



生物制药与无菌制剂的不锈钢工艺模块设计和公用设施应用案例

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- ❖ URS和FS的重要性
- ❖ 工艺设计的要点
- ❖ 公用设施设计的要点
- ❖ 模块化设计优点和缺点
- ❖ 全功能FAT的准备
- ❖ 仪表的选择和维护
- ❖ 工艺报表的设定
- ❖ 红锈问题解决探讨
- ❖ 工艺设备和公用设施的布局问题
- ❖ CIP与SIP的常见问题分析
- ❖ 验证过程管理和GMP实施的关系

后GMP改造时代的工艺设计挑战

- ❖ 手动变成自动后各种问题
- ❖ 多产品生产如CMO带来的问题
- ❖ 节能减排减废控制带来的问题
- ❖ 工艺设计新老方法交替带来的问题
- ❖ 数据完整了，工艺如何稳定的问题
- ❖ 中国式项目管理和国际式项目管理带来的问题
- ❖ 人力短缺和文化变化带来的项目实施和管理问题
- ❖ 生物制药行业的快速发展，一次性概念对传统工厂设计的挑战。模块化工厂的新生。

URS的合理性

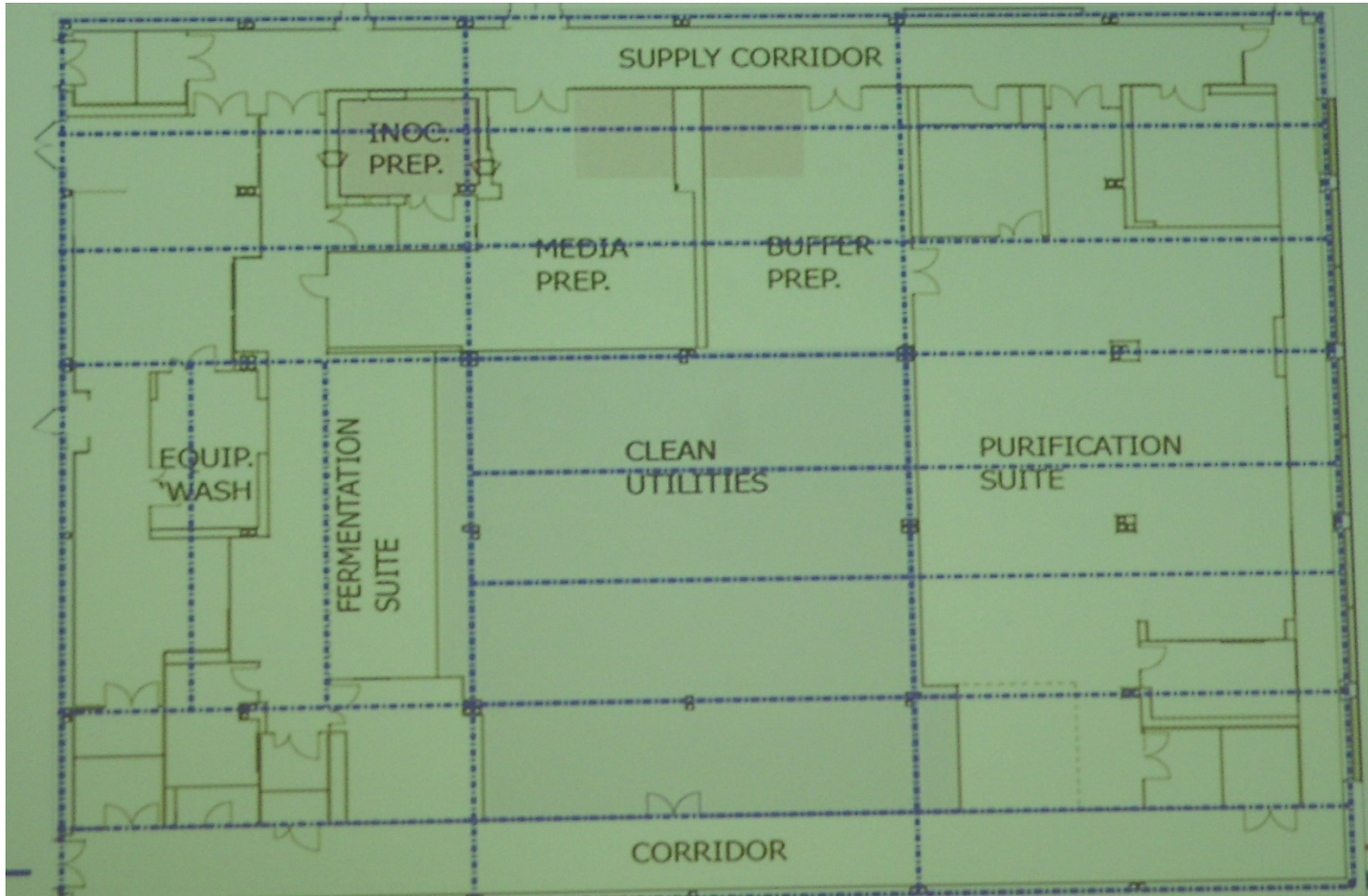
- ❖ URS是客户随心所欲的设计，还是一个模板式的任务
- ❖ URS的高度灵活性也意味着巨大的运行风险。
- ❖ URS是必须最后来回顾的。所以必须是可执行的并且可以测试的。
- ❖ 编写URS的团队应该包括工艺，生产，设备和EHS等团队。
- ❖ URS不能依靠咨询顾问完成，但是必须要有顾问给予指导
- ❖ 设备与设备之间不是隔离的单体，所以系统整合的设计非常重要
- ❖ URS提出的是需求，而不是解决方案，更不是品牌清单。
- ❖ URS对于DQ至关重要，DQ是用来认证URS的可行性和确认执行的过程的，所以没有DQ，URS就是个模板。
- ❖ URS对于自动化和系统记录的定义要切合实际。
- ❖ URS是项目执行和沟通的基础。
- ❖ URS是可以变动的，并且必须更新。但是URS的更新不是降低质量标准，而是将系统的执行更加明确
- ❖ RTM是是一个执行工具，和URS必须一一对应

- ❖ **FS**是对于系统执行的解决方案的详细描述，执行结果和**URS**相对应
- ❖ 首先是工艺流程的确认。对工艺的完整性进行复核
- ❖ 其次是各个分段模块的步骤确认。可以找到原来设计中的缺陷。
- ❖ 对于高度灵活性的系统，出错的概率和风险加大，**FS**的复杂性也很大，人为遗漏或错误步骤概率加大。
- ❖ 最后**FS**可以通过模拟测试，但是**FAT**中才会发现一些实践性问题。所以**FAT**的实际运行可以在出厂前解决不少问题。但是项目周期并不因此缩短，但是可以完善工艺。
- ❖ **FS**必须是工艺和自控人员共同完成的。
- ❖ **FS**是**DQ**的重要环节，却往往在**OQ**或者**FAT/SAT**时才来进行，所以各种不如意
- ❖ **DS**描述了系统的设计如何满足**FS**的功能，可以在**DQ**环节一起来定义完毕。
- ❖ 系统的维修维护需要在**DS**中阐述。

