**重庆药友水土工厂202车间单抗项目**

**超滤系统用户需求**

**URS for Ultrafiltration System of 202 Project**

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1. 目的PURPOSE

本文件目的是定义重庆药友水土工厂202车间单抗项目15,000L生产线的超滤系统的用户需求。

The purpose of this document is to define the user requirements for ultrafiltration 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。本项目包括了超滤系统以及辅助设备（例如中间样品罐体等）。

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

本项目包含1台适合15,000 L原液生产规模的超滤系统，由以下部分组成：

The scope of supply includes 1 set ultrafiltration systems fit for 15,000 L scale of production, which consist of the following parts

* 超滤膜组 Ultrafiltration membrane group holder and
* 主泵 Main pump
* 配套管路及阀门 Matching pipeline and valve
* 过程罐 Process tank
* 监控超滤过程的工艺仪表，包括电子称重系统、流量计、温度计、压力传感器、pH电极、UV监测系统、电导率电极等

Process instruments for monitoring ultrafiltration process, including electronic weighing system, flowmeter, thermometer, pressure sensor, pH electrode, UV sensor, conductivity electrode, etc.

* 膜包完整性测试口 Port of membranes integrity test
* 电控柜 Electric control cabinets

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

超滤系统位于202生产楼15,000L生产线精纯间，将用于15,000 L原液生产规模中的超滤工序。

The ultrafiltration system is located on the 15,000L fermentation Line of production building 202# and will be used for ultrafiltration of 15,000 L bulk production.

本系统应满足每天24小时连续工作，并且连续时间不少于48小时。

The system should work continuously 24 hours a day, and the continuous time should not be less than 48 hours per week.

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

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

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

* + 1. 布局 Layout

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

* + 1. 公用介质 Utility

|  |  |  |  |
| --- | --- | --- | --- |
| **序号 No.** | **公共设施 Utilities** | **用途 Function** | **范围/容量 Conditions** |
|  | 电气  Electric | 供电  Power | 380V±10V，50Hz±10%  220V±10V，50Hz±10% |
|  | 洁净压缩空气  Clean Compressed air | 动力  Drive | 压力 Pressure：0.6 MPa |
|  | 洁净蒸汽  Clean steam | 灭菌  Sterilization | 压力 Pressure：0.3 MPa  温度 Temp. : 121℃ |

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

在编写本URS的内容时已参考，且供应商需要满足下列文档的当前修订版：

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

* 2010中国GMP

NMPA: Good Manufacturing Practice for Drugs (2010 Version)

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

1. 需求REQUIREMENTS

URS的每条要求可按如下分类为：

Each requirement in the URS can be classified as following:

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

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

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

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

* 商业需求：不影响产品质量的商业需求

Business: Business requirements that do not impact product quality

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

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

* 1. 通用要求 General Requirement

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 供应商需提供设备的P&ID, 三维图纸，配合业主完成厂房立体布局图。  The supplier shall provide the P&ID,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。若选型超出推荐表之外，需提交业主批准。  The brand of system components and instruments shall refer to the owner's parts brand recommendation table. | 商务  Commerce |
|  | 设备应贴有统一的设备铭牌，铭牌上应注明名称、产地、出厂日期、型号、重量及其他重要技术参数。  The equipment should be attached with a unified nameplate. The equipment name, origin, date of manufacture, type, weight and other important technical parameters should be specified on the nameplate. | 质量  Quality |
|  | 供应商的P&ID图需要根据业主要求进行更改和修正。  The supplier P&ID drawing needs to be changed and corrected according to the owner’s requirements. | 商务  Commerce |

