**重庆药友水土工厂202车间单抗项目**

**工艺自控系统（PCS）用户需求**

**URS for Process Control 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车间单抗项目工艺自控系统（PCS）的用户需求。

The purpose of this document is to define the user requirements for the Process Control System of 202 project.

1. 范围SCOPE

本文连同其所有附件，详述了PCS系统供应商的工作范围以及系统供货范围、系统组态、硬件及软件集成、技术服务、工程项目实施、产品性能、验证、服务和文档的最低要求。对本URS中未提及的，但为了实现PCS的技术性能和保证系统的完整性又是必要的配置和相关附件，供应商有责任向用户方提出建议，并提供完善的PCS系统配置。

This document, together with all of its appendix, details the scope of work for PCS vendor and the minimum requirements for the scope of system supply, system configuration, hardware and software integration, technical services, engineering project implementation, product performance, verification, services and documentation. For the configuration and relevant accessories not mentioned in this URS, but necessary to achieve the technical performance of PCS and ensure the integrity of the system, the supplier is responsible for making recommendations to the user and providing complete PCS system configuration.

本项目工艺自控系统的基础架构由PCS供应商提供，PCS供应商负责基础架构的设计、制造、集成、安装、现场施工、调试及验证工作。

The PCS infrastructure of this project will be provided by PCS supplier who is responsible for the design， manufacture, assembly, installation, site construction, test and validation. The Henlius will be in charge of the design, programming, test and validation of process control for non-vendor package equipment and data collection and monitor for vendor package equipment, and the PCS supplier shall provide the technical support.

本项目的工艺设备分为自带控制系统的成套设备（以下简称“VPE”）和不带自控系统的非成套设备。对于成套设备，PCS系统需做数据采集或数据交互，并按要求完成报警配置及批次报表，能集中监视这些成套设备；对于非成套设备，PCS系统需要按照要求完成对这些设备的工艺控制。

The process equipment of this project is divided into vendor package equipment with control system (hereinafter referred to as "VPE") and non-VPE without control system. For the vendor package equipment, the PCS system needs to acquire data or interact data, complete alarm configuration and batch report as required, and centrally monitor these complete sets of equipment. For non-VPE, the PCS system needs to complete the process control of these equipment as required.

非成套设备分为不锈钢管罐系统（反应器、培养基配储系统、缓冲液配储系统、中间体系统）与下游纯化设备（层析、超滤、匀浆罐、在线配液系统）两大类。不锈钢管罐系统的工艺控制的设计、组态、调试、验证由重庆药友自主完成，PCS供应商按需提供技术支持；下游纯化设备的工艺控制的设计、组态、调试及验证由设备供应商完成，其数据库合并至不锈钢管罐系统数据库，PCS供应商按需提供技术支持。

Non-VPE is divided into two categories: stainless steel pipe and tank system (bioreactor, media preparation and holing, buffer preparation and holding, process) and downstream purification equipment (chromatography, ultrafiltration, slurry tank, inline conditioning system). The design, configuration, commissioning and validation of the process control of the stainless steel pipe and tank system are led by Henlius, and PCS suppliers provide technical support on demand. The design, configuration, commissioning and validation of the process control of downstream purification equipment are completed by the equipment supplier, whose database will be merged into the database of stainless steel pipe and tank system, and PCS supplier provides technical support on demand.

成套设备的数据采集与监视的设计、组态、调试、验证由重庆药友自主完成，PCS供应商按需提供技术支持。

The design, configuration, test and validation of data acquisition and monitoring of VPE equipment are led by Henlius, and PCS suppliers provide technical support on demand.

## 成套设备 Vendor Package Equipment

工艺自控系统需与成套设备建立通讯，采集生产过程数据，存储关键工艺参数，并集中监视这些的设备的报警。此外，对于部分成套设备（二氧化碳培养箱、离心机、提升系统、蠕动泵、纯化水分配系统、注射用水分配系统），工艺自控系统需与其进行数据交互来实现工艺过程控制。以下设备定义为成套设备：

The shall to establish communication with VPE, collect production process data, store key process parameters, and centrally monitor the alarm of these equipment. In addition, for some VPE (CO2 incubator, centrifuge, hoist system, peristaltic pump, PW distribution system, WFI distribution system), the PCS needs to carry out data interaction with it to achieve process control. The following equipment is defined as VPE:

| **生产线**  Production line | **设备名称**  Equipment name | **数量**  Quantity |
| --- | --- | --- |
| 原液上游  DS Upstream | 生物安全柜  Biological safety cabinet | 2个  2 set |
| 二氧化碳培养箱  CO2 incubator | 2个  2 set |
| Wave反应器  Wave reactor | 2个  2 set |
| 碟式离心机  Disk Centrifuge | 1个  1 set |
| 提升系统  Hoist system | 1个  1 set |
| 超净工作台  Clean bench | 1个  1 set |
| 灭菌柜  Autoclave | 2个  1 set |
| 原液下游  DS Downstream | 提升系统  Hoist system | 1个  1 set |
| 装柱系统  Column packing system | 1个  1 set |
| 部件清洗机  Parts Washer | 2个  2 set |
| 灭菌柜  Autoclave | 1个  1 set |
| 原液公用  DS Common | 纯化水分配  Pure water distribution | 1套  1 set |
| 注射用水分配系统  Water for injection distribution system | 1套  1 set |
| 综合仓库  Warehouse | 称量罩  Weighing Booth | 2个  2 set |
| IBC 清洗机  IBC washer | 1套  1 set |

## 非成套设备 Non - Vendor Package Equipment



### 不锈钢管罐系统 Stainless Steel Tank & Pipe System

如下不锈钢管罐系统由工艺自控系统直接控制:

The following stainless steel system are directly controlled by PCS:

| **工艺段**  Process Section | **设备名称**  Equipment Name | **数量**  Quantity |
| --- | --- | --- |
| 不锈钢反应器  Stainless Steel Bioreactor | 500L反应器  500L bioreactor | 2个  2 set |
| 4,000L反应器  4,000L bioreactor | 2个  2 set |
| 15,000L反应器  15,000L bioreactor | 4个  4 set |
| 上游培养基配储系统  Upstream Media Preparation & Holding System | 200L培养基配制罐  200L media preparation tank | 1个  1 set |
| 1000L培养基配制罐  1000L media preparation tank | 1个  1 set |
| 5,000L 培养基配制罐  5,000L media preparation tank | 1个  1 set |
| 500L上游补料罐  500L media holding tank | 6个  6 set |
| 1000L上游补料罐  1000L media holding tank | 4个  4 set |
| 5000L上游补料罐  5000L media holding tank | 4个  4 set |
| 10,000L 培养基配制罐  10,000L media preparation tank | 1个  1 set |
| 下游缓冲液配储液罐  Downstream Buffer Preparation & Holding System | 500L缓冲液配制罐  500L buffer preparation tank | 1个  1 set |
| 1,500L缓冲液配制罐  1,500L buffer preparation tank | 1个  1 set |
| 4,000L缓冲液配制罐  4,000L buffer preparation tank | 1个  1 set |
| 200L缓冲液储罐  200L buffer holding tank | 2个  2 set |
| 500L缓冲液储罐  500L buffer holding tank | 3个  3 set |
| 1,000L缓冲液储罐  1,000L buffer holding tank | 3个  3 set |
| 1,500L缓冲液储罐  1,500L buffer holding tank | 1个  1 set |
| 2,000L缓冲液储罐  2,000L buffer holding tank | 1个  1 set |
| 2,500L缓冲液储罐  2,500L buffer holding tank | 1个  1 set |
| 4,000L缓冲液储罐  4,000L buffer holding tank | 3个  3 set |
| 3,000L纯化水储罐  3,000L PW holding tank | 1个  1 set |
| 15,000L注射用水储罐  15,000L WFI holding tank | 3个  3 set |
| 中间体罐  Process Tank | 2,000L 离心中转罐  2,000L process tank | 1个  1 set |
| 18,000L 收获罐  18,000L harvest tank | 1个  1 set |
| 1,500L 灭活罐  1,500L Virus inactivation tank | 4个  4 set |
| 10,000L阳离子上样罐  10,000L Cation process tank | 1个  1 set |
| 8,000L阳离子主峰罐  8,000L Cation process tank | 2个  2 set |
| 1,500L阳离子收样罐  1,500L Cation process tank | 4个  4 set |
| 18,000L阴离子上样罐  18,000L Anion process tank | 2个  2 set |
| 18,000L纳滤收样罐  18,000L deviralzation tank | 1个  1 set |
| 5,000L原液稀释罐  5,000L process tank | 1个  1 set |
| CIP站及浓碱分配系统  CIP Station and Alkali Distribution System | 2,000L双罐CIP站  2,000L double tank CIP stations | 9个  9 set |
| 5,000L浓碱罐  5,000L Alkali tank | 1个  1 set |
| 3000L PW罐  3000L PW tank | 1个  1 set |
| 废液灭活系统  Continuous Wastewater Inactivation System | 10000L废水收集罐  10000LWastewater collection tank | 2个  2 set |
| 800L碱液罐  800L Lye tank | 1个  1 set |

### 工艺设备 Process Equipment

如下工艺设备由工艺自控系统直接控制，其数据库合并至不锈钢管罐系统数据库:

The following process equipment are directly controlled by PCS, and its database will be merged into the database of stainless steel system:

| **工艺段**  Process Section | **设备名称**  Equipment Name | **数量**  Quantity |
| --- | --- | --- |
| 下游工艺设备  Downstream Process Equipment | 层析系统  Chromatography system | 3个  3 set |
| 超滤系统  Ultrafiltration system | 1 个  1 set |
| 匀浆罐  Slurry tank | 1个  1 set |
| 在线配液系统  Slurry tank | 2套  2 set |
| 1,500L 跟随罐  1,500L follow tank (Inline conditioning) | 4个  4 set |
| 3000L 跟随罐  3000L follow tank (Inline conditioning) | 2个  2 set |

1. 系统描述SYSTEM DESCRIPTION

## 工厂布局 Plant Layout

## 水土工厂202车间位于重庆市北碚区。本次项目为202单抗项目一期，将建设#202生产楼及其生产线。

## Shuitu factory 202 workshop is located in Beibei District, Chongqing. This project is the first phase of 202 monoclonal antibody project, which will build #202 production building and its production line.生产线 Production Line

本项目将建设1条原液生产线，用于单克隆抗体药物商业化生产。同时预留1条原液生产线的功能间。生产线布局如下：

In this project, one DS production line will be built for the commercial production of monoclonal antibody drugs. And the functional room are reserved for another DS production line which is out of the scope of stage 3. The layout of production lines is as follow:

详见附件1- #202生产楼平面布局图。

Refer to A[ppendix](javascript:;) 1 - The Layout of No.202 Production Building for details.