工艺设计的要点（设备角度）

- ❖ 设备的操作参数范围需要明确
- ❖ 自动化程度的定义清晰，全自动，半自动或者人为参与和确认的步骤
- ❖ **设备的操作空间和维护空间需要合理**
- ❖ 公用设施的需求计算需要考虑余量和节能
- ❖ 保温，平台，周边设施等设计，如何符合**GMP**，往往小东西很头疼，很花钱。
- ❖ 工艺系统的**CIP**，**SIP**能力需要在设备设计中完成
- ❖ 工艺系统的排水和干燥能力及无菌性保护，需要实用可验证。
- ❖ 工艺系统的切换操作定义（多通道阀，分配盘，两通阀等）需要防止交叉污染，同时操作简便
- ❖ 投料和上料系统的设计，简单有效。
- ❖ 灌装管道的**CIP**，**SIP**，无菌连接及管路合理排布。
- ❖ 故障退出和排除机制的设置，确保最大程度的保护产品不受到损失。

模块化设备工艺布局举例



MEDIA / BUFFER HOLD SUPERSKID

培养基/缓冲液保存 超级模块

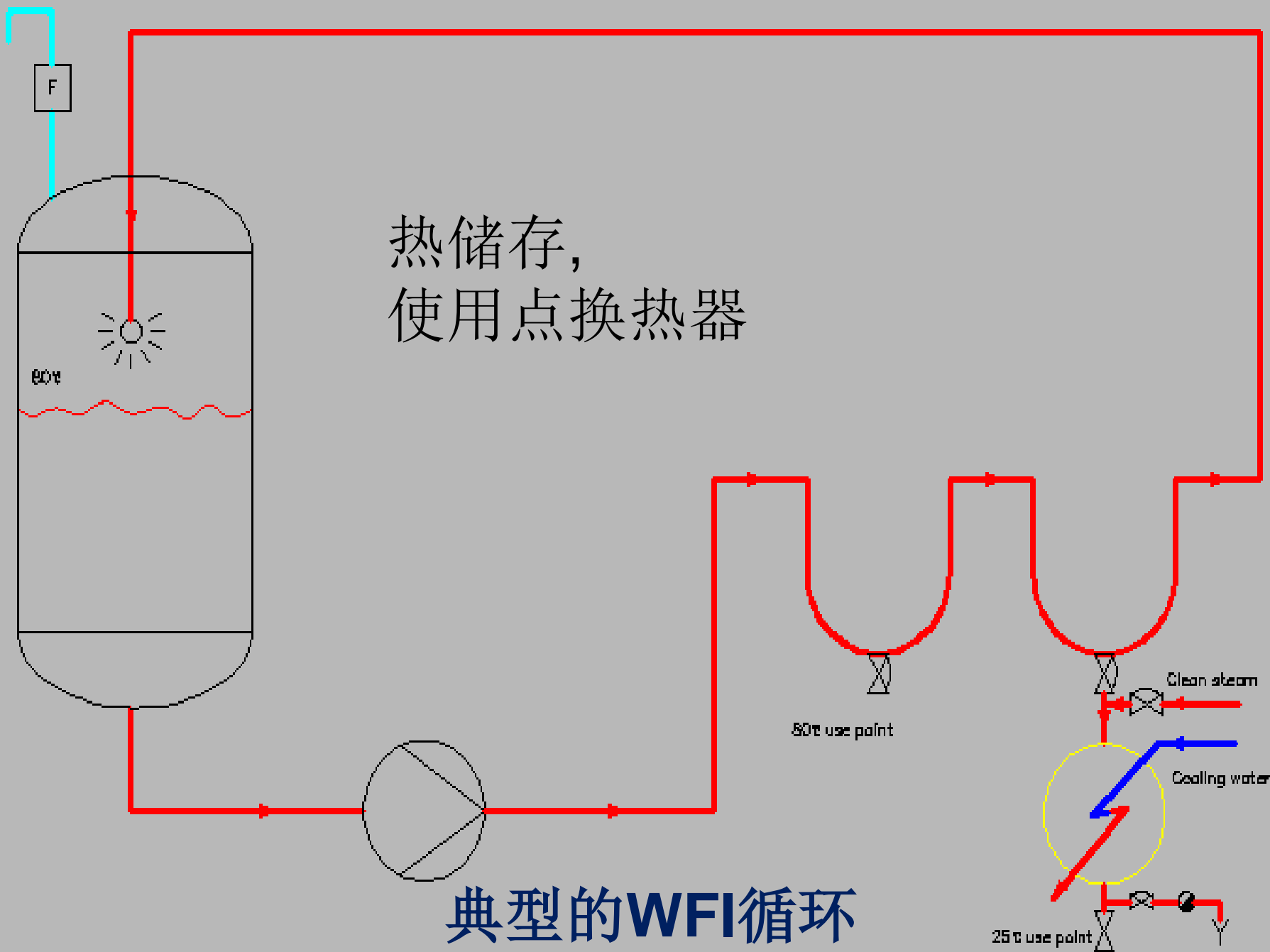


公用设施的设计要点

- ❖ 产能规划有扩展性，但是不要过于放大
- ❖ 节能措施的制定
- ❖ 生产计划的合理安排可以降低投资成本
- ❖ 公用设施的布局合理性
- ❖ 工艺设备与公用设施的连接设计是一个关键点
- ❖ 系统取样，排放，消毒的问题
- ❖ 水系统运行的合理性问题，多点系统，跨多层的系统问题
- ❖ 注射水的降温问题（规范与节能的矛盾，例子见后）
- ❖ 气站系统设计的安全性问题

