QProject Name 项目名称	Area 区域	Module 模块
M2 Downstream Process System and Automation System Project M2 项目下游工艺管罐系统与工艺自控系统工程	N/A	N/A

Project Number 项目编号	Job Number 工作令号
PP20-0098	SMP20-YM-31087

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Signatures 签名

Internal Review 内部审查	Date 日期	Signature 签名
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Reviewed by 审核 Zhang Rongrong 张蓉蓉	2020-12-21	N/A
Reviewed by 审核 Liao Yong 廖勇	2020-12-21	N/A
Approved by 批准 Gao Xianshen 高贤申	2020-12-21	N/A

Client Document Review 客户文件审查		X
1	Accepted 可接受的	
2	Accepted with comments incorporated. Revise & resubmit. 有条件接受/更新后重新提交	
2a	Provisional Acceptance-Interface. Information frozen. 暂时接受，信息冻结	
3	Not Accepted. Revise and resubmit.不接受，更新后重新提交	
4	For information only 供了解	

Signature 签名	Date 日期
N/A	N/A

Permission to proceed does not constitute acceptance of design details, calculations, analysis test methods or materials developed or selected by Supplier from full compliance with contractual obligations.
此放行确认并不免除供应商完全按合同履行如下义务：
详细设计/计算/分析测试方法/材料开发或选型等

Proprietary Information 版本信息

Revision History 版本历史

Rev. 版次	By 编写人	Date 日期	Comment 评论
00	Hu Zhiyong 胡志勇	2020-11-26	Initial issue 首次发布
01	Hu Zhiyong 胡志勇	2020-12-21	Design description response 设计描述响应

Discipline 专业	Client Doc. No.客户文件编号	Rev. 版本
Qualification 确认	N/A	N/A
Document Type 文件类	Document Number 文件编号	Rev. 版本
Design Qualification 设计确认	PP20-0098-T-009694	01
Document Name 文件名称	Status 状态	Pages 页数
DQ of CIP System-DS1 清洗站-DS1 设计确认	Draft	90

方案审核与批准

PROTOCOL REVIEW AND APPROVAL

上海森松制药设备工程有限公司
Shanghai Morimatsu Pharmaceutical Equipment Engineering Co., Ltd.

	印刷体姓名 Printed Name	职 务 Function	签 名 Signature	日 期 Date
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信达生物制药（苏州）有限公司
Innovent Biologics(Suzhou) Co., Ltd.

	印刷体姓名 Printed Name	职 务 Function	签 名 Signature	日 期 Date
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	于庆华	工程项目总监		
	杜明星	QA 主管		

目　　录

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1 目的 PURPOSE

本设计确认的目的是为了提供文件证据来证明信达生物制药（苏州）有限公司（简称“信达生物”）的 M2 项目下游工艺管罐系统与工艺自控系统工程的设计符合客户需求说明 URS 以及相关法规的要求。

The purpose of the Design Qualification(DQ) is to provide documented evidence to prove the design of the M2 Downstream Process System and Automation System Project of Innovent Biologics(Suzhou) Co., Ltd. (hereafter refered to as ”Innovent”) complies with the requirements of the user requirement specification and relevant regulations.

2 范围 SCOPE

本设计确认定义了由上海森松提供给信达生物的 M2 项目下游工艺管罐系统与工艺自控系统工程的工艺、容器、工艺管道、结构、电气和仪表部分的设计输出，需要执行的测试的目的、测试程序和可接受标准。

This DQ defines the purpose, procedure and acceptance criteria of tests to be executed for the mechanical, electrical, instrument and automation parts in M2 Downstream Process System and Automation System Project, which is supplied by SMP and delivered to Innovent.

编号 No.	参考 URS Ref. URS	子系统/模块 Subsystem/sunmodule	设计范围 Design scope
1	M2 下游在线清洗模块用户需求标准（文件编号） M2 URS About Downstream CIP Module	浓碱系统 Concentrated Alkal System	工艺、容器、工艺管道、结构、电气、仪表 Process, vessel, process piping, structure, electrical, instrumentation
2		清洗站-DS1-02 CIP System-DS1-02	
3		清洗站-DS1-03 CIP System-DS1-03	
4		清洗站-DS1-05 CIP System-DS1-05	

3 职责 RESPONSIBILITY

公司 Company	职责 Responsibility
上海森松 SMP	DQ 方案的编制、审核及预批准 DQ Protocol preparation, review and pre-approval 执行 DQ 方案 Implement this DQ protocol 如果出现偏差，与客户授权的人员进行协调 Communicate to authorized Client personnel, if deviations are present 记录及处理 DQ 过程中发生的偏差 Record and deal with non-conformity/deviation occurred during DQ 最终报告的编写 Final report compilation
信达生物 Innovent	执行前审核和批准本方案 Review and approval of this protocol before execution 见证并确认所有测试按照已定义的程序执行 Witness the tests and ensure the procedure is followed 协同收集原始数据并填写相关表格 Assistant to collect raw data and fill in relevant check table 协同记录和处理 DQ 过程中发生的偏差 Assistant to record and deal with the deviation occurred during DQ 审核和批准最终报告 Review and approve the test reports after successful execution

4 缩略语 ABBREVIATION

缩略语 Abbreviations	全称 Full name
SMP	上海森松制药设备工程有限公司 Shanghai Morimatsu Pharmaceutical Equipment Engineering Co., Ltd.
Innovent	信达生物制药（苏州）有限公司 Innovent Biologics(Suzhou) Co., Ltd.
ASME	美国机械工程师学会 American Society of Mechanical Engineers
NMPA	国家药品监督管理局 National Medical Products Administration
CIP	在线清洗 Clean in Place
CSV	计算机化系统验证 Computerized System Validation
DQ	设计确认 Design Qualification
FAT	工厂验收测试 Factory Acceptance Test
FS	功能设计说明 Function Specification
GAMP5	良好的自动化生产实践指南 5 Good Automated Manufacturing Practices –A Risk-Based Approach to Compliant GxP
GDP	良好的文件管理规范 Good Documentation Practice
GMP	药品生产质量管理规范 Good Manufacturing Practice
HDS	硬件设计说明 Hardware Design Specification
HMI	人机界面 Human Machine Interface
ICH	人用药品注册技术要求国际协调会议 International Conference on Harmonisation of Technical Requirement for Registration of Pharmaceuticals for Human Use
ISPE	国际制药工程协会 International Society for Pharmaceutical Engineering
IQ	安装确认 Installation Qualification
OQ	运行确认 Operational Qualification
P&ID	管道与仪表流程图 Piping and Instrument Diagram
RA	风险评估 Risk Assessment
SAT	现场验收测试 Site Acceptance Test

SDS	软件设计说明 Software Design Specification
SIP	在线灭菌 Sterilization in Place
SOP	标准操作程序 Standard Operation Procedure
URS	用户需求说明 User Requirment Specification
WHO	世界卫生组织 World Health Organization

5 参考 REFERENCE

适用标准和法规	Applicable Standards And Regulations
(NMPA) 中国药品生产质量管理规范(2010 年修订版)及其附录	(NMPA) Good Manufacturing Practice, revised in 2010, and related annex
欧盟药品法规第 4 卷 cGMP（人用和兽用药品）及其附录	European Commission. The Rules Governing Medicinal Product in the European Union, Vol. IV, Good Manufacturing Practices. Medicinal products for human and veterinary use, and related annex
(FDA) 联邦法规第 21 篇第 210/211 部分，成品药的现行生产质量管理规范	(FDA) 21 code of Federal Regulations Parts 210/211, Current Good Manufacturing Practice for Finished Pharmaceuticals
(FDA) 联邦法规第 21 篇第 11 部分，电子记录和电子签名	(FDA) 21 code of Federal Regulations Parts 11, Electrical Record and Electrical Signature
(FDA)联邦法规第 21 篇第 177 部分子部 C177.2600-用于反复使用的橡胶制品	(FDA) 21 code of Federal Regulations Parts 11 subpart C section 177.2600-Rubber articles intended for repeated use
固定式压力容器安全技术监察规程 TSG R21-2016	Supervision Regulation on Safety Technology for Stationary P.V. TSG R21-2016
压力容器 GB/T150.1~150.4-2011	Pressure Vessel GB/T 150.1~150.4-2011
压力容器焊接规程 NB/T 47015-2011	Welding Specification for Pressure Vessel NB/T 47015-2011
承压设备无损检测 NB/T 47013-2015	Nondestructive Testing of Pressure Equipment NB/T 47013-2015
机械安全机械电气设备第一部分：通用技术条件 GB5226.1-2008	Safety of machine---Electrical equipment of machines---Part 1:General requirements GB 5226.1-2008
机械安全 防护要求 GB12265.2-2000	Safety of machine Safety distance to prevent danger zones being reached by the lower limbs GB12265.2-2000
工业金属管道工程施工及验收规范 GB50235-2010	Code for construction and acceptance of Industrial Metallic Pipe Engineering GB50235-2010
电气装置安装工程电缆线路施工及验收规范 GB50168-2009	Code for construction and acceptance of cable system electric equipment installation engineering GB50168-2009
电气装置安装工程接地装置施工及验收规范 GB50169-2009	Code for construction and acceptance of earthing system electric equipment installation engineering GB50169-2009
机械电气安全 机械电气设备第一部分：通用技术 EN60204-1-2009	Electrical safety of machine Mechanical Electrical Equipment Part 1:General Technology EN60204-1-2009
药品 GMP 实施指南 （2011 出版）	GMP Implementation Guide (2011)
WHO 数据与记录管理规范指南 2015.09	WHO Guidance on Good Data and Record Management Practices 2015.09
美国机械工程协会生物工艺设备指南，2019 年 6 月 10 日	ASME BPE Bioprocessing Equipment, June 10, 2019

适用标准和法规	Applicable Standards And Regulations
ISPE 良好的自动化生产实践指南_遵从 GxP 计算机化系统监管的风险管理方法，第 5 版	ISPE GAMP5 A Risk-Based Approach to Compliant GxP Computerized System, 5th Edition
ISPE 指南 卷 5：调试与确认（第一版）	ISPE Volume 5: Commissioning and Qualification (First Edition)

6 系统描述 SYSTEM DESCRIPTION

12 sets CIP skids and 4 sets of CIP supply and CIP return manifolds for four DS production lines, refer to P&IDs, each line include:

用于四条原液下游生产线的 12 套 CIP 系统和 4 套 CIP 供回的阀阵，请参照 PID，以一条线为例，包含了：

CIP skid DS1-CIP02, purification system of one DS production line, includes:

用于一条原液生产线的纯化系统除病毒前的 CIP 系统 DS1-CIP02，包含：

- 1200 L washing tank 1200L清洗罐
- 1200 L WFI rinsing tank 1200L润洗罐
- CIP supply pump CIP供给泵
- Double tube & shell heat exchanger 双管板换热器
- Vent filters for tanks 呼吸器
- Process air filter 工艺压空过滤器

CIP skids DS1-CIP03 & DS1-CIP05 share one CIP manifold, for buffer system, post ultra-filtration system of one DS production line, each includes:

两套 CIP 系统（DS1-CIP03 和 DS1-CIP05）及其阀阵，用于一条原液生产线的缓冲液系统、除病毒后的 UF 系统清洗。

- 1500L washing tank 1500L清洗罐
- 1500L WFI rinsing tank 1500L润洗罐
- CIP supply pump 供给泵
- Double tube & shell heat exchanger 双管板换热器
- Vent filters for tanks 呼吸器
- Process air filter 工艺压空过滤器
- Four set of CIP supply and CIP return manifolds, includes: 四套用于CIP供回的阀阵，包含：
- The manifold in DS1-CIP, used for the CIP solution distribution of CIP skid (DS1-CIP03& DS1-CIP05) for for buffer system, post ultra-filtration system of one DS production line.
  阀阵DS1-CIP用于给一条生产线的缓冲液系统、除病毒后的UF系统清洗所用的DS1-CIP03和DS1-CIP05进行分配。
- Other three manifolds will be utilized for the other three production lines . 另外三套阀阵将会给另三条生产线使用。

7 良好的文件填写规范 GOOD DOCUMENTATION PRACTICE

以下为说明一些进行记录测试数据工作的通用规范：
Below are some general practice for test data recording:

保证每一份文件是可追溯的，它应有标题，系统参考（例如测试号）。
Ensure that each document is “traceable” with a title, system reference (for example:Test No.).

文件中每个注解、记录等都应该清楚、易读、有日期和签名。不能使用铅笔，而应使用蓝色或黑色水笔记录数据。
Each comments, entry, etc., on a document must be clear, readable, dated and signed. Do not use pencils to record data, but should use black or blue pen to record data.

为了标示出某些正确或不正确的信息，可以用亮色笔进行标示。对于采用了亮色笔进行标示的测试内容，需要说明所使用的颜色及他们所代表的意义。这些测试内容和相关的附件也必须是原件，并记录日期。

To verify the correct or incorrect information in a specific test, highlighters can be used. Test sheets with highlighted items shall include a description of the used colors and what they represent. The test sheets shall also follow the guidelines above regarding appendices and initial and date.

1） 绿色荧光– 相符合的信息/已安装 Green highlighter – consistent information/installed

2） 红色荧光 – 不相符的信息/未安装 Red highlighter – disconsistent information/uninstalled

3） 黄色荧光–非关键的信息 Yellow highlighter – non critical information

每次测试必须是：
For each test executed, it is necessary to:

4） 以数字化的形式记录结果（如果记录的是某一数值时，PASS/FAIL 是不充分的）
Report the result, when it is applicable, in numberical form (it is not sufficient pass/fail if the result is a value)

5） 如果在本次测试的格式中没有描述测试规程，则应注明参考出处
Note the procedure used for the test if it is not described in the body format used to execute the test

6） 更正与实际系统不符的每一个已核实的文件（接线图、P&ID、布局图等），显示竣工状态，这些文件作为将来更新的基础
Correct each verified document (wiring diagram, P&ID, layout, etc.) that is not corresponding to actual system, showing the as-built situation, these documents will be the base for future updating

7） 附上在测试过程中所产生的打印出来的图，签名并注明日期，写清楚附件编号和测试号，如果一次测试中出现多个附件，每个附件应以 Page X of Y 的形式清楚的表示出来，并签名和注明日期
Attach each print-out/attachment produced during the test execution, signing and dating it, writing a clear Appendix No. and Test No. at which test the print-out/attachment refer to, if is present more than on attachment for the same test, Number progressively the attachment (page X of Y), signing and dating each attachment

8） 每次测试应签名和注明日期（需有执行人和确认人的签名）
Sign and date each test (signatures of those who execute and verify the tests must be present)

9）如果有些测试没有进行，在偏差表中写明未执行的原因和预计执行的日期
If some certain test is not executed, indicate the reason, and give, in the deviation form, a possible date for the execution

日期的格式为年-月-日，签名需与签名日志上的一致。
The date format is yyyy-mm-dd, the format of signature must be consistent with the signature log .

在文件中不能使用修正液，修改错误必须使用以下正确的方式：
Do not use covering liquids or materials. Every writing mistake must be corrected as follows:

~~System XX~~	(签名) DD
System YZ	(日期) 2018-01-31

对于不使用的部分，必须划掉并且签名。或者，填写“NA”，表示不适用。
Space not used must be barred and sign, or filled out with “NA”, which means “Not Applicable”.

8 偏差处理 DEVIATION HANDLING

偏差处理需按照信达生物内部流程，依照文件《确认偏差管理规程》（SMP00209）执行。

Deviation processing shall be carried out in accordance with Innovent’s internal procedures and the document” Deviation Management Procedure of Qualification”(SMP00209).

9 DQ 实施 DQ EXECUTION

9.1 人员的确认 PERSONNEL IDENTIFICATION

9.1.1 目的 PURPOSE

确认所有执行本方案的人员信息和资质。

Identify the information and qualification of all people that involved in protocol execution.

9.1.2 程序 PROCEDURE

记录所有执行本方案的人员（姓名、签名和部门/公司）。

List and identify all personnel involved in the execution of the present protocol (Name. Signature and Department/Company).

确定参与确认的人员有相关的专业资质。

Verify all personnel involved in the DQ execution have suitable qualification.

应对所有参与方案实施的人员进行本方案培训，以实施本方案。

All personnel involved in the execution of the present protocol should be appropriately trained DQ protocol in order to execute the protocol.

9.1.3 可接受标准 ACCEPTANCE CRITERIA

所有执行本方案的人员（姓名、签名和部门/公司）已记录。

All the operators are recorded by Name, Signature and Department/Company.

参与确认的人员有相关的专业资质。

All personnel involved in the DQ execution have suitable majority qualification.

所有执行本方案人员已接受培训。

All the personnel who will execute this DQ protocol have been trained the protocol.

9.1.4 人员的确认检查表 PERSONNEL IDENTIFICATION CHECK TABLE

姓名 Name	部门/公司 Department/ Company	职位 Title	已接受培训？ Trained? (是 Yes /否 No)	签名 Signature	日期 Date

可接受的标准 Acceptance Criteria	是 Yes /否 No
所有的参与人员已确认姓名、签名和部门/公司。 All the participants are identified by Name, Signature and Department/Company.	
参与确认的人员有相关的专业资质。 All personnel involved in the DQ execution have suitable majority qualification.	
所有执行本方案人员已接受培训。 All the personnel who will execute this DQ protocol have been trained the protocol.	
备注 Comments：	

偏差编号 Deviation No.			
执行人 Executed by		日期 Date	
确认人 Verified by		日期 Date	

9.2 设计需求文件的确认 DESIGN REQUIREMENT DOCUMSNTS VERIFICATION

9.2.1 目的 PURPOSE

确认项目设计的需求文件的可用性。

Verify the supplied design requirement documents are available.