* 1. 工艺需求 Process Requirement

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 超滤系统包括：超滤膜组、主泵、用于放置泵和超滤膜组的带轮移动机架。主泵用于向超滤膜组供料。  The ultrafiltration system includes: ultrafiltration membrane group; main pump; wheeled mobile rack for placing the pump and ultrafiltration membrane group. The main pump is used to feed the ultrafiltration membrane group. | 质量  Quality |
|  | 高浓缩比设计，使该设备可以在料液较少的工作状态下也可以运行，生产。  The design of high concentration ratio makes the equipment can be operated and produced in the working state with less material liquid. | 商业  Business |
|  | 低产热设计，保证在工艺过程中产热较低，不对产品产生影响。  The design of low heat generation ensures that the heat generation is low during the process and does not affect the product. | 质量  Quality |
|  | 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 |
|  | 过程罐：采用2000 L不锈钢罐体，对应15000 L生产线规模；具备搅拌功能和称重模块，可与超滤系统、配储液系统、工艺系统关联控制。  Process tank: Adopt 2000 L stainless steel tank, corresponding to 15000 L production line scale respectively, with stirring function and weighing module. It can be associated with ultrafiltration system, Buffer Prep. & Holding system and process system. | 质量  Quality |
|  | 就地控制单元需可以显示当前工艺参数值和趋势曲线。显示时间区间值可调整。  The local control unit needs to be able to display current process parameter values and trend curves. The display time interval is adjustable. | 质量  Quality |
|  | 就地控制单元可以预先设定以下控制，主要包括：根据转移料液的重量，发送控制溶液传输的启停信号；根据过程罐中的料液重量，控制超滤浓缩工艺的终止；根据透过端累积流量，控制换液体积数。  The local control unit can pre-set the following controls, which mainly include: control the start and stop of the according to the weight of the transferred liquid; control the termination of the ultrafiltration process according to the weight of the liquid in the process tank; control the volume of fluid exchanged according to the cumulative flow rate on the permeate end. | 质量  Quality |
|  | 关联控制要求：过程罐的称重信号可关联到超滤系统、配储液系统和工艺系统，反馈控制主泵的启停和中间体/缓冲液的进料，根据过程罐料液重量控制搅拌。  Associated control requirements: the weighing signal of the process tank can be connected to the ultrafiltration system, Buffer Prep. & Holding system and process system, feed back the start and stop of the main pump and the feeding of intermediate / buffer solution, and control the mixing according to the weight of the feed liquid in the process tank. | 质量  Quality |
|  | 控制模式为Feed flow+TMP和Delta P+TMP，两者都可选，同时透过端可以控制压力，Feed Flow能满足不低于360 LMH的通量，TMP和Delta P能满足不低于1.5 bar的压力，另外考虑补料速度能覆盖进料速度。  The control modes are Feed flow +TMP and Delta P+TMP, both of which are optional. Meanwhile, the pressure can be controlled through the end. The Feed Flow can meet the flux of not less than 360 LMH, and the TMP and Delta P can meet the pressure of not less than 1.5 bar. | 质量  Quality |
|  | 接触产品物料的设备应设计确保不使用压缩空气吹扫也能够自排尽。  All equipment in contact with product materials shall be designed to ensure that the equipment can be self-drained without compressed air purging. | 质量  Quality |
|  | 所有与产品物料接触的部位应能耐受碱液在位清洁。  All parts in contact with product shall be capable of being CIP by alkali solution. | 商业  Business |
|  | 应使用CIP循环清洗来去除罐体和管道内的颗粒、污迹和残余溶液。冲洗将使用纯化水，最终淋洗将使用注射用水。  CIP cycle cleaning should be used to remove particles, stains and residual solution in the tank and piping. Purified water will be used for flushing and WFI will be used for final rinsing. | 质量  Quality |
|  | 必须使用核黄素做罐体以及所有关联部件的覆盖检测，包括呼吸器底部，罐顶预留口背面，上封头喷淋测试和罐体全覆盖喷淋测试等。  Riboflavin must be used to perform coverage tests for tanks and all associated components, including the bottom of the vent filter, the back of the tank top reserve, spray tests for the upper head and full coverage spray tests for tanks. | 质量  Quality |
|  | 过程罐和管道在CIP的每步结束步骤，可以实现吹扫。  The tank and pipe should be able to blow dry at the CIP per 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 |
|  | 搅拌器应易于拆卸，可实现CIP和SIP，不会造成产品残留。  The stirrer should be easy for dismantle, can be CIP and SIP, and will not cause the product residue. | 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。  The brand of system components and instruments shall refer to the owner's parts brand recommendation table. | 商务  Commerce |
|  | 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。若有必要，供应商应在公用工程管道上安装必要减压阀和安全阀。  Only one utility connection will be foreseen for each fluid (including in and out) at agreed position for each equipment. Connections between utility interfaces and equipment (including materials and installation) fall within the scope of suppliers. If needed, Vendor will insert on the utilities lines the necessary pressure-reducing valves and safety devices. | 商业  Business |
|  | 所有可拆连管道和仪表接均为快卡连接。  All detachable pipe and instruments connections are clamps. | 商业  Business |
|  | 软管应尽量做到自排尽。  Hose should be self-draining | 质量  Quality |
|  | 管路内容物和流向应在管路上标明，不同内容物采用不同颜色区分。  The contents and direction of the pipeline should be marked, and different contents should be distinguished by different colors. | 商业  Business |
|  | 机械部件和管路的标识样式由业主提供，供应商设计交业主确认。  例如阀门，传感器，泵等。  The identification pattern of mechanical parts and piping shall be provided by the owner, and the supplier's design shall be submitted to the Owner for approval. Such as valves, sensors, pumps, etc. | 商务  Commerce |
|  | 需要考虑CU如何取样，保证有足够的操作空间，安全和人体工程学。  The vendor shall simulate the CU sampling to ensure the adequate space, safety, and ergonomics. | 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** |
| --- | --- | --- | --- |
|  | 夹具容积  Volume of fixture | 40~200 m2 | 质量  Quality |
|  | 跨膜压  Transmembrane Pressure | 范围/Range：0.3~3.0 bar  精度/Accuracy：0.1 bar | 质量  Quality |
|  | PCV开度  PCV Opening | 范围/ Range：0-99%  精度/ Accuracy：1% | 质量  Quality |
|  | 主泵流速  Flow rate of main pump | 流速/ Flow rate：不低于54000 L/h  not less than 54000 L/h  精度/ Accuracy：0.3% | 质量  Quality |
|  | 主泵运行时最低转速  Main pump minimum speed in operation | 应满足至少5%的额定功率运行  Meet at least 5% of the rated power operation | 质量  Quality |
|  | 进口端、透过端和回流端压力  Pressure of inlet, permeate and retentate side | 范围/ Range：0~6 bar  精度/ Accuracy：±0.1 bar | 质量  Quality |
|  | 过程罐重量  Weight of process tank | 量程/ Range：0~2000 kg  精度/ Accuracy：最小工作体积的0.3%  0.3% of the minimum working volume | 质量  Quality |
|  | pH值 | pH检测范围：0-14、  pH2-12范围内精确度：±0.01，具有校正、温度补偿功能。  PH detection range: 0-14  Accuracy within the ph2-12 range: ±0.01, with calibration and temperature compensation functions. | 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 |
|  | 电导率  Conductivity | 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: 0.01-500mS /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 |
|  | 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/cm  High Conductivity: ±1 mS /cm  Low Conductivity: ±0.1μS/cm | 质量  Quality |
|  | UV | 检测波长/ Detection wavelength：280nm  光程/ Optical path：10 mm  量程/ Range：0~3 AU | 质量  Quality |
|  | 温度  Temperature | 范围/ Range：0~150℃  可读性/ Readability：0.1℃ | 质量  Quality |