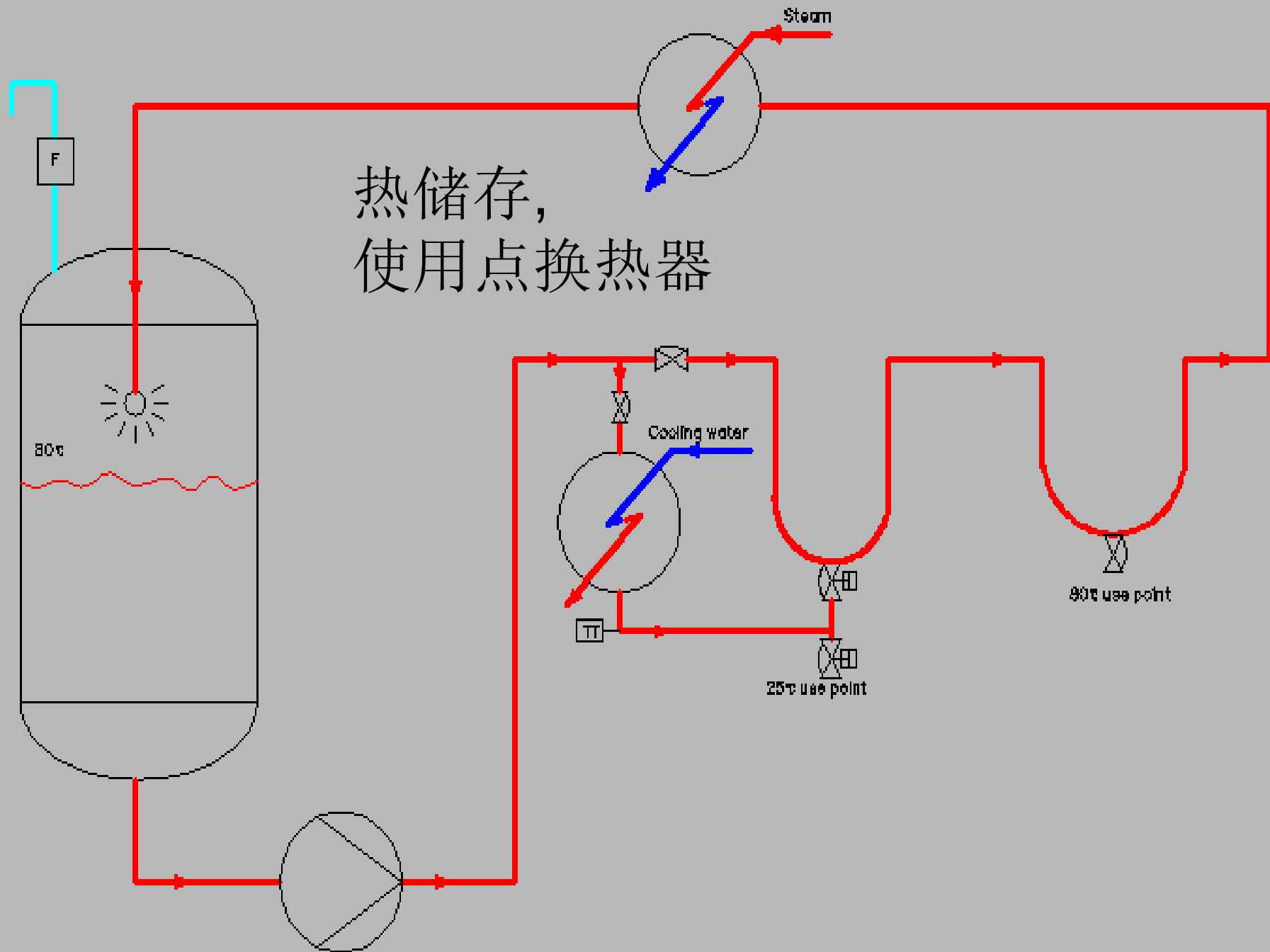
WFI用点设计

热储存，
使用点换热器



典型的WFI循环

热储存， 使用点换热器



WFI System注射用水系统

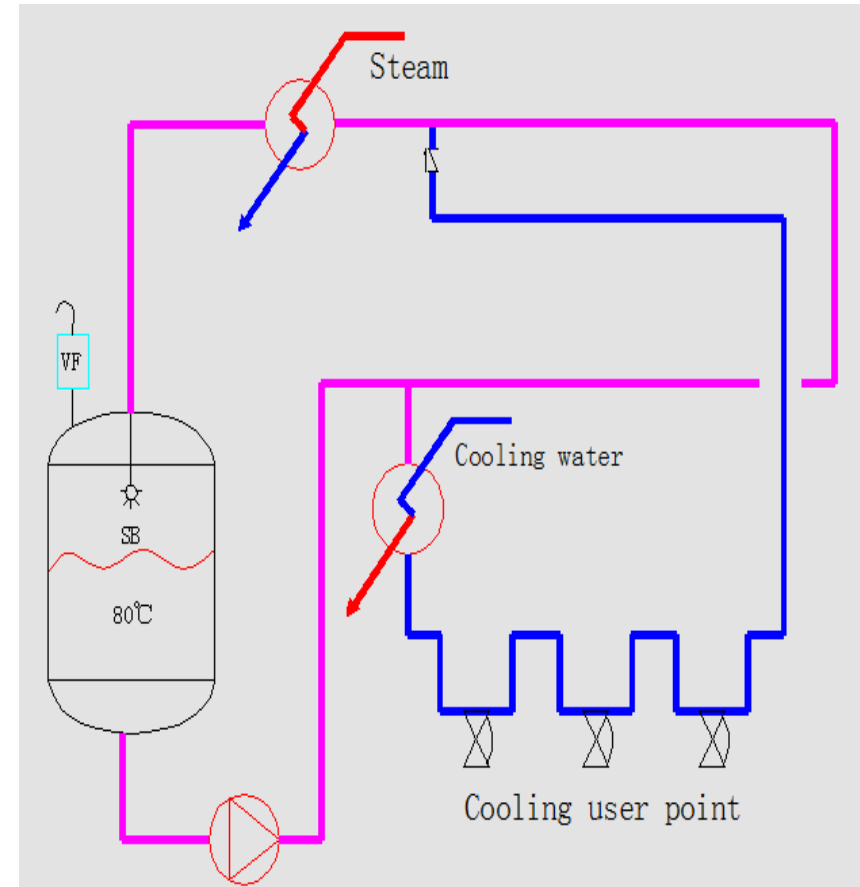
多路冷点回换热器的原因及优点

原因：