## 工艺描述 Process Description



### 上游工艺流程 Upstream Process Flow

在原液上游，细胞经细胞复苏、摇瓶和反应器扩增及培养，并在培养过程中添加培养基，得到的细胞收获液，经离心机处理，再经过深层过滤后得到深层过滤收集液。原液上游工艺设备包括二氧化碳摇床、Wave生物反应器、500L不锈钢生物反应器、4000L 不锈钢生物反应器、15000L不锈钢生物反应器、离心机和深层过滤等。工艺流程如下图：

In DS upstream, after cell resuscitation, flask shaking and reactor amplification and culture, the media is fed in the culture process to obtain the final cell harvesting solution after filtration by centrifuge, and then the depth filtration collection solution is obtained after deep filtration. The upstream process equipment of the original solution includes CO2 incubator, wave reactor, 500L stainless steel bioreactor, 4000L stainless steel bioreactor and 15000L stainless steel bioreactor, centrifuge and depth filtration device etc. The process flow chart is as follows:



### 下游工艺流程 Downstream Process Description

原液下游主要工艺步骤为亲和层析、低pH病毒灭活、离子交换层析、除病毒过滤、超滤以及最终的原液配制。下游主要工艺设备为在线配液系统、层析系统、除病毒系统、超滤系统。详细生产工艺流程图如下：

The purification steps are mainly affinity chromatography, low-pH virus inactivation, ion exchange chromatography, virus filtration, ultrafiltration filtration and final solution preparation. The main downstream process equipments are chromatography system, virus filtration system and ultrafiltration system. The detailed production process flow chart is as follows:



## 工艺自控系统 Process Control System

本项目工艺自控系统划分如下：

The process control system of this project is divided into following parts:

* 基础架构 Infrastructure

工艺自控系统基础架构包括但不限于如下硬件、软件及功能：

The process control system shall have but not limit to following hardware, software and network.

* 系统硬件 System Hardware
* 服务器、操作站 Server、operate station
* 控制器、IO卡件 Controller、IO card
* 系统软件 System Software
* 人机交互界面 Human and machine interface
* 组态及配置软件 Configuration and setting software
* 系统网络 System Network：
* 交换机 Switch
* 网线、光纤 Ethernet cable and fiber optic
* 防火墙 Firewall

工艺自控系统软件至少需具备如下功能：

The software of process control system shall have following functionalities at least:

* 设备监视、控制 Equipment monitor and control
* 批量控制、配方管理 Batch control and recipe management
* 时钟同步 Time Synchronization
* 用户及权限管理 User and authorization management
* 报警记录及数据管理 Alarm record and data management
* 事件记录及数据管理 Event record and data management
* 连续历史记录及数据管理 Continuous history data record and data management
* 批量历史记录及数据管理 Batch history data record and data management
* 批次报告 Batch report
* 电子记录及电子签名 Electronic record and electronic signature
* 审计追踪 Audit trail
* 数据备份及恢复 Data backup and restore
* 系统灾难恢复 System disaster recovery
* 非成套设备工艺控制 Process Control for Non-vendor Package Equipment
* 成套设备数据采集与监视 Supervisory Control and Data Acquisition for Vendor Package Equipment

1. 定义/缩略语DEFINITIONS AND ABBREVIATIONS

本文件中所用的术语和缩略词列于下表中.

The terms and abbreviations used in this document are listed in the following table.

| **术语/简称 ABB.** | **定义 Definition** |
| --- | --- |
| URS | User Requirement Specification 用户需求说明 |
| GMP | Good Manufacturing Practice 药品生产质量管理规范 |
| EU GMP | European Good Manufacturing Practice 欧盟药品质量管理规范 |
| GAMP | Good Automated Manufacturing Practice 良好的自动生产规范 |
| ICE | International [Electrical](javascript:;)Commission 国际电工技术委员会 |
| CFR | Code of Federal Regulations 联邦法规法典 |
| PCS | Process Control System 工艺自控系统 |
| DCS | Distributed Control System 分散控制系统 |
| SCADA | Supervisory Control and Data Acquisition 数据采集与监控系统 |
| PLC | Programmable Logic Controller 可编程逻辑控制器 |
| MES | Manufacturing Execution System 制造执行系统 |
| MCC | Motor Control Center 马达控制中心 |
| VPE | Vendor Package Equipment 供应商成套设备 |
| CSV | Computerized System Validation 计算机化系统验证 |
| SOP | Standard Operating Procedure标准操作规程 |
| DQ | Design Qualification设计确认 |
| FAT | Factory Acceptance Test工厂验收测试 |
| SAT | Site Acceptance Test 现场验收测试 |
| IQ | Installation Qualification安装确认 |
| OQ | Operational Qualification运行确认 |
| PQ | Performance Qualification性能确认 |
| HMI | Human Machine Interface人机界面 |
| P&ID | Pipe & Instrumentation Diagram管道和仪表流程图 |
| PCV | Pressure Control Valve 压力调节阀 |
| DF | Depth Filtration 深层过滤 |
| VF | Virus Filtration纳滤 |
| UF | Ultrafiltration 超滤 |
| DS | Drug Substance 原液 |
| DP | Drug Product 药品 |
| OPC UA | OLE For Process Control UA 过程控制对象链接与嵌入式接口 |
| NTP | Network Time Protocol 网络时钟协议 |
| AMS | Asset Management System 资产管理系统 |

1. 参考资料REFERENCES

在编写本URS的内容时，已参考下列文档的当前修订版：

The current revisions of the documents listed below have been consulted in the preparation of this URS document or govern the content of this document.

| **文件名称 Doc. name** | **文件编号Doc. No.** | **版本Edition** |
| --- | --- | --- |
| 2010中国GMP  NMPA: Good Manufacturing Practice for Drugs (2010 Version) | GMP | 2010 |
| 中国GMP实施指南(2010版)  Implementation guide of GMP(2010 Version) | N/A | 2010 |
| 中华人民共和国药典（2020版）  Pharmacopoeia of the people's Republic of China (2020 Version) | N/A | 2019 |
| 中华人民共和国药品管理法实施条例  [Regulations for the Implementation of the Drug Administration Law of the People's Republic of China](http://en.pkulaw.cn/display.aspx?cgid=00030b1c88989837bdfb&lib=law) | N/A | N/A |
| US FDA: 21 CFR Parts 210 and 211 | N/A | N/A |
| US FDA: 21 CFR Part 11 | N/A | N/A |
| EU GMP Volume Ⅳ | N/A | N/A |
| GAMP 05 | N/A | N/A |
| EU GMP | N/A | N/A |
| IPSE 制药工程指南及附录  IPSE Pharmaceutical Engineering Guide and Appendix | N/A | N/A |
| JB/T20093-2007 制药机械行业标准  JB/T20093-2007 Pharmaceutical Machinery Industry Standard | N/A | N/A |
| ISO standard | N/A | N/A |

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HSE

## 通用要求 General Requirements



### 基本要求 Basic Requirements

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 供应商在报价文件内需要提供PCS系统网络架构图及详细的配置清单（需包含品牌和型号），以便确认可否满足所有的功能需求。  The supplier shall provide the system network architecture diagram and bill of materials (including brand and type) of PCS in the quotation document, so as to confirm whether all functional requirements can be met. | 商务  Commercial |
|  | 供应商必须为本项目成立专门的硬件设计和实施团队，团队应由资深的项目经理、硬件设计工程师、软件安装工程师及技术工程师组成，报价文件中需提供技术支持工程师工时费用明细。在项目实施期间，无特殊情况，不允许更换项目组成员。  The supplier must set up a dedicated hardware design and implementation team for the project, which shall be composed of senior project managers, hardware design engineers, software installation engineers and technical engineers, and provide details of the working hours of technical support engineers in the quotation document. During the implementation of the project, members of the project team are not allowed to be replaced without special circumstances. | 商务  Commercial |
|  | 供应商应提供物料清单，包括服务器、控制器、卡件、机柜等的品牌、型号、数量及详细的硬件和系统软件的配置清单。  The supplier should provide the BOM, including the brand, model and quantity of servers, controllers, cards, cabinets, etc., and the detailed hardware and operating system configuration list. | 商务  Commercial |
|  | 供应商技术方案中需包含与MES系统深度融合的技术要求，以便满足后期能从MES系统下装配方参数，启/停程序等功能需求。  The supplier's technical proposal should include the technical requirements for deep integration with MES system, so as to meet the functional requirements of loading formula parameters from MES system, start/stop system procedures, etc. | 商务  Commercial |
|  | 供应商需配合业主在VPE设备FAT期间完成PCS与VPE设备的通讯测试工作。  The supplier shall cooperate with the owner to complete the communication test between PCS and VPE equipment during VPE FAT. | 商务  Commercial |
|  | 供应商需为本项目上提供成熟稳定的硬件及软件技术。  The supplier shall provide the reliable and stable hardware and software technology for this project. | 商务  Commercial |
|  | PCS系统设计必须满足安全和方便扩展的要求，即当后续生产线建设过程中，不能对已投运系统造成任何影响。  PCS system design must meet the requirements of safety and easy expansion, that is, when the subsequent production line construction process, do not have any impact on the system in operation. | 商业  Business |
|  | PCS系统需满足7\*24小时生产的需求。  The PCS system shall meet the requirement of 7\*24 hours manufacture. | 商业  Business |



## 系统硬件 System Hardware

### 服务器配置 Server Configuration

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 历史数据记录服务器：   * 连续历史服务器2台 * 批量历史服务器1台   Historical data recording server :  - 2 history servers  - 1 batch history server | 商业  Business |
| 历史数据记录服务器用于储存与管理过程数据、报警和事件记录及批量历史数据，其它操作员、工程师及批量功能站均应能随时调用相应的历史趋势和数据。  The historical data recording server is used to store and manage process data, alarm and event records and batch history data. Other operators, engineers and batch function stations should be able to call the corresponding historical trend and data at any time. | 质量  Quality |
|  | 批量服务器，需至少配置1台  One batch server must be configured at least. | 商业  Business |
| 批量服务器用于执行批量控制程序和管理批次信息。  Batch server is used to execute batch control procedures and manage batch information.。 | 质量  Quality |
|  | 系统工程师站，需配置1台。  One engineer station must be configured for PCS. | 商业  Business |
| 工程师站用于编写控制程序、绘制监控流程图、配置系统所包含的硬件及软件功能等，须具有需具备对PCS系统全数据库的自动及手动备份和恢复的功能。  Engineer station is used to program, draw graphics, and configure the hardware and software functions included in the system, and must backup and restore the PCS database automatically or manually | 质量  Quality |
|  | OPC服务器:   * OPC server 服务器1台 * OPC 客户服务器1台   OPC server:  - 1 OPC server station  - 1 OPC client station | 商业  Business |
| PCS系统需支持OPC UA通讯协议，OPC Server用于为第三方系统提供PCS系统数据，OPC客户端用于读取第三方系统数据。  The PCS system must support the OPC UA communication protocol, the OPC Server is used to provide PCS system data to third-party systems, and the OPC client is used to read data from third-party systems. | 质量  Quality |
|  | 短信报警服务器：配置1台。  1 SMS alarm server. | 商业  Business |
| 短信报警服务器需配置40个永久用户授权，用于满足本期及一期PCS系统短信报警功能需求；系统需支持报警信息推送及确认、移动终端访问实时及历史数据曲线、网络安全防护、用户及终端权限管理及报警信息推送记录追溯等功能。  The SMS alarm server shall be equipped with 40 permanent user authorization to meet the SMS alarm function requirements of the current and first phase PCS system; The system should support alarm information push and confirmation, mobile terminal access real-time and historical data curve, network security protection, user and terminal authority management and alarm information push record traceability functions, etc. | 质量  Quality |
|  | Webservice接口服务器，配置1台。  1 websevice interface server is configured. | 商业  Business |
| Webservice接口服务器用为第三方系统提供Web访问服务，系统支持第三方系统访问连续、批量及报警等历史数据，并提供Web接口开发函数包。  The Webservice interface server is used to provide Web access services for the third-party system. The system supports the third-party system to access historical data such as continuous, batch and alarm, and provides the Web interface development function package. | 质量  Quality |
|  | 病毒库管理服务器，配置1台。  1 virus library management server. | 商业  Business |
| 病毒库管理服务器用于保护PCS系统安全，管理和维护PCS系统安装了杀毒软件的服务器或操作站，具有从Internet自动更新经技术测试后的病毒库。  The virus library management server is used to protect the security of the PCS system, and manages and maintains the servers or operating stations that have installed antivirus software for the PCS system, and updates the virus libraries that have been tested by technology automatically from the Internet. | 质量  Quality |
|  | AMS智能仪表管理服务器，配置1台。  1 AMS intelligent instrument management server. | 质量  Quality |
| 用于管理不锈钢系统的Hart仪表及Profibus-DP执行器。  It uses for management of Hart meter and Profibus-DP actuator of stainless steel system |
|  | 服务器硬件配置最低要求：  - CPU：双CPU；  - 内存：16G；  - 磁盘阵列：历史服务器RAID10，其它RAID1；  - 硬盘：600G /块；  - 网口：5个以上；  - 供电方式：冗余；  - CD/DVD光盘驱动器；  - 显示器：24寸以上。  The type of historian record workstation should be server type, the lowest requirements for hardware configuration:  - CPU: dual CPU;  - memory: 16Gb;  - array of disks: the historical server RAID10，other RAID1;  - hard disk: 600G/ block;  - network port: more than 5;  - power supply mode: redundant;  - Display screen: over 24 inches. | 质量  Quality |