* 1. 部件要求 Components Requirement
     1. 超滤膜包 Ultrafiltration module

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | TMP控制范围：0.3~3.0 bar，控制精度：0.1 bar。  TMP control range: 0.3 ~ 3.0 bar, control accuracy: 0.1 bar. | 质量  Quality |
|  | 进口端和透过端可显示累计流量，并根据工艺需求进行清零操作。  The cumulative flow can be displayed include the inlet side and permeate side, and auto-zero according to the process requirements. | 质量  Quality |
|  | 进口端：管道尺寸需匹配流速需求，采用316 L不锈钢，管道Ra ≤0.4 μm；夹具入口前具有进口端压力、质量流量计在线检测功能；具有进口压力报警功能。  Inlet: pipe size need to match flowrate requirement ,316 L stainless steel, pipeline Ra≤0.4 μm;  Before the fixture entrance, it has the function of on-line inspection of inlet pressure and mass flow meter. With inlet pressure alarm function. | 质量  Quality |
|  | 回流端：管道尺寸需匹配流速需求，采用316 L不锈钢，管道Ra ≤ 0.4 μm；设计完整性测试仪接口和自动调节阀；可通过TMP设置自动反馈调节阀门开度，并实现TMP压力报警功能；设计取样口。  Retentate line: pipe size need to match flowrate requirement ,using 316 L stainless steel, pipeline Ra ≤0.4 μm; with integrity testing port, sampling port and automatic adjustment valve; automatic valve opening controlling should be achieved according to TMP setting; and with TMP alarm function. | 质量  Quality |
|  | 透过端：管道尺寸需匹配流速需求，采用316 L不锈钢，管道Ra ≤0.4μm；设计pH、电导率、质量流量计和UV280在线监测；具有UV报警功能。  Permeate line: pipe size need to match flowrate requirement ,using 316 L stainless steel, pipe Ra ≤0.4μm; design pH, conductivity , Mass flow meter and UV280 online monitoring; with UV alarm function. | 质量  Quality |
|  | 透过端配备质量流量计，可累计透过体积，实现水通量自动测定功能；同时可进行设定，满足一定的透过体积后，可进行提示或反馈控制主泵、补料及其他阀门，实现洗滤终点自动控制。  The permeate pipe is equipped with a mass flow meter, which can accumulate the permeate volume and realize the automatic calculation of NWP; As the certain permeate volume reached, system should prompt and even stop the main pump, , and other valves. | 质量  Quality |
|  | 透过端配备pH、电导率计，可在透过体积达到设置值后，检测透过液满足设定pH/电导率条件，可进行提示或反馈控制主泵、补料及其他阀门，实现终点自动控制。  The permeate line is equipped with a pH and conductivity meter, which can detect whether the permeated liquid meets the set pH / conductivity conditions after the permeate volume reaches the set value, and it can prompt or control the main pump, and other valves. Realize automatic control of the diafiltration end point. | 质量  Quality |
|  | 一体化超滤膜组夹具，可支持200 m2的超滤膜包，配备手动液压装置。  The integrated ultrafiltration membrane group holder, can hold 150 m2 ultrafiltration membrane cassettes, equipped with manual hydraulic device. | 商业  Business |
|  | 当膜包进口端管路压力超过一定限度时，压力控制器报警并关闭泵。  When the pressure of membrane inlet pipe exceeds a certain limit, the pressure controller alarms and shuts down the pump. | 商业  Business |
|  | 超滤单元机械表面应光滑，无裂缝、毛刺和尖锐突角。  The mechanical surface of the ultrafiltration unit should be smooth, free of cracks, burrs and sharp corners. | 商务  Commerce |