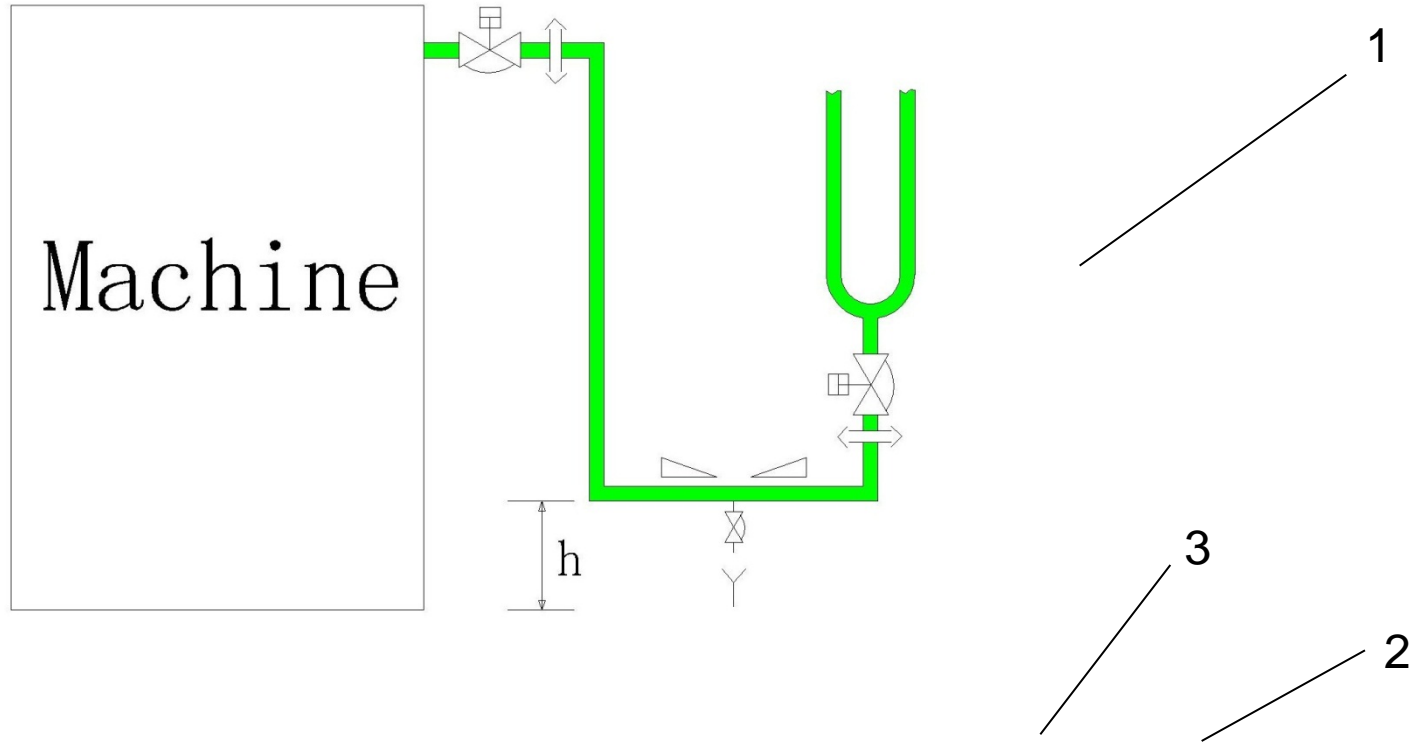
由于冷点比较多，如果每次用水结束后直接回主管道的话，会造成主管道的温度下降，这点在GMP的角度上会有很大问题，因为大面积的冷水会造成很大风险

优点：

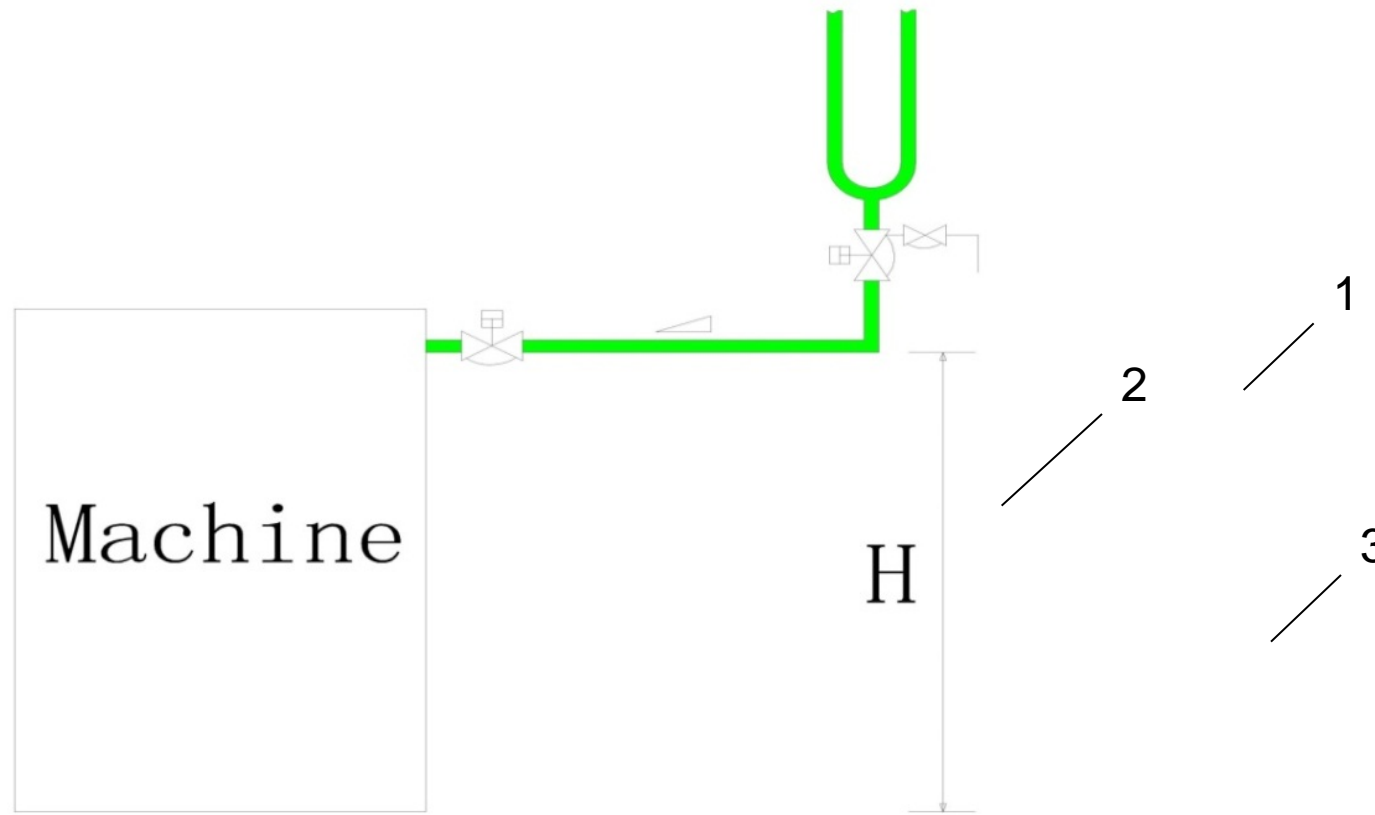
把这些冷水直接回到末端换热器的前端，这样的话 这些冷水直接通过换热器进行加热，从而使风险降到最低