### 操作员站 Operator Station

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 配置4台普通操作员站。  The PCS shall have 4 common operator stations. | 商业  Business |
| 普通操作员站配置最低需求：   * 带主机的工业机型； * 24寸或以上显示器，其中两台采用双屏显示器； * 1台操作员站具备工程的组态功能； * DP高清信号接口。   Minimum requirements for common operator station configuration:  - Industrial computer with host;  - 24 "or above display, two of which have dual display;  - 1 operator station has the engineering configuration function ;  - DP Indicates HD signal ports. | 质量  Quality |
|  | 配置29台洁净室操作员站。  The PCS shall be provided with 29 sets of clean room operator stations. | 商业  Business |
|  | 洁净室操作员站配置需求：   * 安装方式：立柱或悬臂式，需防振动设计； * 屏幕：采用工业级彩色触摸屏，尺寸为21.5~24寸； * 键盘：美式覆膜键盘及轨迹球鼠标； * 防护等级：IP65； * 材质：采用SS304及以上不锈钢，抛光度<0.8μm； * 分辨率：1920 x 1080； * 时钟：需支持NTP通讯协议，确保本地时间及日期与PCS系统或工厂主时钟保持一致； * 配置专用通讯缆线。   Clean room operator station configuration requirements:  - installation mode: column or cantilever mode, and required vibration proof design;  - Screen: Industrial colourful touch screen, size of screen is 21.5~24 inches;  - Keyboard:American film keyboard and trackball mouse;  - Protection level: IP65;  - Material: stainless steel SS304 or above, polishing degree＜ 0.8μm;  - Size of touch screen: 21.5~24 inches;  - Resolution: 1920 x 1080;  - Clock: The NTP protocol is supported to ensure that the local time and date are consistent with the PCS system clock or factory clock.  - Configure dedicated communication cables | 质量  Quality |
|  | 操作员站应具备操作控制、画面浏览、图形显示、报警监视和确认、数据处理、实时趋势图创建或查询、信息调用等功能。  The operator station shall have the functions of operation control, screen browsing, graphic display, alarm monitoring and confirmation, data processing, real-time trend graph creation or query, and information call. | 质量  Quality |

### 控制器 Controller

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 控制配置需求：   * 不锈钢反应器至少配置4对PK750控制器； * 培养基配制至少配置1对PK750控制器； * 缓冲液配制及储存至少配置2对PK750控制器； * 中间体罐配制至少配置2对PK750控制器； * 下游工艺设备PK300及PK750控制器各配置1对，并配置电源和光电转换器，以便安装于就地控制柜； * VPE设备数据采集配置1对PK300控制器。   Controller configuration requirements:   * 4 pairs of PK750 controllers shall be provided for stainless steel bioreactor. * 1 pairs of PK750 controller shall be provided for media preparation. * 2 pairs of PK750 controllers shall be provided for buffer preparation and holding. * 2 pairs of PK750 controllers shall be provided for process. * Each pair of PK300 and PK750 controllers shall be provided for process devices，and equipped with power supply and photoelectric converter for installation in the local control cabinet. * 1 pairs of controller shall be provided for VPE devices . | 商业  Business |
|  | 控制器需冗余配置，当主控制器出现故障时，应能自动切换到备用控制器运行，控制器切换不应对生产过程控制和数据可靠性造成影响。  The controllers shall be redundant. When the primary controller is faulty, it can be automatically switched over to the secondary controller. This does not affect process control and data integrity. | 质量  Quality |
|  | 冗余控制器的切换需在操作界面上有报警显示。  The switch of redundant controller requires an alarm display on the operation interface. | 质量  Quality |
|  | 控制器必须低负荷运行，控制器负荷率应控制在60%左右，系统需支持控制器负荷率查询确认功能。  The controller must run at low load, the load rate of controller should be controlled at about 60%, and the system needs to query and confirm the controller load rate function. | 质量  Quality |
|  | 控制器需支持1秒或更少的扫描速率，可根据具体应用配置。  The controller shall support 1 second or less scan rate. The scan rate could be configured as needed. | 质量  Quality |
|  | 控制器必须支持增量型的下装方式，具有离线参数与在线运行参数的比较和提示功能。  The controller must support incremental download method, and have the function of comparing and prompting offline parameters and online operating parameters.. | 质量  Quality |

### 输入输出模块 I/O Module

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | PCS系统必须具有以下类型的输入输出模块：   * 带Hart协议的模拟量输入卡件 * 模拟量输出卡件 * 数字量输入、输出卡件 * Modbus RTU/ASCII串口卡件 * Modbus TCP/IP卡件 * Profibus DP卡件   The PCS shall have following types of I/O modules:   * Analogue Input with hart protocol Card * Analogue Output Card * Discrete Input / Output Card * Modbus RTU/ASCII Serial Card * Modbus TCP /IP Card * Profibus DP Card | 商业  Business |
|  | 所有输入、输出卡件必须支持任意位置热插拔的功能。  All input and output cards must support the [function](javascript:;) of hot swap at any position. | 质量  Quality |
|  | PCS系统必须具备监视IO通道信号质量的功能（如：信号断线、超量程等），信号质量能在画面中的过程量上以不同颜色区分。  The PCS must be able to monitor the quality of IO channel signal, eg: signal cable break, over range, etc and which is displayed it in different color on process value of the graphics. | 质量  Quality |
|  | PCS需为不锈钢配储液及中间体罐的MCC配置独立的Profibus DP卡件。  The dedicated Profibus DP card shall be provided for MCC of stainless steel preparation | 商务  Commercial |
|  | PCS供应商需为固定设备的Profibus DP链路配置有源终端电阻，有源终端电阻安装在PCS控制柜中。  The PCS supplier shall configure an active terminal resistor for the Profibus DP link of the fixed device. The active terminal resistor is installed in the PCS control cabinet. | 商务  Commercial |
|  | PCS供应商需为移动设备的Profibus DP链路配置中继器，使得移动设备在链路中的移动不对整条链路的正常运行产生影响。培养基配制、缓冲液配制、纯化工段的蠕动泵均为移动设备。  The PCS supplier shall configure repeater for the Profibus DP link of the moveable device so that the movement of the device in the link does not affect the whole link. The peristaltic pumps in media preparation, buffer preparation and purification are removable device. | 商务  Commercial |
|  | 上游设备Profibus DP卡件数量配置不少于12块。  The quantity of Profibus DP cards for upstream devices shall be no less than 12 pieces. | 商业  Business |
|  | 不锈钢配储液及中间体罐系统Profibus-DP卡件数量配置不少于13块。  The quantity of Profibus-DP modules for stainless steel preparation and holding and process system shall be no less than 13 pieces. | 商业  Business |
|  | IO通道分配必须考虑风险分散的原则，且须经业主确认。  The IO allocation must consider the principle of risk dispersion, and must be confirmed by the owner. | 商务  Commercial |
|  | 输入输出模块的数量除了满足IO点数量外，需留10%余量。  In addition to meet the IO quantity,10% spare of I/O module shall be reserved. | 商务  Commercial |
|  | 不锈钢反应器系统IO统计如下。  The Stainless steel bioreactor IO statistics:   |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | | 生产线名称 Production Line Name | AI | AO | DI | DO | AI-DP | AO-DP | DI-DP | DO-DP | | 500L反应器 500L Bioreactor | 90 | 18 | 58 | 46 | 12 | 10 | 36 | 204 | | 4000L反应器 4000L Bioreactor | 104 | 24 | 58 | 54 | 20 | 10 | 46 | 248 | | 15KL反应器 15KL Bioreactor | 224 | 56 | 116 | 108 | 84 | 44 | 128 | 608 | | 公用管线 Utility Pipeline | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 44 | | 总计 Total | 420 | 98 | 232 | 208 | 116 | 64 | 210 | 1104 |   详见附件3不锈钢反应器系统IO统计  Refer to Appendix 3 for the IO summary of stainless steel bioreactor system. | 商业  Business |
|  | 不锈钢配储液及中间体系统IO统计如下：  The Stainless steel preparation and holing and process IO statistics:   |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | 生产线名称 Production Line Name | AI | RTD | AO | DI | DO | AI DP | AO DP | DI DP | DO DP | Pulse | | CIP系统 CIP system | 129 | 18 | 9 | 136 | 52 | 42 | 21 | 63 | 807 | 1 | | 超滤系统 Ultrafiltration system | 14 | 0 | 1 | 2 | 1 | 2 | 1 | 3 | 44 | 0 | | 培养基配置系统 Media preparation systeam | 161 | 18 | 7 | 35 | 22 | 44 | 22 | 349 | 742 | 18 | | 缓冲液配置系统 Buffer preparation system | 128 | 21 | 6 | 51 | 45 | 12 | 6 | 309 | 801 | 3 | | 中间体系统 Process system | 218 | 17 | 23 | 62 | 53 | 44 | 22 | 326 | 952 | 18 | | 深滤系统 Deep filtration system | 13 | 0 | 1 | 6 | 0 | 2 | 1 | 3 | 51 | 0 | | 灭活系统 Inactivation system | 8 | 0 | 1 | 16 | 3 | 4 | 2 | 6 | 47 | 0 | | 公用 Utility | 0 | 0 | 0 | 130 | 80 | 0 | 0 | 0 | 0 | 0 | | 总计 Total | 671 | 74 | 48 | 438 | 256 | 150 | 75 | 1059 | 3444 | 40 |   详见附件4不锈钢配储液及中间体系统IO统计  Refer to Appendix 4 for the IO summary of stainless steel preparation and holing and process system. | 商业  Business |
|  | 下游工艺设备IO统计如下表，且MODBUS TCP通讯设备授权数量为10个。   |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | | 生产线名称 Production Line Name | AI | AO | DI | DO | AI DP | AO DP | DI DP | DO DP | | 下游工艺设备 Downstream Devices | 175 | 125 | 0 | 0 | 0 | 0 | 0 | 0 | | 商业  Business |
|  | VPE设备通讯协议及IO统计表，详见附件5.  Refer to Appendix 5 for VPE devices communication protocol and IO statistics table. | 商业  Business |