* + 1. 主泵 Main pump

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 主泵采用卫生级进口泵（转子泵），泵头内部接触物料部分的材料均为316 L不锈钢，Ra ≤0.4 μm；可变频调速，机械密封性为SIC/SIC，卫生型TC接口，减速电机选用主流进口品牌，防护等级IP54。  The main pump adopts hygienic imported pump（lobe pump）. The material of the pump head that contacts the product is 316 L stainless steel, Ra ≤0.4μm; with variable frequency speed regulation, mechanical seal is SIC / SIC, hygienic TC interface, the gear motor uses the mainstream of imported brand, protection grade IP54. | 质量  Quality |
|  | 主泵最大流速不低于54000 L/h。  The maximum flow rate of the main pump is not less than 54000 L/h. | 质量  Quality |
|  | 主泵工作压力：< 6 bar。  Working pressure of main pump: <6 bar. | 质量  Quality |

* + 1. 过程罐 Process Tank

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 采用2000 L不锈钢罐体；采用316 L不锈钢材质。抛光度Ra≤0.4μm。  Use 2000 L stainless steel tank; use 316 L stainless steel material. Polishing Ra≤0.4μm. | 质量  Quality |
|  | 过程罐上需具备检测pH、电导功能。检测最低体积不得大于200L。最终原料出料为利用压缩空气从罐底泵前管道输出。  The pH and conductance of the process tank should be tested.The minimum test volume shall not be greater than 200L. The final raw material is discharged from the front pipe of tank bottom pump by using compressed air. | 商业  Business |
|  | 过程罐需要配制底部磁力搅拌器，需确保工作体积范围（200L~2000L）内的混匀效果。  The process tanks should be equipped bottom magnetic stirrer, it is necessary to ensure the mixing effect within the working volume range (200L~2000L). | 质量  Quality |
|  | 应配置称重模块，并与系统整合，可进行校准，能与控制系统形成反馈调节。  Weighing module should be configured and integrated with the system, can be calibrated, and can form feedback adjustment with the control system. | 质量  Quality |
|  | 称重传感器应为316 L不锈钢。  The load sensor should be 316L stainless steel. | 质量  Quality |
|  | CIP 过程中底部磁力搅拌需要被浸没。  Bottom magnetic stirrer may be submerged during CIP. | 质量  Quality |
|  | 搅拌器应易于拆卸，可实现CIP和SIP，不会造成产品残留。  The stirrer should be easy for dismantle, can be CIP and SIP, and will not cause the product residue. | 质量  Quality |
|  | 磁力搅拌可调速，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 |
|  | 过程罐使用隔膜式罐底阀。  The process 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。  PH electrode can be displayed continuously, with online correction 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桨叶的清洗要求设置喷淋球的位置和数量，罐体/管道清洁无死角。喷淋球为固定式，压力不低于1.5 bar。  The system supplier shall set the position and number of spray balls according to the cleaning requirements of the stirring blades, and the tank / pipeline shall be clean without dead angle. The spray ball is fixed with a pressure of not less than 1.5 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 |
|  | 配有压力传感器和空气滤器方便排除罐中空气。  Equipped with pressure sensor and air filter to facilitate the removal of air from the tank. | 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 |
|  | 留有方便观察液位的观察口。  There is an observation window for easy observation of the liquid level. | 商业  Business |
|  | 当过程罐内样品重量达到设定的低位报警限时，系统会发出警告或报警，并停止主泵运行。  When the weight of the sample in the process tank reaches set low alarm limit, the system will issue a warning or alarm and stop the operation of the main pump. | 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隔膜阀采用锻造隔膜阀。Forged diaphragm valves should be equipped in contact with product, pure steam or cleaning water. | 质量  Quality |
|  | 纯蒸汽采用洁净卫生型减压阀。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 adopts clean and sanitary pressure reducing valve. 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 1mm 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 |
|  | 所有与产品和物料接触的阀门金属材质均应最低为SS 316L不锈钢，电抛光粗糙度不大于0.4μm，并钝化处理。  All metal in contact with product and buffer shall be stainless steel 316L as a minimum, electro polishing to a roughness of less than 0.4 um and passivation treatment. | 质量  Quality |
|  | 回流端PCV阀门应为卫生级气动隔膜阀，阀体材质316 L不锈钢，双膜EPDM/PTFE，卫生型TC接口。  The PCV valve at the retentate side should be a sanitary pneumatic diaphragm valve, the body material is 316 L stainless steel, double membrane EPDM / PTFE, hygienic TC interface. | 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** |
| --- | --- | --- |
|  | 罐体侧面预留至少1个1.5” NA接口用于安装一次性取样器和1个2”的NA接口用于验证取样。  At least one 1.5 " NA interface shall be reserved for installation of disposable sampler and one 2" NA interface for verification sampling on the side of tank. | 质量  Quality |
|  | 工艺用水和纯蒸汽需安装取样阀；取样阀设置位置需便于操作，不易污染, 取样阀下方安装接水盘。  Sampling valves shall be installed for process water and pure steam; The location of the sampling valve should be easy to operate and not easy to pollute. The water tray should be installed below the sampling valve. | 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 should be provided. The validity period of instruments should be covered until PQ is completed. | 商业  Business |
|  | 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 |
|  | 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. | 商业  Business |
|  | 系统应配备探头/传感器，监测以下内容，包括但不限于：  The system shall be equipped with probes/sensors to monitor the following, including but not limited to:   * 进口端压力 Inlet Pressure * 回流端压力 Retentate Pressure * 透过端压力 Permeate Pressure * 进口端流速 Flow rate of Inlet * 透过端流速 Flow rate of Permeate * 透过端电导率 Permeate Conductivity * 透过端pH Permeate PH * 透过端UV Permeate UV * 储罐称重 Tank Weighing * PCV开度 PCV Opening * 透过端温度 Permeate Temperature | 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. | 商业  Business |