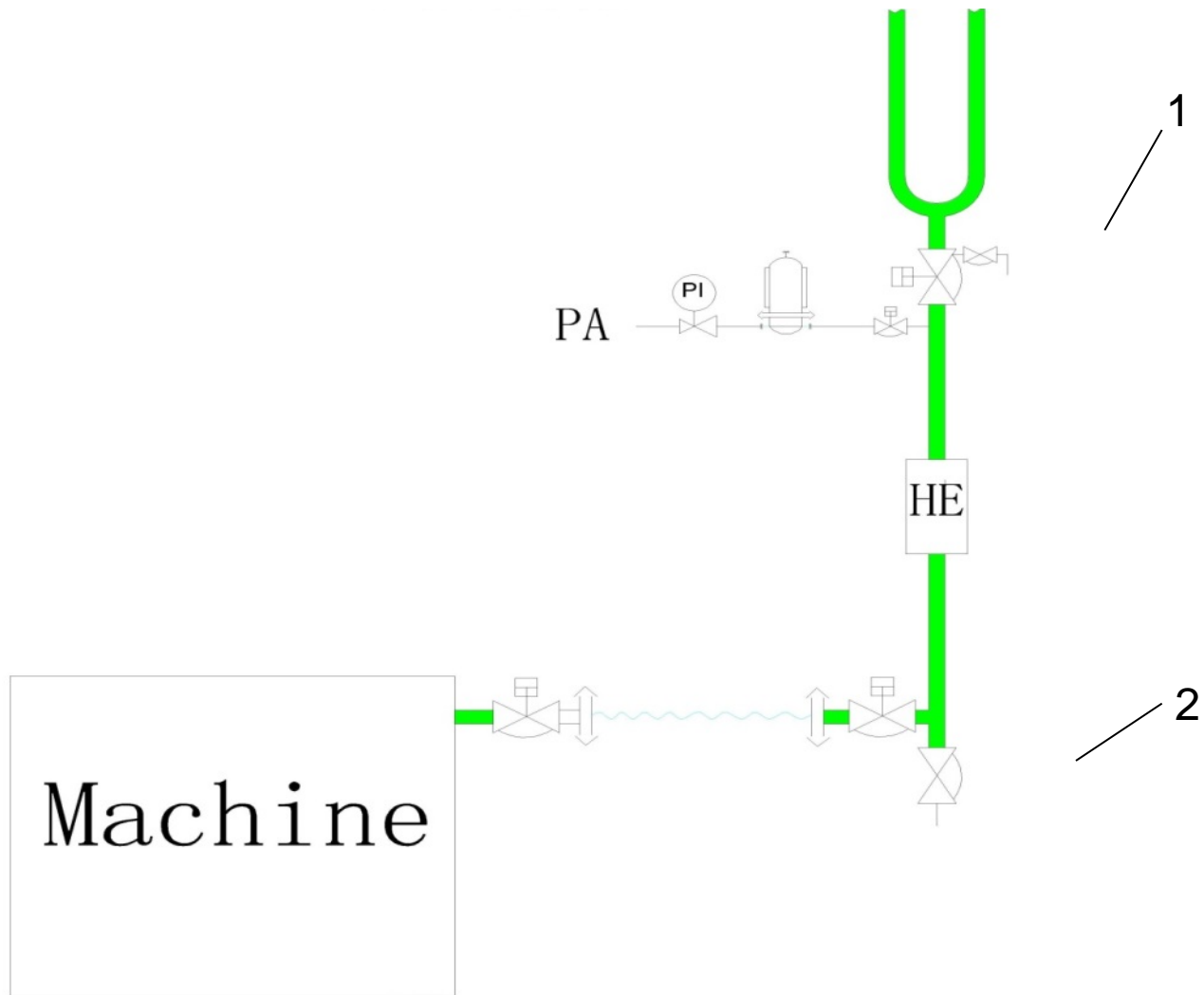
用点连接1



用点连接2



用点连接3

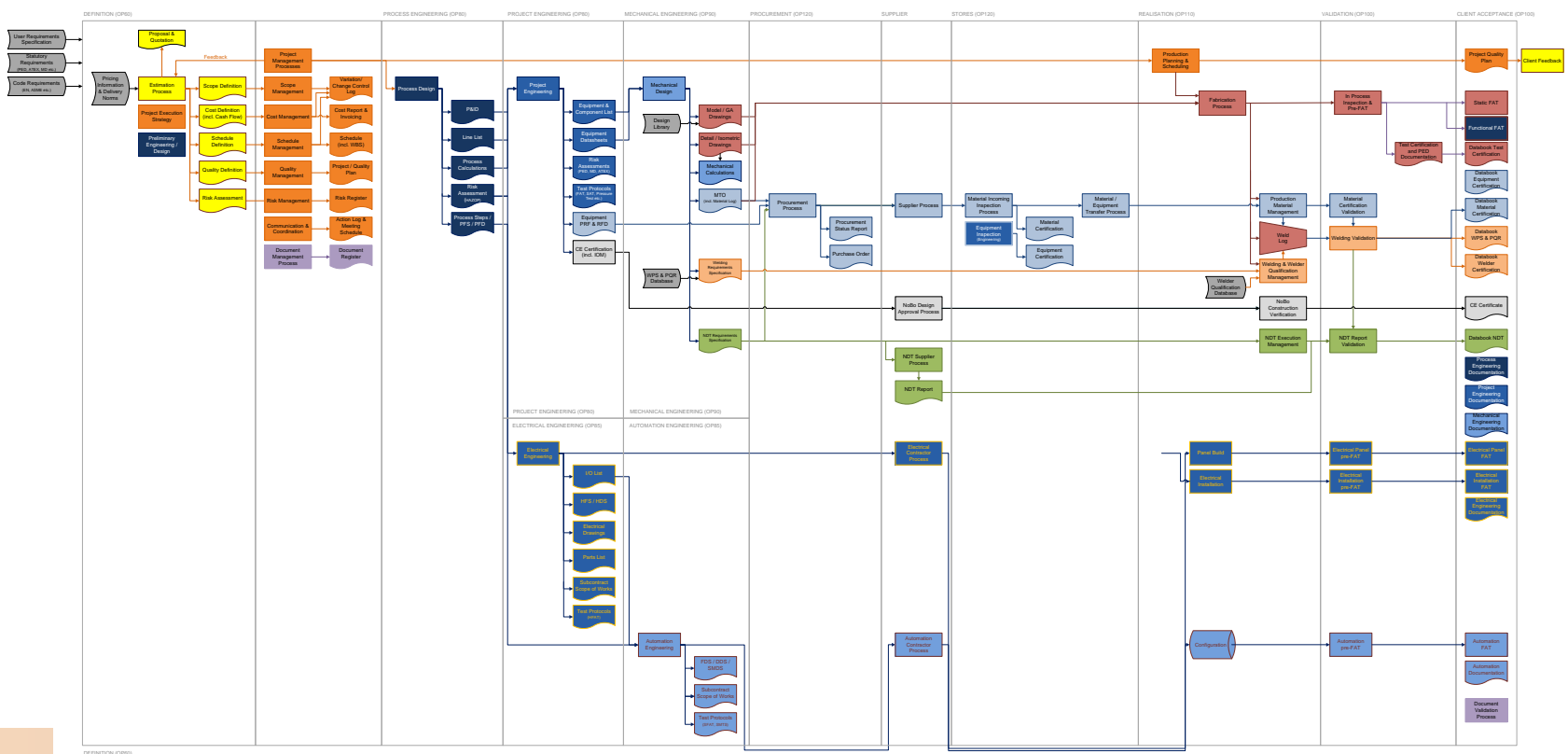


模块化系统执行过程和实例

Product Realisation Process 产品实现过程

Product Realisation Process is fully documented in the Quality Management System (QMS).