### 网络及交换机 Network and Switch

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | PCS系统的控制网络需采用冗余星型或冗余环形网络。  The control network of PCS shall be redundant star or redundant ring. | 质量  Quality |
|  | 当主控网络交换机出现重大故障时，能立即自动切换到备用网络交换机运行，切换过程不能对整个系统的控制、画面显示、数据收集、数据计算的功能造成任何影响。  When there is a major failure in the main control network switch, it can immediately switch to the standby network switch for operation without any impact on the control of the entire system, diagram display, data collection, data calculation functions. | 质量  Quality |
|  | 交换机采用工业级交换机。  The switch shall be industrial switch. | 质量  Quality |
|  | 交换机的配置应符合下列要求：   * 交换机的端口速率应能充分满足其应用位置的数据通信要求，单台交换机的端口数量不应大于24个； * 用于不同交换分区的交换机不宜共用； * 交换机应采取冗余供电的方式。   The configuration of the switch shall meet the following requirements:   * The port rate of the switch shall fully meet the data communication requirements of its application location, and the number of ports of a single switch shall not be more than 24; * The switches used in different switching zones should not be shared; * The switch should adopt redundant power supply. | 质量  Quality |
|  | PCS具备监视到网络交换机的通讯状态的功能，并能在系统画面上实时显示网络状态。  PCS has the function of monitoring the communication status of network switches and can display the network status on the system diagram in real time. | 质量  Quality |
|  | 交换机数量配置满足项目要求，不同层级交换机预留15%的备用网口。  The number of switches is configured to meet the requirements of the project, and switches at different levels reserve 15% of spare network ports. | 商业  Business |
|  | VPE通讯网络的交换机需按照不同的通讯协议进行配置。  The VPE network switch shall be configured according to different communication protocols. | 商业  Business |
|  | VPE设备现场设备到PCS系统网络柜所需网线和附件由业主采购和安装。  The network cables and accessories required from the field equipment of the VPE to the PCS system network cabinet are purchased and installed by the owner. | 商务  Commercial |

### 打印机 Printer

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | PCS系统必需具备配置网络打印机的功能，可在系统上打印工艺画面、趋势图、报警/事件、报表等。  PCS system must be equipped with the function of network printer, which can print process picture, trend chart, alarm/event, report, etc. | 质量  Quality |
|  | PCS需为各个服务器、操作员站配置专用的打印网络，并在交换机上至少预留4个打印机网络接口，打印机由重庆药友IT提供。  The PCS shall configure a dedicated printer network for each server and operator station, and reserve 4 Ethernet port for printer which is provided by Henlius IT. | 商业  Business |

### 马达控制中心 Motor Control Center

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 不锈钢反应器系统所需的MCC柜及变频器由不锈钢反应器系统供应商提供。  The MCC cabinet and frequency converter for the stainless steel bioreactor system are provided by the stainless steel bioreactor system supplier. | 商务  Commercial |
|  | 不锈钢配储液系统及中间体罐系统所需的MCC柜及变频器由PCS供应商提供。MCC机柜需按区域分开配置：培养基配制及存储、缓冲液配制及存储、中间体罐系统。  The MCC cabinet and frequency converter for the stainless steel preparation and holding system and process tank system shall be provided by the PCS supplier. MCC cabinets need to be configured separately by areas: media preparation and holding, buffer preparation and holding, process tank system. | 商务  Commercial |
|  | MCC柜柜面颜色可选，柜体架、顶盖、后壁和底板的板材厚度不低于：1.5mm，柜门板材厚度：2.0mm，柜内镀锌安装板厚度：3.0mm，长宽深尺寸：2200mm\*800mm\*600mm，且满足IP55防护等级要求。  The MCC cabinet surface color of all control cabinets is optional, the thickness of the cabinet body frame, top cover, back wall and bottom plate is not less than 1.5mm, the thickness of the cabinet door plate is 2.0mm, the thickness of the galvanized installation plate inside the cabinet is 3.0mm, and meets the IP55 protection grade requirements. | 商业  Business |
|  | 配置固态继电器柜，为不锈钢管罐系统电加热器提供电源，电加热器数量共计74个。  Solid state relays need to be provided power for stainless steel tube tank system electric heater in the state relay cabinet. there are 74 electric heaters in total. | 商业  Business |
|  | MCC柜及固态继电器柜安装在5层MCC机柜间。  MCC cabinets will be installed in MCC cabinet room of fifth floor. | 商业  Business |
|  | PCS系统与MCC柜内变频器采用Profibus-DP或经业主许可的通讯协议。  The communication protocol between PCS system and variable frequency drivers of in MCC cabinet adopts Profibus-DP or owner approved communication protocol. | 商业  Business |
|  | 不锈钢配储液及中间体罐系统电机数量统计如下：  Stainless steel reparation and holing and process system motor number statistics:   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **设备名称 Device name** | **功率（KW） Power(KW)** | **额定电压（V） Nominal voltage(V)** | **数量 Quantity** | **变频启动 Variable frequency** | | CIP站和浓碱分配 CIP Station and Alkali Distribution | 0.55 | 380 | 18 | NO | | CIP站和浓碱分配 CIP Station and Alkali Distribution | 2.2 | 380 | 1 | YES | | CIP站和浓碱分配 CIP Station and Alkali Distribution | 3 | 380 | 8 | YES | | CIP站和浓碱分配 CIP Station and Alkali Distribution | 4 | 380 | 8 | YES | | CIP站和浓碱分配 CIP Station and Alkali Distribution | 5.5 | 380 | 3 | YES | | 中间体 Process | 0.75 | 380 | 9 | YES | | 中间体 Process | 1.5 | 380 | 3 | YES | | 中间体 Process | 2.2 | 380 | 1 | YES | | 中间体 Process | 3 | 380 | 4 | YES | | 中间体 Process | 5.5 | 380 | 2 | YES | | 灭活 Virus inactivation | 0.75 | 380 | 1 | NO | | 灭活 Virus inactivation | 4 | 380 | 2 | YES | | 上游配储液 Upstream Buffer Preparation & Holding | 0.37 | 380 | 1 | YES | | 上游配储液 Upstream Buffer Preparation & Holding | 0.75 | 380 | 6 | YES | | 上游配储液 Upstream Buffer Preparation & Holding | 1.5 | 380 | 5 | YES | | 上游配储液 Upstream Buffer Preparation & Holding | 2.2 | 380 | 5 | YES | | 上游配储液 Upstream Buffer Preparation & Holding | 4 | 380 | 1 | YES | | 深层过滤 Deep filtration | 5.5 | 380 | 1 | YES | | 下游配储液 Downstream Buffer Preparation & Holding | 0.37 | 380 | 1 | YES | | 下游配储液 Downstream Buffer Preparation & Holding | 0.75 | 380 | 1 | YES | | 下游配储液 Downstream Buffer Preparation & Holding | 2.2 | 380 | 1 | YES |   详见附件6。  Refer to Appendix 6 for the motor quantity of stainless steel preparation and holing and process system | 商业  Business |

### PCS机柜 PCS Cabinet

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | PCS系统供应商需选用机架式服务器，配置服务器机柜，并增加一面同型号的MES网络机柜，服务器机柜将安装在#3生产楼四层服务器机柜间。  The supplier shall select rack-mounted server and provide the server cabinets which will be installed in server cabinet room of the fourth floor of No.3 manufacturing building, and add an MES network cabinet of the same model. | 商业  Business |
|  | PCS系统供应商需配置网络柜，网络柜将安装在#3生产楼四层服务器机柜间与PCS控制柜间。  The supplier shall provide the network cabinets which will be installed in server cabinet room and PCS control cabinet room of the fourth floor of No.3 manufacturing building. | 商业  Business |
|  | PCS系统供应商需配置控制柜，控制柜将安装在#3生产楼四层PCS控制柜间。  The supplier shall provide the control cabinets which will be installed in PCS control cabinet room of the fourth floor of No.3 manufacturing building. | 商业  Business |
|  | PCS系统供应商需配置电源分配柜，电源分配柜将安装在#3生产楼四层PCS控制柜间。  The supplier shall provide the power distribution cabinet which will be installed in PCS control cabinet room of the fourth floor of No.3 manufacturing building. | 商业  Business |
|  | 所有的PCS机柜采用底部进线方式，机柜底部需安装线缆固定支架，所有进线需固定在线缆支架上。  All PCS cabinets are routed from the bottom. The cable racks shall be installed at the cabinet bottom , and all cables must be secured to cable racks. | 商业  Business |
|  | 所有的控制机柜的柜面颜色可选，柜体架、顶盖、后壁和底板的板材厚度不低于：1.5mm，柜门板材厚度：2.0mm，柜内镀锌安装板厚度：3.0mm，长宽深尺寸：2200mm\*800mm\*800mm，且满足IP55防护等级要求。  The cabinet surface color of all control cabinets is optional, the thickness of the cabinet body frame, top cover, back wall and bottom plate is not less than 1.5mm, the thickness of the cabinet door plate is 2.0mm, the thickness of the galvanized installation plate inside the cabinet is 3.0mm, dimension 2200mm\*800mm\*800mm, and meets the IP55 protection grade requirements. | 商业  Business |
|  | 不锈钢反应器的PCS系统主控制器机柜中需集成2台S7-1200 PLC，并为其提供24V供电电源和MODBUS-RTU通讯电缆。  Two S7-1200 PLCs should be integrated into the main controller cabinet of PCS system of stainless steel reactor, and 24V power supply and MODBUS-RTU communication cable should be provided for them. | 商业  Business |
|  | 机柜需预留15%的输入输出模块扩展空间，并且此扩展不应对控制器模块有额外的需求。  The cabinet shall reserve 15% space for expansion of IO modules, and the expansion does not require additional requirements for controller modules. | 商务  Commercial |
|  | 控制柜内，电缆线颜色和线径需要根据电压等级加以区分。  In the control cabinet, the color and diameter of the cable wires need to be distinguished according to the voltage level. | 商业  Business |
|  | 控制机柜内电气元件，如：空气开关、24V直流电源、断路器、继电器等必须采用进口品牌，详见附件2品牌推荐表。  The electrical components in the main control cabinet and MCC cabinet, such as: air switch, 24V DC power supply, circuit breaker, relay, etc. must use imported brands, the appendix 2 which is the brand recommendation table. | 商业  Business |