|  | 管路中的压力仪表及模拟输入信号的校准和自行调节功能需可在就地控制单元上进行操作。  The calibration and self-adjusting functions of the pressure instruments and analog input signals in the pipeline need to be operable on the local control unit. | 商业  Business |
|  | 进口、回流、透过端分别配备压力传感器，可实现TMP 自动计算及控制。在压力过高时可自动停止系统的运行。  The inlet, retentate, permeate sides are equipped with pressure sensors, which can realize automatic calculation and control of TMP. The system can be automatically stopped when the pressure is too high. | 质量  Quality |
|  | 过压保护（TMP压力过高时）。  Overpressure protection ( when TMP pressure is too high). | EHS |
|  | 膜包进口端、透过端和过程罐进口端均使用质量流量计；应采用 316 L 不锈钢。  Mass flow meters are used at the inlet, the permeate side and the inlet of tank side; Imported mass flow meters of 316 L stainless steel should be used. | 质量  Quality |
|  | 流量计：在操作界面上显示进口端流速，同时该进口端流速反馈控制主泵。  The flowmeter: The inlet flow rate is displayed on the operation interface, and the feedback of inlet end flow rate controls the main pump. | 质量  Quality |
|  | 透过端配备电导率探头，对CIP后清洗效果进行电导监测确认。  The permeate side is equipped with a conductivity probe to monitor conductivity and confirm the cleaning effect after CIP. | 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 |
|  | 透过端配备UV传感器，对超滤过程中是否有蛋白透过进行监测和报警。  The permeate side is equipped with a UV sensor to monitor if there is protein penetration during the ultrafiltration process, then alarm. | 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 |
|  | 透过端配备UV传感器，对超滤过程中是否有蛋白透过进行监测和报警。  The permeate side is equipped with a UV sensor to monitor if there is protein penetration during the ultrafiltration process, then alarm. | 质量  Quality |
|  | 超滤过程罐采用称重单元进行测量，选用的称重单元工作时，应不受设备其他部件振动的影响。关机状态下移动时，不会对称重单元精度造成影响。  The ultrafiltration process tank uses a weighing unit for measurement. When the selected weighing unit is working, it should not be affected by the vibration of other parts of the equipment. When moving it in the shutdown state, the accuracy of the weight unit will not be affected. | 质量  Quality |
|  | 过程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 tank 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SS 316L不锈钢，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 AISI 316L as a minimum. 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 |
|  | UV传感器与料液接触部分应采用316 L不锈钢。  The part where the UV sensor contacts the product should be 316 L stainless steel. | 质量  Quality |
|  | 罐体外表面还原处理，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 process tanks shall be reduced 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 |
|  | 所有支腿、框架、外罩、取样口和钢平台应采用不锈钢SS304制造，表面无毛刺。  All legs, framework, exterior cover, sampling ports and platform shall be manufactured from stainless steel SS 304. The surface is smooth without burrs. | 商务  Commerce |
|  | 设备外表面应易于清洁。不允许出现尖角、锐边、突出物等导致设备难以清洁或清洁用具破损的异常状况。  Equipment external surface shall be easy to clean. No sharp corners, sharp edges or protrusions are allowed, which leads to some abnormal situation, such as difficult to thoroughly clean or easy to break the cleaning tools. | 商业  Business |
|  | 与产品接触的非金属材质（如软管、波纹管、垫圈）表面应符合FDA和NMPA的要求，并提供材质证明（FDA或USP ClassVI）。  The surface of non-metallic materials (such as hoses, bellows, washers) in contact with the product shall meet FDA and NMPA requirements and provide material certification (FDA or USP ClassVI). | 质量  Quality |
|  | 与产品接触或洁净室内的表面不允许进行表面喷涂（电机外壳除外）。  There shall be no painted surfaces local to product or in cleanroom (except motor housing). | 质量  Quality |
|  | 所有设备与产品接触的不锈钢原材料均须追溯至炉批号。  Raw material traceability must be maintained for all materials of construction used to manufacture the equipment. | 质量  Quality |
|  | 制造材料不得释放颗粒物（不脱落、无添加、不反应、不会因清洗或湿热灭菌而降解）。  Materials of construction shall not release particles. (MOC’s shall be non-shedding, non-additive, non-reactive and will not degrade due to cleaning or autoclaving). | 质量  Quality |
|  | 所有需高温灭菌的设备/部件材质应能够耐受135℃高温，持续时间至少30分钟。  All equipment/components requiring high temperature sterilization should be material to withstand temperatures up to 135°C for at least 30 minutes. | 质量  Quality |
|  | 非产品接触的表面应能经受消毒剂The surface of non-product contact parts shall be resistant to the sanitizing agents:  - 30%的双氧水 30% H2O2  - 70%酒精 70% alcohol  - 4.5%的过氧乙酸4.5% peracetic acid  - 杀孢子剂 Sporicide  - 甲醛 Formaldehyde  - 异丙醇 IPA | 商业  Business |
|  | 所有运动部件均应经过润滑。有润滑的设备需保证润滑剂不会泄漏到工艺系统和公用工程中也不会泄漏到洁净室环境中。  All moving parts shall be lubricated. The design of the lubrication equipment shall ensure that the lubricant cannot leak into the process, direct utilities or into the cGMP area. | 商业  Business |
|  | 如使用润滑剂，应使用易于清洗的食品级润滑剂。供应商应提供所有润滑剂的相关证明文件。  Food grade lubricants that are easy to clean using WFI, shall be used for all locations where mechanical failure of lubricant seals would allow the lubricant to leak into areas where it may come into contact with the vials. The Vendor shall provide supporting documentation for each lubricant. | 质量  Quality |
|  | 电磁干扰和无线电波干扰：此台设备应抗电磁干扰和无线电波干扰。应符合CE认证电磁干扰和排放的要求。  Electromagnetic interference and radio wave interference: This equipment should be resistant to electromagnetic interference and radio wave interference. It should meet the requirements of CE certification for electromagnetic interference and emissions. | 商业  Business |

