**重庆药友水土工厂202车间单抗项目**

**层析系统用户需求**

**URS for Chromatography System of 202 Project**

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1. 目的PURPOSE

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

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

1. 范围SCOPE

本文连同其所有附件，涵盖了所有工作范围以及设计、制造、检查、交付、调试和性能测试的最低要求。

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.

本项目包含1台满足流速在200-5000L/h的亲和层析系统，1台满足流速在200-5000L/h的阴离子层析系统，1台满足流速在200-5000L/h阳离子层析系统，由以下部分组成：

The scope of supply includes one affinity chromatography system meets the flow rate of 200-5000L/h, one anionic chromatography system meets the flow rate of 200-5000L/h, and one cation chromatography system meets the flow rate of 200-5000L/h，which consist of the following parts

* 主机 mainframe
* 电控柜 Electric control cabinet
* 和设备相关的管道、阀门、配件等 pipes, valves and accessories related to the equipment

本系统服务于202生产楼15,000L生产线。

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

需要提供的范围包括：

The scope of supply shall include:

* 详细设计Detail Design
* 设计确认 Design Qualification
* 建造 Fabrication
* 工厂接收测试 FAT
* 交付 Delivery
* 调试以及现场接收测试 Commissioning & SAT
* 安装确认和运行确认 IQ & OQ
* 性能确认协助 PQ Assistance
* 操作人员的培训 Operation Personnel Training
* 文件 Documentation
* 移交 Handover
1. 系统描述SYSTEM DESCRIPTION
	1. 设施/设备/仪器/系统描述 Facility/ Equipment/ Instrument/ System Description

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

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

本系统应满足每天24小时连续工作，并且连续时间不少于7\*24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层析柱以及辅助设备的设计。若设备有额外的布局要求，应告知业主并由业主批准。

Vendor should design the chromatography columns and support system according to the owner's layout. Any additional layout requirements for the 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 | D级区，18~25℃Grade D Area, 18~25℃ |
|  | 房间湿度要求Room Humidity Requirement | 30~70%RH |
|  | 房间布局图Room Layout | 参见平面布局图See layout |

* + 1. 公用介质 Utility

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

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

在编写本URS的内容时已参考，且供应商需要满足下列文档的当前修订版：

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

* 2010中国GMP

NMPA: Good Manufacturing Practice for Drugs (2010 Version)

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

URS的每条要求可按如下分类为：

Each requirement in the URS can be classified as following:

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

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

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

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

* 商业需求：不影响产品质量的商业需求

Business: Business requirements that do not impact product quality

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

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

* 1. 通用要求 General Requirement

| **序号****ID No.** | **需求描述****Requirement Description** | **需求分类****Requirement Category** |
| --- | --- | --- |
|  | 供应商需提供设备的三维图纸，配合业主完成厂房立体布局图。The supplier shall provide the 3D drawings of the equipment and cooperate with the owner to complete the 3D layout of the plant. | 质量Quality |
|  | 系统部件及仪器仪表的品牌参考业主的零部件品牌推荐表。所有零部件选型应依据URS要求，提交业主审核；若选型不一致，需提交业主批准后方可执行。The brand of system components and instruments shall refer to the owner's parts brand recommendation table. The selection of all parts should be submitted to the Client for review according to URS requirements; if the type selection is inconsistent, it should be submitted to the Client for approval before implementation. | 商务Commerce |
|  | 设备应贴有统一的设备铭牌，铭牌上应注明名称、产地、出厂日期、型号、重量及其他重要技术参数。The equipment should be attached with a unified nameplate. The equipment name, origin, date of manufacture, type, weight and other important technical parameters should be specified on the nameplate. | 质量Quality |
|  | 层析系统与不锈钢管罐系统交接面：层析系统各个进出口预留一个阀门，此阀门和层析系统一起清洗。 预留的阀门和不锈钢管罐系统之间的管路的连接和安装由不锈钢管罐系统的供应商负责。跟随罐到预留的阀门之间的管路由清洗跟随罐的CIP站负责清洗。层析系统到中间体罐之间的管路由清洗中间体罐的CIP站负责清洗。如下示意图：Interface between the chromatography system and the stainless steel pipe tank system: a valve is reserved for each inlet and outlet of the chromatography system, which is cleaned together with the chromatography system. The connection and installation of the pipelines between the reserved valves and the stainless steel pipe tank system is the responsibility of the supplier of the stainless steel tube pipe system. The pipeline between the follow-tank and the reserved valve is cleaned by the CIP station that cleans the follow-tank. The pipeline between the chromatography system and the intermediate tank is cleaned by the CIP station that cleans the intermediate 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** |
| --- | --- | --- |
|  | 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 |
|  | 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 |
|  | 所有管道均需要自排空。最低点的排空坡度考虑至少1%。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 acceptance standard of dead leg L/d shall meet the corresponding requirements of the current vision of ASME BPE for different pipe diameters. | 质量Quality |
|  | 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 |
|  | 管道标识的样式由业主提供，供应商设计交业主确认。The style of the pipe mark shall be provided by the owner, and the supplier design shall be confirmed by the owner. | 商务Commerce |
|  | 层析系统进层析柱前的阀门要实现在线CIP，具有自循环清洗功能。The valve before the tomographic system enters the tomographic column should realize CIP on line and have self-circulating cleaning function. | 质量Quality |
|  | 层析系统进出口各需要一个温度传感器，用于监测进出口温度。The inlet and outlet of the chromatography system need a temperature sensor for monitoring the inlet and outlet temperature. | 质量Quality |
|  | 层析进口端配备液体滤器用于过滤产品，选用3芯30”滤器，滤壳具有在线CIP功能。需配备相应的喷淋球，管道，阀门等。Need liquid filter（triple core 30”） for chromatography system，filter housing can do inline cleaning，relative spray ball ,pipe and valves. | 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 |
| --- | --- | --- | --- |
|  | 系统耐压The system pressure | 0-6 bar | 质量Quality |
|  | 系统在最高流速下的耐压Pressure resistance of the system at maximum flow rate | ≤1bar | 质量Quality |
|  | UV检测波长UV wavelength | 280/254nm | 质量Quality |
|  | pH检测pH test | 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: 0-14Accuracy 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 |
|  | 电导率检测Conductivity test | 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/cmHigh Conductivity: ±1 mS /cm Low Conductivity: ±0.1μS/cm | 质量Quality |
|  | 流速Flow rate | 流速范围在：200-5000L /h，在200-5000L h流速范围内精确度：≤±2%。Velocity range: 200-5000L/h, accuracy: ≤±2% within the velocity range of 200-5000L/h 流速范围在：350-8000L /h，在350-8000L h流速范围内精确度：≤±2%。Velocity range: 350-8000L/h, accuracy: ≤±2% within the velocity range of 350-8000L/h  | 质量Quality |
|  | 温度Temperature | 温度范围：0-60℃，在2-60℃范围内精确度：±0.2℃。Temperature range: 0-60℃, within 2-60℃ accuracy: ±0.2℃. | 质量Quality |