9.2.2 程序 PROCEDURE

记录项目上交流产生的与 DQ 相关的文件，包括 URS，会议纪要、邮件等文件，并记录文件名称、版本号、发布日期。

Record the requirement documents generated from communications in project are available, include URS, meeting summary, mail and so on, then record document title, version and date of issued.

9.2.3 可接受标准 ACCEPTANCE CRITERIA

所有的需求性文件必须是可用的。

All required documents must be available.

9.2.4 设计需求文件的确认检查表 DESIGN REQUIREMENT DOCUMENTS VERIFICATION CHECK TABLE

文件描述 Document Description	文件编号 Doc. No.	版本/日期 Version/Date	是否可用？Available? (是 Yes /否 No)
用户需求说明（URS） User Requirement Spec.			
风险评估（RA） Risk Assessment			
会议纪要 Meeting Summary			
电子邮件 E-mail			
问题清单 Issue List			

可接受的标准 Acceptance Criteria	是 Yes /否 No
所有的需求性文件是可用的。 All required documents are available.	
备注 Comments：	

偏差编号 Deviation No.			
执行人 Executed by		日期 Date	
确认人 Verified by		日期 Date	

9.3 设计文件的确认 DESIGN DOCUMENTS VERIFICATION

9.3.1 目的 PURPOSE

确认设计文件的可用性和文件规范性。

Verify the design documents are available and standard.

9.3.2 程序 PROCEDURE

将 DQ 所需的设计文件和图纸记录于下表中，并逐个确认每个文件的名称、文件编号、版本号和相关的批准状态。

Record the design documents and drawings required by the DQ execution in the table below, and verify the document name, document number, version and the relevant approval status for each document.

9.3.3 可接受标准 ACCEPTANCE CRITERIA

所有需要的设计文件已生成并可用，且已记录文件的名称、文件编号、版本号等内容。

All the design documents and drawings required have been issued and available, the documents name, number and version have been recorded.

9.3.4 设计文件的确认检查表 DESIGN DOCUMENTS VERIFICATION CHECK TABLE

序号 No.	文件描述 Document Description	文件编号 Doc. No.	版本 Version	已批准? Approved or Not? (是 Yes /否 No)
1.	管道仪表流程图 P&ID	E01-203201-1-163 E01-203201-1-164 E01-203201-1-165 E01-203201-1-166	01	
2.	设备一览表 Process Equipment List	PP20-0098-T-009428	01	
3.	管线一览表 Piping Line List	PP20-0098-T-004170	01	
4.	泵数据表 Pump Datasheet	PP20-0098-T-000062 PP20-0098-T-000082 PP20-0098-T-000083 PP20-0098-T-000084 PP20-0098-T-000085 PP20-0098-T-000159 PP20-0098-T-000446 PP20-0098-T-000458 PP20-0098-T-000781 PP20-0098-T-000782 PP20-0098-T-000795 PP20-0098-T-000798	02 02 02 02 02 01 01 02 02 02 01 01	
5.	膜过滤器数据表 Filter Datasheet	PP20-0098-T-000449 PP20-0098-T-000450 PP20-0098-T-000451 PP20-0098-T-000452 PP20-0098-T-000453 PP20-0098-T-000454 PP20-0098-T-000455 PP20-0098-T-000456 PP20-0098-T-000457 PP20-0098-T-000459 PP20-0098-T-000460 PP20-0098-T-000462 PP20-0098-T-000463	01 01 01 01 01 01 01 01 01 01 01 01 01	
6.	调节阀数据表 Control Valve Datasheet	PP20-0098-T-000070 PP20-0098-T-000850 PP20-0098-T-001042 PP20-0098-T-001044 PP20-0098-T-004187 PP20-0098-T-004188	01 01 04 03 02 02	
7.	减压阀数据表 Pressure Reduce Valve Datasheet	PP20-0098-T-000857 PP20-0098-T-000858 PP20-0098-T-000859	02 02 02	
8.	安全阀数据表 Pressure Safety Valve	PP20-0098-T-001045 PP20-0098-T-001046	01 01	

序号 No.	文件描述 Document Description	文件编号 Doc. No.	版本 Version	已批准？ Approved or Not? (是 Yes /否 No)
	Datasheet			
9.	疏水阀数据表 Steam Trap Datasheet	PP20-0098-T-000853 PP20-0098-T-000854 PP20-0098-T-000855 PP20-0098-T-000856	03 03 03 03	
10.	管道过滤器数据表 Piping Strainer Datasheet	PP20-0098-T-000686 PP20-0098-T-000716 PP20-0098-T-000717 PP20-0098-T-000718 PP20-0098-T-000805	01 01 01 01 01	
11.	止回阀数据表 Check Valve Datasheet	PP20-0098-T-000390 PP20-0098-T-000394 PP20-0098-T-000819 PP20-0098-T-000821 PP20-0098-T-000822 PP20-0098-T-000823 PP20-0098-T-004261 PP20-0098-T-004262	02 02 03 02 03 02 01 01	
12.	球阀数据表 Ball Valve Datasheet	PP20-0098-T-000071 PP20-0098-T-000102 PP20-0098-T-000103 PP20-0098-T-000105 PP20-0098-T-000106 PP20-0098-T-000118 PP20-0098-T-000129 PP20-0098-T-000130 PP20-0098-T-000130 PP20-0098-T-000131 PP20-0098-T-000132 PP20-0098-T-000134 PP20-0098-T-000135 PP20-0098-T-000137 PP20-0098-T-000138 PP20-0098-T-000140 PP20-0098-T-000142 PP20-0098-T-000144 PP20-0098-T-000145 PP20-0098-T-000146 PP20-0098-T-000147 PP20-0098-T-000148 PP20-0098-T-000149 PP20-0098-T-000151 PP20-0098-T-000152 PP20-0098-T-004378	01 02 01 04 01 06 03 03 01 03 02 01 05 01 04 05 01 05 02 04 01 01 01 01 03 01	
13.	隔膜阀数据表 Diaphragm Valve Datasheet	PP20-0098-T-000040 PP20-0098-T-000041	01 02	

序号 No.	文件描述 Document Description	文件编号 Doc. No.	版本 Version	已批准? Approved or Not? (是 Yes /否 No)
		PP20-0098-T-000042 PP20-0098-T-000043 PP20-0098-T-000044 PP20-0098-T-000045 PP20-0098-T-000046 PP20-0098-T-000049 PP20-0098-T-000050 PP20-0098-T-000051 PP20-0098-T-000052 PP20-0098-T-000053 PP20-0098-T-000054 PP20-0098-T-000055 PP20-0098-T-000056 PP20-0098-T-000058 PP20-0098-T-000059 PP20-0098-T-000086 PP20-0098-T-000119 PP20-0098-T-000120 PP20-0098-T-000121 PP20-0098-T-000122 PP20-0098-T-000123 PP20-0098-T-000124 PP20-0098-T-000125 PP20-0098-T-000126 PP20-0098-T-000127 PP20-0098-T-000128 PP20-0098-T-000763 PP20-0098-T-000764 PP20-0098-T-000862 PP20-0098-T-000863 PP20-0098-T-000947 PP20-0098-T-000948 PP20-0098-T-000949 PP20-0098-T-000950 PP20-0098-T-000951 PP20-0098-T-000952 PP20-0098-T-000953 PP20-0098-T-000954 PP20-0098-T-000955 PP20-0098-T-000956 PP20-0098-T-000957 PP20-0098-T-001643	02 02 02 02 02 02 02 02 02 02 01 02 02 01 01 01 01 01 01 01 01 01 02 02 02 02 02 01 01 01 01 01 01 01 01 01 01 01 01 01 01 01	
14.	爆破片数据表 Rupture Datasheet	PP20-0098-T-000710 PP20-0098-T-000711 PP20-0098-T-001593	02 02 01	
15.	热排换热器数据表 Heat-Exchanger Datasheet	PP20-0098-T-000962	04	

序号 No.	文件描述 Document Description	文件编号 Doc. No.	版本 Version	已批准? Approved or Not? (是 Yes /否 No)
16.	电加热套数据表 Filter-Electric Heat Tracing Datasheet	PP20-0098-T-001611 PP20-0098-T-001613	01 02	
17.	防混阀数据表 Seat Valve Datasheet	PP20-0098-T-000688	01	
18.	提升机数据表 Hoist Datasheet	PP20-0098-T-009724 PP20-0098-T-009725	01 01	
19.	物料桶数据表 Bucket Datasheet	PP20-0098-T-010215	01	
20.	容器图纸 Vessel Drawing	WC02-26319 WC02-26320 WC02-26321 WC02-26322 WC02-26323	01	
21.	灯数据表 Light Datasheet	PP20-0098-T-001607	01	
22.	CIP 换热器图纸 CIP Exchanger Draw	WE02-26389	01	
23.	温度变送器数据表 Temperature Transmitter Datasheet	PP20-0098-T-000169 PP20-0098-T-000704 PP20-0098-T-000776	02 03 03	
24.	压力变送器数据表 Pressure Transmitter Datasheet	PP20-0098-T-000179 PP20-0098-T-000461 PP20-0098-T-000466	02 02 02	
25.	压力表数据表 Pressure Gauge Datasheet	PP20-0098-T-000961 PP20-0098-T-001028 PP20-0098-T-001658	01 01 01	
26.	科氏力流量计数据表 Coriolis Flowmeter Datasheet	N/A	N/A	
27.	电磁流量计数据表 Electro Magnetic Flowmeter Datasheet	N/A	N/A	
28.	差压液位计数据表 Differential Pressure Level Transmitter Datasheet	PP20-0098-T-000757	01	
29.	电导率仪数据表 Conductivity Meter Datasheet	PP20-0098-T-000063 PP20-0098-T-000064	02 02	
30.	pH 计数据表 pH Meter Datasheet	N/A	N/A	
31.	音叉开关数据表 Tuning Fork Level Switch Datasheet	N/A	N/A	
32.	电气设计施工说明 Electrical	N/A	N/A	

序号 No.	文件描述 Document Description	文件编号 Doc. No.	版本 Version	已批准? Approved or Not? (是 Yes /否 No)
	design requirement			
33.	仪表索引表 Instrument List	PP20-0098-T-009489	01	
34.	电气设备汇总表 Motor and Equipment Device List	PP20-0098-T-009479	01	
35.	电缆表 Cable List	PP20-0098-T-000825 PP20-0098-T-009643	02 02	
36.	盘柜材料表 BOM	(Vavle Power Supply BOX): PP20-0098-T-009617 (MCC Panel): MCC-DS1-CIP-001 (Charm IO Panel): 3287830-DWG-AC-SA-48NIS-A	 01 D N/A	
37.	仪表气路管线图 Instrument Pneumatic Architecture	PP20-0098-T-004175	01	
38.	设备布置图 Equipment Layout	PP20-0098-T-009514 PP20-0098-T-009525 PP20-0098-T-009529 PP20-0098-T-009530 PP20-0098-T-009551 PP20-0098-T-009552	01 01 01 01 01 01	
39.	管道布置图 Piping Layout	PP20-0098-T-009526~009528 PP20-0098-T-009531~009532 PP20-0098-T-009550 PP20-0098-T-009554~009556	01 01 01 01	
40.	管道等级索引表 Piping Class Index	PP20-0098-T-000012	01	
41.	管道设计说明 Piping Design Specification	PP20-0098-T-010289	01	
42.	公用工程清单 Utility List	PP20-0098-T-010293	01	
43.	报警联锁清单 Alarm&Interlock List	PP20-0098-T-004379	01	
44.	EM_CIP	PP20-0098-T-010281	0.1d	
45.	功能说明 FS	PP20-0098-T-010272 PP20-0098-T-010273 PP20-0098-T-010274 PP20-0098-T-010276 PP20-0098-T-010277 PP20-0098-T-010278 PP20-0098-T-010279 PP20-0098-T-010280	00 00 0.1 0.1 0.1 0.1a 0.1a 0.1b	
46.	钢结构加工制作说明	PP20-0098-T-001101	01	

可接受的标准 **Acceptance Criteria**	**是 Yes /否 No**
所有的设计文件是可用的。 All required design documents are available.	
备注 Comments：	

偏差编号 Deviation No.			
执行人 Executed by		日期 Date	
确认人 Verified by		日期 Date	

9.4 URS 符合性的确认 URS COMPLIANCE VERIFICATION

9.4.1 目的 PURPOSE

确认设计文件和图纸符合用户需求说明。

Verify that design documents and drawings are compatible with URS.

9.4.2 程序 PROCEDURE

1. 将批准的 URS 中的每一条需求按顺序输入到下表中。

   Input the each requirement of URS one by one in the table below.

2. 确定 URS 的类别。URS 中的需求可以分为 Q，C，I 三种类型。三种类型的判别标准如下：

   Identify the classification of each requirement which can be classified as Q, C, I. The criteria for the three categories are as follows:

   Q 类(Qualification)：为 GMP 相关的关键性需求，会直接影响产品质量、数据完整性、患者安全。需要以设计文件中的内容进行响应，并需要在调试和确认阶段进行确认。

   Category Q(Qualification): Critical requirements related to GMP, which will impact equipment performance, product quality, data integrity and patient safety. Need to respond that within design documents, and need to confirm during commissioning and qualification phase.

   C 类(Commissionging)：为非 GMP 相关的需求，不会直接影响产品质量、数据完整性和患者安全，但会影响设备性能和 HSE。需要以设计文件中的内容进行响应，但只需要在调试阶段进行确认。

   Category C(Commissionging): Requirements for HSE and Non-GMP related requirements, which will not impact equipment performance, product quality, data integrity and patient safety. Need to respond that within design documents, only need to confirm during commissioning phase.

   I 类(Instruction)：不涉及设计方面的说明和信息类的需求，无需进行设计响应。如：项目描述、交付条款、保修等。

   Category I(Instruction): other requirements for specification and information that won't involve design aspects, no need to responsd. Such as project description, project delivery and warranty.

3. 以设计文件中的相关内容响应每一个识别为 C 类的 URS 需求。对于 N 类需求的响应只是提供参考信息，而对于识别为 I 类的需求，无需进行设计确认。

   Utilize the relevant specific information from design documents and drawings to respond every "C"requirements identified. The respond to the "N"requirements is to provide the reference only, and It doesn't need to respond the identified "I "requirements during DQ phase.

9.4.3 可接受标准 ACCEPTANCE CRITERIA

URS 中的要求都有设计文件进行响应，且可接受。

The requirements in URS have been responded to by design documents, and the response is acceptable.

9.4.4 URS 符合性的确认检查表 URS COMPLIANCE VERIFICATION CHECK TABLE

URS 编号 URS No.	URS 描述 URS Description	URS 分类 URS Classification (Q, C, I)	设计文件名称 Design Doc. Name	设计文件编号 Design Doc. No.	设计描述 Design Description	是否可接受 Acceptable Yes 是/No 否
URS1	The CIP skids will be used in DS line to provide CIP solution for the process systems for manufacturing of monoclonal antibodies (mAb) and Fc fusion protein products, all these products are derived from CHO cell lines. All products, which are defined by project owner, are non-toxigenic, non-pathogenic during process. 原液线的 CIP 模块将会为用于单克隆抗体和 Fc 融合蛋白产品生产的工艺系统提供清洗液，所有这些产品均来自于 CHO 培养（中国仓鼠卵巢细胞）。所有产品的工艺加工过程中都是无毒的，无致病性的	I	N/A	N/A	N/A	
URS2	System design in this project will be subjected to BL1-LS, according to NIH Guidelines for Research Involving Recombinant DNA Molecules, Appendix K. 该项目的系统设计将按照 BL1-LS 来设计，遵循重组 DNA 分子指南 NIH 附录 K 的要求	I	N/A	N/A	N/A	
URS3	The vender should use P&IDs and associated Datasheets and Specifications which are referred from various tags to design the system. Any deviation from P&IDs should be approved by project Owner before execution. The Supplier shall fully guarantee that the equipment provided will achieve its individually specified process and operating functions. The system should be able to be running under a 24 hours / 7 days operation	I	N/A	N/A	N/A	