* + 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). | 质量  Quality |
|  | 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). | 安全  EHS |

* + 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ASME BPE要求的自动焊接。  All clean tubing will be orbital welded as per requirement of 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 |
|  | 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 |
|  | 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 |
|  | 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. 控制系统 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，不在超滤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 ultrafiltration system supplier. | 商业  Business |
|  | 超滤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 ultrafiltration 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 |
|  | 超滤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 ultrafiltration system supplier ensures that all IO signals are not disturbed during redundancy switching of DCS controllers. | 质量  Quality |
|  | 超滤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 ultrafiltration system. | 商业  Business |
|  | 超滤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需求等。  The ultrafiltration 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 |
|  | 超滤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 ultrafiltration 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 |
|  | 超滤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 ultrafiltration 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 |
|  | 超滤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，超滤系统供应商不得拷贝DCS系统完整的数据库。  The ultrafiltration 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 ultrafiltration system supplier shall not copy the complete database of DCS system. | 商业  Business |
|  | 超滤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 ultrafiltration 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 |
|  | 超滤系统及其辅助设备的所需的pH、电导、温度、称重传感器及变送器均由超滤系统供应商提供。  The required pH, conductivity, temperature, load cell and transmitter of Ultrafiltration system and its auxiliary equipment shall be provided by the supplier of Ultrafiltration system. | 商务  Commerce |
|  | 需配置磁力搅拌转速信号转换器，监测磁力搅拌器实际转速。  Magnetic stirring speed signal converter needs to be equipped to monitor the actual speed of the magnetic stirrer. | 质量  Quality |

* + 1. 操作面板 Operation Panel

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 超滤系统的现场操作HMI及键盘不在超滤系统供应商供货范围，将由甲方统一配置和安装，若需安装在超滤系统模块上，超滤系统供应商应负责设计安装位置。  The field operation HMI and keyboard of the ultrafiltration system is no longer within the scope of the supply of the ultrafiltration system supplier, and shall be uniformly configured and installed by Henlius. If it needs to be installed on the ultrafiltration system module, the ultrafiltration 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 |
|  | 超滤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 ultrafiltration system or between external devices and the gas pipe should be fed into the bottom of the electric control cabinet. | 质量  Quality |
|  | 超滤系统电控柜至PCS系统夹层分支桥架线槽穿线管由超滤系统供应商负责完成安装，从并完成超滤系统侧线缆接线。  The wiring pipe between the electric control cabinet of the ultrafiltration system and the bridge cable trough of the sandwich branch of the PCS system shall be installed by the supplier of the ultrafiltration system, and the cable connection from the side of the ultrafiltration system shall be completed. | 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 |