## 供电与接地 Power and Grounding

### 系统供电 System Power Supply

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | PCS供应商需提供电源分配柜，用于给PCS机柜、HMI、操作台等供电。电源分配柜的设计需考虑三相平衡。  The PCS supplier needs to provide a power distribution cabinet to power PCS cabinets, HMI, and operation console. Three-phase balance should be considered in the design of power distribution cabinet. | 商业  Business |
|  | PCS供应商需提供电源计算表，以便甲方为PCS的电源分配柜配电。  The PCS supplier shall provide the power consumption table for Henlius to distribute power to the PCS power distribution cabinet. | 商业  Business |
|  | PCS的380VAC供电回路需设计为双路供电，一路为市电供电，一路为UPS供电。当其中一路供电断电的情况下，PCS应能正常运行。  The 380VAC power supply loop of PCS must have two power supplies, one for the plant power and another for the UPS. PCS should operate normally when one of the power supplies is cut off. | 质量  Quality |
|  | PCS电源分配柜至PCS各个用电设备的线缆、施工由PCS供应商完成。  The cables and construction of PCS power distribution cabinet to each electrical equipment of PCS shall be completed by PCS suppliers. | 商务  Commercial |

### 系统接地 System Grounding

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | PCS系统需可靠接地，接地线缆的线径、汇流排的设计、接地线缆的连接均需符合系统的接地规范，系统上电前需提供机柜绝缘报告及接地报告。  The PCS system must be grounded securely. The diameter of the ground cable, the design of the grounding bar, and the connection of the ground cable must comply with the grounding specifications of the system. Before powering on the system, the cabinet insulation report and grounding report must be provided. | 质量  Quality |
|  | PCS系统供应商需提出对工厂总接地的需求以便满足PCS系统接地的要求。  The PCS system supplier shall propose the requirements for the plant grounding in order to meet the grounding requirements of the PCS system. | 商务  Commercial |
|  | PCS供应商负责PCS至总接地点的接地线缆、汇流排等接地材料的供货及安装。  The PCS supplier is responsible for supplying and installing grounding materials such as ground cables and ground bars from PCS to the plant ground point. | 商务  Commercial |

## 系统软件及功能 System Software

### 通用要求 General Requirements

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 所应用的软件必须满足IEC1131-3的工业标准。  Application software implemented shall be according to industrial standard IEC 1131-3. | 商务  Commercial |
|  | PCS系统软件应基于标准操作系统和PCS供应商标准控制系统平台。  PCS system software shall be based on standard operating system and PCS manufacturer's standard control system platform. | 商务  Commercial |
|  | PCS系统软件应为经过测试的成熟的新版软件，严禁使用未经发布的测试版本软件。  PCS software shall be mature and tested version. It is strictly prohibited to use unpublished test version software; | 商业  Business |
|  | PCS系统软件授权：   * 所有相关软件都应为经过授权的正式版本，并且使用权限是永久的； * 经过测试的正版杀毒软件； * 包括备用设备在内的所有硬件都应能在不受软件授权限制的情况下同时使用； * 提供软件原厂安装光盘，不得使用镜像刻录形成的软件安装光盘。   PCS system software licensing:   * All relevant software shall be the authorized official version and the usage rights should be permanent; * Tested version genuine anti-virus software * All hardware including standby equipment shall be able to be used at the same time without restriction of software authorization; * Provide original software installation CD-ROMs. Do not use software installation CD-ROMs formed by image burning. | 质量  Quality |
|  | 软件的IO点授权数量应有至少10%的余量；  The I/O license shall have 10% spare at least. | 商业  Business |
|  | PCS必须提供全套的Windows操作系统安装软件及必要的补丁或驱动安装包安装光盘。  PCS shall be equipped with a complete set of operating system software and necessary tool software. | 质量  Quality |
|  | PCS系统工程组态软件：   * 单点状态和实时值的强制功能。 * 应支持离线组态和仿真调试功能。 * 应具备在线参数修改和下装组态数据的功能。 * 在线查看控制程序的功能。   PCS Engineering configuration software:   * Mandatory function of single point status and real-time value. * The configuration software should support offline configuration and simulation debugging function. * The configuration software shall have the functions of online modification and downloading configuration data.   View the function of the control program online | 质量  Quality |
|  | PCS系统软件应该具备硬件诊断功能，能实时监视系统内各功能站、控制器、网络交换机、IO卡件及其通道的健康状况，并能以报警的形式在系统在功能站和操作员站上显示。  The PCS software should have hardware diagnostic functions, which can monitor the health status of each functional station, controller, network switch, IO card and its channel in the system in real time, and can be in the form of an alarm on the functional station and operator station display. | 质量  Quality |
|  | 系统需支持16个字符的点位编码。  The system should support the point tag which is 16 characters. | 商务  Commercial |
|  | 系统需支持Hart仪表的管理功能。  The system shall support the management function of the Hart instruments. | 商业  Business |
|  | AMS系统软件须具有配置、管理智能仪表及执行器，并能监测和诊断智能仪表及执行器报警及故障信息。  AMS system software must be capable of configuring and managing intelligent instruments and actuators, and monitoring and diagnosing alarms and fault information of intelligent instruments and actuators. | 质量  Quality |
|  | PCS系统必须具有制药行业专用的工艺设备画面和控制类功能包，并能提供相关的验证测试文件。  The PCS must have special process equipment screens and control function packages for the pharmaceutical industry, and can provide relevant verification test files. | 商业  Business |
|  | PCS系统必须符合FDA 21CFR Part11中电子签名的标准和要求。  The PCS system must meet the standards and requirements of the electronic signature in FDA 21CFR Part11. | 质量  Quality |

### 域控及组策略Domain Controller and Group Policy

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | PCS系统需配置主、副域控用于组策略的集中管理，主、副域控可以是独立的服务器或者由PCS功能站兼任。  The PCS should have primary and secondary domain controllers for management of the group policy. The domain controllers can be dedicated server or can be performed by PCS application server. | 质量  Quality |
|  | PCS供应商需提供组策略配置文档。  PCS supplier shall provide configuration document of group policy. | 商业  Business |

### 系统时间及时钟同步 System Time and Time Synchronization

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | PCS系统的时间格式使用24小时制YYYY-MM-DD HH:MM:SS (UTC+08:00)。  Time format of the PCS utilizes 24-hour clock YYYY-MM-DD HH:MM:SS and be based on time zone (UTC+08:00) Beijing, Chongqing, Hong Kong, Urumqi. | 质量  Quality |
|  | PCS系统需支持NTP协议，并预留NTP时钟信号接口。  PCS system should support NTP protocol and reserve NTP clock signal interface. | 质量  Quality |
|  | PCS的服务器、操作站、HMI、控制器等均需实现时钟同步。  The server, operator station, HMI and controller of PCS shall synchronize its time. |  |
|  | 整个PCS系统的内部时钟应与 NTP授时服务器标准时间保持±3秒/每天的精度和同步性，并具备监视各功能站及控制器时钟的功能。  The internal clock of the entire PCS system should maintain the accuracy and synchronization of ± 3 seconds / day with the standard time of the NTP time server, and have the function of monitoring the clocks of each functional station and controller. | 质量  Quality |
|  | NTP授时服务器将由业主自行购买和安装。  The NTP timing server will be purchased and installed by the owner. | 商务  Commercial |

### 用户账户及权限管理 User account and Authority management

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | PCS系统必须具有可配置的，全面综合性的用户安全和权限控制功能。此功能可管理PCS所有工作站的画面，数据和系统功能的使用权限。  The PCS shall include a configurable, comprehensive user security and access control function. This function shall govern the access to displays, data, and system functions at all system workstations. | 质量  Quality |
|  | PCS系统必须支持一个或多个用户组形式的权限管理功能。  The system shall support the organization of users into one or more groups for the purpose of establishing system access and permission profiles on a group-by-group basis. | 质量  Quality |
|  | 此系统必须可以对特定的用户组授权特定的系统功能和画面。  The system shall have the ability to define what system functions and screens are visible to a user group. | 质量  Quality |
|  | 对于每一个用户必须要有一个唯一的用户ID和密码，系统账户设置数量不少于99个。  Each user shall be assigned with an individual account with a unique User Identification (User ID) and password combination. The number of system accounts is not less than 99. | 质量  Quality |
|  | 密码应采用不固定的期限有效期，一般期限为90天。  The password shall be valid for an unset period of time. The general period is 90 days | 质量  Quality |
|  | 密码必须包括如下要求：   * 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位字符或可自定义； * 密码应强制要求满足复杂性要求，如包括大写字母，小写字母，数字，特殊字符等； * 当输入密码时，系统不允许显示或者打印密码； * 强制密码历史次数不小于3次。   The passwords must have the following requirements:  Force a user to change a new/reset password at first use.  Automatically prompt the user to change their passwords upon expiration.   * Password length: minimum 8 characters or configurable. * Password should meet the complexity requirements, for example, password should include at least the three of capital letter, lowercase letter, numeric and special character. * The system must not permit the display or printing of passwords when they are entered into the system. * Enforce password history: at least 3 | 质量  Quality |
|  | 从安全角度考虑，PCS系统必须支持用户在登陆后，若一段时间无任何操作，可以自动注销登录的功能，并且此时间可以配置的。  The system shall support the automatic logoff of a user session after a pre-established duration of inactivity at the workstation. This duration shall be configurable by the system administrator. | 质量  Quality |
|  | 系统权限至少分为以下5级：   * 系统管理员，具有对系统的操作和管理权限，但不可具有工艺控制的操作权限，防止使用最高权限操作时误操作。具有数据备份权限、恢复的权限。 * 工程师，能修改系统配方、控制程序、工艺流程图及工艺参数。 * 维护工程师，日常系统维护、系统备份、数据导出。 * 操作员，可调用配方、启/停设备及程序，修改设定值、读取数据、报警查询和确认、调取历史和实时曲线。操作员权限可按照区域进行划分。 * 访客，仅可观察。   The system permissions should at least 5 levels:   * A system administrator who has the permission to operate and manage the system but cannot have the permission to operate the process. This prevents misoperation when using the highest permission. Has the permission to back up and restore data. * Engineer, can modify recipe, control program, process graphic or process parameters * Maintenance engineer, daily system maintenance, system backup, data export. * Operators can call recipes, start / stop equipment and programs, modify set values, read data, alarm query and confirmation, and retrieve historical and real-time curves. Operator rights can be divided by area. * Visitors, view only | 质量  Quality |

### 常规控制准则 Conventional Control Philosophy

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | PCS系统必须包括常用的控制算法功能块，如：IO功能块、模拟量控制功能块、数学运算功能块及逻辑运算功能块等算法。  The PCS system must include commonly used control algorithm function blocks, such as IO function blocks, analogue control function blocks, mathematical operation function blocks, and logic operation function blocks. | 商业  Business |
|  | 所有的功能块均支持在线仿真功能。  All function blocks shall support online simulation. | 商业  Business |
|  | PID控制算法必须支持以下功能：   * 串级、自动及手动控制模式。 * 抗积分饱和。 * 前馈计算。 * 设定值跟踪和无扰模式切换。 * 设定值和PID计算值输出限值设定。 * 正/反作用。   The PID control algorithm must support the following functions:   * Cascade, automatic and manual control modes. * Anti-saturation. * Feed forward calculation. * Set value tracking and bump less mode switching. * Set value and PID calculated value output limit setting. * Positive / reverse effects. | 商业  Business |
|  | 电机控制算法必须支持以下功能：   * 手自动模式切换； * 远程就地判断； * 联锁保护； * 故障判断；   The motor control algorithm must support the following functions:   * automatic and manual control modes. * Remote and local verify. * Interlock. * Alarm verify. | 商业  Business |