URS 编号 URS No.	URS 描述 URS Description	URS 分类 URS Classification (Q, C, I)	设计文件名称 Design Doc. Name	设计文件编号 Design Doc. No.	设计描述 Design Description	是否可接受 Acceptable Yes 是/No 否
	供应商应该使用 PID 以及相关联的数据表和技术要求来设计系统。所有同 PID 偏离的地方在项目执行前需要得到业主的批准。供应商需要完全保证所提供的设备要达到各自特定的工艺和操作功能。系统应该能够 7 天每天 24 小时连续运转					
URS4	The tank is utilized to store PW for flushing and prepare cleaning solution for CIP cycles. 该罐子用于存储纯化水做清洗之用，以及清洗周期中的清洗液的准备	Q	P&ID（DS1-CIP02/ DS1-CIP03/ DS1-CIP05）	E01-203201-1-164~ E01-203201-1-166	The wash tank can be utilized to store PW for flushing and prepare cleaning solution for CIP cycles. WASH TANK 可储存纯化水，同时可以进行循环配碱。	
URS5	The CIP solution tank will also be used for recirculation of CIP solutions. CIP 清洗罐可以用来供 CIP 清洗液的循环清洗	Q	P&ID（DS1-CIP02/ DS1-CIP03/ DS1-CIP05）	E01-203201-1-164~ E01-203201-1-166	The CIP solution tank can be used for recirculation of CIP solutions. 清洗罐可实现 CIP 的循环清洗。	
URS6	CIP 设备需具有自动循环清洁功能	Q	P&ID（DS1-CIP02/ DS1-CIP03/ DS1-CIP05）	E01-203201-1-164~ E01-203201-1-166	The wash and rinse tank can be used for recirculation of CIP solutions by pipe. 清洗罐和润洗罐均设有自身循环的管路，可实现自动循环清洗。	
URS7	The combination of a dished pressure tank and outlet leg provides adequate net positive suction head (NPSH) for the CIP pump with a minimal volume of water in the tank. 具有蝶形封头罐，在罐内最小工作体积时能够为 CIP 泵提供足够正压头（NPSH）的出口接管	Q	容器图纸 Vessel Drawing FS 程序设计说明	WC02-26320 WC02-26321 WC02-26322 WC02-26323 PP20-0098-T-010272 PP20-0098-T-010273 PP20-0098-T-010274 PP20-0098-T-010276 PP20-0098-T-010277 PP20-0098-T-010278 PP20-0098-T-010279 PP20-0098-T-010280	CIP tank is a dished pressure tank with leg support; Can set the min.level in FS to provide enough head for NPSHr. CIP 罐是蝶形封头,带支腿； 在 FS 中可设计罐子最小液位提供足够正压	

URS 编号 URS No.	URS 描述 URS Description	URS 分类 URS Classification (Q, C, I)	设计文件名称 Design Doc. Name	设计文件编号 Design Doc. No.	设计描述 Design Description	是否可接受 Acceptable Yes 是/No 否
URS8	Differential pressure level sensors shall be used for tank liquid level control. 用于罐体液位控制的压差液位计	Q	容器图纸 Vessel Drawing	WC02-26320 WC02-26321 WC02-26322 WC02-26323	All CIP tanks have differential pressure level sensors shall be used for tank liquid level control. CIP 罐子上均配置压差液位计	
URS9	0.2 um Vent filter shall be equipped with electrical heater. 配有 0.2um 呼吸器，带电加热套	Q	容器图纸 Vessel Drawing P&ID（DS1-CIP02/ DS1-CIP03/ DS1-CIP05）	WC02-26320 WC02-26321 WC02-26322 WC02-26323 E01-203201-1-164~ E01-203201-1-166	Wash tank and rinse tank have vent nozzle 0.22 um Vent filter equipped with electrical heater. 清洗罐和润洗罐留有呼吸器口 均配有 0.22 um 的呼吸器，且配有电加热套	
URS10	The tank is utilized to store WFI for final rinsing in a CIP sequence. Dished tank will be used. 该罐体用以存储在清洗程序中最终的润洗用的注射用水。该罐体需要使用碟形封头	Q	容器图纸 Vessel Drawing	WC02-26320 WC02-26321 WC02-26322 WC02-26323	The rinse tank use Dished head. CIP 罐体使用碟形封头 The tank is utilized to store WFI for final rinsing in a CIP sequence. Dished tank will be used. 润洗罐储存最终润洗用的注射用水。	
URS11	H/D ratio = 1.0~1.3 高径比为 1.0~1.3	C	容器图纸 Vessel Drawing	WC02-26320 WC02-26321 WC02-26322 WC02-26323	H/D ratio meet 1.0~1.3 设备高径比满足 1.0~1.3	
URS12	Differential pressure level sensors shall be used for tank liquid level control. 用于罐体液位控制压差液位计	Q	容器图纸 Vessel Drawing	WC02-26320 WC02-26321 WC02-26322 WC02-26323	CIP tanks have differential pressure level sensors shall be used for tank liquid level control. CIP 罐的液位控制使用的是压差液位计	
URS13	0.2 um Vent filter shall be equipped with electrical heater. 配有 0.2um 呼吸器，带电加热套	Q	容器图纸 Vessel Drawing P&ID（DS1-CIP02/ DS1-CIP03/ DS1-CIP05）	WC02-26320 WC02-26321 WC02-26322 WC02-26323 E01-203201-1-164~ E01-203201-1-166	Wash tank and rinse tank have vent nozzle 清洗罐和润洗罐留有呼吸器口 The rinse tank is utilized to store WFI for final rinsing in a CIP sequence. Dished tank will be used.	

URS 编号 URS No.	URS 描述 URS Description	URS 分类 URS Classification (Q, C, I)	设计文件名称 Design Doc. Name	设计文件编号 Design Doc. No.	设计描述 Design Description	是否可接受 Acceptable Yes 是/No 否
					清洗罐和润洗罐均配有 0.22 um 的呼吸器，且配有电加热套	
URS14	The function of the sanitary centrifugal pump is to provide the CIP solution to equipment to be washed at defined flow rate and pressure. 这台卫生级离心泵将会按照特定的流速和压力把清洗液泵送到被清洗设备	Q	FS（PH_C_AT）	PP20-0098-T-010273	The sanitary centrifugal pump can provide the CIP solution to equipment to be washed at defined flow rate and pressure. 离心泵会按程序设定的流速和压力把清洗液泵送到被清洗设备	
URS15	The speed of pump is adjustable automatically. It provides the solution variable feeding flow rate and pressure according to CIP washing and rinsing recipes. These ranges of parameters are illustrated in Section 泵的流速可以自动调节。它可以按照 CIP 清洗和润洗配方以非恒定的流速和压力提供清洗液。这些参数的设置可以参照章节 3.4.2，URS27	Q	FS（PH_C_AT）	PP20-0098-T-010273	The speed of pump is adjustable automatically. It provides the solution variable feeding flow rate and pressure according to CIP washing and rinsing recipes. These ranges of parameters are illustrated in Section 泵的流速可以自动调节。它可以按照 CIP 清洗和润洗配方以非恒定的流速和压力提供清洗液。	
URS16	The function of the sanitary water ring pump is to boost washing solution back into tank. 这台卫生级液环泵的用途是将清洗液泵回到罐体中	Q	FS（PH_C_PUR_CHT）	PP20-0098-T-004206	The sanitary water ring pump can boost washing solution back into tank. 液环泵可以将清洗液泵回到罐体中	
URS17	Tube-shell heat exchanger 管壳式换热器	Q	Design condition table of heat exchanger in CIP station CIP 站换热器设计条件表	PP20-0098-T-000765	Tube-shell heat exchanger in CIP station。 CIP 站配置管壳式换热器	

URS 编号 URS No.	URS 描述 URS Description	URS 分类 URS Classification (Q, C, I)	设计文件名称 Design Doc. Name	设计文件编号 Design Doc. No.	设计描述 Design Description	是否可接受 Acceptable Yes 是/No 否
URS18	The heat exchanger is to heat up the washing solution when required. Sanitary double tube sheet heat exchanger will be used. 需要的时候换热器将会将清洗液升温和降温功能，需要使用卫生级的管壳式换热器	Q	Design condition table of heat exchanger in CIP station CIP 站换热器设计条件表	PP20-0098-T-000765	The sanitary heat exchanger could heat up and cold down the washing solution when required. 卫生级的管壳式换热器可以将清洗液升温和降温。	
URS19	Process air will be used for blowing out the residue water or cleaning solutions in the piping system after the rinsing or solution circulation procedure. 工艺压空用来吹扫润洗或者循环清洗流程之后管路系统里存留的水或者清洗液。	Q	FS（PH_C_PUR_CHT）	PP20-0098-T-004206	Process air will be used for blowing out the residue water or cleaning solutions in the piping system after the rinsing or solution circulation procedure. 工艺压空可以吹扫润洗或者循环清洗流程之后管路系统里存留的水或者清洗液。	
URS20	The sanitary filters shall be designed for off-situ integrity testing of the sterile 卫生级过滤器适用于无菌离线完整性测试的需求。	Q	P&ID（DS1-CIP02/ DS1-CIP03/ DS1-CIP05）	E01-203201-1-164~ E01-203201-1-166	The sanitary filters can be designed for off-situ integrity testing of the sterile 卫生级过滤器可以进行无菌离线完整性测试。	
URS21	The alkali and acid feed metering pump are used to transfer the alkali and acid detergent to the system for washing. 用于把浓酸浓碱传输到系统中供清洗之用的酸碱计量泵。	Q	P&ID（DS1-CIP02/ DS1-CIP03/ DS1-CIP05）	E01-203201-1-164~ E01-203201-1-166	The metering pump can transfer the alkali and acid detergent to the system for washing. 计量泵可以把酸碱传出到 CIP 系统中	
URS22	The manifold in DS1-CIP, used for the CIP solution distribution of CIP skid (DS1-CIP03& DS1-CIP05) for for buffer system, post ultra-filtration system of one DS production line. 阀阵 DS1-CIP 用于给一条生产线的缓冲液系统、除病	Q	P&ID（DS1-CIP DISTRIBUTION）	E01-203201-1-163	The manifold in DS1-CIP, used for the CIP solution distribution of CIP skid (DS1-CIP03& DS1-CIP05) for for buffer system, post ultra-filtration system of one DS production line. 阀阵 DS1-CIP 设计有用于给一条生产线的缓冲液系统、除病毒后的 UF 系统清	

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	毒后的 UF 系统清洗所用的 DS1-CIP03 和 DS1-CIP05 进行分配。				洗所用的 DS1-CIP03 和 DS1-CIP05 进行分配	
URS23	Other three manifolds will be utilized for the other three production lines . 另外三套阀阵将会给另三条生产线使用。	Q	P&ID（DS1-CIP DISTRIBUTION）	E01-203201-1-163	Other three manifolds in DS1-CIP will be utilized for the other three production lines . 阀阵 DS1-CIP 中另外三套阀阵将会给另三条生产线使用	
URS24	The CIP of buffer system, post ultra-filtration system etc, in one production line will be serviced by two CIP skids DS1-CIP03 and DS1-CIP05. However, these two CIP skids will be shared in case of heavy cleaning workloads. 缓冲液系统和除病毒后超滤系统的清洗将通过两套 CIP 模块 DS1-CIP03 和 DS1-CIP05 共同完成。然而，在清洗负荷过高的情况下，这两套 CIP 系统将会交替使用。	Q	FS（PH_C_PUR_CHT）	PP20-0098-T-004206	The CIP of buffer system, post ultra-filtration system etc, in one production line is preferred be serviced by CIP skids DS1-CIP03 DS1-CIP05 can be used when DS1-CIP03 is occupied. 缓冲液系统和除病毒后超滤系统的清洗默认优先使用 CIP 模块 DS1-CIP03，当 DS1-CIP03 被占用时 DS1-CIP05 可以被使用。	
URS25	The function of the manifold is to switch over the CIP solution from two CIP skids and distribute the CIP solution to equipment to be washed. 阀阵的功能是将 CIP 清洗液从两个 CIP 站分配到被清洗设备。	Q	FS（PH_C_BP /PH_C_UF）	PP20-0098-T-001610 /PP20-0098-T-009437	The manifold can switch over the CIP solution from two CIP skids and distribute the CIP solution to equipment to be washed. 阀阵可以将 CIP 清洗液从两个 CIP 站分配到被清洗设备。	
URS26	The manifold skid includes the separated supply manifold and return manifold. Mix-proof valve matrix or diaphragm valves matrix will be used for the manifolds as indicated in P&IDs.	Q	P&ID（DS1-CIP DISTRIBUTION）	E01-203201-1-163	The manifold skid includes the separated supply manifold and return manifold. Mix-proof valve matrix be used for the manifolds. 阀阵系统包含了单独的供给阀阵和回水阀阵。阀阵系统中使用防混阀组，	

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	阀阵系统包含了单独的供给阀阵和回水阀阵。阀阵系统中需要使用防混阀组或隔膜阀组，详见 PID					
URS27	The typical washing/rinsing sequence combines process phases as: 典型的清洗/润洗流程包含了以下工艺步骤： – PW washing phase: 纯化水清洗 ➢ <PW>, PW wash step (once through) PW 清洗（直冲直排） ➢ <BW>, Base detergent wash step (circulating) 碱洗（循环） ➢ <BS>, Base detergent supply step (once through) 碱液配制（一次配制） ➢ <SP>, CIP tank self-PW washing step CIP 罐自清洗步骤 – WFI rinsing phase: WFI 润洗步骤 ➢ <WR>, WFI rinsing step (back check) WFI 润洗（缓冲） ➢ <WS>, WFI supply step (once through) WFI供给（直排） ➢ <SW>, CIP tank WFI flushing step CIP罐的 WFI冲洗步骤 – Process air (PA) blowing phase: 压空吹扫步骤	Q	P&ID（DS1-CIP02/ DS1-CIP03/ DS1-CIP05） FS（PH_C_PUR_CHT） FS（PH_C_AT）	E01-203201-1-164~ E01-203201-1-166 PP20-0098-T-004206 PP20-0098-T-010273	The relevant cleaning strategy is described in FS. FS 中描述了相关清洗策略。 PW washing phase: 纯化水清洗 <PW>, PW wash step (once through) PW 清洗（直冲直排） <BW>, Base detergent wash step (circulating) 碱洗（循环） <BS>, Base detergent supply step (once through) 碱液配制（一次配制） <SP>, CIP tank self-PW washing step CIP 罐自清洗步骤 WFI rinsing phase: WFI 润洗步骤 <WR>, WFI rinsing step (back check) WFI 润洗（缓冲） <WS>, WFI supply step (once through) WFI 供给（直排） <SW>, CIP tank WFI flushing step CIP 罐的 WFI 冲洗步骤 Process air (PA) blowing phase: 压空吹扫步骤 <AB>, PA blowing to equipment step 压空吹扫设备 Hold up phase: 等待步骤 <ED>, Equipment drain step 排放步骤 <HO>, Hold up step 等待	

<table>
<tr><th>URS 编号
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Design Description</th><th>是否可接受
Acceptable
Yes 是/No 否</th></tr>
<tr><td></td><td>➢ <AB>, PA blowing to equipment step 压空吹扫设备
– Hold up phase: 等待步骤
➢ <ED>, Equipment drain step 排放步骤
➢ <HO>, Hold up step 等待</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>URS28</td><td>The critical process parameters are required as:
所需的关键工艺参数如下
<table><tr><th>Process Data
工艺数据</th><th>Range
范围</th><th>Monitor
监测</th><th>Control
控制</th><th>Critical alarm
关键报警</th></tr><tr><td>CIP solution supply flow rate
CIP 清洗液供给流速</td><td>25-187LPM</td><td></td><td>FIC
流量计</td><td>√</td></tr><tr><td>CIP solution supply pressure
CIP 清洗液供给压力</td><td>1-4.5barg</td><td></td><td>PIC
压力传感器</td><td>√</td></tr><tr><td>CIP solution supply temperature
CIP 清洗液供给温度</td><td>20-90°C</td><td></td><td>TIC
温度传感器</td><td>√</td></tr><tr><td>Base solution supply conductivity</td><td>TBD</td><td></td><td>AIC
电导率仪</td><td>√</td></tr></table></td><td>Q</td><td>EM_CIP Alarm&Interlock List
连锁报警清单</td><td>PP20-0098-T-010281
PP20-0098-T-004379</td><td>The critical process parameters are satisfied
所需关键工艺参数满足要求</td><td></td></tr>
</table>

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	碱液电导率 / Acid solution supply conductivity 酸液电导率: TBD; AIC 电导率仪; √ CIP return resistivity CIP 回的电阻: 0-20us/cm; AIC 电导率仪; √ CIP return temperature CIP 回的温度: 20-90°C; TIC 温度传感器; √					
529	Black utilities 非洁净公用工程 Plant steam 工业蒸汽: 143°C @ 3 barg Instrument air 仪表空气: 6 barg Electricity 用电: 380V/3ph/50Hz, 220V/1ph/50Hz	Q	Piping Class Index 管道等级索引表 Motor List 马达设备清单	PP20-0098-T-000012 PP20-0098-T-009479	The operating conditions of clean utilities meet the URS requirements. 洁净公用工程的操作条件符合 URS 要求。	
530	Clean utilities 洁净公用工程 Process air 工艺压空: 3 barg Clean steam 纯蒸汽: 143 °C @ 3 barg Purified water 纯水: Ambient @ 2 barg HWFI (hot loop) 注射用水: 80-85 °C @ 2 barg	Q	Piping Class Index 管道等级索引表	PP20-0098-T-000012	The operating conditions of clean utilities meet the URS requirements. 洁净公用工程的操作条件符合 URS 要求。	
531	The main system interfaces are: 主要的系统界面有： – Plant utilities (black and clean) 工业蒸汽（非洁净和洁净） – Equipment / system to be washed 待清洗的设备/系统 – Control system of equipment to be washed 待	Q	PID	E01-203201-1-163 E01-203201-1-164 E01-203201-1-165 E01-203201-1-166	PID shows the scope. 在 PID 中显示了系统界面。	