* 1. 部件要求 Components Requirement
		1. 系统泵 Pump

| **序号****ID No.** | **需求描述****Requirement Description** | **需求分类****Requirement Category** |
| --- | --- | --- |
|  | 系统泵：双泵梯度系统，采用卫生级隔膜泵，泵腔为无菌设计。System pump: dual pump gradient system, adopt sanitary diaphragm pump, pump chamber is aseptic design. | 质量Quality |
|  | 系统泵每个泵头需均配备隔膜破裂报警探头，有膜破裂漏液报警。报警信息可在控制软件中设置。The system pump is equipped with diaphragm rupture alarm probe, with Membrane rupture and leakage alarm. Alarm information can be set in control software. | 质量Quality |
|  | 进口：每台泵2个进口，应具有空气传感器，用于上样时气泡的检测，检测灵敏度可调。阀门选用零死角隔膜阀，并且能够通过电信号反馈阀门位置状态。阀门带有隔膜报警功能。Inlet: Each pump have 2 inlet, equipped with air sensors for the detection of bubbles during sample loading with adjustable detection sensitivity.The valve adopts the zero dead Angle diaphragm valve and can feedback the valve position through the electric signal.Valve with alarm function. | 质量Quality |
|  | 1台系统流速：达到200-5000L/h，且在A、B进行配比梯度时，满足最低流速要求。供应商应提供系统支持的梯度配比范围曲线。梯度范围：B：200-5000L/h、精确度：≤±2%。1台系统流速：达到200-3000L/h，且在A、B进行配比梯度时，满足最低流速要求。供应商应提供系统支持的梯度配比范围曲线。梯度范围：B：200-3000L/h、精确度：≤±2%。Three system flow rate: reach 200-5000L/h, and meet the minimum flow rate requirement when the ratio gradient of A and B is carried out.The supplier shall provide a system-supported gradient ratio range curve.Gradient range: B: 200-5000L/h, accuracy: ≤±2%.Six system flow rate: reach 350-8000L/h, and meet the minimum flow rate requirement when the ratio gradient of A and B is carried out.The supplier shall provide a system-supported gradient ratio range curve.Gradient range: B: 350-8000L/h, accuracy: ≤±2%. | 质量Quality |
|  | 出口：4个。阀门选用零死角隔膜阀，并且能够通过电信号反馈阀门位置状态。阀门带有隔膜报警功能。Exits: 4 ports. The valve adopts the zero dead Angle diaphragm valve and can feedback the valve position through the electric signal. Valve with alarm function. | 质量Quality |