产品实现过程完全记录在质量管理系统中（QMS）。



Project Management: Definition & Planning Phases 项目管理：定义及方案阶段

Task Name	Duration	Start	Finish
Order Confirmation / Contract (Milestone 1 - Contract Award)	0 days	Fri 07-12-12	Fri 07-12-12
Project Kick Off / Client Specifications	11 days	Fri 07-12-12	Fri 12-12-12
Engineering & Design	159 days	Thu 03-04-13	Tue 26-06-13
Engineering	159 days	Thu 03-04-13	Tue 26-06-13
Process Calculations	56 days	Thu 03-04-13	Fri 22-03-13
Data Sheets Review	87 days	Thu 10-01-13	Wed 15-05-13
Data Sheets Approval	109 days	Thu 17-01-13	Mon 24-06-13
Mechanical Design	159 days	Thu 03-04-13	Tue 26-06-13
Architectural Drawings issued to BCD	2 days	Thu 03-04-13	Fri 04-04-13
Preliminary Vessel Drawings	8 days	Thu 03-04-13	Mon 14-01-13
Issue Preliminary Model for Vessel approval	2 days	Tue 15-01-13	Wed 16-01-13
30% Model	16 days	Thu 17-01-13	Wed 26-03-13

QUALITY PLAN PROJECTS			
Client:	Job No:		
Purchase Order No:	Rev:		
Project Serial No.:	Prepared By:		

No.	Activity Description	Responsible	Verifyin g Dec.	Verifyin g Proc.	Code / Standard Ref.	QC Activity	Required Action				Confirmed Complete by Originator	Confirmed Complete by Project Manager	
							JD	ENV	DO	IEE			
Project Report							Client:	Project No.:					
Date:							Schedule Review:						
Activities Last Period: 1. Item 2. Item 3. Item							1. Progressed Schedule 2. Procurement 3. Item						
Activities Next Period: 1. Item 2. Item 3. Item							Risks & Constraints: 1. Item 2. Item 3. Item						
Action Log: 1. Item 2. Item 3. Item													
Change Management: 1. Item													

- **Quality Plan describes how the requirements of the contract will be met throughout the project lifecycle.**
质量计划描述了怎样通过项目周期来满足合同要求
- **Schedule Development in MS Project**
Ms Project格式的进度计划
- **Project Meetings (Internal & Client).**
项目会议（与内部或与客户）
- **Action Log.**
操作记录
- **Constraint & Risk Review.**
约束条件与风险回顾
- **Change Management**
变更管理
- **Project Reporting.**
项目报告

Design Phase 设计阶段

HAZOP STUDY - FORMAT / EXAMPLE			
Project:	Food & hot water skids, SK002 & SK003	In Attendance:	Mark Lee, John Geary, Rebecca Wolfe, Jerry McHugh
Client:	Millipore	Date:	15/07/08
Job No.:	SME002	Client Project Ref.:	00-010
Report Completed By:		Checked by:	
Print Name:		Print Date:	
Printed:		Printed Date:	
Rev:	0	Rev:	0
Status:	As Built	Doc No.:	SME002-A-008
Status:		Status:	For construction



Item	Node	Guideword	Keywords
1	1	Flow	PED 97/23/EC Risk Assessment

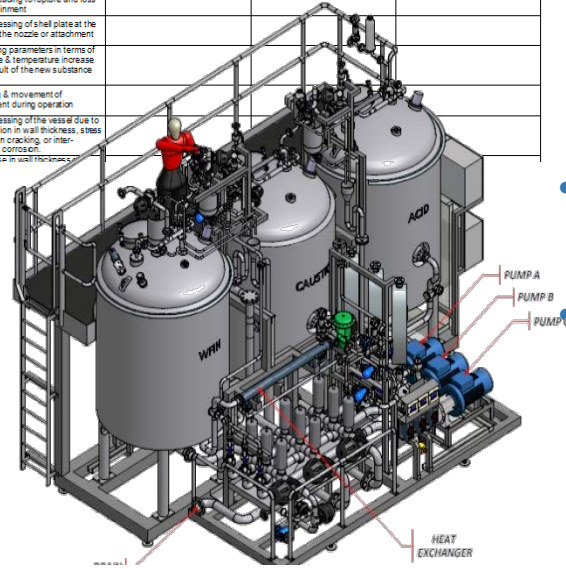
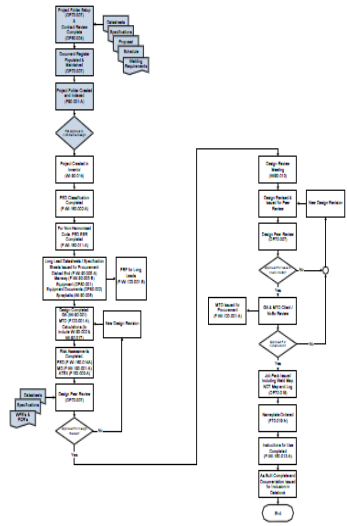


Client:	«Client_Name»	Document No.:	«Project_Numbers- PRA»	Prepared By:	«Mech_Engineers»
Job Number:	«Project_Numbers»	Revision No.:	0	Checked By:	
Equipment Description:	«Equipment_Descriptions»				

In the design, manufacture, inspection and testing of the equipment. Attention is drawn to the vessel data book, noting to the design of the vessel, the materials used, and the inspection & testing carried out.

Risk	Safe Guards	Recommendation	Action
Leaking of vessel leading to containment			
Use in material allowable leading to rupture and loss of content			
Use in material allowable leading to rupture and loss of content			
Leaking of shell plate at the flange or attachment			
Incorrect parameters in terms of pressure & temperature increase			
Leaking & movement of vent during operation			
Leaking of the vessel due to corrosion in wall thickness, stress on cracking, or internal corrosion			

Operating Procedures	Revision: 2	BCD
Engineering Design Vessels	OP90-001	Date: 08-Apr-13
		Page: 2 of 7



- Procedures are in place to define the design process
定义设计过程的程序已落实
- Where in BCD scope, HAZOP's are executed.
在BCD范围内，已经执行HAZOP分析。
- Design risk assessments are completed for pressure equipment, machinery and ATEX risks, where applicable.
设计风险评估在压力设备、机器以及适用的防爆风险中已经是完善的。
- Design is subject to peer review.
设计是经过内部审核的
- Internal & client design review meetings and model reviews are conducted.
会进行内部及客户设计审查会议和模块审查。

This procedure is the property of the BCD Engineering Ltd and shall not be used, reproduced or disclosed to anyone without prior written permission and shall be returned on request.