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	清洗设备的控制系统					
32	The owner's facility, where the two cell culture lines within the scope of work are located, is an existing building at SIP, Suzhou City, Jiangsu Province, PRC. The building shell has been established with three floors. The CIP skids are designed to be located at 2nd floor. 两条细胞培养生产线都在业主位于中国江苏省苏州市工业园区的现有厂房内。已建成的厂房共有三层。CIP 系统将会摆放在 2 层	I	N/A	N/A	N/A	
33	It is designed that the four DS production lines ,The supplier should consider the feasibility when rotating equipment or a component during the fabrication design. 四条原液生产线，供应商需要考虑在施工进场方案时的翻转设备的可行性	I	N/A	N/A	N/A	
34	The maximum ceiling height will be 4.4m. 最高的吊顶高度为4.4米	C	Second Floor Equipment Module Layout 2 楼设备模块布置图	PP20-0098-T-000021	The maximum ceiling height is 4.5m for CIP area and module height is 3.5m. 目前 CIP 吊顶高度为 4.5m,CIP 站模块高度 3.5m。	
35	The supplier should provide detailed equipment layout and section drawings, a 3D model for four lines, for the arrangement of equipment and platform structures within scope of work.	I	N/A	N/A	N/A	

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	供应商需要提供具体的设备布局图，轴测图，并提供四条线的 3D 模型，用于设备和钢结构的排布。					
536	The operative environment is considered to be CNC production level, non-hazardous, and non-explosive area. 设备将放置在 CNC 区域，无危险，非防爆区	I	N/A	N/A	N/A	
537	Room for system shall be managed as a controlled area through AHU. CIP 房间将会通过空调机组来控制温度 Room temperature: 18 ~ 30 °C 房间温度为 18-30 度	I	N/A	N/A	N/A	
538	Supplier shall arrange their system in the dedicated technical room rationally for better performance. 供应商应该将其管道架合理的布置在技术间里	C	Second Floor Equipment Module Layout 2 楼设备模块布置图	PP20-0098-T-000021	Meet the requirements 满足。 The CIP stations were arranged in the technical room rationally for convinient oparation and maintenance . CIP 站合理的布置在技术间利于房间操作和维护。	
539	The CIP skids shall be provided with safety systems in compliance with the standards, codes, regulations and specifications. The required safety interlocks should be detailed in DDS. CIP 模块应该按照相应标准，国家法规及技术说明的要求配备安全系统。在详细的技术说明里应该详细描述安全互锁	C	P&ID（DS1-CIP02/ DS1-CIP03/ DS1-CIP05） Alarm&Interlock List 连锁报警清单	E01-203201-1-164~ E01-203201-1-166 PP20-0098-T-004379	The CIP skids have provided with safety systems such as bursting disc and pressure safety valves in compliance with the standards, codes, regulations and specifications. The required safety interlocks are detailed in Alarm&Interlock List. CIP 模块按照相应标准，国家法规及技	

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					术说明的要求配备爆破片，安全阀等安全系统。在报警连锁清单文件中详细描述了安全互锁	
540	The following safety devices shall be provided for the package. 该 CIP 包需要配置以下的安全设施： Protective guards shall be placed around all moving parts. 所有可移动的部件需要配有防护设施。 The Supplier shall detail all operator and process safeguards included as standard in the bid. 供应商需要在标书中详细描述所有操作和工艺的防护措施。 The design of CIP skid shall provide for the safe operation and maintenance of all system components. To ensure that products are safely contained, the design shall conform to requirements of China National Act of Labor Protection, and OSHA. Major components and valves shall be accessible and removable for maintenance. CIP 系统的设计需要所有系统部件的安全操作和维护。为了保证产品的安全生产，设计需要满足中国国家劳动法的要求以及 OSHA。主要的部件和阀门都是	C	Equipment Layout 设备布置图 Piping Layout 管道布置图	PP20-0098-T-009514 PP20-0098-T-009525 PP20-0098-T-009529 PP20-0098-T-009530 PP20-0098-T-009551 PP20-0098-T-009552 PP20-0098-T-009526~009528 PP20-0098-T-009531~009532 PP20-0098-T-009550 PP20-0098-T-009554~009556	The design of CIP skid will provide safe operation and maintenance of all system components. To ensure that products are safely contained, the design conform to requirements of China National Act of Labor Protection, and OSHA. Major components and valves can be accessible and removable for maintenance. CIP 系统的设计需要所有系统部件的安全操作和维护。为了保证产品的安全生产，设计满足中国国家劳动法的要求以及 OSHA。主要的部件和阀门都是可以触及的，并且可以拆卸下来用来维护。	

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	可以触及的，并且可以拆卸下来用来维护					
541	The Supplier shall fully guarantee that the equipment provided will achieve its individually specified process and operating functions. 供应商需要完全保证所提供的设备应该达到它们各自特定的工艺和操作功能。 – Under a 24 hours / 7 days operation 能够连续 7 天 24 小时运转 – Under the whole range of operating, climatic and site conditions specified. 特定的气候和场地条件下在允许的范围内进行操作 – Using the specified equipment which are compliant with the data sheets designed by the Supplier and with Owner approval. 所使用的设备需要满足供应商所设计及业主批准的数据表 – Minimize and guarantee system power and utilities consumption. 减少和确保系统用电及公用工程耗量	C	N/A	N/A	Will be tested during FAT, SAT 将在 FAT,SAT 中测试	

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642	The project Owner designed drawings, including Piping and Instrument Diagrams (P&ID's), are utilized to lead Supplier's shop mechanical design. The Supplier is in responsible to update the P&IDs with that the portions might be changed to meet actual installation condition and good system performance practice. Changes shall be tracked by Supplier and to be approved by Owner. 业主设计的图纸用来指引供应商进行深化的机械设计，这其中包括了 PID 图。供应商应该对 PID 中需要更改使之满足实际的安装条件和更好的系统性能的地方进行优化。供应商应该标识出更新的地方并由业主批准	I	N/A	N/A	N/A	
643	All necessary items shall be provided by Supplier to ensure that the overall system performs to meet or exceed the process required. 供应商应该提供所有必须的设计来确保整体系统能够满足或者超过工艺需求	I	N/A	N/A	N/A	
644	The complete mechanical design shall be the responsibility of the Supplier, subject to be reviewed by the Owner. Supplier shall design the system for minimum floor space without sacrificing ease of operation and maintenance. 整体的机械设计将由供应商负责，业主进行审核。供应商需要考虑在不牺牲操作和维护性能的基础上尽可	I	N/A	N/A	N/A	

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	能减少占地面积					
545	Supplier shall design arrangement of equipment to provide the minimal number of skids. 供应商应该进行设备的布局设计从而减少模块的数量	I	N/A	N/A	N/A	
546	Lifting lugs shall be provided for all equipment in excess of 20 kg. The lugs or other structure shall be designed in accordance with GB and ANSI standards. 对于重量超过 20kg 的设备需要配有吊耳。吊耳或其他结构的设计需要按照 GB 和 ANSI 标准	C	容器图纸 Vessel Drawing	WC02-26319 WC02-26320 WC02-26321 WC02-26322 WC02-26323	All vessels are equipped with lifting lugs, which are designed and manufactured according to GB standards 所有的容器均配有吊耳，吊耳的设计按照国标选型设计，制造	
547	All pressure vessels shall be designed, fabricated, examined, inspected, and tested in accordance with Chinese Pressure Vessel Code GB150. 所有的压力容器应该按照中国容规 GB150 来设计，制造，检查，监查和测试	C	容器图纸 Vessel Drawing	WC02-26319 WC02-26320 WC02-26321 WC02-26322 WC02-26323	All pressure vessels are designed, manufactured, inspected, monitored and tested in accordance with GB150 所有的压力容器均按照中国容规 GB150 来设计，制造，检查，监查和测试	
548	Manufacturer's (Code) stamp shall be in an easily visible location, or else as directed by the Owner's inspector. Stamp shall be completely seal welded to bracket and bracket completely seal welded to the vessels or heat exchangers. All information shall be embossed on the stamp or otherwise permanently affixed.	C	N/A	N/A	将在 FAT,SAT 时检查	

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	供应商的标识需要刻在设备清晰可见的位置，或者业主的监查人员指定的位置。标牌必须完全密封焊接到支架上，支架完全密封焊接到容器或换热器上。所有的信息都应体现在标牌或其他永久性的标志上					
549	Bolts and nuts shall be stainless steel or better corrosion resistant alloy. Teflon type is NOT allowed in using on piping with product contact. 螺栓螺母需要是不锈钢的或者其他更好的抗腐蚀的合金材料。特氟龙材料是不可以用在于物料接触的地方的	C	钢结构加工制作说明 Piping Class Index 管道等级索引表	PP20-0098-T-001101 PP20-0098-T-000012	Materials for bolts and nuts are austenitic stainless steel, grade A2 螺栓螺母材质均为不锈钢，等级 A2。 The gasket used for clean fluid is PTFE. 接触物料的垫片为 PTFE。	
550	Materials shall be of the highest quality, free from defects and imperfections 材料必须要提供最高品质的，无瑕疵无缺陷的	C	N/A	N/A	Will be checked during FAT, SAT 将在 FAT,SAT 时检查	
551	Generally, stainless steel materials used for process equipment described in this specification shall be type 316L except the special specified, or other material agreed to by the project owner. Where type 316L is specified, the material of the automatic weld end shall conform to the requirements for chemical composition as prescribed in ASME BPE 2016 Chapter 3 MATERIALS section MM-5.2.1.1 and Table MM-2.1-1. 本规范所述工艺设备所用不锈钢材料一般为 316L 型，但项目业主同意的特殊规定或其他材料除外。使用 316L 材质的管件在自动焊接时，焊接材料应符合	Q	Piping Class Index 管道等级索引表	PP20-0098-T-000012	The piping material for PW,WFI,Celan air,Clean steam and CIP is 316L,the application of piping components,valves,instruments compliance with ASME BPE 2019. The piping material of jacket,drain,condensation and instrument air is 304. PW，WFI，洁净压空，纯蒸汽，CIP 等介质管道材质 316L,管道件、阀门、仪表选用符合 ASME BPE 2019 的要求。 其他夹套、排放、疏水、仪表压空等使用 304 材质。	

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	ASME BPE 2016 章节 3 MATERIALS section MM-5.2.1.1 and Table MM-2.1-1 中对于化学物质的要求					
52	The dimensions for sanitary tubing, fittings and connection of equipment or component shall follow the requirements in ASME BPE 2016 Chapter 4 PROCESS COMPONENTS Part DT. 卫生管的尺寸，配件和设备或构件的连接应按要求在 ASME BPE 2016 4 章工艺部分 DT	Q	Piping Class Index 管道等级索引表	PP20-0098-T-000012	The piping size and connection for PW,WFI,Celan air,Clean steam and CIP compliance with ASME BPE 2019. 纯化水、注射水、洁净压空、洁净蒸汽和 CIP 管道的尺寸和连接形式符合 ASME BPE 2019 的要求。	
53	Nonmetallic process components shall meet the requirements as prescribed inASME BPE Chapter 3 MATERIALS Table PM-2.2.1-1 or meet the client provided specification. 非金属组件应满足 ASME BPE 章节 3 的材料表 pm-2.2.1-1 规定或满足客户提供的规格	Q	Piping Class Index 管道等级索引表	PP20-0098-T-000012	The gaskets for clean fluid is PTFE compliance with FDA. The flexible hose for clean fluid is Pt-silicone compliance with FDA and USP Class VI. 洁净物料的垫片使用 PTFE，符合 FDA 要求。洁净物料的软管使用铂金硫化硅胶，符合 FDA 和 USP Class VI 要求。	
54	All legs and framework, platform structures, exterior cover will be manufactured from stainless steel AISI 304, which finishes will be Ra ≤1.2μm with vertical brush direction. 所有的支腿和框架，平台结构，外盖使用 AISI 304 不锈钢制造，外表面按照垂直方向抛光至 RA≤1.2μm	C	钢结构加工制作说明	PP20-0098-T-001101	All legs and framework, platform structures, exterior cover will be manufactured from stainless steel AISI 304, which finishes will be Ra ≤1.2μm with vertical brush direction. 所有的支腿和框架，平台结构，外盖使用 AISI 304 不锈钢制造，外表面按照垂直方向抛光至 RA≤1.2μm	

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55	Non-metal surfaces in contact with product have to be FDA, SFDA (e.g. hoses, bellows, and gaskets). 与产品接触的非金属表面必须由 FDA、国家食品药品监督管理局（如软管、波纹管和垫圈）	Q	Piping Class Index 管道等级索引表	PP20-0098-T-000012	The gaskets for clean fluid is PTFE compliance with FDA. The flexible hose for clean fluid is Pt-silicone compliance with FDA and USP Class VI. 洁净物料的垫片使用 PTFE，符合 FDA 要求。洁净物料的软管使用铂金硫化硅胶，符合 FDA 和 USP Class VI 要求。	
56	Raw material traceability shall be maintained for all materials of construction. 所有建造材料都应保持原材料的可追溯性	Q	N/A	N/A	Material quality certification will be checked at FAT,SAT and IQ. 将在 FAT,SAT,IQ 时检查材料的质量证明	
57	Materials of construction shall not release particles. (MOC's shall be non-shedding, non-additive, non-reactive and will not degrade due to CIP or SIP). 建造的材料不得释放颗粒。（制造材料应为无脱落、无添加剂、无反应，不会因 CIP 或 SIP 而降级）	Q	Piping Class Index 管道等级索引表	PP20-0098-T-000012	The material of piping components,valves,instruments is 316L or 304 stainless steel. The material of gaskets is PTFE or EPDM, flexible hose is silicone or PTFE. All these material will not release particles and will be non-shedding. 管道、阀门、仪表等材料均为 316L 或 304 不锈钢，垫片为 PTFE 或 EPDM，软管为硅胶或 EPDM。以上材料均不释放颗粒、不脱落。	
58	The materials shall be selected that are capable of withstanding the steam sterilisation temperature (125˚C) and being washed with hot WFI (80˚C). 应选择的材料能够承受蒸汽灭菌温度（125˚C）和热注射用水冲洗（80˚C）	Q	管道等级索引表 Piping Class Index	PP20-0098-T-000012	The materials will be selected that are capable of withstanding the steam sterilisation temperature (125˚C) and being washed with hot WFI (80˚C) for clean lines. 对于洁净管线，选择的材料能够承受蒸汽灭菌温度（125˚C）和热注射用水冲洗（80˚C）	

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559	All manual welds shall be 100% recorded in the supplier's documentation with related welder and welding information. 所有手工焊接应在供应商的文件中记录 100%，并配有相关焊工和焊接信息	Q	Piping Design Specification 管道设计说明	PP20-0098-T-010289	All manual welds will be 100% recorded in SMP's documentation with related welder and welding information. 所有手工焊，SMP 的文件中 100%记录，并配有相关焊工和焊接信息	
560	The supplier shall provide boroscope picture for 20% automatic welds and 100% maunal welds. 供应商应提供自动焊 20%的焊缝缺陷探测器图片和 100%手动焊缝缺陷探测器图片.	Q	Piping Class Index 管道等级索引表 Piping Design Specification 管道设计说明	PP20-0098-T-000012 PP20-0098-T-010289	SMP will provide boroscope picture for 20% automatic welds and 100% maunal welds for clean pipings. 对于洁净管道，SMP 提供自动焊 20%的焊缝内窥镜拍片和 100%手动焊内窥镜拍片.	
561	All MTRs (material testing report) shall be provided. 应提供所有材料的 MTR（材料试验报告）	Q	N/A	N/A	Material quality certification will be checked at FAT,SAT and IQ. 将在 FAT,SAT,IQ 时检查材料的质量证明	
562	Certificates of Compliance (C of Cs) for all polymeric and other non-metallic process components shall be provided. 应提供所有聚合物和其他非金属加工部件的合格证书	Q	Piping Class Index 管道等级索引表	PP20-0098-T-000012	Piping class SF1/SF4 gaskets reqire FDA certificate of compliance. SF1/SF4 等级的垫片要求 FDA 符合证明	
563	The surface finish requirement shall be compliant with general piping specifications defined by hygienic equipment specification. 设备的表面处理应符合的卫生级设备规范	Q	容器图纸 Vessel Drawing	WC02-26319 WC02-26320 WC02-26321 WC02-26322 WC02-26323	The surface of the equipment is polished as required to meet the sanitary requirements 设备的表面按照要求进行抛光，满足卫生级要求	

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64	Tank internal surfaces in contact directly with product and WFI shall be SF4 内表面直接接触产品和注射用水的罐体为 SF4	Q	Piping Class Index 管道等级索引表	PP20-0098-T-000012	Tank internal surfaces in contact directly with product and WFI is SF4 内表面直接接触产品和注射用水的罐体为 SF4	
65	Clean steam post regulator shall be SF1 at least. 清洁蒸汽调压阀后应至少为 SF1	Q	Piping Class Index 管道等级索引表	PP20-0098-T-000012	Clean steam post regulator is SF1. 清洁蒸汽调压阀后为 SF1	
66	CIP supply and return lines shall be SF1 CIP 供应和回流管路应为 SF1	Q	Piping Class Index 管道等级索引表	PP20-0098-T-000012	CIP supply and return lines is SF1 CIP 供应和回流管路为 SF1	
67	Drain line, kill drain line, and clean condensate post block valve shall be SS304 . 排放管线，杀菌排放管线，和清洁冷凝水切断阀后应为 SS304 不锈钢	C	Piping Class Index 管道等级索引表	PP20-0098-T-000012	Drain line, kill drain line, and clean condensate post block valve will be SS304 . 排放管线，杀菌排放管线，和清洁冷凝水切断阀后为 SS304 不锈钢	
68	Process gases and vent lines post sterile filters shall be SF1 at least. 工艺空气和无菌过滤器后排气线应至少为 SF1	Q	Piping Class Index 管道等级索引表	PP20-0098-T-000012	Process gases and vent lines post sterile filters were SF1. 工艺空气和无菌过滤器后管线为 SF1	
69	Other lines and equipment which connecting with black utilities and without direct contact with product will be figured out by supplier to comply to current industry standard and operation requirements. All external surfaces of material in the production room shall allow easy cleaning with hot water and cleaning agents normally used in the food and / or pharmaceutical	C	Piping Class Index 管道等级索引表	PP20-0098-T-000012	Other lines and equipment which connecting with black utilities and without direct contact with product is figured out by SMP to comply to current industry standard and operation requirements. All external surfaces of material in the production room shall allow easy cleaning with hot water and cleaning agents normally used in the food and / or pharmaceutical industry.	