* + 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 |
|  | 超滤系统应至少连续记录以下批次数据：  The ultrafiltration system shall continuously record the following date as minimum during the batch run:  - 主泵流速 Flow velocity of main pump  - 进口端累计流量 Cumulative flow of Inlet  - 透过端流速 Flow rate of Permeate  - 透过端累计流量 Cumulative flow of Permeate  - 过程罐重量 Weight of process tank  - 透过端pH Permeate pH  - 透过端电导 Permeate Conductivity  - 透过端UV Permeate UV  - 透过端温度 Permeate Temperature  - 跨膜压 Transmembrane Pressure  - 回流端PCV开度 PCV Opening of Retentate | 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DCS系统进行存储和输出。  All data will be stored and output by DCS 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** |
| --- | --- | --- |
|  | 人机界面采用英文界面。  The HMI language shall be preferable English interface. | 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 events, text input  - 查看趋势图 Visualization of trends.  - 操作模式的切换（自动、维护、手动模式） Changing modes of operation (auto, maintenance, manual).  - 执行下载 Initiation of Download | 商业  Business |
|  | 操作者应能在系统操作界面上输入或直接显示以下信息：  The machine control system shall prompt the operator to enter or display the following alphanumeric data:   * 操作者名称Operator identity * 产品名称或项目号Product name or project number * 批号Batch number * 日期 Date   以上信息应作为保存的批生产记录的开头。  The above information shall be saved at the beginning of the batch record. | 质量  Quality |
|  | 参数查看和历史数据查阅应不会干扰或暂停当前设备运行。  Parameter viewing and historical data access should not interfere with or suspend device operation. | 商业  Business |
|  | 屏幕显示的参数单位应是公制标准单位。  Display parameter units shall be metric standard units. | 商业  Business |