Fabrication Phase 制造阶段

BCD has a comprehensive welding and welder qualification system:

BCD有完善的焊接和焊工资格审核系统

- **Library of Procedure Qualification Records (PQR's).**
工艺评定记录的程序库
- **Library of Welding Procedure Specifications (WPS's).**
焊接工艺评定的程序库
- **Notified Body Approved.**
公告机构批准
- **Dual Qualified (EN/ASME).**
双标准 (EN/ASME)
- **Stainless Steel, Higher Alloys, Titanium, Carbon.**
不锈钢、高合金、钛、碳
- **Manual & Semi-Automatic Welding.**
手动焊及半自动焊
- **Low Ferrite Welding.**
低铁素体焊接
- **Range of Processes.**
广阔的工艺范围



Test Facilities 测试设施

Test Facilities Include:

测试设施包括:

- **RO Water**
RO水
- **Plant Steam**
工厂蒸汽
- **Clean Steam**
洁净蒸汽
- **Clean Dry Air**
清洁干燥空气
- **Vessel Test Bay**
容器试验台
- **Sprayball testing**
喷淋测试
- **Calibrated inspection equipment includes:
Micrometers, Profilometers, Ferritescope,
Digital Protractors, Positive Material
Identification (PMI).**

校准检测设备包括: 千分尺, 表面粗糙度仪, 铁离子检测仪, 数显角度仪, 材料检测仪 (PMI)。



Shipping Phase 运输阶段



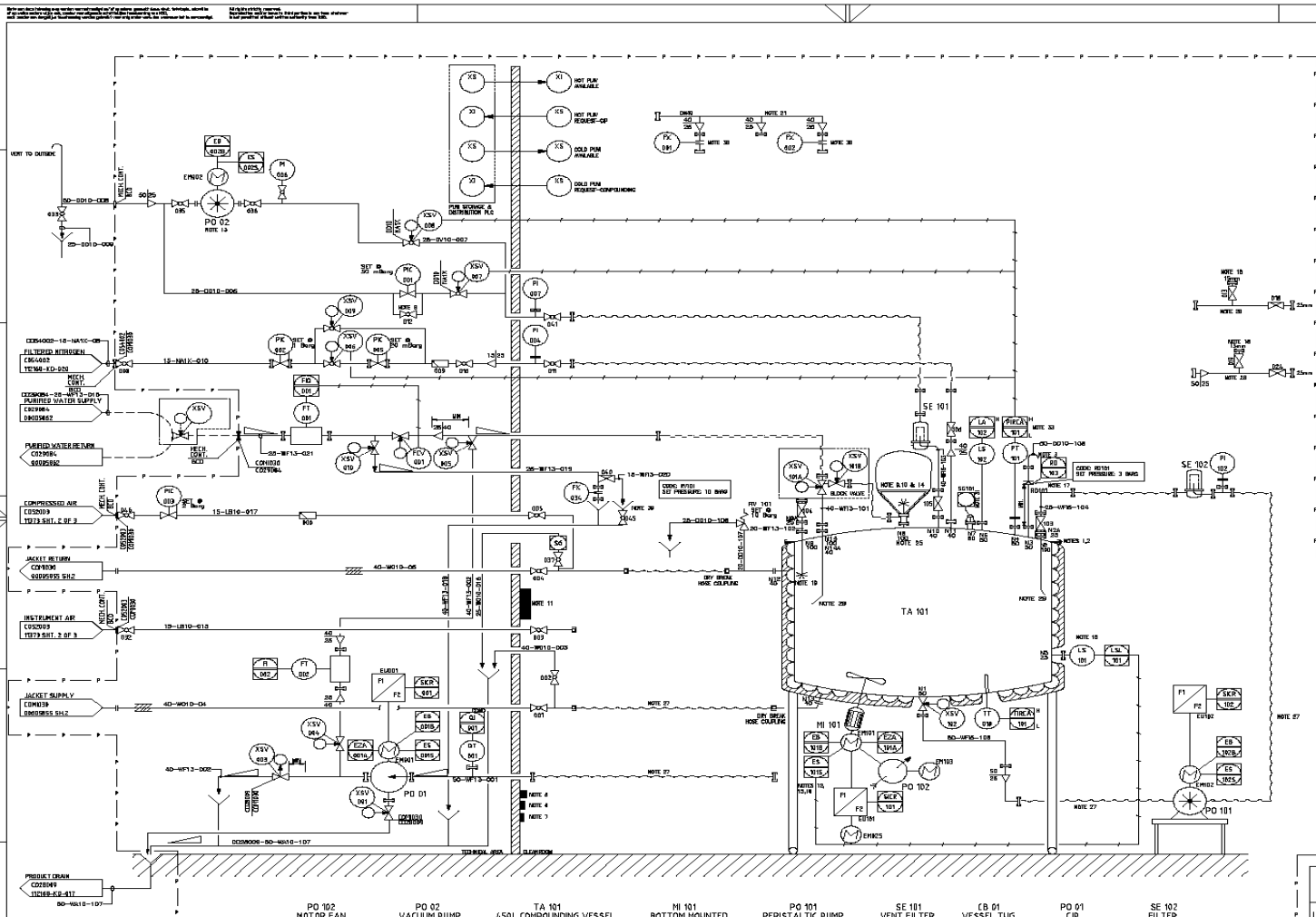
Experienced in delivering large scale projects throughout the globe.

有交付全球大规模项目的丰富经验。

All aspects of logistics.