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	industry. 其他与公用设施连接且与产品无直接接触的线路和设备将由供应商计算，以符合现行的行业标准和操作要求。生产区域的所有材料的外部表面应允许用热水和通常用于食品和/或制药工业的清洁剂进行简单的清洗				其他与公用设施连接且与产品无直接接触的线路和设备由 SMP 计算，以符合现行的行业标准和操作要求。生产区域的所有材料的外部表面许用热水和通常用于食品和/或制药工业的清洁剂进行简单的清洗。	
570	All clean tubing will be orbital welded as per requirement of ASME BPE 2016 Chapter 5 FABRICATION, ASSEMBLY, AND ERECTION part MJ. Supplier shall propose method to be used to assure weld quality. Client to review controls before manufacturing commences. Minimum 20% of all product/WFI contact welds shall be tested/inspected and certified. All weld beam shall be correctly tagged and tag number shall be permanently marked on pipe in correspondence with that in documents. 所有的清洁管将按 ASME BPE 2016 章 5 制造，装配，安装部分 MJ 要求进行轨道焊接。 供货商应提出措施来保证焊接质量。在开始制造前，客户将确立审查控制。20%以上所有产品/注射用水接触的焊缝应测试/检验。 所有焊缝应正确标记，标签号码应该永久性的标记到管道上并和相应的文件符合	Q	Piping Class Index 管道等级索引表 Piping Design Specification 管道设计说明	PP20-0098-T-000012 PP20-0098-T-010289	SMP will provide boroscope picture for 20% automatic welds and 100% manual welds for class SF4 and SF1. All welds will be correctly tagged and tag number will be permanently marked on pipe in correspondence with that in documents. 供应商提供 SF4 和 SF1 等级管道 20%自动焊和 100%手动焊接点的内窥镜照片。 所有焊缝将正确标识，同时标识号码永久地标记在管路上，并与在文件存档的内容一致。	

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571	Insulation, for tubing with temperature higher than 60ºC (exclude CIP pipe, branch pipe of pure steam and the piping before steam trap) and lower than dew point. External surface temperature with insulation shall be lower than 45°C during all phases. All product transfer lines are unnecessary to be insulated. 保温的范围是温度高于 60℃（对 CIP 流体管道，洁净蒸汽支管和冷凝水管道不做保温）和低于露点的管道。保温后的外表面温度应该任何阶段都低于 45℃。所有产品管线是不需要做保温的	C	Piping Design Specification 管道设计说明 Piping Line List 管线一览表	PP20-0098-T-010289 PP20-0098-T-004170	Cooling water,Glycol pipelines need cold insulation. Industrial steam haeader and branch need hot insulation. Clean steam headers need hot insulation. The insulation protection will be stainless steel or PVC. The thickness of insulation is determined by fluid temperature and piping size to meet the requirement. Hot iinsulation material is glass wool,and clod insulation material is rubber. 冷却水和乙二醇管道保冷，工业蒸汽主管、支管热保温，洁净蒸汽主管热保温。保温外壳使用不锈钢或 PVC。根据流体温度和管径确定保温厚度，以满足要求。保热材质为离心玻璃棉，保冷材质为橡塑。	
572	The design shall aim at including as few deadlegs as possible. The identification of dead leg (“min.” in P&D) is “3D rule”. Short pipe sections shall preferably be designed with a 1% slope and long pipe sections shall be designed with a 0.5% slope. Slopes below 0.5% can only be accepted in exceptional cases. 设计应尽可能减少死角。死角的标识（“min”）是“3D”规则。 较短管段的设计应以 1％的坡度设计和长管段应以 0.5％的坡度设计。低于 0.5％倾角的管路只能在特殊情况下接受	Q	Piping Design Specification 管道设计说明 Piping Class Index 管道等级索引表		The design aim at including as few deadlegs as possible. The identification of dead leg (“min.” in P&D) is “3D rule”. Short pipe sections were preferably be designed with a 1% slope and long pipe sections shall be designed with a 0.5% slope. 设计尽可能减少死角。死角的标识（“min”）是“3D”规则。 较短管段的设计以 1％的坡度设计和长管段以 0.5％的坡度设计。	

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573	Equipment shall be designed to be easy to clean. Sharp corners, edges or nuts that tear cleaning tissues and prevent easy wiping are not allowed The design of all equipment that will contain pharmaceutical materials shall ensure that all water will be self drain, to achieve efficient drying. Parts that hide or trap spilled product are to be avoided. 设备应设计为易于清洗。 不允许出现会撕破擦拭工具的尖角，锋利的边缘以及不易擦拭的地方。 所有含有制药原料的设备的设计应确保所有的水都能自排净，以实现高效干燥。 避免出现会藏留产品的部位。 所有用于洁净室的材料应能耐受消毒剂，如 IPA，杀菌剂	C	容器图纸 Vessel Drawing Piping Design Specification 管道设计说明 Piping Class Index 管道等级索引表	WC02-26319 WC02-26320 WC02-26321 WC02-26322 WC02-26323 PP20-0098-T-010289 PP20-0098-T-000012	Vessels are designed to be easy to clean. There is no Sharp corners, edges or nuts that tear cleaning tissues and easy wiping The vessels are all water self drain. 设备为卫生级设计，易于清洗。不会出现会撕破擦拭工具的尖角，锋利的边缘以及不易擦拭的地方。设备能自排净。 Module sharp corners,edges will be polished or chamfered, which will make the cleaning easily. 模块尖角、边缘都进行打磨或倒角处理，易于清洁。 All Piping,valves materials used in cleanroom shall be compatible with sanitizers, such as IPA, sporicidal agent. 所有用于洁净室管道阀门材料能耐受消毒剂，如 IPA，杀菌剂。	
574	The Supplier shall be responsible for adequacy of design in accordance with applicable code requirements, based on temperatures, pressures and other conditions. 基于设计温度，压力以及其他的条件，供应商应该充分考虑使其满足容规的要求。 Vessels shall be self-supporting, and the supports shall incorporate seismic force requirements in their design.	C	容器图纸 Vessel Drawing	WC02-26319 WC02-26320 WC02-26321 WC02-26322 WC02-26323	The design temperature and pressure of the tank are higher than the actual use temperature and pressure of the equipment, and meet the requirements of the standard. The tank body is supported by the legs, which are designed to meet the load requirements 罐体的设计温度，设计压力均高于设备的实际使用温度和压力，且满足容规的要求。 罐体为支腿支撑，支腿的设计满足载	

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	罐体要有支腿，支腿的设计需要考虑载荷的要求				荷的要求	
575	Sufficient tank insulation should be done. 需要考虑足够的罐体保温	C	容器图纸 Vessel Drawing	WC02-26320 WC02-26321 WC02-26322 WC02-26323	The insulation thickness of the tank is 50mm, and the material is centrifugal glass wool 罐体保温均为50mm,材料为离心玻璃棉	
576	The CIP supply pump shall be a sanitary centrifugal pump. Casing material shall be at least identical to material of piping connected. The Supplier is responsibility to supply the whole pump including head, gear box, motor, VFD and local MCC connection box, etc. 供给泵需要选择卫生级离心泵。壳体的材料至少要和连接管道的材料等同。供应商需要提供整个泵，包含泵头，齿轮箱，马达和本地的 MCC 柜。	Q	CIP pump data sheet CIP 泵数据表	PP20-0098-T-000082/ PP20-0098-T-000083	The CIP supply pump is a sanitary centrifugal pump. Casing material is 316L material. The Supplier is responsibility to supply the whole pump including head, gear box, motor, VFD and local MCC connection box, etc. 供给泵是 316L 材质的卫生级离心泵。供应商需要提供整个泵，包含泵头，齿轮箱，马达和本地的 MCC 柜。	
577	Pump, driver and accessories shall be designed for continuous operation at the operating conditions. 泵体，驱动器以及附属设备的设计需要满足连续长时间的运行。	C	CIP pump data sheet CIP 泵数据表	PP20-0098-T-000082/ PP20-0098-T-000083	Pump, driver and accessories can be designed for continuous operation at the operating conditions. 泵体，驱动器以及附属设备的设计可以连续长时间的运行。	
578	Pumps inner parts shall be open design to allow for easy cleaning. Casing drain shall be at low point to permit complete draining. 泵的内部应该采用开放式设计以便容易清洁。排水口需要设置在最低点以保证全排空。	Q	CIP pump data sheet CIP 泵数据表	PP20-0098-T-000082/ PP20-0098-T-000083	Pumps inner parts have open design to allow for easy cleaning. Casing drain at low point to permit complete draining. 泵的内部采用开放式设计以便容易清洁。排水口设置在最低点以保证全排空。	

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579	Centrifugal pump rated capacity shall not exceed capacity at the best efficiency point. Pump design shall permit installation of a larger impeller that would increase rated head by as much as 10%. 离心泵额定功率不应超过最佳效率点的功率。泵的设计应允许安装较大的叶轮，使额定扬程增加 10%。	C	CIP pump data sheet CIP 泵数据表	PP20-0098-T-000082/ PP20-0098-T-000083	Centrifugal pump rated capacity can not exceed capacity at the best efficiency point. Pump design cuold permit installation of a larger impeller that would increase rated head by as much as 10% at least. 离心泵额定功率不会超过最佳效率点的功率。泵的设计可以安装较大的叶轮，使额定扬程增加至少 10%。	
580	Sanitary pumps' connection shall be sanitary type, tri-clamp is preferred 卫生级泵的管道连接也要采用卫生型的，最好适用卡箍接口。	Q	CIP pump data sheet CIP 泵数据表	PP20-0098-T-000082/ PP20-0098-T-000083	Sanitary pumps' connection is sanitary tri-clamp type. 卫生级泵的管道连接采用卫生卡箍连接。	
581	Bearings shall be open, flush-through type (to prevent over-lubrication). Lubrication shall be with food-grade grease or oil. Pumps shall be furnished with O-ring seals. 轴承应打开，冲洗类型（防止过度润滑）。润滑应使用食品级润滑脂或机油。泵应该配置 O 形环密封。	Q	CIP pump data sheet CIP 泵数据表	PP20-0098-T-000082/ PP20-0098-T-000083	Bearings are open, flush-through type (to prevent over-lubrication).No need lubrication， water and materials can self-lubricate. Pumps are furnished with O-ring seals. 轴承是打开，冲洗类型（防止过度润滑）。不需要润滑油，用水和物料自润滑，泵配置 O 形环密封。	
582	The heat exchangers which are used in clean process shall be shell and tube with double tube sheet design and welded seamless tubes or tube in tube type. 使用在洁净工艺中的换热器需要使用双管板管壳换热器设计，使用焊接的无缝管；或者是管中管换热器。	Q	Heat exchanger calculations and drawings 换热器计算书和图纸	PP20-0098-T-000766	The heat exchangers which are used in clean process is shell and tube with tube in tube type. 使用在洁净工艺中的换热器使用的是管中管换热器设计。	

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83	Nozzles shall not be located on weld seams, nor shall pads overlap weld seams. 焊缝处不可开孔，焊缝也不得相互搭接。	C	容器图纸 Vessel Drawing CIP 换热器图纸 CIP Exchanger Draw	WC02-26319 WC02-26320 WC02-26321 WC02-26322 WC02-26323 WE02-26389	No holes in the welds, and no lap between the welds. 焊缝处不开孔，焊缝之间也不会搭接。	
84	Nozzle necks shall be flush with the inside surface of the shell or channel. Inner corners of nozzle necks shall be rounded off to remove sharp corners. 管嘴应与筒体或腔体的内表面平齐。管嘴内部应该是圆滑过渡，不得有尖角	C	容器图纸 Vessel Drawing CIP 换热器图纸 CIP Exchanger Draw	WC02-26319 WC02-26320 WC02-26321 WC02-26322 WC02-26323 WE02-26389	The nozzle should be polished to a level with the inner surface of the barrel or cavity.Smooth transition without sharp corners 管嘴应与筒体或腔体的内表面均打磨平齐。圆滑过渡，没有尖角	
85	Connections for vent and drain shall be provided for each exchanger. 每台换热器都要配有排气和排水口	C	CIP 换热器图纸 CIP Exchanger Draw	WE02-26389	Heat exchangers are equipped with exhaust and drain outlets 换热器都配有排气和排水口	
86	Impingement plates shall not be located in necks of nozzles. 接口处不应设置冲击板	C	CIP 换热器图纸 CIP Exchanger Draw	WE02-26389	There is no impact plate at the nozzles 接口处没有冲击板	
87	For tube-shell-heat exchanger. Tube side and shell side shall be designed for complete drainage in the designated mounting position. 关于管板式换热器,管程和壳程在规定的安装位置下都要设计成全排净的	C	CIP 换热器图纸 CIP Exchanger Draw	WE02-26389	The pipe and shell sides of CIP heat exchangers are designed to be fully drained CIP 换热器的管程和壳程均设计为全排净	

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88	Exchangers shall be self-supporting designed according to the specified seismic criteria. 换热器需要根据特定的荷载设计支撑	C	CIP 换热器图纸 CIP Exchanger Drawing	WE02-26389	The design of the heat exchanger takes into account the specific load and designs the support similar to the saddle 换热器的设计考虑了特定的荷载，设计了类似鞍座的支撑	
89	The Supplier shall try the most possibility to the install product contacted filters, pump and other capital equipment on one mounting skid. The hanger specification refers to General Piping specification as attached. 供应商需要尽最大的可能性将与产品接触的过滤器，泵及其他的关键部件都集成在一个模块上。	C	Equipment Layout 设备布置图	PP20-0098-T-009514 PP20-0098-T-009525 PP20-0098-T-009529 PP20-0098-T-009530 PP20-0098-T-009551 PP20-0098-T-009552	The filters, pumps, tanks, Panel and other critical components are installed in one CIP module by SMP. SMP 将过滤器、泵、罐子、电柜及其他的关键部件都集成在一个 CIP 模块上。	
90	Industrial pressure gauges will be isolated with ball valves. Sanitary pressure gauges and temperature gauges will have 1 or 1.5 inch tri-clamp connection. 工业级压力表需要利用球阀隔断。卫生级压力表，温度表需要使用 1 寸或 1.5 寸的卡箍接口。	C	P&ID（DS1-CIP02/ DS1-CIP03/ DS1-CIP05）	E01-203201-1-164~ E01-203201-1-166	Industrial pressure gauges will be isolated with ball valves. Sanitary pressure gauges and temperature gauges will have 1 or 1.5 inch tri-clamp connection. 工业级压力表用球阀隔断。卫生级压力表，温度表使用 1 寸或 1.5 寸的卡箍接口。	
91	Part of temperature elements (RTD) and gauges shall be installed through suitable thermowells, on the basis of PID. 部分温度探头或表需要配备合适的套管，以 PID 为准。	C	N/A	N/A	The CIP module does not require a thermometer with a casing CIP 模块无需带套管的温度计	

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592	All equipment and components will be mounted where can be maintained. Manually operated equipment and components shall be located where the operators can easily access. 所有设备和部件的安装都要考虑到维护的空间。手动操作的设备和部件需要安置在操作人员能够触及到的位置。	C	Equipment Layout 设备布置图 管道布置图 Piping Layout	PP20-0098-T-009514 PP20-0098-T-009525 PP20-0098-T-009529 PP20-0098-T-009530 PP20-0098-T-009551 PP20-0098-T-009552 PP20-0098-T-009526~009528 PP20-0098-T-009531~009532 PP20-0098-T-009550 PP20-0098-T-009554~009556	All equipment and components will be mounted where can be maintained. Manually operated equipment and components are located where the operators can easily access. 所有设备和部件的安装都考虑了维护的空间。手动操作的设备和部件需要安置在操作人员能够触及到的位置。	
593	All components and instrumentations that are on vent line shall be verified as “Failed Open” type. 所有安装在排气管线上的部件和仪表都能够在失效时自动打开。	C	P&ID（DS1-CIP02/ DS1-CIP03/ DS1-CIP05）	E01-203201-1-164~ E01-203201-1-166	All components whice on vent line are normally open can be verified as “Failed Open” type. 所有安装在排气管线上的常开阀门都能够在失效时自动打开。	
594	The pipe work system shall be designed with the minimum number of connections commensurate with installation and maintenance requirements. All connections and pipe works will be in accordance with General Piping Specification. 所有的管路系统都需要尽可能少的连接，这个也是和安装维护的要求相对应的。所有的连接和管路系统都要满足通用的管道技术要求。	C	管道布置图 Piping Layout	PP20-0098-T-009526~009528 PP20-0098-T-009531~009532 PP20-0098-T-009550 PP20-0098-T-009554~009556	The pipe work system is designed with the minimum number of connections. All connections and pipe works will be in accordance with General Piping Specification,such as ASME BPE 2019. 所有的管路系统都尽可能少的连接。所有的连接和管路系统都要满足通用的管道技术要求，如 ASME BPE 2019。	
595	The skid, platform shall be supported by adequate numbers of square shaped 304 SS or better column. Supplier is in responsibility for load calculation.	C	N/A	N/A	The skids, platforms are supported by adequate numbers of square shaped 304 SS. Load calculation has been done. 已使用足够量的 SS304 方钢来支撑模块和钢平台。已完成荷载计算。	