* + 1. 气泡陷阱 Bubble trap

| **序号****ID No.** | **需求描述****Requirement Description** | **需求分类****Requirement Category** |
| --- | --- | --- |
|  | 具有在线自动脱气功能（气泡陷阱），气泡陷阱具有高低液位检测器，能够在不暂停生产流程的情况下，自动补液。With online automatic qigong (bubble trap), the bubble trap with patented flow path design has a high and low liquid level detector , and can automatically rehydrate without suspending the production process. | 质量Quality |
|  | 气泡陷阱也能够彻底的CIP清洗。The bubble trap can also be thoroughly CIP cleaning. | 质量Quality |

* + 1. 柱位：Column position

| **序号****ID No.** | **需求描述****Requirement Description** | **需求分类****Requirement Category** |
| --- | --- | --- |
|  | 柱位：具有正向、反向和旁路三个流向的管路连接。管路连接紧凑，死体积小要求不超过10L。Column position: pipe connection with forward, reverse and bypass flow directions.Pipe connection compact, The dead volume should not exceed 10L | 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** |
| --- | --- | --- |
|  | 系统阀门采用具有模块化多通路阀门组，可任意组合，信号灯外部可观察，确保生产安全。The system valve adopts the modular multi-channel valve group, which can be combined arbitrarily, and the signal lamp can be observed externally to ensure production safety. | 质量Quality |
|  | 关键部位阀门需配置单反馈装置，使用感应式反馈装置，反馈装置需要配置LED灯。反馈装置和阀门应采用同一品牌。没有反馈装置的阀门需要配置可视化装置用于现场观察阀门状态。Valves at key parts shall be equipped with single feedback device, and it should use inductive feedback unit. The feedback device needs to be equipped with LED lights. Feedback device and valves should use the same brand. And the valves without feedback device need to be equipped with visualization device to observe the valve status on site. | 质量Quality |
|  | 与物料和洁净介质接触的阀门采用隔膜阀，隔膜阀的安装角度须与隔膜阀供应商的要求一致，膜片材质应采用EPDM/PTFE复合膜片，材质符合FDA和NMPA的要求，附相关材质证书；Valves in contact with materials and clean utility are diaphragm valves. The installation angle of diaphragm valves should be in accordance with the requirements of valves suppliers. The diaphragm materials should be EPDM/PTFE composite diaphragm, the material should meet the requirements of FDA and NMPA, and the relevant material certificate should be attached. | 质量Quality |
|  | 所有与物料和洁净介质接触的阀门须提供与阀体一一对应的材质证明。All valves in contact with materials and clean utility should be provided with material certification corresponding to the valve body. | 质量Quality |
|  | 所有与物料、纯蒸汽或清洗用水接触的阀门采用锻造隔膜阀。Forged diaphragm valves should be equipped in contact with product, pure steam or cleaning water. | 质量Quality |
|  | 压力调节阀：泵后有一个压力调节阀，用于控制入口压力，防止上游料液直接流穿系统，同时防止料液互混。Pressure regulating valve: there is a pressure regulating valve behind the pump, which is used to control the inlet pressure, prevent the upstream feed liquid directly flowing through the system, and prevent the feed liquid from mixing with each other. | 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 SS 316L as a minimum, electro polishing to a roughness of less than 0.4 um and passivation treatment. | 质量Quality |

* + 1. 仪表 Instruments

| **序号****ID No.** | **需求描述****Requirement Description** | **需求分类****Requirement Category** |
| --- | --- | --- |
|  | 仪器仪表应提供由第三方校验机构出具的检验合格证。检验有效期需覆盖至PQ完成。Certificates for instruments issued by third-party verification agency should be provided. The validity period of instruments should be covered until PQ is completed. | 商业Business |
|  | 温度传感器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 used for the temperature sensor, and the part in direct contact with the medium is made of 316L, with 4-20mA signal output or RTD signal output. Any other connection forms shall be approved by the owner. | 质量Quality |
|  | 系统应配备探头/传感器，监测以下内容，包括但不限于：The system shall be equipped with probes/sensors to monitor the following, including but not limited to:* 电导 Conductivity sensor
* pH pH sensor
 | 质量Quality |
|  | 流速反馈：根据流量计反馈控制流速。压力控制流速：通过压力的变化调节流速的功能。Flow rate feedback: control the flow rate according to the flow meter feedback.Pressure control flow rate: the function of adjusting flow rate through changes in pressure. | 质量Quality |
|  | 管路中的压力仪表及模拟输入信号的校准和自行调节功能需可在就地控制单元上进行操作。The calibration and self-adjusting functions of the pressure instruments and analog input signals in the pipeline need to be operable on the local control unit. | 商业Business |
|  | 质量流量计：柱前配备E+H药用级质量流量计，反馈调节泵速。可自动累计体积和进行手动清零操作。Mass flowmeter: E+H medical-grade mass flowmeter is equipped before the column, and the pump speed is adjusted by feedback. The flow meter can automatically accumulate volume and manually autozero. | 质量Quality |
|  | 紫外检测：至少两波长连续检测，检测波长必须支持280/254nm，提供可变检测光径量程。UV detection: at least two wavelength continuous detection, the test wavelength must support 280/254nm. provide variable test optical range. | 质量Quality |
|  | 柱前柱后具备压力传感器和柱前空气传感器，用于层析柱的保护；空气传感器的灵敏度可调。在最大灵敏度下，传感器可以检测到小至2毫米的气泡。There are pressure sensors and air sensors in front of the column to protect the column. Need pressure sensor install after column to monitor pressure.The sensitivity of the air sensor is adjustable. At maximum sensitivity the sensor detects bubbles as small as 2 mm. | 质量Quality |

