Check- 仪器仪表安装检查 Instrument Installation- 保温检查 Insulation inspection- 标签检查 Labeling inspection- 材质证书检查 Material Certificates- 焊接检查 Welding Certificates- 100%内窥镜检查 100%Endoscope Welding Shots- 焊工资质检查 Welders Certification- 压力容器报告检查 Pressure Vessel Certificates- 压力测试报告检查 Pressure Test Reports- 管道清洁报告检查 Welding and Piping Cleaning Reports- 管道钝化报告检查 Welding and Piping Passivation Reports | 商务Commerce |
|  | 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 |
|  | 供应商应派遣经验丰富的培训师，并明确培训的内容、时间、人员等。Suppliers should send experienced trainers and clarify the contents, time and personnel of the training. | 商务Commerce |
|  | 提供每台设备不少于10个名额的培训，培训内容应包括设备基本原理和操作技能培训，应确保培训的系统全面。The provision of not less than 10 training places for each equipment should include training in basic principles and operational skills of the equipment, and ensure that the training system is comprehensive. | 商务Commerce |

* 1. 维护保养 Maintenance

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

* 1. 后期服务 Service

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

* 1. 备品备件 Spares

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

* 1. 包装运输要求 Packing and Transportation

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

* 1. 文件要求 Documentation

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

1. 版本历史REVISION HISTORY

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

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

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

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

| **序号****No.** | **文件名称****Document Name** | **语言****Language** | **纸质版/电子版****Hard copy****/Electronic** | **电子版格式(Word, Excel, PDF. Etc.)** | **纸版份数****Num of Hard copy** | **文件提供时间****Doc Provide Time** |
| --- | --- | --- | --- | --- | --- | --- |
|  | URS响应表Compliance to URS | 中文或英文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Component 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 | 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 |
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* 1. 相关区域布局图 Relevant Layout
	2. 管道等级表 Piping Class Index