### 标准界面 Standard Graphic

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | PCS需具备但不限于如下的标准界面，这些界面无需进行从无到有的开发，仅需要进行配置更改：   * 系统报警界面 * 过程报警界面 * 导航功能界面 * 位号搜索界面； * 调节界面 * 操作面板界面 * 历史趋势界面 * 系统维护界面 * 系统诊断界面   PCS should have, but not be limited to, the following standard interfaces, which do not require development and only require configuration changes:   * System Alarm Window * Process Alarm Window * Navigator Window * Tag Search Navigation Window * Tuning Window * Faceplate Window * Historical Trend Window * System Maintenance Window * System Diagnostic Window | 商业  Business |

### 历史数据记录History Data Record

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | PCS需具备历史数据的记录、存储、查看、归档、备份及恢复的功能。  The PCS shall have function of history data record, archive, view , backup and restore. | 质量  Quality |
|  | 历史数据储存单元的储存能力应为：  - 关键参数的存储间隔周期不大于1s；  - 确保储存时间不少于180天。  The storage capacity of the history data storage unit shall be:  - The interval for storing critical parameter is not greater than 1s;  - The storage time is not less than 180 days. | 质量  Quality |
|  | 储存变量的授权数量需满足不锈钢系统及数据采集系统IO总点数要求外，再为下游工艺设备配置1000点授权，并在总授权点数基础上留10%的余量；  The number of storage variables needs to meet the requirements of the total number of IO points in the stainless steel system and data acquisition system, and also reserve 10% margin; | 商务  Commercial |
|  | PCS系统需具有将超过180天的历史数据自动归档功能。  The PCS system shall have the function of automatic archive when historical data is over 180 days. | 质量  Quality |
|  | PCS系统必须支持创建自定义实时趋势图，并且能保存供再次调出使用。  The PCS system must support the creation of custom real-time trend graphs, and can be saved for recall again. | 质量  Quality |
|  | 趋势必须要能在人机界面中显示，且可通过彩色打印机打印或者保存至其他的备份存储设备。  Trends can be displayed on man-machine screen and printed out on a color printer or saved on a separate backup medium. | 质量  Quality |
|  | 趋势画面中的时间轴和数值轴的范围和间隔要能手动调整，并且支持基于时间的筛选功能。  The range and interval of the time axis and value axis in the trend screen must be manually adjustable, and support the time-based filtering function. | 质量  Quality |
|  | 趋势画面中的线条颜色和粗细可以调整、并且可任意增加和删减变量。  The color and thickness of the lines in the trend picture can be adjusted, and variables can be added and removed arbitrarily. | 质量  Quality |
|  | 趋势画面需要支持数据导出功能（例如Excel）。  It shall be possible to export trend data in a suitable form to other system (e.g. Excel) for further processing. | 质量  Quality |

### 报警及事件记录 Alarm and Event Record

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | PCS系统作为全厂工艺设备集中监控系统，必须配置完整的报警监视功能，对于系统所产生的全部报警都必须在监控屏幕上实时显示出来。  As a centralized monitoring system for process equipment of the whole plant, the PCS must be equipped with a complete alarm monitoring function. All alarms generated by the system must be displayed on the monitoring screen in real time. | 质量  Quality |
|  | PCS必须按顺序和时间标记自动记录所有的报警事件、过程变量报警值及报警确认操作。  The PCS must automatically record all alarm events, process variable alarm value and alarm confirmation operation. | 质量  Quality |
|  | PCS应具有对报警和事件记录分类、过滤、筛选、检索的功能。  PCS shall have the function of classifying, filtering, filtrating and retrieving alarm and event records. | 质量  Quality |
|  | PCS应具有硬件、软件故障诊断功能，应能自动记录故障并发出报警，过程控制层的诊断至少包括以下内容：   * I/O模件故障； * 通信故障； * 控制器故障； * 电源故障。   PCS shall have the function of hardware and software fault diagnosis, and shall be able to automatically record the fault and send out an alarm, the diagnosis of process control layer shall at least include the following contents:   * I / O module failure; * Communication failure; * Controller failure; * Power failure. | 质量  Quality |
|  | 报警功能必须包含模拟量，数字量和用户自定义报警。  It shall provide alarming capabilities for analogue, discrete and user defined alarms. | 质量  Quality |
|  | 所有的报警产生时间以秒为单位，报警必须是在控制器中产生。  Alarms shall be generated and time stamped within 1 second at the source and alarms are generated in controllers. | 质量  Quality |
|  | 对于每一个报警信息都能定义相应的报警级别。  It shall be possible to assign a priority to each alarm with the system accommodating at multiple priority levels. | 质量  Quality |
|  | 用户能够配置每个报警级别的名字，报警声音和颜色显示。  The user shall have the ability to configure each level based on priority name, horn sound and color. | 质量  Quality |
|  | 对于相应的工艺单元要能定义相应的报警组，报警种类和级别。  It shall be possible to assign alarm groups by process area, process location, asset type and alarm priority. | 质量  Quality |

### 审计追踪 [Audit](javascript:;) [Trial](javascript:;)

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | PCS系统必须具备审计跟踪功能。系统必须能够提供跟踪记录报表文件用以追溯某段时间内某个操作员的所有操作及登入、登出记录。  The PCS system shall have the audit trail function. The system shall be able to provide a report to trace all operations and login and logoff activities of an operator. | 质量  Quality |
|  | 审计追踪记录信息必须包括但不限于以下几点：   * 修改的时间和日期 * 修改前的数值修改后的数值 * 修改人的用户名 * 修改的地点   The audit trail record shall include but not be limited to following information:   * The date and time the change was made * Old values replaced, new value entered * User name of the individual making the change * Location from where the change was made | 质量  Quality |
|  | 系统必须能够生成审计跟踪数据的电子文件，并且能够打印出来。  The system shall be able to generate electronic copies of all audit trail data files, and be able to print these files. | 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未经授权的用户关闭。当审计追踪被关闭时，PCS系统应能记录该事件。  Audit trail records cannot be modified or deleted. The audit trail function cannot be disabled by unauthorized user. The event of disabling the audit trail shall be recorded by PCS. | 质量  Quality |
|  | 所有生成的记录无法被修改，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 |

### 报表 Report

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | PCS系统必须支持第三方商业化专业的报表软件，用于开发复杂的报表。  PCS systems must support third-party commercial, professional reporting software for the development of complex reporting. | 质量  Quality |
|  | 所有报表可以通过打印机打印或者自动生成PDF文件存储。  All reports can be printed on a printer or automatically generated PDF file for storage. | 质量  Quality |
|  | 生成的报表可以通过PCS监控界面打开并进行浏览、打印。  The generated report could be open, review and print from PCS operate graphics. |  |
|  | PCS系统不允许终端用户修改报表的内容，包括报表中的数据。  The PCS system does not allow end users to modify the contents of the report, including the data in the report. | 质量  Quality |
|  | 报表二次开发由甲方完成，PCS供应商需为报表开发按需提供技术支持。  The secondary development of report will be completed by Henlius, and the PCS supplier shall provide the technical support on demand. | 商务  Commercial |

### 批量控制与配方管理 Batch Control and Recipe Management

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 批量单元授权数量不少于120个，并额外预留10%。  The quantities of batch unit license shall be no less than 110，and reserve additional 10% spare.. | 商业  Business |
|  | PCS系统必须含有批量程序组态和控制执行的标准软件包功能。  The PCS shall have standard software functions to configure and control a fully automated batch process. | 质量  Quality |
|  | 批量管理软件必须符合美国仪表协会（ISA）88-1995中的批量控制标准。  The batch management software functions shall conform to the Instrument Society of America (ISA) 88-1995 batch control standard. | 商务  Commercial |
|  | 批量配方管理程序对任意一个配方必须支持以下配置信息但不仅限于：   * 步骤 * 计算公式 * 设备需求 * 其他必要信息   The Batch Recipe Management procedure configuration tool shall provide the ability to configure the following information for each recipe:   * Procedure. * Formula. * Equipment requirements. * Header and other information. | 质量  Quality |
|  | 配方流程必须支持以下几个层次，以符合ISA88-1995标准中的流程步骤模型：   * 配方程序 * 单元程序 * 操作 * 阶段   Recipe procedures must support the following levels to meet process step model in the ISA88-1995 standard:   * Recipe Procedure * Unit Procedure * Operation * Phase | 质量  Quality |
|  | phase功能程序需包括开始、停止、中止、运行、暂停和重启等运行状态程序，并与操作员的批次启/停操作画面保持一致。  The phase functional program should include start, stop, abort, run, hold, and restart running status programs, consistent with the batch start/stop operator’s operation diagram. | 质量  Quality |
|  | PCS系统需具有ISA S88的所规定的流程图层次。流程编辑必须支持条件转移，逻辑分支，平行分支，循环结构和用于监控和控制的动态模块标签等功能。  The PCS system shall have the flow diagram hierarchy specified in ISA S88. Procedure editing must support conditional transitions, logical branching, parallel branching, loop structures, and dynamic module tags for monitoring and control. | 质量  Quality |
|  | 配方管理需具有密码保护功能。  The formula management needs to have the password protection function. | 质量  Quality |

### 数据存储及备份恢复 Data Storage and Backup and Restore

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 历史记录工作站具有检测硬盘数据存储空间的功能，当剩余空间不足20%时，需产生提示或者报警。  The history recording workstation has the function of detecting the hard disk data storage space. When the remaining space is less than 20%, a prompt or alarm needs to be generated. | 质量  Quality |
|  | PCS具有对如下数据或文件的备份、恢复、归档及管理功能：   * 事件及报警数据； * 连续历史及批量历史数据； * 审计追踪数据； * 组态数据库及画面；   The PCS is able to backup, restore, archive and manage following data and/or files:   * Alarm and Event * Continuous history and batch history * Audit trail * Database and graphics | 质量  Quality |
|  | 数据的备份和归档功能既可以手动完成也可以自动完成。  The PCS must support manual and/or automatic full database backup function. | 质量  Quality |
|  | PCS系统要能重新导入备份数据并且不受软件授权的限制。  It must be possible to re-store the collected data from backups and do not impact on the software licenses. | 质量  Quality |
|  | PCS系统要能支持数据的灾难恢复功能。  The PCS system and data could recovery from disaster. | 质量  Quality |

## 网络安全 Cyber Security

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | PCS系统的所有物理计算机必须安装杀毒软件，严禁使用未经过测试的杀毒软件及其病毒库更新包。  Anti-virus software must be installed on the system.PCS shall have an anti-virus software control central, which can remotely install updates to the other workstations computers, servers. | 质量  Quality |
|  | PCS系统需支持所有功能站的USB口禁用功能，除历史记录工作站以外，其它功能站USB口全部禁用。  The PCS shall be able to disable USB port of all function stations. Except for the history workstation, the USB ports of other function stations are all disabled. | 质量  Quality |
|  | PCS系统与第三方系统的数据传输需经过防火墙。防火墙由重庆药友配置，PCS供应商需配合防火墙的配置。  The data transmission between the PCS and the third party system through a firewall. The firewall will be configured by Henlius, and the PCS vendor shall support. | 商务  Commercial |