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

| **序号****ID No.** | **需求描述****Requirement Description** | **需求分类****Requirement Category** |
| --- | --- | --- |
|  | 所有与产品和溶液接触的金属材质均应为不锈钢SS316L，内表面电抛光至粗糙度不大于0.4μm并钝化处理； All metal in contact with product or buffer shall be stainless steel SS 316L. The inner surface should be electropolished to a roughness of no more than 0.4 μm and passivated. | 质量Quality |
|  | 所有不接触产品及所有介质的金属材质均应为不锈钢SS304材质（包括所有支腿、框架、外罩、取样口和钢平台等），表面无毛刺。All metal materials which is not touch the product and all media should be stainless steel SS304 (including all legs, frames, enclosures, sampling ports and steel platforms, etc.) without burrs on the surface. | 质量Quality |
|  | 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 |
|  | 所有隔膜阀及与料液接触材质的部件需提供化学耐受性。Chemical tolerance shall be provided for all diaphragm valves and parts in contact with material. | 质量Quality |
|  | 为满足卫生要求，系统、管路所有流路材质需耐受1.0M NaOH溶液在位清洗一小时以上。All the flowpath shall be able to stand 1.0M NaOH over one hour. | 质量Quality |

* + 1. 焊接要求 Welding

| **序号****ID No.** | **需求描述****Requirement Description** | **需求分类****Requirement Category** |
| --- | --- | --- |
|  | 所有洁净管路应尽可能采用符合现行ASME BPE要求的自动焊接。All clean tubing will be orbital welded as per requirement of current ASME BPE. | 质量Quality |
|  | 所有的人工焊接，包括焊工和焊接信息均应记录在供应商焊接记录中。All manual welding, including welder and welding information, should be recorded in the supplier's welding record. | 质量Quality |
|  | 所有焊缝均应正确标识，标识号应刻印在管道上且与文件中的记录保持一致。All weld beams shall be correctly tagged and tag number shall be permanently marked on pipe in correspondence with that in documents. | 质量Quality |
|  | 供应商应根据交付文件列表中的要求交付焊接相关文件。Supplier shall deliver the welding documents according to the requirements of the delivery documents list. | 质量Quality |
|  | 洁净管道需充氩保护焊接，避免内部氧化，接用惰性保护气体纯度必须达到99.999%，需要提供正式的报告。Hygienic pipes need to be filled with argon protection welding to avoid internal oxidation, and the purity of the inert shielding gas used must reach 99.999%, and an official report needs to be provided. | 质量Quality |
|  | 自动焊接和手动焊接都必需提供焊接工艺评定。WPS must be provided for both automatic and manual welding. | 质量Quality |
|  | 焊样留取的要求：1. 焊样应保留原色，不得处理。
2. 在更换参数时必需提供焊样。（管道尺寸或焊接参数）
3. 焊样必需是对焊，不得假焊。
4. 焊样的记录必需递交，并对每个焊样进行编号。

焊样应作为竣工资料的一部分保存备查，不得丢弃。Requirements for the retention of weld samples.1. The weld sample shall be retained in its original color and shall not be processed.
2. Weld samples must be provided when changing parameters. (pipe size or welding parameters)
3. welding samples must be butt weld, no false welding.
4. Records of weld samples must be submitted and each weld sample must be numbered.

Weld samples shall be kept as part of the as-built data and shall not be discarded. | 质量Quality |
|  | 内窥镜摄像要求：1. 须为实时彩色摄像片段，提供照片，且必需刻制成光盘。
2. 必须显示完整的焊道。
3. 必须可以看到氧化区的颜色。

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

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

Welding position should be documented on the welding diagram and can be traced back to the welder, welding log should indicate the heat number of the material on both sides of the weld. | 质量Quality |

* 1. 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，不在层析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 chromatography system supplier. | 商业Business |
|  | 层析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 chromatography 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 |
|  | 层析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 chromatography system supplier ensures that all IO signals are not disturbed during redundancy switching of DCS controllers. | 质量Quality |
|  | 层析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 chromatography system. | 商业Business |
|  | 层析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 chromatography 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 |
|  | 层析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 chromatography 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 |
|  | 层析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 chromatography 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 |
|  | 层析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，层析系统供应商不得拷贝DCS系统完整的数据库。The chromatography 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 chromatography system supplier shall not copy the complete database of DCS system. | 商业Business |
|  | 层析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 chromatography 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 |