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	需要使用足够量的 SS304 方钢或更好的支柱来支撑模块和钢平台。供应商负责荷载计算。					
96	Step ladder shall be designed and installed according to local safety code in working place. 步梯需要按照当地的安装规范来进行设计和安装。	C	N/A	N/A	Step ladder is not used in this module. 此模块无步梯	
97	Each instrument, component and valve, which is identified by a tag or equipment number on the P&ID or data sheets shall be supplied with a nameplate, engraved with the tag or equipment number and mechanically fixed to the equipment. The nameplate shall be of stainless steel. The information and format on nameplate shall be confirmed by owner's QA department before fabrication. 每一个仪表、部件和阀门，由标签或设备号上的 P&ID 或数据表标识，应提供一个铭牌，上面刻有标签或设备号，并机械固定在设备上。铭牌应该是不锈钢的。铭牌上的信息和格式在生产前由业主 QA 部门确认。	Q	P&ID（DS1-CIP02/ DS1-CIP03/ DS1-CIP05）	E01-203201-1-164~ E01-203201-1-166	Instrument parts and valves have been marked on the P&ID and the integrity and correctness of the number plate will be checked in FAT,SAT and IQ 仪表、部件和阀门等已在 P&ID 上标识了位号。位号牌的完整性和正确性将在 FAT,SAT,IQ 中检查	
98	There will be 5 PLC based control systems to control 12 CIP skids on this project. 一共使用 5 套 PLC 控制系统去控制本项目中的 12 套 CIP 站。 PLC #1, to control CIP-05-01	Q	硬件设计说明书 (emerson)	3287830-PAS-HFDS-00001-0	Design one emerson PK controller to control all CIP skid of DS1. 设计一个艾默生 PK 控制器控制 DS1 的所有 CIP 站	

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	PLC #1 控制 CIP-05-01 PLC #2, to control CIP-05-02 and CIP-05-03 PLC #2 控制 CIP-05-02 和 CIP-05-03 PLC #3, to control CIP-05-04 and CIP-05-05 PLC #3 控制 CIP-05-04 和 CIP-05-05 PLC #4, to control CIP-05-06 and CIP-05-07 PLC #4 控制 CIP-05-06 和 CIP-05-07 PLC #5, to control CIP-05-08 and CIP-05-09 PLC #5 控制 CIP-05-08 和 CIP-05-09					
99	The complete automation design related to the CIP Skid hardware and software is performed by the Supplier. 和 CIP 系统相关的硬件和软件的自动化设计都是由自动化供应商完成。	I	N/A	N/A	N/A	
100	The supplier shall provide FDS in their design for the CIP skid. The FDS shall specify clearly all aspects of the automation design and their compliance with this specification and owner's FRS, based on the selected hardware / software platform. 供应商需要提供 CIP 模块的硬件设计说明。基于选定的硬件/软件的平台，硬件设计说明需要清晰的阐述自动化设计的所有方面，以及与本技术要求和业主的硬件设计要求的符合性。	Q	硬件设计说明书 (emerson)	3287830-PAS-HFDS-00001-0	Emerson provide HFDS in their design for the CIP skid. The HFDS specify clearly all aspects of the automation design and their compliance with this specification and owner's FRS, based on the selected hardware / software platform. Emerson 提供 CIP 模块的硬件设计说明。基于选定的硬件/软件的平台，硬件设计说明阐述自动化设计的所有方面，以及与本技术要求和业主的硬件设计要求的符合性。	

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S101	The FDS on approval by client shall be the basis of the execution of the supply. 由业主批准的硬件设计说明作为项目供货和执行的基准。	I	N/A	N/A	N/A	
S102	The Supplier shall have fully documented coding guidelines and procedures. These documents shall be available for review. 供应商需要提供文件来证明其编程符合规定。这些文件可以用以审查。	I	N/A	N/A	N/A	
S103	A description of the software modules shall be included in the software design specification. 软件设计说明中需要包含软件模型的描述。	Q	N/A	N/A	The control system design standard and requirement of this project is based on the client's URS about Process Automation System(DCS). 本项目控制系统设计标准与要求，基于客户的工艺自控系统（DCS）用户需求标准。	
S104	PLC software design shall follow the GAMP5 life cycle approach + ISA S88 Philosophy. Traceability matrices for GAMP compliance will be undertaken. PLC 软件设计需要满足 GAMP5 和 ISA88 的设计准则。需要提供满足 GAMP 的可追踪的矩阵。	Q	N/A	N/A	The control system design standard and requirement of this project is based on the client's URS about Process Automation System(DCS). 本项目控制系统设计标准与要求，基于客户的工艺自控系统（DCS）用户需求标准。	
S105	The package shall be 21CFR part 11 compliant. 本包要满足 FDA CFR 第 11 章节的要求。	Q	N/A	N/A	The control system design standard and requirement of this project is based on the client's URS about Process Automation System(DCS). 本项目控制系统设计标准与要求，基于客户的工艺自控系统（DCS）用户需求标准。	

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106	Source code reviews shall be required. 源代码需要提供以供审查。	Q	N/A	N/A	The control system design standard and requirement of this project is based on the client's URS about Process Automation System(DCS). 本项目控制系统设计标准与要求，基于客户的工艺自控系统（DCS）用户需求标准。	
107	The control system, including all electrical systems shall be CE certified. 控制系统，包括所有的电气系统都要满足 CE 标准。	C	N/A	N/A	The control system design standard and requirement of this project is based on the client's URS about Process Automation System(DCS). 本项目控制系统设计标准与要求，基于客户的工艺自控系统（DCS）用户需求标准。	
108	Within the operating system, each user will be assigned to a user group. These groups are as detailed below: 在操作系统中，每一名用户都将会被分配到一个用户组里。这些组请见如下： **User Group 用户组** / **Access 权限** System Administrator 系统管理员 / Access to operating system 可以进行系统操作 Supervisor 主管 / Change Cleaning Recipe/Phase parameters. 更改清洗配方/步骤参数 Maintenance 维护人员 / Perform calibration of instruments, start and stop motors, open and close valves, when no recipe is active. 进行仪表校准，启停马达，打开和关闭阀门。 Operator 操作工 / Start processes, enter batch details, configure	Q	N/A	N/A	The control system design standard and requirement of this project is based on the client's URS about Process Automation System(DCS). 本项目控制系统设计标准与要求，基于客户的工艺自控系统（DCS）用户需求标准。	

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	trends, Operate valves and drives under manual control. 开启，进入批界面，进入趋势图，在手动状态下操作阀门和驱动。 View (User Not Logged On) 监查(用户不登录) View only (default/logged off user) 只检查（缺省/注销用户）					
109	When a user logs onto the application, the user name and password is verified by the operating system. The user is then given access rights according to the user group he/she belongs to. 当用户登录，操作系统将会检查用户名和密码，然后用户将会被系统根据他所在用户组分配相应的权限。	Q	N/A	N/A	The control system design standard and requirement of this project is based on the client's URS about Process Automation System(DCS). 本项目控制系统设计标准与要求，基于客户的工艺自控系统（DCS）用户需求标准。	
110	The system shall consist of Phases (& Recipes, if required) which will fulfill the process requirements described in sections 3 of this document and process description document. 系统必须由满足工艺需求的步骤（和配方，如要求）组成，工艺需求已在本文件第三章和工艺描述文件中进行了说明。	Q	N/A	N/A	The control system design standard and requirement of this project is based on the client's URS about Process Automation System(DCS). 本项目控制系统设计标准与要求，基于客户的工艺自控系统（DCS）用户需求标准。	
111	The control system is required to produce its own batch reports. The Supplier is to advise on the capability of their off the shelf control system to generate customized batch reports.	Q	N/A	N/A	The control system design standard and requirement of this project is based on the client's URS about Process Automation System(DCS). 本项目控制系统设计标准与要求，基于客户的工艺自控系统（DCS）用户需	

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	控制系统需要能够生成批报表。供应商能基于项目的控制系统对客户定制的批报告提供建议。				求标准。	
5112	The reports shall be in the PDF format. 批报告应采用 PDF 格式。	Q	N/A	N/A	The control system design standard and requirement of this project is based on the client's URS about Process Automation System(DCS). 本项目控制系统设计标准与要求，基于客户的工艺自控系统（DCS）用户需求标准。	
5113	Alarms and events shall be configured in a manner to allow the filtering of GMP critical data. 报警与事件可以采用配置的方式来筛选出 GMP 的关键数据。	Q	N/A	N/A	The control system design standard and requirement of this project is based on the client's URS about Process Automation System(DCS). 本项目控制系统设计标准与要求，基于客户的工艺自控系统（DCS）用户需求标准。	
5114	Alarms shall be generated in the controller and shall only be active when the phase or sequence generating the alarm is operational. Alarms shall not be generated in the SCADA or HMI software. 报警应由现场控制器中生成，且只能在产生报警的阶段或功能运行时才能激活，而不能在上位机 SCADA 或触摸屏 HMI 中产生报警信号。	Q	N/A	N/A	The control system design standard and requirement of this project is based on the client's URS about Process Automation System(DCS). 本项目控制系统设计标准与要求，基于客户的工艺自控系统（DCS）用户需求标准。	
5115	On alarm, an audible alert shall sound, with appropriate indication on the HMI. 报警出现时，发出声音报警，并在 HMI 上显示相应的指示。	Q	N/A	N/A	The control system design standard and requirement of this project is based on the client's URS about Process Automation System(DCS). 本项目控制系统设计标准与要求，基	

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					于客户的工艺自控系统（DCS）用户需求标准。	
5116	The CIP skid control system interfaces to the: CIP 模块控制系统接口： – Utility system 公用工程 – Process equipment controller via DP. 采用 DP 通讯与工艺设备控制器通讯。	C	N/A	N/A	The control system design standard and requirement of this project is based on the client's URS about Process Automation System(DCS). 本项目控制系统设计标准与要求，基于客户的工艺自控系统（DCS）用户需求标准。	
5117	The POU valve of PW or WFI loop on CIP skid will be opened directly by CIP skid when necessary. 必要时在 CIP 模块中就可以打开 PW 和 WFI 供水回路中用户取点的阀门。	Q	P&ID （ DS1-CIP02/ DS1-CIP03/ DS1-CIP05）	E01-203201-1-164~ E01-203201-1-166	The POU valve of PW or WFI loop on CIP skid design as directly open in DCS when necessary. CIP 模块中的 PW 和 WFI 供水回路中用户取点的阀门设计为在必要时直接在 DCS 系统内打开。	
5118	The interface to the process equipment packages to co-ordinate the transfer of CIP fluids to/from the process equipment packages. 与工艺设备的接口包括 CIP 流入和流出工艺设备的管路配套工程包。	Q	P&ID（DS1-CIP02/ DS1-CIP03/ DS1-CIP05）	E01-203201-1-164~ E01-203201-1-166	The interface to the process equipment packages to co-ordinate the transfer of CIP fluids to/from the process equipment packages. 与工艺设备的接口包括 CIP 流入和流出工艺设备的管路配套工程包。	

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5119	Process system set CIP request to CIP station. CIP station set ready signal to process system to start CIP. CIP recipe is stored in DCS. 工艺系统向 CIP 站发出请求，CIP 站发出信号表明 CIP 站已经准备完毕，可以开始进行 CIP 清洗操作。清洗配方储存在 DCS 中。	Q	FS(EM_CIP)	PP20-0098-T-010281_EM_CIP	CIP phase set command to EMs of CIP station,and wait for EM status feedback ready to start CIP.CIP recipe is stored in DCS. 清洗程序向 CIP 站的 EMs 发出命令，且等待 EM 状态反馈准备就绪，开始进行 CIP 清洗操作。清洗配方储存在 DCS 中。	
5120	The Control Panel shall be provided as part of the overall CIP skid. 控制柜属于整个 CIP 模块的一部分。	Q	平面布置图 Layout Drawing	PP20-0098-T-009620 PP20-0098-T-009622 PP20-0098-T-009626	The Control Panel shall be provided as part of the overall CIP skid. 控制柜设计在整个 CIP 模块的一部分	
5121	The CIP skids control panel shall contain but not be limited to the following: CIP 控制柜应包括但不限于以下内容： – Process Controller 过程控制器 – Operator Interface Terminal shall be at least 15” operator panel with membrane touch or touch screen 操作员界面至少 15“及以上的 HMI，带有薄膜式或触摸界面。 – Input /Output Cards: The use of remote I/O termination modules is acceptable 输入/输出卡：可以使用远程 I / O 端接模块 – The control system may include an Ethernet	Q	Charm IO 柜的图纸 The Drawing of Charm IO Panel	3287830-DWG-AC-SA-48NIS-A	The CIP skids control panel shall contain but not be limited to the following: CIP 控制柜应包括以下内容： Process Controller 过程控制器 Operator Interface Terminal shall be at least 21.5” operator panel with touch screen HMI 操作员界面 21.5“，带有触摸界面。 Input/output card: Remote I/O terminal module is used 输入/输出卡：使用远程 I / O 端接模块 The control system may include an Ethernet communication module for interface to Utility system and process equipment interface 控制系统包括一个以太网通讯模块与公用工程和工艺设备接口。 Power Supply to CPU and HMI/ CPU 与 HMI 的供电 E-Stop pushbutton on panel door and HMI	

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	communication module for interface to Utility system and process equipment interface 控制系统包括一个以太网通讯模块与公用工程和工艺设备接口。 – Power Supply to CPU and HMI/ CPU 与 HMI 的供电 – E-Stop pushbutton on panel door and HMI 控制柜和 HMI 设有急停按钮				控制柜和 HMI 设有急停按钮	
5122	The HMI shall be mounted on the control panel, which shall be suitable for continuous use and shall be easily accessible. HMI shall be suitable for use while operator is wearing latex gloves 人机界面应安装在控制柜面板上，该面板应适合连续使用且应易于操作。 HMI 应可以在操作员戴着乳胶手套条件下使用。	C	N/A	N/A	The HMI is mounted on the control panel, which is suitable for continuous use and shall be easily accessible. HMI are suitable for use while operator is wearing latex gloves 人机界面安装在控制柜面板上，该面板适合连续使用且应易于操作。 HMI 可以在操作员戴着乳胶手套条件下使用。	
5123	The e-stop shall be located on the CIP skid control panel and instrument control panel. When the e-stop is activated, power shall be removed from all outputs e.g. motors and valves. The e-stop shall not affect the power to the controller or HMI. 急停按钮应装在 CIP 模块控制柜和仪表柜中，急停被激活，应能切断输出回路的电源（如电机与阀门），紧急停止并不能影响控制器与 HMI 的供电。	Q	Charm IO 柜图纸 The Drawing of Charm IO Panel HMI 图纸艾默生还未提供	3287830-DWG-AC-SA-48NIS-A	The emergency stop button shall be installed on the HMI panel of CIP module and on site. The control cabinet and HMI are powered by the PDP cabinet， When the e-stop is activated, power can removed from all outputs e.g. motors and valves. The e-stop have not affect the power to the controller or HMI. 急停按钮应装在 CIP 模块的 HMI 面板上、现场，急停被激活，应能切断输出回路的电源（如电机与阀门），控制柜和 HMI 的供电来自于 PDP 柜。紧急停止并不能影响控制器与 HMI 的供	

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					电。	
5124	All instrumentation used on the skids will be sourced from reputable suppliers with a proven track record in the bio-pharmaceutical industry. 所有仪表必须是知名供应商产品，信誉度好，生物制药行业有良好记录的供应商 Instrumentation shall be provided that will be capable of monitoring and/or controlling the following process conditions: 仪表能够监控或控制以下工艺条件： – Flow CIP supply /CIP 供应管路流量 – Pressure CIP supply /CIP 供应管路压力 – Temperature CIP supply and return /供水及回水管路温度 – Conductivity CIP supply and return /供水或回水管路电导率 – Tank level 罐液位	Q	仪表索引表 Instrument List	PP20-0098-T-009489	All instrumentation used on the skids are sourced from reputable suppliers with a proven track record in the bio-pharmaceutical industry. 所有仪表是知名供应商产品信誉度好，生物制药行业有良好记录的供应商 Instrumentation is provided that will be capable of monitoring and/or controlling the following process conditions: 仪表能够监控或控制以下工艺条件： Flow CIP supply /CIP 供应管路流量 Pressure CIP supply /CIP 供应管路压力 Temperature CIP supply and return /供水及回水管路温度 Conductivity CIP supply and return /供水或回水管路电导率 Tank level 罐液位	
5125	The flow rates of the CIP liquid shall be measured with a metal rotor flowmeter. Each flow meter shall be supplied and installed with its display oriented for ease of	Q	转子流量计数据表 PP20-0098-T-000136	PP20-0098-T-000136	The flow rates of the CIP liquid are measured with a metal rotor flowmeter. Each flow meter is supplied and installed with its display oriented for ease of readability. The flow measurement is	