## 安装及施工Installation and Construction、

### 标识 Identification

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 机柜采用相同规格的铭牌标识，铭牌的编号及规格须经业主确认。  Cabinets are configured with nameplates of the same specifications, the number and specification of the nameplate shall be confirmed by the owner. | 商业  Business |
|  | 柜内元器件需配置规格统一的标签标识。  The components in the cabinet shall be configured with uniform label identification. | 商业  Business |
|  | 系统功能站、操作员需配置统一的标签标识，并与系统组态保持一致。  The system function station and the operator need to configure a unified label identification, which is consistent with the system configuration. | 商业  Business |
|  | 系统网络交换机需配置统一的标签标识。  The system network switch needs to be configured with a unified label identification. | 商业  Business |
|  | 系统电缆和网线需配置标牌或标签，能从线缆标签识别起点和终点。  The cables and network cables must be configured with cable labels. | 商业  Business |
|  | 电缆线号标识需与IO List点位号保持一致。  The cable number identification should be consistent with the IO List single point tag. | 商业  Business |

### 线缆及安装 Cable and Installation

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | PCS系统供应商需提供PCS系统所需的全部电缆、网线及安装附件材料。  The PCS system supplier shall provide all cables, network cables and all attachment material for installation for the PCS system. | 商务  Commercial |
|  | Profibus-DP 电缆必须选用带屏蔽紫色、红绿两芯的标准电缆。  Profibus-DP cable must protective layer, purple, red and green two-core standard cable. | 商业  Business |
|  | PCS系统至现场设备的DP、Modbus-RTU通讯线缆由PCS系统供应商提供，并完成接线。  The PCS system supplier provides DP and Modbus-RTU communication cables between the PCS system and field devices, and complete the wiring. | 商业  Business |
|  | Modbus-RTU电缆必须选用屏蔽双绞线。  Modbus-RTU cable must use shielded twisted pair. | 商业  Business |
|  | 网线采用带屏蔽超5类及以上网线。  The network cable adopts shielded super category 5 and above network cable. | 商业  Business |
|  | 信号电缆采用绝缘屏蔽多芯电缆，线径≥1.0 mm2。  The signal cable adopts insulated and shielded multi-core cable. | 商务  Commercial |
|  | 动力电缆采用多芯电力电缆。  The power cable adopts multi-core power cable. | 商业  Business |
|  | 接地电缆采用黄绿单股电缆，控制柜至工厂接地汇流排电缆线径严格按照系统规范的标准进行配置，接地线缆线径≥25 mm2。  The ground cable adopts yellow and green single cable, and the cable diameter of the control cabinet to the factory ground bus is are configured strictly in accordance with the system specifications. | 商务  Commercial |
|  | PCS系统所有机柜安装的基础材料及机柜间静电地板由PCS系统供应商提供，机柜基础材料需做防锈和绝缘处理,并完成机柜基础及静电地板安装施工。  The PCS system supplier provides all base material for cabinet installation and anti-electrostatic floor in the cabinet room , which must be treated with rust prevention and insulation, and the complete to install the base of cabinet and anti-electrostatic floor. | 质量  Quality |
|  | 所有线缆需采用抗阻燃材质。  So cables need to be made of flame retardant material. | 质量  Quality |
|  | 所选电缆品牌详见附件2品牌推荐表。  Refer to the appendix 2 which is the brand recommendation table for the selected cable brand. | 商务  Commercial |

### 现场施工及设计 Site Construction and Design

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | PCS供应商需负责PCS系统现场项目管理、安装、调试和验收工作。  The PCS supplier shall be responsible for the on-site project management, installation, commissioning and acceptance of the PCS system. | 商务  Commercial |
|  | PCS供应商需设计PCS系统机柜间的平面布局图。  The PCS supplier needs to design the plane layout diagram of PCS cabinet room. | 商务  Commercial |
|  | PCS供应商负责电缆桥架的设计和安装工作。  The PCS supplier shall be responsible to design and install for cable tray. | 商务  Commercial |
|  | PCS供应商负责PCS系统机柜的安装工作。  The PCS supplier shall install PCS cabinet. | 商务  Commercial |
|  | PCS供应商负责设计和安装功能站、普通操作员站及净室现场操作员站的工作。  The PCS supplier shall design and install function station, operator station and clean room site operator station. | 商务  Commercial |
|  | PCS供应商负责PCS机柜到现场工艺设备间电缆敷设及接线工作。  PCS supplier is responsible for Cable laying and wiring work from system cabinet to on-site process equipment. | 商务  Commercial |
|  | PCS供应商负责控制柜之间电缆和网线敷设及接线工作。  PCS supplier is responsible for laying and wiring of cables and network cables between control cabinets. | 商务  Commercial |

## 测试及验证要求 Test and Validation Requirements

### 通用要求 General Requirement

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | PCS供应商负责PCS基础架构及系统全局功能的测试及验证。  The PCS supplier shall be responsible for testing and validation for PCS infrastructure and global function. | 商务  Commercial |
|  | 业主负责工艺控制的测试及验证，PCS供应商按需提供技术支持。  The owner shall be responsible for the testing and verification of process control, and the PCS supplier shall provide technical support on demand. | 商务  Commercial |
|  | 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  Commercial |
|  | 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:   1. 验证计划 Validation plan 2. 风险评估 Risk assessment 3. 设计确认 DQ 4. 预FAT(工厂内部测试) Pre-FAT(VIT) 5. 工厂验收测试 FAT 6. 现场验收测试 SAT 7. 调试 Commissioning 8. 安装/运行确认 I/OQ 9. 现场计算机验证 CSV on the owner’s site 10. 协助性能确认 PQ assistance | 商务  Commercial |
|  | 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  Commercial |
|  | 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  Commercial |
|  | 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  Commercial |

### 出厂验收测试 Factory Acceptance Test

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 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.   1. 已在工厂调试完毕并有测试报告PCS has been debugged in the manufacturer and has test report 2. 工厂根据合同技术附件、功能设计文件和有关标准等编制工厂验收程序   PCS manufacturer shall prepare factory acceptance procedures according to contract technical attachments, functional design documents and relevant standards;   1. 100%输入/输出及环路测试 100% I/O and loop checks 2. 100%报警和联锁测试 100% alarm and interlock testing 3. 100%电气图纸检查100% Electrical Drawings checks 4. 布局图一致性检查 GA compliance check 5. 制造材质确认 Material of construction verification 6. 电气检查，包括接线、终端等 Electrical verification including wiring, terminations etc. 7. 控制面板检查、设备盘点及实物检查 Control panel visual inspection, equipment inventory & physical checks 8. 标签标牌检查 All items tagged and labelled as per specification 9. 100%文件检查 Documentation check; all documents 10. 21 CFR Part 11符合性确认，权限测试 21 CFR Part 11 compliance verification, security tests. | 商务  Commercial |
|  | 所有的设备须接受工厂验收测试（FAT）确认。  All system has to be accepted by a Factory Acceptance Test (FAT). | 商务  Commercial |
|  | FAT方案由供应商起草并在FAT执行前由业主批准。FAT测试将在供应商工厂进行，业主将见证所有的测试执行。  FAT protocols are to be prepared by the supplier and approved by owner prior to the FAT. The supplier shall execute tests at their premises and owner will witness all the tests. | 商务  Commercial |
|  | 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  Commercial |
|  | 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  Commercial |
|  | 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  - 接线标签和颜色检查 Labelling and color  - 硬件及控制器配置检查 Hardware and Controller Configuration  - 功能站和操作员配置检查 Workstation and Operator Station Configuration | 商务  Commercial |
|  | 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:  - 权限测试 Privilege testing  - 批量控制、配方管理 Batch control and recipe manageme  - 时钟同步 Time Synchronization  - 用户及权限管理 User and authorization management  - 报警记录及数据管理 Alarm record and data management  - 事件记录及数据管理 Event record and data management  - 连续历史记录及数据管理 Continuous history data record and data management  - 批量历史记录及数据管理 Batch history data record and data management  - 批次报告 Batch report  - 电子记录及电子签名 Electronic record and electronic signature  - 审计追踪 Audit trail  - 数据备份及恢复 Data backup and restore  - 系统灾难恢复 System disaster recovery | 商务  Commercial |
|  | FAT系统配置检查：   * 各设备、部件的型号、规格和外观应符合要求； * 软件的规格、数量和版本应符合要求。   System configuration check:   * The model, specification and appearance of equipment and components shall meet the requirements. * The specification, quantity and version of software shall meet the requirements. | 商务  Commercial |
|  | FAT工厂验收报告应包括以下内容：   * 工厂验收的步骤； * 检查和测试的结果； * 最终验收结论。   The factory acceptance report shall include the following contents:   * Steps of factory acceptance; * Inspection and test results;   Final acceptance conclusion. | 商务  Commercial |
|  | 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:   * 系统信号处理精度测试（AI、AO、DI、DO等I/O模件）； * 系统的冗余和容错测试； * 系统接地测试。   System performance test:   * System signal processing accuracy test (AI, AO, DI, DO and other I / O modules); * Redundancy and fault tolerance test of the system;   System grounding test. | 商务  Commercial |

### 联合出厂测试 Integrated FAT

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 完成工厂内FAT测试验收后，PCS系统供应商需发货至不锈钢系统供应商工厂做联合FAT。  After completing the FAT test and acceptance in the factory, the PCS supplier needs to ship to the stainless steel liquid distribution system supplier factory to execute the integrated FAT. | 商务  Commercial |
|  | 联合FAT以下项需100%检查，但不限于：   * 与阀岛Profibus DP通讯测试； * 阀门反馈及接线测试； * MCC柜与电机连接测试； * 现场仪表接线测试；   The following items of integrated FAT require 100% inspection, but not limited to:   * Profibus DP communication test with valve terminal; * Valve feedback and wiring test; * MCC cabinet and motor connection test; * Field instrument wiring test; | 商务  Commercial |

### 现场验收测试 Site Acceptance Test

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 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  Commercial |
|  | 现场设备验收和安装准备应符合下列要求：   * 各设备和部件的规格、数量应与装箱单一致，运输过程应无损坏； * 设备安装符合要求； * 设备在软件安装和组态数据装载后应正常运行； * 所有硬件应按工厂的程序进行测试，并100%正常工作。   Site equipment acceptance and installation preparation shall meet the following requirements:   * The specification and quantity of all equipment and parts shall be consistent with the packing list, and there shall be no damage during transportation; * Equipment installation meets the requirements; * PCS equipment shall operate normally after software installation and configuration data loading;   All hardware shall be tested in accordance with the procedures of the PCS manufacturer and shall work normally. | 商务  Commercial |
|  | 现场验收应包括以下内容：   * 审阅工厂验收报告和现场调试记录； * 组态检查（同工厂验收内容）； * 系统信号处理精度测试，AI、AO、DI、DO等I/O模件应100%检查； * 系统的冗余和容错功能测试； * 第三方设备与PCS集成后的标准功能应满足要求； * 测试PCS与第三方设备的通信功能和实际数据交换，第三方的通信设备或者通信设备中应带有实际应用的通信数据。   Site acceptance shall include the following:   * Review PCS factory acceptance report and site commissioning record; * Configuration inspection (the same as factory acceptance content); * System signal processing accuracy test, AI, AO, DI, DO and other I / O modules should be 100% checked; * Redundancy and fault tolerance function test of the system; * The standard functions of the third-party equipment integrated with PCs shall meet the requirements;   Test the communication function and actual data exchange between PCS and the third-party equipment, and the communication equipment or communication equipment of the third-party shall have the communication data of actual application. | 商务  Commercial |
|  | 现场验收报告应包括以下内容：   * 现场验收的步骤； * 检查和测试结果； * 最终验收结论。   The site acceptance report shall include the following contents:   * Site acceptance steps; * Inspection and test results;   Final acceptance conclusion. | 商务  Commercial |