* + 1. 电控柜 Electric Control Cabinet

| **序号****ID No.** | **需求描述****Requirement Description** | **需求分类****Requirement Category** |
| --- | --- | --- |
|  | 电控柜材质采用SS304不锈钢，防护等级为IP54或以上，并满足洁净室使用要求。The electric control cabinet shall be SS304 stainless steel. Its protective level shall be IP54 or above. And the electric control cabinet shall meet the requirements of clean room. | 商业Business |
|  | 电控柜应稳固安装在层析系统模块上，柜门开门角度不得小于90°。The electric control cabinet shall be firmly installed on the chromatography system module, and the door can be open more than 90°. | 商业Business |
|  | 电控柜内元器件、线槽应合理布局，元器件的安装需符合各元器件的安装规范，线槽与元器件之间需有足够的距离显示线缆标识。The components and ducting in the electric control cabinet must be properly arranged. The components must be installed in accordance with the installation specifications of each component. There must be a sufficient distance between the ducting and the components to display the cable labels. | 商业Business |
|  | 电控柜上需安装过滤减压阀用于过滤阀岛气源并调节气源压力。层析控制系统需监视过滤减压阀压力低报警。The electric control cabinet shall be equipped with filter relief-pressure valve to filtrate the compressed air and adjust the pressure of compressed air. The pressure low alarm shall be monitored by chromatography control system. | 质量Quality |
|  | 直流24V开关电源应冗余配置，并且每个开关电源可以单独断电进行维护和更换。层析控制系统需监视开关电源故障报警。24VDC power supply shall be redundant. Each power supply could be turn off respectively. The alarm of power supply shall be monitored by chromatography control system. | 质量Quality |
|  | 电控柜内需安装照明灯，当柜门打开时照明灯自动点亮，当柜门关闭时照明灯自动熄灭。Light should be installed in the electric control cabinet. When the door is opened, the light shall be automatically turned on, and when the door is closed, the lights shall be automatically turned off. | 商业Business |
|  | 层析系统及其电控柜应安全接地。Chromatography system and its electric control cabinet shall be securely grounded. | 安全EHS |
|  | 供应商应提供电控柜设计图纸以及层析系统用电功率。Supplier shall provide the design drawing of electric control cabinet and power calculation. | 商业Business |
|  | 层析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 chromatography system or between external devices and the gas pipe should be fed into the bottom of the electric control cabinet. | 质量Quality |
|  | 层析系统电控柜至PCS系统夹层分支桥架线槽穿线管由层析系统供应商负责完成安装，从并完成层析系统侧线缆接线。The wiring pipe between the electric control cabinet of the chromatography system and the bridge cable trough of the sandwich branch of the PCS system shall be installed by the supplier of the chromatography system, and the cable connection from the side of the chromatography system shall be completed. | 商业Business |

* + 1. 操作面板 Operation Panel

| **序号****ID No.** | **需求描述****Requirement Description** | **需求分类****Requirement Category** |
| --- | --- | --- |
|  | 层析系统现场操作HMI及键盘不在层析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，层析系统供应商应负责设计安装位置。The field operation HMI and keyboard of the chromatography system is no longer within the scope of the supply of the chromatography system supplier, and shall be uniformly configured and installed by Henlius. If it needs to be installed on the chromatography system module, the chromatography system supplier shall be responsible for designing the installation position. | 商业Business |
|  | 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** |
| --- | --- | --- |
|  | 层析系统内的线缆、气管等需敷设在穿线管、方钢或线槽中，动力线缆和信号线缆需分开走线。The cables and gas pipes in the chromatography shall be laid in the cable pipe, square steel or ducting. The power cables and signals cables shall be routed separately. | 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 wire shall be firmly wired. | 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 |