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	readability. The flow measurement shall be used for controlling the flow rate of the CIP supply. CIP 供水管路应采用转子流量计，每台流量计都带显示屏。流量测量值用来控制 CIP 供水的流量				used for controlling the flow rate of the CIP supply. CIP 供水管路采用转子流量计，每台流量计都带显示屏。流量测量值用来控制 CIP 供水的流量	
126	A pressure transmitter shall be provided on the CIP supply. The pressure measurement shall be used for controlling the pressure of the CIP supply. CIP 供水管路设有压力变送器，压力测量值用来控制 CIP 管路供水压力	Q	P&ID（DS1-CIP02/ DS1-CIP03/ DS1-CIP05）	E01-203201-1-164~ E01-203201-1-166	The pressure transmitter is provided on the CIP supply. The pressure measurement can be used for controlling the pressure of the CIP supply. CIP 供水管路设有压力变送器，压力测量值可用来控制 CIP 管路供水压力	
127	A non-sanitary pressure gauge shall be provided on the plant steam supply. 工业蒸汽管路应装设非卫生型压力表	C	温度计数据表 Temperature Datasheet	PP20-0098-T-000963	A non-sanitary pressure gauge are provided on the plant steam supply，Thread pressure gauge. 工业蒸汽管路装设非卫生型压力表，螺纹压力表。	
128	Temperature supply: The measurement shall be used for controlling the temperature controller using plant steam supply to the heat exchanger. The temperature must also be used for compensating the CIP supply conductivity measurement. 供水温度：温度测量用于控制热交换器的工业蒸汽量。温度测量也用于计算 CIP 站电导率测量的补偿量	Q	P&ID（DS1-CIP02/ DS1-CIP03/ DS1-CIP05）	E01-203201-1-164~ E01-203201-1-166	The CIP temperature supply supply measurement can be used for controlling the temperature controller using plant steam supply to the heat exchanger. And it also can be used for compensating the CIP supply conductivity measurement. CIP 供水温度测量可以用于控制热交换器的工业蒸汽量。温度测量也可以用于计算 CIP 站电导率测量的补偿量	
129	Temperature return: The measurement shall be used for measuring the CIP return liquid. 回水温度：用来测量 CIP 回流的温度	Q	P&ID（DS1-CIP02/ DS1-CIP03/ DS1-CIP05）	E01-203201-1-164~ E01-203201-1-166	The CIP temperature return measurement can be used for measuring the CIP return liquid. CIP 回水温度可以用来测量 CIP 回流的温度	

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130	Conductivity supply: The measurement shall be used for securing that the mixed caustic or acid solution is inside the specified ranges and will measure ms/cm. The conductivity must be compensated according to temperature. The compensation must be based on a separate temperature measurement and not the internal measurement in the instrument. 供水电导率：用来测量 CIP 站配酸或配碱混合后溶液达到设定的合格范围，测量范围为 ms/cm；电导率必须带有温度补偿功能，温度补偿的温度必须要求独立的温度测量，而不仅是电导率仪表内部的补偿	Q	电导率仪数据表 Conductivity Meter Datasheet	PP20-0098-T-000063 PP20-0098-T-000064	Conductivity supply: The measurement is used for securing that the mixed caustic or acid solution is inside the specified ranges and will measure ms/cm. The conductivity is compensated according to temperature. The compensation is based on a separate temperature measurement , The pipe is equipped with temperature transmitter ,and not the internal measurement in the instrument. 供水电导率：用来测量 CIP 站配酸或配碱混合后溶液达到设定的合格范围，测量范围为 ms/cm；电导率带有温度补偿功能，温度补偿的温度有独立的温度测量，管道上配有温度变送器，而不仅是电导率仪表内部的补偿	
131	Conductivity return: The measurement shall be used for verification of final rinse (µS/cm) 回水电导率：测量用于最终漂洗效果的验证(µS/cm)	Q	P&ID（DS1-CIP02/ DS1-CIP03/ DS1-CIP05） 电导率数据表	E01-203201-1-164~ E01-203201-1-166 PP20-0098-T-000063	The CIP Conductivity return measurement can be used for verification of final rinse. 回水电导率可以测量用于最终漂洗效果的验证	
132	The tank level shall be measured for controlling the added amount of water into the CIP tank. Pressure differential type level transmitter and sanitary level switches will be used. 测量罐内液位来控制 CIP 罐的进水量，采用差压式液位变送器或卫生级液位开关	Q	P&ID（DS1-CIP02/ DS1-CIP03/ DS1-CIP05）	E01-203201-1-164~ E01-203201-1-166	The tank level are measured for controlling the added amount of water into the CIP tank. Pressure differential type level transmitter and sanitary level switches is used. 测量罐内液位来控制 CIP 罐的进水量，采用差压式液位变送器。	
133	3Ph, 380V, 50 Hz 1Ph, 220V, 50Hz	C	MCC 柜图纸 The Drawing of MCC Panel	MCC-DS1-CIP-001	3Ph, 380V, 50 Hz 1Ph, 220V, 50Hz	

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5134	Power supply shall be brought by owner to each main power cabinets only. All cables between control cabinets for machines shall be supplied by the supplier. Cable tray inside the skids shall be provided by supplier. The cables inside the scope of suppler shall be laid down by supplier. All cables shall be LSZH flame retardant cable The use of connectors shall be maximizing with the advantage of reduced installation time by having a reliable connection on the equipment. 电源将由业主送到每个主电源柜。所有机器的控制柜之间的电缆应由供应商提供。 模块内的电缆桥架应由供应商提供。供应商的范围内的电缆应由供应商敷设。 所有电缆应无卤低烟阻燃电缆 利用在设备上有可靠连接的连接器，其使用应最大程度地减少安装时间	C	电缆表	PP20-0098-T-009646 PP20-0098-T-000826	Power supply is brought by owner to each main power cabinets only. All cables between control cabinets for machines is supplied by the supplier. Cable tray inside the skids are provided by supplier. The cables inside the scope of suppler is laid down by supplier. All cables is LSZH flame retardant cable Make use of the WAIN multi-core connector on the device, easy to use and install. 电源由业主送到每个主电源柜。所有机器的控制柜之间的电缆由森松提供。 模块内的电缆桥架由森松提供。森松的范围内的电缆由森松敷设。 所有电缆应无卤低烟阻燃电缆 利用在设备上有 WAIN 多芯的连接器，使用，安装便利。	
5135	Design and construction of panels shall be in accordance with Local Standards or IEC equivalent code. Emergency Stop switches compliant with CE requirements must be provided. The power cabinet, includes all the necessary components to ensure the safe operation of the plant,	C	MCC 柜图纸 The Drawing of MCC Panel	MCC-DS1-CIP-001	Design and construction of panels could be in accordance with Local Standards or IEC equivalent code. Emergency Stop switches compliant with CE requirements could be provided. The power cabinet, includes all the necessary components to ensure the safe operation of the plant, such as: Thermal protector for each motor. Contactor for each motor and heater.	

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	such as: – Magneto-thermal Mains switch. – Thermal protector for each motor. – Contactor for each motor and heater. – Power supplies for the control equipment. – Signal converters for the different sensors – Interconnecting terminals. Live parts of electrical equipment (e.g. junction boxes, panel boxes, receptacle outlets, equipment cabinets, etc.) and/or junction points shall be provided with proper covers. Panels of cabinets shall be designed and built to meet the specified area classification. Unless otherwise specified all electrical cabinets and panels shall be IP54 or better. 面板的设计和建造应符合当地标准或 IEC 等效代码。 必须提供符合 CE 要求的紧急停止开关。 电力柜，包括所有必要的组件，以确保工厂的安全运行，如： – 热磁电源开关。 – 每个电机的热保护器。 – 每个电机和加热器的接触器。 – 控制设备的电源。				Power supplies for the control equipment. Signal converters for the different sensors Interconnecting terminals. Live parts of electrical equipment (e.g. junction boxes, panel boxes, receptacle outlets, equipment cabinets, etc.) and/or junction points is provided with proper covers. Panels of cabinets is designed and built to meet the specified area classification. Unless otherwise specified all electrical cabinets and panels is IP54 . 面板的设计和建造应符合当地标准或 IEC 等效代码。 提供符合 CE 要求的紧急停止开关。 电力柜，以下组件，以确保工厂的安全运行，如： 每个电机的热保护器。 每个电机和加热器的接触器。 控制设备的电源。 不同传感器的信号转换器 互连终端。 带电设备（如接线盒、面板盒、插座、设备柜等）和/或连接点的带电部分有适当的覆盖物。柜面板设计和建造，以满足指定区域的分类。除非另有说明，所有电气机柜及面板满足 IP54.	

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	– 不同传感器的信号转换器 – 互连终端。 带电设备（如接线盒、面板盒、插座、设备柜等）和/或连接点的带电部分应有适当的覆盖物。柜面板应设计和建造，以满足指定区域的分类。除非另有说明，所有电气机柜及面板应满足 IP54 或更高标准					
5136	Identify both ends of cables using slide on plastic markers with the same identification as shown on the wiring diagrams and terminals. Enclose cabling in slotted plastic trunking to 60% capacity of trunking only. Termination to external equipment must be via terminals. Connect all incoming and outgoing mA, mV and 24V signals to disconnect terminals type. Connect no more than two cores to one side of any terminal. Terminals shall be identified with the same identity as shown on the wiring diagrams. The cable tray in skid shall be closed type and ease of cleaning. 识别电缆两端塑料标志，其标识与接线图和接线端子相同。将槽形塑料槽中的电缆封闭到仅 60%的中继容量。 对外部设备的终止必须通过终端。将所有传入和传出的 mA，MV 和 24V 信号断开端子型。 任何终端的两个核心到一边。接线端子应与接线图上	C	电气图纸 Electrical Drawing 端接表 Termination List	PP20-0098-T-009475 MCC-DS1-CIP-001	Identify both ends of cables using slide on plastic markers with the same identification as shown on the wiring diagrams and terminals. Enclose cabling in slotted plastic trunking to 60% capacity of trunking only. Termination to external equipment is via terminals. Connect all incoming and outgoing mA, mV and 24V signals to disconnect terminals type. Connect no more than two cores to one side of any terminal. Terminals is identified with the same identity as shown on the wiring diagrams. The cable tray in skid is closed type and ease of cleaning. 识别电缆两端塑料标志，其标识与接线图和接线端子相同。将槽形塑料槽中的电缆封闭到仅 60%的中继容量。 对外部设备的终止是通过终端，将所有传入和传出的 mA，MV 和 24V 信号断开端子型。 任何终端的两个核心到一边。接线端子与接线图上所示的标识相同。 模块的电缆桥架使用密闭式的并易于清洁	

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	所示的标识相同。 模块的电缆桥架应使用密闭式的并易于清洁					
5137	Ensure all equipment items are fully earth bonded. Provide an M6 earth stud on the inside and outside of metallic control panels and junction boxes for connection to the main earth system. Provide an earth bar inside control panel insulated from the panel, for signal earths and screens of external cables. 确保所有设备都是完全接地的。 在金属控制板和接线盒的内部和外部安装一个 M6 接地螺栓，以便连接到主接地系统。在控制面板上为接地电缆和外部电缆提供绝缘板	C	接地图 Grounding Layout 电气图纸 Electrical Drawing	PP20-0098-T-009432 PP20-0098-T-009628 PP20-0098-T-009630 MCC-DS1-CIP-001	all equipment items are fully earth bonded. Provide an M6 earth stud on the inside and outside of metallic control panels and junction boxes for connection to the main earth system. Provide an earth bar inside control panel insulated from the panel, for signal earths and screens of external cables. 所有设备都是完全接地的。 在金属控制板和接线盒的内部和外部安装一个 M6 接地螺栓，以便连接到主接地系统。在控制面板上为接地电缆和外部电缆提供绝缘板.	
5138	The supplied design must compliance with all applicable safety, health codes and industrial standards of China or manufacturer-location zone. The supplied equipment shall have guards to prevent injuries from moving parts, sharp edges, flying chips, electric shocks, sparks and burns, and to ensure that no objects will fall into the moving parts. All elements, which are required for operational reasons, must be easily accessible from the production room and comply with cGMP. External surface temperature with insulation shall be	C	管道设计说明 设备布置图 2 楼设备模块布置图 泵数据表	PP20-0098-T-010289 PP20-0098-T-009514 PP20-0098-T-009525 PP20-0098-T-009529 PP20-0098-T-009530 PP20-0098-T-009551 PP20-0098-T-009552 2 楼设备模块布置图 PP20-0098-T-000082~84	按照国家规范和标准进行模块的设计。 CIP 站以模块化进行设计，罐、泵、换热器等设备均布置在模块内部，收到一定的保护。 根据厂房布置图，洁净室隔墙厚度为 50mm，穿墙套管将按照这个规格进行设计。 CIP 站所在的技术间内，CIP 模块有序布置，有足够的操作检修通道。 CIP Pump conform to an average of <75 dBA weighted scale and peak	

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	lower than 45°C during all phases. Hot spots access shall be signaled and protected. All equipment shall conform to an average of <75 dBA weighted scale and peak noise of 80 dBA when measured at 1 meter in any direction from the equipment when operating at all maximum loads and speeds. 提供的设计必须符合所有适用的安全，健康法规和中国工业标准或当地标准。 所提供的设备应有防护装置，以防止移动部件、尖锐边缘、飞片、电击、火花和烧伤造成的伤害，并确保没有物体落入运动部件。 供应商提供的密封面板或密封环在房间之间。洁净室隔断厚度为 50mm。 所有由于操作原因所必需的元件，必须从生产房间容易进入，并遵守 cGMP。 在所有阶段，外部表面绝缘温度应低于 45°C。热点接入应标识并加以保护。 所有设备在所有的最大负荷和速度下运行时，在任何方向上 1 米范围外测量应满足平均 75 分贝，峰值 80 分贝噪声				noise of 80 dBA when measured at 1 meter in any direction from the equipment when operating at all maximum loads and speeds. CIP 泵在所有的最大负荷和速度下运行时，在任何方向上 1 米范围外测量应满足平均 75 分贝，峰值 80 分贝噪声。	
5139	The owner approved P&ID for construction will be provided. The P&ID shall be updated if changes occurred during the execution of the project. The final as-built P&ID will be sent to owner for approval prior FAT.	I	N/A	N/A	N/A	

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	业主将提供批准的 P&ID 建造图纸。如在项目执行过程中发生变更，应更新 P&ID 编号。在 FAT 之前最后的竣工 P&ID 图纸将被提交给业主批准					
140	Supplier shall design and deliver the process documents, eg Tag List, Datasheet, Calculation Sheets etc based on the provided P&IDs. 根据所提供的 P&ID，供应商应设计和交付过程文件，如标签清单，数据表，计算表等	I	N/A	N/A	N/A	
141	Templates of ISO and ISA standardized datasheet are provided by owner. The CIP skid supplier shall design datasheet for verifying all individual component and instrumentation shown on P&IDs. ISO 和 ISA 标准数据表的模板由业主提供。CIP 模块供应商应设计数据表，以验证所有显示在 P&IDS 上的单个组件和仪表	I	N/A	N/A	N/A	
142	In a cost or time effective issue, Supplier may change to use different sub-supplier, or model of equipment. However, specification has to be approved by owner or its Engineering Consultant prior to use. 处于成本或时间上的考虑，供应商可能会变更使用不同的子供应商，或设备型号。但是，规格标准必须经过业主或其工程顾问批准	I	N/A	N/A	N/A	

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5143	Moreover, instrumentation datasheet shall be approved by owner appointed process automation system supplier to make sure the connectiability of electrical signal and IA, as well as the effective control abilities on them. However, process fluidic and sanitary characteristics shall be verified by CIP skid supplier. 此外，仪表数据表应由业主指定的过程自动化系统供应商的批准，确保电气信号和 IA 的连接性，以及对其有效的控制能力。但是，工艺流体和卫生特性应由 CIP 模块供应商验证	I	N/A	N/A	N/A	
5144	Risk analysis on the systems within scope of work (Failure mode and effects analysis, FMEA) 对工作范围内的系统进行风险分析（失效模式和影响分析，FMEA）	I	N/A	N/A	N/A	
5145	Prior to the performance of fabrication, the supplier must complete the design qualification. The supplier shall develop a design qualification protocol for owner's review and approval before execution. 在制造之前，供应商必须完成设计确认。供应商应在执行前制定业主审查和批准的 DQ 方案	I	N/A	N/A	N/A	
5146	Prior to the fabrication, the fabrication level GA (General Arrangement of system) in 3D model shall be designed by the supplier based on the P&IDs provided by owner.	I	N/A	N/A	N/A	

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	在制造之前，应由供应商根据业主提供的 P&ID 进行制造级别的三维模型图纸设计（GA 系统整体布置）					
147	The 3D model shall show actual equipment / components dimension, connection type and location etc for final fabrication with compliance to the dedicated equipment / component installation requirements. 三维模型应显示实际的设备/部件尺寸、连接类型和位置等，以便按照专用设备/部件安装要求进行最终制造	I	N/A	N/A	N/A	
148	3D GA shall be approved by owner, and the Vessel Drawinging as well. 三维应该被客户批准，容器图纸也需要被批准	I	N/A	N/A	N/A	
149	The supplier shall develop a Quality Plan for owner's review and approval. 供应商应制定质量计划，供业主审查和批准	I	N/A	N/A	N/A	
150	Before system to be delivered. The plan shall be provided and approved. 在交付系统之前。应提供并批准该计划	I	N/A	N/A	N/A	
151	All system has to be accepted by a Factory Acceptance Test (FAT) executed in the supplier's workshop or factory before delivery.	C	N/A	N/A	将在 FAT 时测试	