### 安装确认及运行确认 IOQ

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | PCS系统硬件及软件I/OQ方案由供应商起草并在I/OQ执行前由业主批准。I/OQ测试将在业主现场进行，业主将见证所有的测试执行。  I/OQ protocols of hardware and software of PCS are to be prepared by the supplier and approved by owner prior to the I/OQ. The supplier shall execute tests on the owner’s site and owner will witness all the tests. | 商务  Commercial |

### 性能确认 PQ

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 供应商协助业主进行PQ。  The supplier assists owner in carrying out PQ. | 商务  Commercial |

## 文件 Documents

### 文件清单 Document list

| **文件组 Documentation group** | **文件类别 Type of Document** | **是否需要业主审批(Y/N) Approved by owner?(Y/N)** | **文件递交日期  Document delivery date** |
| --- | --- | --- | --- |
| 一般文件 General documentation | URS响应表 Compliance to URS | N | B |
| 项目及建设进度表 Project and production schedule | Y | K |
| 项目质量计划 Project Quality Plan | Y | K |
| 图纸清单 Drawing list | Y | D |
| 机柜装配图 Cabinet assembly drawing | Y | D |
| ISO证书 ISO certificate | N | D |
| 文件递交日期 Document delivery date | Y | K |
| 设备重量信息 weight information of equipment | N | F |
| 变更控制规程 Change Order Procedure | N | K |
| 供应商文件列表 Vendor document schedule | Y | D |
| 货运文件 Shipping documentation | N | F |
| 规程 Procedures | 历史数据备份恢复规程 Historical data backup and recovery procedures | Y | F |
| 全数据备份规程 Full database backup procedures | Y | F |
| 全数据库备份灾难恢复规程 Full database backup disaster recovery procedures | Y | F |
| 手册/数据记录 Manuals/Data sheets | 系统维护手册 System Maintenance manual | N | S |
| 软件安装手册 Software Installation manual | N | S |
| 操作手册 Operation manual | N | S |
| 控制系统手册 Control system manual | N | S |
| 设备数据表 Equipment data sheets | N | S |
| 电气数据表 Electrical data sheets | N | S |
| 标签清单 Tag list | N | F |
| 电气部分 Electrical | 电气部件列表 Electrical part list | N | D |
| 电气图 Electrical diagrams | Y | D |
| 电气负荷 Electrical load (kW, V, Phase, Frequency) | N | D |
|  | I/O列表及地址列表 I/O List and address table | Y | D |
| 自动化  Automation | 控制功能块说明Standard control function block specification | Y | D |
| Profibus-DP网络图 Profibus-DP Network diagram | Y | D |
| 系统网络架构图System network architecture diagram | Y | D |
| 系统电缆清册 System cable inventory | Y | D |
| 系统接地图 [System](javascript:;) earthing diagram | Y | D |
| 机柜布局图 Cabinets layout diagram | Y | D |
| VPE设备通讯列表 VPE equipments communication list | N | D |
| VPE设备信号交换列表 VPE equipments signal exchange list | N | D |
| 参数设定值 Parameter settings | Y | D |
| 运行描述 Operation Description | Y | D |
| 互锁列表 Interlock list | Y | D |
| 报警列表Alarm list | Y | D |
| 硬件设计说明 Hardware Design Specification | Y | D |
| 软件设计说明 Software Design Specification | Y | D |
| 功能设计说明 Functional Design specification | Y | D |
| 证明 Certificates | 接地检查记录 Earthing continuity check records | Y | F |
| 机柜金属部件的材质证明 Material certificates for metallic parts | N | F |
| 机柜合格证书 Cabinet [qualification](javascript:;) [certificate](javascript:;) | N | F |
| 验证 Qualification | 验证计划 Validation Plan | Y | K |
| 风险评估及报告 Risk Assessment and Report | Y | K |
| DQ方案/报告 DQ protocol /report | Y | D |
| 需求追溯矩阵 RTM | Y | D |
| FAT方案/报告 FAT protocol/report | Y | F |
| SAT方案/报告 SAT protocol/report | Y | S |
| IQ方案/报告 IQ protocol/report | Y | O |
| OQ方案/报告 OQ protocol/report | Y | O |
| 备品 Spares | 备品清单 Spares part list | N | S |

B：招标后2周内 Within 2 weeks after bidding

K：启动会之后2周以内 Within 2 weeks after kickoff meeting

D：主体设计完成2周以内 Within 2 weeks after subject design

F：FAT实施前4周 Within 4 weeks before FAT execution

S：SAT实施前4周 Within 4 weeks before SAT execution

O：I/OQ实施前4周 Within 4 weeks before I/OQ execution

P：PQ实施前4周 Within 4 weeks before PQ execution

注：供应商出具的文件可根据实际文件体系合并或拆分，但要求的内容应包涵在内。

Note: the documents issued by the supplier can be merged and split according to the actual document system, but the contents of the request should be included.

### 文件要求 Documentation

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 需提供三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。  Three (3) hard copies as “AS BUILT” documentation plus electronic form (CD). Drawings and documents shall be made in AUTOCAD and Microsoft Office. | 商务  Commercial |
|  | 需提供三份纸质以及一份电子版的运行、安装、维护手册。  Three (3) hard copies of Installation, Operating and Maintenance Manuals | 商务  Commercial |
|  | 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  Commercial |
|  | PCS系统的图纸及部件的编号，须经业主确认。  PCS drawings and component numbers shall be confirmed by the owner. | 商务  Commercial |

### 文件提供时间节点 Document delivery date

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 所有文件的递交时间节点已在文件清单中进行说明。  The delivery time of all documents is descripted in the document list. | 商务  Commercial |

## 维护要求 Maintenance Requirements

### 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  Commercial |
|  | 房间高度3500mm。若有超出3500 mm的维修高度要求，供应商必须告知业主。  There is a clear height for the room of 3500 mm. Important Note it is essential that the supplier notify if more than 3500mm is required. | 商务  Commercial |
|  | 设备周围应留有足够的维护空间，开启角度≥90°，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 angle of the gate is more than 90°. The opening direction should meet the layout and maintenance requirements of the workshop. | 商业  Business |
|  | 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  Commercial |
|  | 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  Commercial |

### 备品备件 Spares

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 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  Commercial |
|  | 5年内常规部件的采购价格要按照原设备零部件报价来执行。  The purchase price of conventional parts shall be based on the quotation of the original equipment and parts. | 商务  Commercial |
|  | PCS的备品备件不应低于保证系统运行3年的数量。  The spare parts of PCS shall not be less than the quantity of 3-year system operation. | 商务  Commercial |
|  | I/O卡件的备用量不应少于5%，并确保各类IO卡件不少于1件，增加控制器、通信模件、变频器、固态继电器以及电源模件备件各一套。  The spare quantity of I/O card shall not be less than 5%, and at least one spare shall be reserved for each. Add a set of spare part for controller, communication module frequency converter, solid-state relay and power module. | 商务  Commercial |
|  | PCS供应商应保证系统所需的备品备件15年的供应期。  The PCS supplier shall guarantee the supply period of spare parts required by the system for 15 years. | 商务  Commercial |
|  | 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  Commercial |

## 服务及培训要求 Service and Training Requirements

### 技术服务 Technical services

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 供应商在整个工程项目进行过程中应提供相关得技术咨询服务。  Supplier shall provide relevant technical consulting services during the whole project. | 商务  Commercial |
|  | 供应商应提供其所有交付文件、资料和设备的技术澄清服务。  Supplier shall provide technical clarification services for all delivery documents, data and equipment. | 商务  Commercial |
|  | 供应商在工厂验收和现场验收过程中提供相关得资料，并配备专门的工程技术人员配合验收工作。  Supplier shall provide relevant data during factory acceptance and site acceptance, and provide special engineering and technical personnel to cooperate with the acceptance. | 商务  Commercial |
|  | 供应商应对所供货的产品提供必要的组态、操作、使用和维护培训，并提供相应的培训资料。  Supplier shall provide necessary configuration, operation, use and maintenance training for the supplied products, and provide corresponding training materials. | 商务  Commercial |

### 现场服务 Field service

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | 供应商应配备有资质的工程技术人员配合PCS的现场安装、调试、通电工作，并应对结果负责。  Supplier shall be equipped with qualified engineering and technical personnel to cooperate with PCs on-site installation, commissioning and power on, and shall be responsible for the results. | 商务  Commercial |
|  | 在工程批生产期间，PCS供应商应配备有资历的工程技术人员在现场值班，随时解决开工过程中PCS出现的故障。  During engineering batch production, the PCS supplier shall be equipped with qualified engineering and technical personnel on duty on site to solve the problems of PCs during the start-up at any time. | 商务  Commercial |

### 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  Commercial |
|  | 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  Commercial |
|  | 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  Commercial |
|  | 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  Commercial |
|  | 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  Commercial |
|  | 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  Commercial |
|  | 供应商应承担由于包装、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  Commercial |
|  | 从设备合同签订到设备抵达业主指定场地，时间不超过6个月。  It is not more than 6 months from the signing of the equipment contract to the equipment to the owner's designated site. | 商务  Commercial |
|  | PCS系统与不锈钢管罐系统联合FAT完成后，PCS供应商需负责将PCS系统所有货物运至业主现场。  After the PCS system and the stainless steel tube and tank system are combined with FAT, the PCS supplier shall be responsible for transporting all the goods of the PCS system to the owner's site. | 商务  Commercial |

* + 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  Commercial |
|  | PCS出现故障后，供应商应在24h内派出有资质的工程技术人员前往故障现场。  After PCS failure, supplier shall send qualified engineering and technical personnel to the failure site within 24 hours. | 商务  Commercial |

### 培训要求 Training requirements

| **序号**  **ID No.** | **需求描述**  **Requirement Description** | **需求分类**  **Requirement Category** |
| --- | --- | --- |
|  | PCS供应商应对所供货的产品提供必要的组态、操作、使用和维护培训，并提供相应的培训资料。  PCS supplier shall provide necessary configuration, operation, use and maintenance training for the supplied products, and provide corresponding training materials. | 商务  Commercial |
|  | 提供不少于45个培训名额，包括15个工程师培训名额和30个操作员课程培训名额。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。  Provide no less than 45 training places, including 15 engineer training places and 30 operator training places. The training contents shall include the training of basic principles and operation skills of the equipment, and the training system shall be comprehensive. | 商务  Commercial |
|  | 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  Commercial |
|  | 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  Commercial |

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 |  |

1. 附录APPENDIX

|  |  |
| --- | --- |
| 附件一  Appendix I | 202#楼平面布局图  Layout of building No.202 |
| 附件二  Appendix II | PCS系统元器件品牌推荐表  PCS system component brand recommendation table |
| 附件三  Appendix III | 不锈钢反应器系统IO统计  IO summary of stainless steel bioreactor |
| 附件四  Appendix IV | 不锈钢配储液及中间体系统IO统计  IO summary of stainless steel preparation and holding and process |
| 附件五  Appendix V | VPE设备通讯协议及IO统计表  VPE devices communication protocol and IO statistics table |
| 附件六  Appendix VI | 不锈钢配储液及中间体罐系统电机数量统计  Motor summary of stainless steel preparation and holding and process |