* + 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 |
|  | 软件应能够避免UV丢峰、部件不响应、部件响应延迟、部件不反馈等等问题，并且没有出现过上述问题。The software should be able to avoid UV peak loss, component non-response, component response delay, component non-feedback, and other problems, and did not occur. | 质量Quality |
|  | 层析系统具有可编程的逻辑监控、操作界面、数据采集和控制软件，能够实现工艺的自动化运行、实时监控、方法编辑和结果分析功能。The tomographic system has programmable logic monitoring, operation interface, data acquisition and control software, which can realize automatic process operation, real-time monitoring, method editing and result analysis. | 质量Quality |
|  | 软件具有方法编辑功能，实现方法的自动运行。The software has the function of method editing, realizing automatic operation of method. | 质量Quality |
|  | 软件具有手动命令，能够在方法运行过程中，进行控制。The software has manual commands that can be controlled during method runs. | 质量Quality |
|  | 软件可实现报警保护功能。触发报警后系统停止运行，报警解除后可继续恢复运行。The software can realize the Alarm protection function.After the alarm is triggered, the system stops operation and can resume operation after the alarm is lifted. | 质量Quality |
|  | 软件可对重要操作节点进行设置，如平衡终点、组分收集起点和终点、填料再生终点等。The software can set important operation nodes, such as balance end point, component collection start and end point, packing regeneration end point, etc. | 质量Quality |
|  | 软件具有主峰的不同收集模式，如按峰收集、固定体积收集、UV斜率触发收集、UV值触发收集、UV峰-谷值触发收集等。The software has a variety of component collection modes, such as peak collection, fixed volume collection, UV slope trigger collection, UV value trigger collection, UV peak-valley trigger collection, etc. | 质量Quality |
|  | 软件具有在线监控功能，能够监控设备运行状态（如：准备、运行、停机等）、系统程序运行进程（如：运行的阶段、进行的操作等）、显示设备运行过程中的实时在线检测的数据（如：流速、紫外吸收、电导率等）及相应数值变化曲线、系统管路及阀门的连接及开闭状态、报警设置和显示生产批号。Software with functions of on-line monitoring, to monitor equipment operation state (such as: preparation, operation, stop, etc.), system program running processes (such as: operation phase, operation, etc.), display the real-time on-line detection in the process of equipment operation data (such as velocity, ultraviolet absorption, electric conductivity, etc.) and the corresponding numerical change curve, the linking of system piping and valves, and open and close status, alarm Settings and display production batches. | 质量Quality |
|  | 软件能够显示系统流路图，并实时反馈阀门状态、流路和检测器状态。The software can reflect the system flow diagram and feedback the valve status, flow status and detector status in real time. | 质量Quality |
|  | 层析系统必须能够在不同阀位间实现自动切换，且在控制系统中显示对应流路。The tomographic system must be able to switch between different valve positions automatically and display corresponding flow paths in the control system. | 质量Quality |
|  | 软件具有结果分析模块，可进行自动积分、拟合、测定HETP、多批次曲线对比等功能。The software has the result analysis module, can carry on the automatic integration, the fitting, has the determination HETP, comparative analysis of multi-batch curves and so on the parameter function. | 质量Quality |
|  | 系统内部含有控制单元，可在电脑断电/死机等意外情况下记录当前运行的所有数据，并在恢复电脑供电/重启后，可以继续保持原有运行模式。保证系统的稳定性和安全性。The system contains the control unit, which can record all the data of the current operation in case of computer power failure/crash and other unexpected circumstances, and can continue to maintain the original operation mode after the computer power supply/restart.Ensure system stability and security. | 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，批报告存储路径可由用户配置。The system must be able to generate a batch report after each batch is completed. And the batch report storage path can be specified by the user. | 质量Quality |
|  | 软件所记录的原始数据不可修改，保护数据的完整性。The original data recorded by the software cannot be modified to protect the integrity of the data. | 质量Quality |
|  | 软件支持数据进行导出，但不可直接对元数据文件进行拷贝和删除。保护数据的安全性。The software supports data export, but can not directly copy and delete metadata files.Secure your data. | 质量Quality |
|  | 数据可以打印，或上传至中央服务器。Data can be printed or uploaded to central server. | 商业Business |
|  | 实时数据采集频率：至少每秒一次。数据打印频率：至少每分钟一次。系统至少可存储一年生产数据。Real-time data acquisition frequency: at least once per second. Printing data frequency: at least once per minute. The system can store production data for at least one year. | 商业Business |

* + 1. 系统界面 System interface

| **序号****ID No.** | **需求描述****Requirement Description** | **需求分类****Requirement Category** |
| --- | --- | --- |
|  | 人机界面采用英语界面。The HMI language shall be preferable English interface. | 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 |
|  | 密码应采用不固定的期限有效期；The password shall be valid for an unset period of time. | 质量Quality |
|  | 在一定次数的失败登录尝试之后系统能够锁定该账户，只有授权的用户才能解锁用户账户。After a certain number of failed login attempts, the system can lock the account, and only authorized users can unlock the user account. | 质量Quality |
|  | 日期和时间应被保护，未经授权的人不得修改。The date and time should be protected from unauthorized modification. | 质量Quality |
|  | 系统权限至少分为以下5级：The system permissions should at least 5 levels:* 系统管理员，有操作系统的权限，但不可具有操作的权限，防止使用最高权限操作时，误操作。应有备份权限。Administrator, operating system permissions, but can not have the right to operate, to prevent the use of the highest authority operation, disoperation. There should be backup privileges.
* 主管，能修改系统配方或工艺参数。Supervisor, can modify recipe or process parameters
* 维护人员，可执行仪表的校准、设备维护、组件动作控制。Maintenance, calibration of instruments, equipment maintenance and action control.
* 操作员，可调用配方，读取数据，查阅记录。operator, recipes calling, data reading and records checking.
* 访客，仅可观察。visitor, only observable.
 | 质量Quality |
|  | 供应商提供详细的权限分级，由业主确认。The detailed security list should be provided by the vendor and approved by client. | 商务Commerce |
|  | 不同组别的账户，系统界面功能相应有所不同。The accounts of different groups have different interfaces function.  | 商业Business |
|  | 业主具有设施、设备、仪器或系统所附带的软件的永久使用权。The Owner has the permanent right to use the software attached to the facilities, equipment, instruments or systems. | 商务Commerce |