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	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 indicate which tests will be witnessed by them. The system will only be released for delivery when all FAT documents are closed out by the owner. Following are some work need to be carried out before FAT. – 100% Drawings checks – P&ID compliance check – GA compliance check – Pneumatic/vacuum testing of vessels & pipeworks. – Material of construction verification. – Surface finish verification. Check on condition of process surfaces including planarity, surface roughness, and drainability etc. – Slope verification. – All items tagged and labelled as per specification – Documentation check; all documents – 所有系统必须接受出厂验收测试（FAT），交货前在供应商车间或工厂执行。					

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	FAT 文件是由供应商准备的，在 FAT 之前由业主批准。供应商应在其工厂进行测试，业主将指定他们将见证哪些测试。 只有当所有的 FAT 文件被业主关闭时，系统模块才会放行发货。 下面一些工作需要在 FAT 之前进行。 – 100%图纸检查 – P&ID 符合检查 – GA 符合检查 – 容器和管道系统压力/真空试验 – 施工材料验证。 – 表面光洁度验证。检查工艺条件包括表面粗糙度、表面平整度、排尽等， – 坡度确认。 – 所有项目标记和标签按规格 – 文件检查；所有文件					
5152	During the FAT, a fault log and comment/deviation log must be issued documenting any issues that have been raised/ observed during FAT on a daily basis. The FAT shall include, but not be limited to, the following	C	N/A	N/A	将在 FAT 时测试	

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	tests: – Fabrication & assembly inspection – Including mechanical verification and dimension verification to approved drawings, P&ID walk down and components inspection, Insulation and labeling, Welding, Slope verification, Dead-leg absence check in process piping, Drainability, Installation orientation etc. – Riboflavin spray coverage test – Components operation performance – Documents, certificates, specifications verification – Instrument calibration (excludes disposable sensors) – Control system functional testing (I/O test, Trend, Alarm) – Software module structural testing – HMI operational testing – Performance test 在 FAT 期间，必须记录一份故障日志和评论/偏差日志，记录每天在 FAT 中发现/观察到的任何问题。 FAT 应包括但不限于以下试验： – 制造和装配检验 – 包括机械检验和批准图纸的尺寸验证、工					

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	艺管道、排放管道、安装定位等的 P&ID 符合，部件的检验，保温，焊接，坡度验证，死角检查。 – 核黄素喷淋球全覆盖试验 – 组件运行性能 – 文件、证书、规格说明 – 仪表校验（不包括一次性传感器） – 控制系统功能性测试（I/O 测试，趋势图，报警） – 软件模型结构测试 – HMI 操作测试 – 性能测试					
5153	The commissioning stage shall include calibration, loop tuning and all other adjustments required to ensure the equipment performs as specified in the requisition. The supplier shall be responsible for executing all stages of commissioning, with support as required from the Site Construction team. The supplier shall estimate the number of days required to complete the commissioning and quote a daily rate for Site attendance. 调试阶段需要包括校准，loop tuning 以及所有其他的调整使其按照要求运行。供应商在总包商的帮助下，	I	N/A	N/A	N/A	

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	需要在整个调试阶段对其负责。供应商应该预估整个调试过程所需的时间，并且需要提供现场人工的单位报价					
154	A Commissioning Manual including all checklists, test methods and procedures shall be submitted for review and approval prior to execution. 调试手册应包含所有的目录清单，测试方法和工序。这些在实施之前需要提交给业主审核批准	I	N/A	N/A	N/A	
155	The equipment operation manual should be provided before commissioning. 设备运行手册在调试前需要提供	I	N/A	N/A	N/A	
156	The completed commissioning shall provide documented evidence that all equipment, instruments and controls are functioning correctly. This will then be formally demonstrated by way of a SAT (Site Acceptance Test) which generally includes a repeat of the FAT plus any additional testing as required. 完整的调试需要提供文件证明所有的设备，仪表以及控制系统都满足功能。这些将会在 SAT 阶段被证明，SAT 阶段将包括重复 FAT 测试的工作和一些必须的额外测试	C	N/A	N/A	将在 SAT 时核查	

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5157	Within one month after the installation. The system SAT shall be executed by supplier and owner will be in attendance. 设备安装完成的 1 个月内。开始 SAT 工作时，业主和供应商都将在场。	I	N/A	N/A	N/A	
5158	SAT test protocols are to be prepared by the supplier and approved by owner prior to the SAT. SAT 测试工作文件有供应商准备，业主批准 SAT 文件后才开始 SAT	I	N/A	N/A	N/A	
5159	Final and successful SAT report will be provided by supplier. 最终版 SAT 文件和 SAT 报告由供应商提供	I	N/A	N/A	N/A	
5160	In general FAT tests shall be repeated. Some tests will be confirmed by spot check. 通常情况 FAT 的测试内容可能会在 SAT 阶段重复，一些测试内容需要现场确认。 – Protocols for commissioning and the site acceptance test (SAT) shall be produced by the supplier and approved by owner. 调试和 SAT 文件有供应商提供，并得到业主批准。 – Instruments calibration at site. 现场仪表校验	C	N/A	N/A	将在 SAT 时核查	
5161	IQ/OQ protocols will be prepared by supplier with owner approval and the test execution is by supplier with witness by owner. The supplier shall be responsible for troubleshooting within scope of	I	N/A	N/A	N/A	

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	work. Validation procedure and timeline refer to the VMP provided by owner at a later date. 检查文件由供应商准备并经业主审核批准。IQ/OQ 工作由业主组建的验证团队或聘请的第三方团队完成.供应商应配合业主完成 IQ/OQ 工作并及时解决出现的问题。验证程序和时间参考业主稍晚时间提供的验证主计划（VMP）					
162	The CIP skid supplier shall be responsible for executing tests during all stages of commissioning or acceptance activities, with witness as required from the owner team. Both suppliers shall take responsibility on communication and coordination with each other during design, fabrication, commissioning and qualification period for the right interface information exchange. CIP 模块供应商和业主指定的自动化供应商应负责在调试或验收活动的所有阶段执行测试，并根据业主的要求进行见证。双方供应商都有责任在设计，制造，调试和确认阶段沟通和协调正确的信息交流	I	N/A	N/A	N/A	
163	Spare parts and accessories for 2-year operation with detailed list (part no., amount, ISO no. (if applicable), price and delivery time). 2 年操作的备品备件和附件及清单（部件号，数量、ISO 图号、价格、交付时间）	C	N/A	N/A	竣工文件中包含 2 年操作的备品备件清单。	
164	The supplier shall take responsibility for all handling and lifting operations and physical assembly of process equipment components. The supplier shall be	I	N/A	N/A	N/A	

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	responsible for performing checks and tests on the equipment to confirm correct installation. The supplier shall cooperate in planning the installation work. The following work will be performed by Others: – General construction works including civil, structural and architectural. 供应商应负责所有处理和提升操作以及工艺设备部件的物理装配。供应商应负责对设备进行检查和测试，以确认安装是否正确。供应商应合作策划安装工作。以下工作将由其他人执行： – 一般建筑工程，包括土木、结构和建筑					
5165	All parts of the equipment must be readily accessible for maintenance, servicing and cleaning. The supplier shall provide lifting points for equipment that must be removed for routine maintenance. The supplier shall advise where lifting aids are required to maintain equipment. The supplier's maintenance manual shall include a preventive maintenance plan with times, frequencies and costs for each activity. The supplier shall provide drawings to show access requirements to operate and maintain the equipment. The supplier shall provide details of support available either in or close to site. 设备的所有部分必须便于检修、维修和清洁。供应商应提供设备的起吊点，以便进行日常维护。	C	N/A	N/A	将在竣工前完成检查	

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	供应商应告知在何处需要起重设备以维持设备。 供应商的维修手册应包括每项活动的时间、频率和成本的预防性维修计划。 供应商应提供图纸以显示操作和维护设备的存取要求。 供应商应提供可在现场或接近现场提供的详细资料					
166	The supplier shall include in proposal the cost of adequate training of operators, supervisors and maintenance staff. 供应商应在方案中包括对操作员、主管和维修人员进行充分培训的费用	I	N/A	N/A	N/A	
167	The supplier shall guarantee that the equipment part of the scope of supply meet design and performance requirements specified, and alter and/or replace, at his own cost, any piece of equipment which fails to meet these requirements (work and factory trained supervision necessary included). Warrant all materials and labour included here to be free from defects for a period of 24 months from date of owner. Replace any parts found defective due to manufacture and reinstall new ones at no cost to owner. The warranty period shall be calculated from the date when PQ of equipment or system is completed. 供应商应保证供应范围内的设备符合设计和性能要求，并根据自己的成本，调整和/或更换任何不能满足这些要求的设备（包括必要的工作和工厂培训）。 保证与业主商定的时间起 24 个月内，设备的材	I	N/A	N/A	N/A	

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	料和劳务不会出现缺陷。替换任何发现有缺陷的部件，由此造成的制造和安装费用与业主无关。质保期自设备或系统完成 PQ 之日起计算。					
168	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. 包装类型的使用应充分考虑到所选择的航运方式，环境因素和在运输，装卸和储存过程中可能遇到的问题	I	N/A	N/A	N/A	
169	Equipment shall be adequately protected during shipping to site. All loose parts shall be adequately boxed crated or bagged. 设备在运输至现场过程中已应充分保护。所有松散的零部件应考虑装盒，装袋或装箱	I	N/A	N/A	N/A	
170	Small items such as bolts, nuts washers, shims, packers and small items of equipment shall be provided in waterproof grit free containers. 如螺栓，螺母垫圈，垫片，设备部件等小件物品应提供无沙防水容器	I	N/A	N/A	N/A	
171	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. 所有可能转动的设备如电机，风机等，其中运动部件会由于运输振动而损坏，应根据生产厂商建议进行妥当保护	I	N/A	N/A	N/A	

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172	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 smaller equipment which contacts the process fluid shall be bagged and tagged to prevent contact with moisture and dust. 管道和管型部件应有封头防止湿气，灰尘等外界异物影响管道质量。可能会接触工艺流体的管件和小部件应袋装保护并有标识，防止其接触湿气和灰尘。	I	N/A	N/A	N/A	
173	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. 暴露的机械加工和抛光表面可以用易剥落的膜或不用试剂就可除去的化合物涂层保护。	I	N/A	N/A	N/A	
174	The method of delivery of equipment associated with this contract is to be organised with owner. 本合同中相关设备的发货方法由业主组织。	I	N/A	N/A	N/A	
175	The cost of delivery of the equipment is within the supplier’s scope of supply. 设备运输费用在供应商供货范围内。	I	N/A	N/A	N/A	
176	The cost of insurance of the equipment delivery is within the supplier’s scope of supply. 设备运输途中的保险费用在供应商供货范围内。	I	N/A	N/A	N/A	

URS 编号 URS No.	URS 描述 URS Description	URS 分类 URS Classification (Q, C, I)	设计文件名称 Design Doc. Name	设计文件编号 Design Doc. No.	设计描述 Design Description	是否可接受 Acceptable Yes 是/No 否
177	The supplier shall provide complete documents showing and describing in detail the equipment being furnished, including mechanical, construction and equipment detail, and other pertinent data as per design documents, for checking and approval. 供应商应提供完整的文件来详细展示设备生产装配过程，包括机械，结构和设备细节，以及其他相关设计数据，以备检查和批准	C	N/A	N/A	将在 FAT,SAT 时检查	
178	The supplier documentation shall contain sufficient information to enable owner to proceed with engineering activities. 供应商文件应包含足够的信息保证业主工程活动能正常开展	C	N/A	N/A	将在 FAT,SAT 时检查	
179	Number of copies in English: 英文版文件副本数： – Three (3) hard copies as "AS BUILT" documentation plus electronic form (CD). Drawings and documents shall be made in AUTOCAD and Microsoft Office. The Sub-supplier documentation that will be not available in electronic form shall be scanned. 3 份纸质文件作为"竣工"文档，另加电子版（CD）.图纸和文件分别以 AUTOCAD 和 Microsoft Office 2007 格式。分包供应商不能提供电子版文档的，应提供扫描版。 – Three (3) hard copy of Installation, Operating and Maintenance Manuals, Certification Dossier and Technical Manual in English shall be made available at site before start-up for comments/approval.	C	N/A	N/A	将在竣工前检查	

URS 编号 URS No.	URS 描述 URS Description	URS 分类 URS Classification (Q, C, I)	设计文件名称 Design Doc. Name	设计文件编号 Design Doc. No.	设计描述 Design Description	是否可接受 Acceptable Yes 是/No 否
	– 3 份纸质文件，安装，运行和维护手册，证书和技术手册，必须在现场开机前审批					
180	The supplier documents shall be written in both Chinese and English (Chinese mainly) and all units of measurement shall be metric units. 供应商文件以中英文编写（中文为主），所有测量单位为公制单位	C	N/A	N/A	将在 FAT,SAT 时检查	
181	The supplier shall adopt only his own numbering system of the drawings. 供应商采用自己的编号系统。	C	N/A	N/A	将在 FAT,SAT 时检查	
182	The supplier shall adopt only his own numbering system for lines and components. 供应商在提供的管线和组件上采用自己的编号系统。 – Equipment number 设备编号 – Supplier job number 供应商作业号 – Supplier document number and revision. 供应商文件编号和版本号 The documents will not be acceptable unless all required information is incorporated. 文件信息必须完整，才能被接受	C	N/A	N/A	将在 FAT,SAT 时检查	
183	The supplier shall provide a documented response to any technical and/or commercial issues within one (1) week from receipt of inquiry from owner. 供应商应提供的响应，可以在一周内答复对于来自业主关于技术或商业问题的询问及，响应可记录。	I	N/A	N/A	N/A	

URS 编号 URS No.	URS 描述 URS Description	URS 分类 URS Classification (Q, C, I)	设计文件名称 Design Doc. Name	设计文件编号 Design Doc. No.	设计描述 Design Description	是否可接受 Acceptable Yes 是/No 否
5184	The supplier is not relieved from his responsibility for proper detailing of the design specified on owner contract documents by approval of owner documents. 供应商有责任提供合适的详细设计说明文件直至在业主批准。	I	N/A	N/A	N/A	
URS185	The supplier is not relieved from his responsibility for satisfactory construction, compliance with the design documents and applicable codes, for errors of omissions of any kind in the final product by approval of owner of documents. 供应商有责任提供符合要求的施工，符合文件和应用规范的设计，以及任何需要提交的最终文件中遗漏的部分，直至业主批准。	I	N/A	N/A	N/A	

可接受的标准 Acceptance Criteria	是 Yes /否 No
URS 中的要求都有设计文件进行响应，且可接受。 The requirements in URS have been responded to by design documents, and the response is acceptable.	
备注 Comments：	

偏差编号 Deviation No.			
执行人 Executed by		日期 Date	
确认人 Verified by		日期 Date	

10 附件清单 APPENDIX LIST

附件编号 Appendix No.	附件描述 Appendix Description	总页数 Total page

11 执行结果的审批 EXECUTION REVIEW AND APPROVAL

设计确认活动已执行完毕，测试表格均已填写完整。结果汇总如下：

The Design Qualification activities has been executed completely, and all of DQ checklists have been fulfilled. The results of tests are summarized in the table below:

测试编号 Test No.	测试名称 Tests Name	结 论（通过/失败） Conclusion(Pass/Fail)	偏差号 Deviation #	签字/日期 Sign/Date
9.1	人员的确认 PERSONNEL IDENTIFICATION	☐Pass ☐Fail		
9.2	设计需求文件的确认 DESIGN REQUIREMENT DOCUMSNTS VERIFICATION	☐Pass ☐Fail		
9.3	设计文件的确认 DESIGN DOCUMENTS VERIFICATION	☐Pass ☐Fail		
9.4	URS 符合性的确认 URS COMPLIANCE VERIFICATION	☐Pass ☐Fail		

根据上述执行结果，本次设计确认结论如下：
Based on the above execution results, the conclusion of the DQ is as follows:

☐ 实施过程和结果符合要求。没有未解决的偏差存在。该系统被授权进行下一步确认活动。
The execution and the results fulfill the requirements. No any open deviation is present. The system has been authorized to proceed to next qualification step.

☐ 实施过程和结果不能完全符合要求。有未解决的偏差存在，但不影响确认的最终结果。该系统被授权进行下一步确认活动。
The execution and the results do not completely fulfill the requirements. Open deviations are present, but do not affect the final result of the qualification. The equipment has been authorized to proceed to next qualification step.

☐ 实施过程和结果不能符合要求。有未解决的偏差存在，且影响了确认的最终结果。该系统不能被授权进行下一步确认活动。必须采取进一步的措施。纠偏结果分别进行记录。
The execution and the results do not fulfill the requirements. Open deviations are present, and do affect the final result of the qualification. The equipment has been not authorized to proceed to next qualification step. Further measures have to take place. Corrections have to be documented separately.

备注 Comments:

_____

_____

_____

以下的签名表明设计确认已经完成。
The signatures below indicate that the DQ has been completed.

上海森松制药设备工程有限公司 **Shanghai Morimatsu Pharmaceutical Equipment Engineering Co., Ltd.**			
	职务 **Function**	**签名** **Signature**	**日期** **Date**
审核 Reviewed by	验证经理 Validation Manager		
审核 Reviewed by	设计经理 Design Manager		
信达生物制药（苏州）有限公司 **Innovent Biologics (Suzhou) Co., Ltd.**			
	职务 **Function**	**签名** **Signature**	**日期** **Date**
审核 Reviewed by			
审核 Reviewed by			
审核 Reviewed by			
审核 Reviewed by			
批准 Approved by			