* + 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超滤系统停机。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 ultrafiltration system to stop. The reason for the stop shall be recorded and displayed alarm on the operator panel:  - 设定压力超标 Out of specification pressure set points  - 设定UV超标 Out of specification temperature 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** |
| --- | --- | --- | --- |
|  | | 超滤系统在意外断电情况下自动进入保护状态，避免设备内部环境遭到破坏。供应商应详细说明，断电后超滤系统的保护状态及持续时间。  The ultrafiltration system automatically enters the protection state under the condition of accidental power failure, avoiding the internal environment of the equipment being polluted. The supplier shall specify the protection state and duration time of the ultrafiltration system after power failure. | 商业  Business |
|  | | 当超滤过程罐内样品重量达到设定的低位报警限时，系统会发出警告或报警，并停止主泵运行。  When the weight of the sample in the ultrafiltration process tank reaches the set low alarm limit, the system will issue a warning or alarm and stop the operation of the main pump. | EHS |
|  | | 系统具有干转保护（过程罐液体较少时的导致泵的空转）。  The system has idling protection (the pump will idle when the liquid in the process tank is low). | EHS |
|  | 超滤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 the system shall design and install the motor emergency stop, remote/local switch button, run and fault status indicator lamp. | | 安全  EHS |
|  | | 如果设备功能失调或失控的情况下，应该按照以下优先级别保护:人员→设备→产品  If the device is out of control or functioning, it should be protected according to the following priority: personnel > equipment > products. | EHS |
|  | | 软件系统如果有可替换的高版本操作系统，厂家须提供升级服务，升级后满足工艺和使用要求。  If there is a replacement version of the operating system, the manufacturer must provide upgrade services, upgrade to meet the requirements of the process and use. | 商务  Commerce |
|  | | 控制系统应与公用工程互锁，以防止在公用工程不足时运行程序。  The control system should be interlocked with the utility to prevent the program from running when there are insufficient utilities. | 质量  Quality |
|  | | 系统突然断电时，机器逐渐停稳，以保护操作工、设备和产品。恢复供电后设备不能自动开机，必须人工启动。  When the system suddenly loses power, the machine gradually stops to protect operators, equipment and products. The equipment cannot be started automatically after power supply is restored, but must be started manually. | 质量  Quality |
|  | | 设备应配置有防电涌装置。  Surge protection devices should be equipped. | EHS |
|  | | 超滤系统框架需充分考虑人员的安全防护。  The safety protection of personnel should be fully considered in the design of ultrafiltration system frame. | EHS |
|  | | 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 |
|  | FAT电气测试应包括，但不限于：  The FAT electrical tests shall include, but not be limited to, the following tests:   * 安装检查 Installation Check * 电控柜布局检查 Control Cabinets Layout * GMP关键仪器校验证书确认   Verify Calibration Certificates of GMP Critical Instruments   * GMP关键仪器回路检查及功能测试   Loop Check of GMP Critical Instruments and Functional Testing   * 接线标签和颜色检查 Labelling and color * 硬件及DCS配置检查 Hardware and DCS Configuration | 商务  Commerce |
|  | FAT系统功能测试应包括，但不限于：  The FAT control system functional tests shall include, but not be limited to, the following tests:   * 屏幕菜单、图形测试 Menus and Mimics Check * 100%输入输出测试 100% Input/output test * 参数/配方测试 Parameter/ recipe test * 报警测试 Alarm test * 趋势记录测试 Trend test * 权限测试 Security test * 备份/恢复测试 Back-up/ restore test * 审计追踪测试 Audit trail test | 商务  Commerce |
|  | FAT性能测试应包括，但不限于：  The FAT performance tests shall include, but not be limited to, the following tests:   * 流速测试 Flow rate test * 参数反馈调节测试 Parameter feedback adjustment test * 仪器仪表校准调节测试 Instrument calibration adjustment test * 设计功能测试 Design function test | 商务  Commerce |
|  | 工厂验收测试的内容应在现场验收测试中重复执行，但根据项目质量计划和验证计划中关于测试引用的描述，部分的测试可以引用FAT的结果或进行抽样检查。  In general FAT tests shall be repeated in SAT. According to the description of test references in Project Quality Plan and Validation Plan, part of the tests can refer to the results of FAT or be confirmed by spot check. | 商务  Commerce |
|  | SAT的方案由供应商起草，业主审核批准。  Protocols for the site acceptance test (SAT) shall be produced by the Vendor and approved by Owner. | 商务  Commerce |
|  | IQ方案由供应商起草并在IQ执行前由业主批准。IQ测试将在业主现场进行，业主将见证所有的测试执行。  IQ protocols are to be prepared by the supplier and approved by owner prior to the IQ. The supplier shall execute tests on the owner’s site and owner will witness all the tests. | 商务  Commerce |
|  | 供应商需协助业主进行PQ方案的起草和执行。  The supplier shall assist the owner in the drafting and implementation of PQ scheme. | 商务  Commerce |
|  | 调试阶段包括校准、回路调整和确保设备运行满足需求说明的所有调整。  The commissioning stage shall include calibration, loop tuning and all other adjustments required to ensure the equipment performs as specified in the Requisition. | 商务  Commerce |
|  | 供应商应对整个调试阶段负责，包括配合现场施工团队。供应商应估计完成调试所需的天数，并给出每日工作安排。  The supplier shall be responsible for the entire commissioning phase, including cooperation with the site construction team. Vendor shall estimate the number of days required to complete the commissioning and quote a daily rate for Site attendance. | 商务  Commerce |
|  | 供应商应配备足够的备件和材料以确保调试过程能够顺利完成。调试用的备件和材料应与设备一同运至业主现场。  The Vendor shall include for adequate spares and materials to ensure that the commissioning process can be successfully carried out. These shall be delivered to Site in the same shipment as the equipment. | 商务  Commerce |

* 1. 培训要求 Training

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 供应商负责所有技术指导和人员培训，包括：图纸、工艺、操作、设备维护、设备性能及问题解答等。  Supplier is responsible for all technical guidance and personnel training, including drawings, processes, operations, equipment maintenance, equipment performance and problem solving. | 商务  Commerce |
|  | 供应商应派遣经验丰富的培训师，并明确培训的内容、时间、人员等。  Suppliers should send experienced trainers and clarify the contents, time and personnel of the training. | 商务  Commerce |
|  | 供应商有能力和义务为业主提供指定产品的UF/DF操作参数优化方案并协助业主完成方案实施。  The supplier has the ability and obligation to provide the owner with the UF / DF operating parameter optimization program for the specified product and assist the owner to complete the program implementation. | 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 |
| --- | --- | --- | --- | --- | --- | --- |
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|  | 设备重量信息  Weight information of equipment | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | FAT开始2周前  2 weeks before the start of FAT |
|  | 变更控制规程  Change Order Procedure | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | DQ 开始前  Before DQ |
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|  | 仪表标签列表 Instrument Label Schedule | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | FAT开始2周前  2 weeks before the start of FAT |
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|  | 铭牌信息  Nameplate data's | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | FAT开始2周前  2 weeks before the start of FAT |
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|  | 钝化规程  Passivation procedure | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | 系统交付前  Before System Handover |
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|  | 安装手册  Installation manual | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 2 | 系统交付时  System Handover |
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|  | 消耗品及耐耗品/配件清单  List of consumables and wear/spare parts | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | SAT开始4周前  4 weeks before the start of SAT |
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|  | 电气负荷  Electrical load (kW, V, Phase, Frequency) | 中英双语Bilingual | 纸质和电子版  Hard copy &Elec | PDF | 1 | DQ 开始前  Before DQ |
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