* + 1. 故障和报警 Fault/alarm

| **序号****ID No.** | **需求描述****Requirement Description** | **需求分类****Requirement Category** |
| --- | --- | --- |
|  | 故障和报警应有声光报警指示。Fault and alarm should be able to trigger audible and visual alarm.  | 质量Quality |
|  | 至少应在每个单独房间的电控柜上设置一个蘑菇型、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 electric control cabinet 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** |
| --- | --- | --- |
|  | 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. | 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）。标识和铭牌等任何部位不应有锋利的边缘和尖角。The safety protection of personnel should be fully considered in the design of system frame and steel platform. (e.g. Guardrails, wide steps and anti-skidding).There shall be no sharp edge and sharp angle at any part of logo, nameplate, etc. | 安全EHS |
|  | 所有设备应满足在最大负荷和运行速度的情况下，距设备任何方向1m处的噪音不超过80dBA。All equipment shall conform to peak noise of 80 dBA measured at 1 meter in any direction from the equipment when operating at all maximum loads and speeds. | 安全EHS |
|  | 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 |

* 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
* 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 PLC 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 |
| --- | --- | --- | --- | --- | --- | --- |
|  | URS响应表 Compliance to URS | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | DQ 开始前Before DQ |
|  | 项目质量计划 Project Quality Plan  | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | DQ 开始前Before DQ |
|  | 图纸清单Drawing list | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | DQ 开始前Before DQ |
|  | 竣工PID图As-built P&ID | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | 系统交付时System Handover |
|  | 装配图General assembly drawing | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | 系统交付前Before System Handover |
|  | ISO证书ISO certificate | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | DQ 开始前Before DQ |
|  | 文件递交日期 Document delivery date | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | DQ 开始前Before DQ |
|  | 设备重量信息 Weight information of equipment | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | FAT开始2周前2 weeks before the start of FAT |
|  | 变更控制规程 Change Order Procedure | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | DQ 开始前Before DQ |
|  | 项目及建设进度表 Project and production schedule | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | DQ 开始前Before DQ |
|  | 仪表标签列表 Instrument Label Schedule | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | FAT开始2周前2 weeks before the start of FAT |
|  | 公用介质消耗列表 Utilities consumption schedule | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | DQ 开始前Before DQ |
|  | 供应商文件列表 Vendor document schedule | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | DQ 开始前Before DQ |
|  | 铭牌信息Nameplate data's | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | FAT开始2周前2 weeks before the start of FAT |
|  | 货运文件 Shipping documentation | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | 系统交付前Before System Handover |
|  | 钝化规程 Passivation procedure | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | 系统交付前Before System Handover |
|  | 校准规程 SOP for Calibrations | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | FAT开始2周前2 weeks before the start of FAT |
|  | 焊接规程Welding procedure  | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | FAT开始2周前2 weeks before the start of FAT |
|  | 液压/气动测试规程 Hydrostatic & Pneumatic test procedure | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | FAT开始2周前2 weeks before the start of FAT |
|  | 机抛光规程 Mechanical polishing procedure | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | FAT开始2周前2 weeks before the start of FAT |
|  | 维护手册 Maintenance manual | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 2 | 系统交付时System Handover |
|  | 安装手册 Installation manual | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 2 | 系统交付时System Handover |
|  | 操作手册 Operation manual | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 2 | 系统交付时System Handover |
|  | 控制系统手册 Control system manual | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 2 | 系统交付时System Handover |
|  | 消耗品及耐耗品/配件清单 List of consumables and wear/spare parts | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | SAT开始4周前4 weeks before the start of SAT |
|  | 设备数据表 Equipment data sheets | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | SAT开始4周前4 weeks before the start of SAT |
|  | 电子数据表 Electrical data sheets | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | SAT开始4周前4 weeks before the start of SAT |
|  | 仪器数据表 Instrument data sheets | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | SAT开始4周前4 weeks before the start of SAT |
|  | 标签清单 Tag list | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | FAT开始2周前2 weeks before the start of FAT |
|  | 组件清单 Components list | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | FAT开始2周前2 weeks before the start of FAT |
|  | 部件数据表 Component datasheet | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | DQ 开始前Before DQ |
|  | PID图 P&IDs | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | DQ 开始前Before DQ |
|  | 容器图及接口清单 Vessel drawings & Nozzle list | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | DQ 开始前Before DQ |
|  | 布局图Layout | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | DQ 开始前Before DQ |
|  | 电气部件列表 Electrical part list | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | DQ 开始前Before DQ |
|  | 电气图 Electrical diagrams | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | DQ 开始前Before DQ |
|  | 电气负荷 Electrical load (kW, V, Phase, Frequency) | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | DQ 开始前Before DQ |
|  | I/O列表及地址列表 I/O List and address table | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | DQ 开始前Before DQ |
|  | 参数设定值 Parameter settings | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | DQ 开始前Before DQ |
|  | 控制系统功能主文件 FDS main document incl. controller | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | DQ 开始前Before DQ |
|  | 运行描述 Operation Description | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | DQ 开始前Before DQ |
|  | 互锁列表 interlock list | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | DQ 开始前Before DQ |
|  | 仪器列表 Instrument list | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | DQ 开始前Before DQ |
|  | 报警列表Alarm list | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | DQ 开始前Before DQ |
|  | 信号交换列表Signal exchange list | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | DQ 开始前Before DQ |
|  | 硬件设计说明 Hardware Design Specification | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | DQ 开始前Before DQ |
|  | 软件设计说明 Software Design Specification | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | DQ 开始前Before DQ |
|  | 功能说明 Functional specification | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | DQ 开始前Before DQ |
|  | 灾难恢复计划 Disaster recovery plan | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | DQ 开始前Before DQ |
|  | 数据备份规程 Date backup procedure | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | 主体设计完成2周以内 Within 2 weeks after subject design |
|  | 焊接设备及参数 Welding equipments and parameters | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | FAT开始2周前2 weeks before the start of FAT |
|  | 焊接规程Welding procedure | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | FAT开始2周前2 weeks before the start of FAT |
|  | 焊点总表 Weld summary | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | FAT开始2周前2 weeks before the start of FAT |
|  | 焊接记录及检查记录 Welding and inspection log | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | FAT开始2周前2 weeks before the start of FAT |
|  | 20%焊缝照片 20% Weld seam pictures | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | FAT开始2周前2 weeks before the start of FAT |
|  | 焊接样品（每个程序及每个工人）Weld samples(per program and per manual welder) | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | FAT开始2周前2 weeks before the start of FAT |
|  | 其他测试的报告（内窥镜，X光，铁素体）Test result of other tests (borescope, x-ray, ferrite) | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | FAT开始2周前2 weeks before the start of FAT |
|  | 脱脂证明 Degreasing certification | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | FAT开始2周前2 weeks before the start of FAT |
|  | 校验证书 Calibration certificate | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | FAT开始2周前2 weeks before the start of FAT |
|  | 接地检查记录 Earthing continuity check records | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | FAT开始2周前2 weeks before the start of FAT |
|  | 钝化证明 Passivation certification | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | FAT开始2周前2 weeks before the start of FAT |
|  | 焊工及检查员资质证明 Welder &Inspector Certificates | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | FAT开始2周前2 weeks before the start of FAT |
|  | CE认证证书 CE conformity declarations | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | FAT开始2周前2 weeks before the start of FAT |
|  | 测试仪器设备校验证书Certificates for test instruments/equipments | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | FAT开始2周前2 weeks before the start of FAT |
|  | 液压/气动测试证明 Hydrostatic & Pneumatic certificate | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | FAT开始2周前2 weeks before the start of FAT |
|  | 电抛光证明 Electro polishing certification | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | FAT开始2周前2 weeks before the start of FAT |
|  | 清洁证明Certificate about cleaning and rinsing | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | FAT开始2周前2 weeks before the start of FAT |
|  | 金属部件的材质证明 Material certificates for metallic parts | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | FAT开始2周前2 weeks before the start of FAT |
|  | 非金属部件的材质证明Material certificates for non-metallic parts | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | FAT开始2周前2 weeks before the start of FAT |
|  | 表面抛光度证书 Surface finishing certificates  | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | PDF | 1 | FAT开始2周前2 weeks before the start of FAT |
|  | 验证计划 Validation Plan | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | Word | 1 | DQ 开始前Before DQ |
|  | 风险评估及报告 Risk Assessment and Report | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | Word | 1 | DQ 开始前Before DQ |
|  | DQ方案/报告 DQ protocol /report | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | Word | 1 | DQ 开始前Before DQ |
|  | 需求追溯矩阵 RTM | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | Excel | 1 | DQ 开始前Before DQ |
|  | FAT方案/报告 FAT protocol/report | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | Word | 1 | FAT开始2周前2 weeks before the start of FAT |
|  | SAT方案/报告 SAT protocol/report | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | Word | 1 | SAT开始4周前4 weeks before the start of SAT |
|  | IQ方案/报告 IQ protocol/report | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | Word | 1 | IQ开始4周前4 weeks before the start of IQ |
|  | OQ方案/报告 OQ protocol/report | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | Word | 1 | IOQ开始4周前4 weeks before the start of IOQ |
|  | 备品清单 Spares part list | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | Word | 1 | SAT开始4周前4 weeks before the start of SAT |
|  | 特殊工具清单 Special tools list | 中英双语Bilingual | 纸质和电子版Hard copy &Elec | Word | 1 | SAT开始4周前4 weeks before the start of SAT |

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