全方位物流

COMPOUNDING SKID P&ID 配料模块PID图



NOTES

1. VESSEL TO COME WITH A FINNED LEAD WEIGHT REMOVAL WHICH OPERATE BY AN ORDER FUNCTION.
2. TOP VIEW OF VESSEL TO BE SHOWN THROUGH DESIGN.
3. VENT TO SAFE LOCKDOWN AT FLOOD LEVEL.
4. LIGHT LIFT TO COME WITH A LE FILTER.
5. JERRY CONNECTION FOR POWER SUPPLY TO THE ACTUATOR MOTOR.
6. COMMUNICATION CONNECTION BETWEEN PANEL AND VESSEL.
7. CLEAN POWER SOCKETS.
8. REVERSE ACTING REGULATING WHEN VESSEL PRESSURE 140 HPS/PSI VALVE OPENING.
9. CLAP HORNWAY TOWARDS DEVICE.
10. PLATFORM ADDD WHEN ACCESSING HEAD OF VESSEL WHILE CHANGING FORMULA.
11. HMI PANEL MOUNTED ON SKID.
12. ACTUATOR IS CONTROLLED BY COMPOUNDING PLC WHEN IN COMPOUNDING MODE. ACTUATOR IS MANUALLY CONTROLLED WHEN IN BELLEMIANT MODE.
13. SYSTEM SHALL BE ABLE TO PROVIDE A VOLUME OF 700 HRS.
14. ACTIVE INCREMENT SHALL BE ADDED AT AN INDEPENDENT OF GROUND.
15. IF LABEL IS BELONG LOW LEVEL SWITCH THEN ACTUATOR STOPS (DUALISED INTERLOCK AND JACKET HEATING IS DEACTIVATED (OFF LINE INTERLOCK), JACKET COOLING IS STOP INTERLOCKED WITH THE LEVEL.
16. MAXIMUM VESSEL VOLUME 50L.
17. DELETED.
18. ONE MORE FOR CONNECTION TO THE BELLEMIANT.
19. STATIC SPRINGBALL.
20. DELETED.
21. CLEANING MANIPULATED WITH RESTRICTION ORIFICE NO AS NOT TO SPARGE SPRINGBALL. MANIPULATED FITTED TO SPRINGBALL AND ON TUBES.
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1. LINE SYMBOL LIST OF VALVES ETC. INSTRUMENTS LIST
EQUIPMENT-INSTRUMENT-VALVES AND LINE SERIAL NUMBERS ON THIS DRAWING SHOULD BE READ AS PRECEDED BY: UNLESS OTHERWISE STATED.

LA. AB VAL AC-BIS BL1 AC-BIS
CW130
LAST PIPE NUMBER: 025
LAST VALVE NUMBER: 016

PROJECT TITLE: LYOSPHERE COMMERCIALISATION
PROJECT NUMBER: 123158

STATUS: **ISSUE FOR CONSTRUCTION**

REV	NO	DATE	DESCRIPTION	BY	CHKD	APPD
0	11-08-01	BASE FOR CONSTRUCTION	DNW	PF	JE	CK
1	01-08-01	BASE FOR TENDER	DNW	DN	JE	CK
2	09-01-14	BASE FOR DESIGN	DNW	DN	JE	CK
3	14-02-13	FC-BASE FOR TENDER	JE	DN	JE	CK
4	08-12-10	BASED FOR TENDER	JE	DN	JE	CK
5	11-11-10	BASED FOR FILL STUDY	DNW	DN	JE	CK
6	26-10-12	BASED FOR SAFETY REVIEW	LN	DN	JE	CK
7	22-09-13	FINAL ISSUE	JE	DN	JE	CK

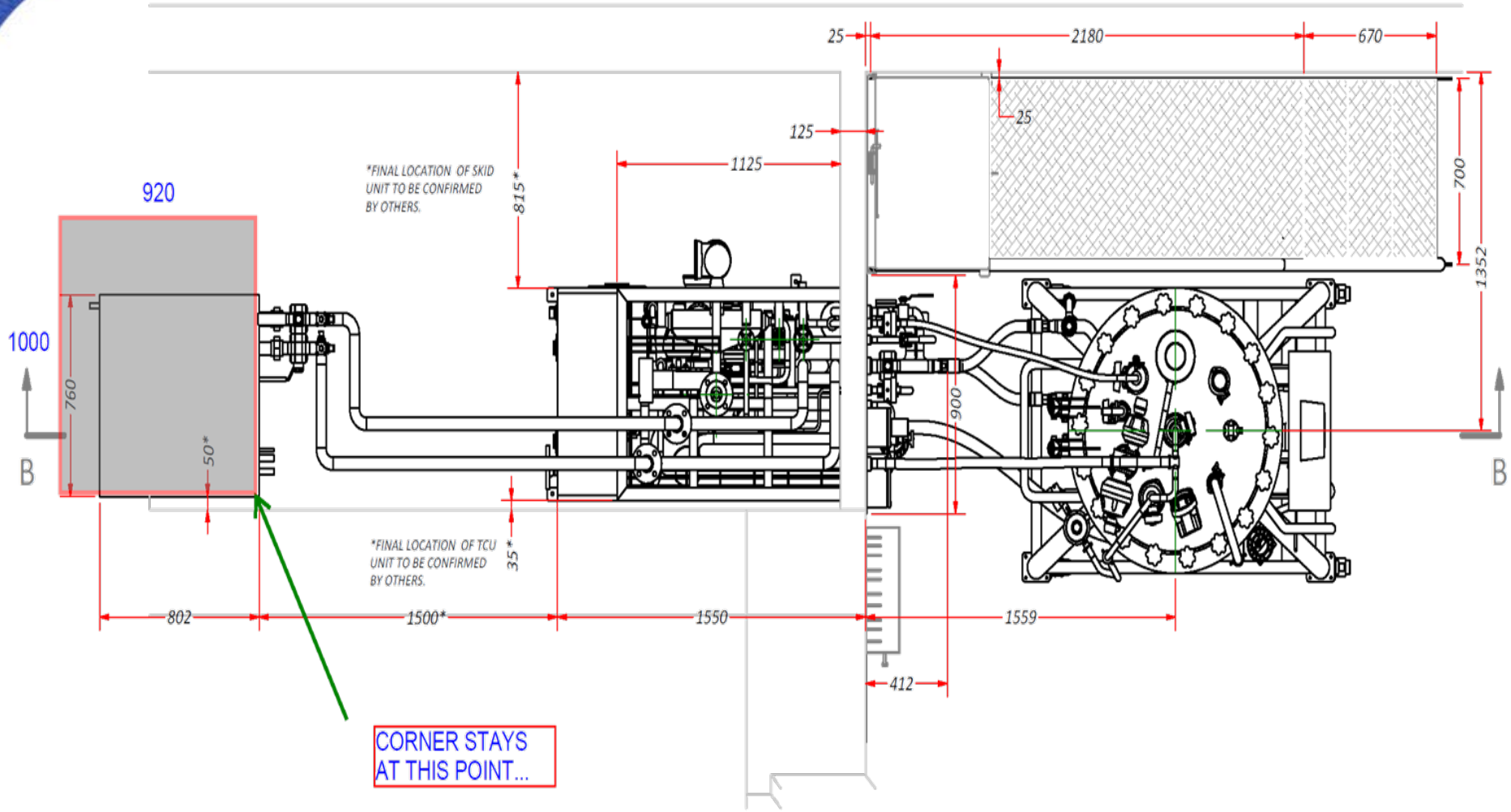
PIID COM130
LYOSPHERE COMMERCIALISATION
COMPOUNDING AREA

PROJECT/CLIENT	DATE	SCALE	NO	SIZE	LAYER	TYPE	PROJECT/CLIENT	REV
CDM130	2013	1/1000	10	A1	LAY	PIID	CDM130	0

Drawing No: 80069855
 Issue No: 001

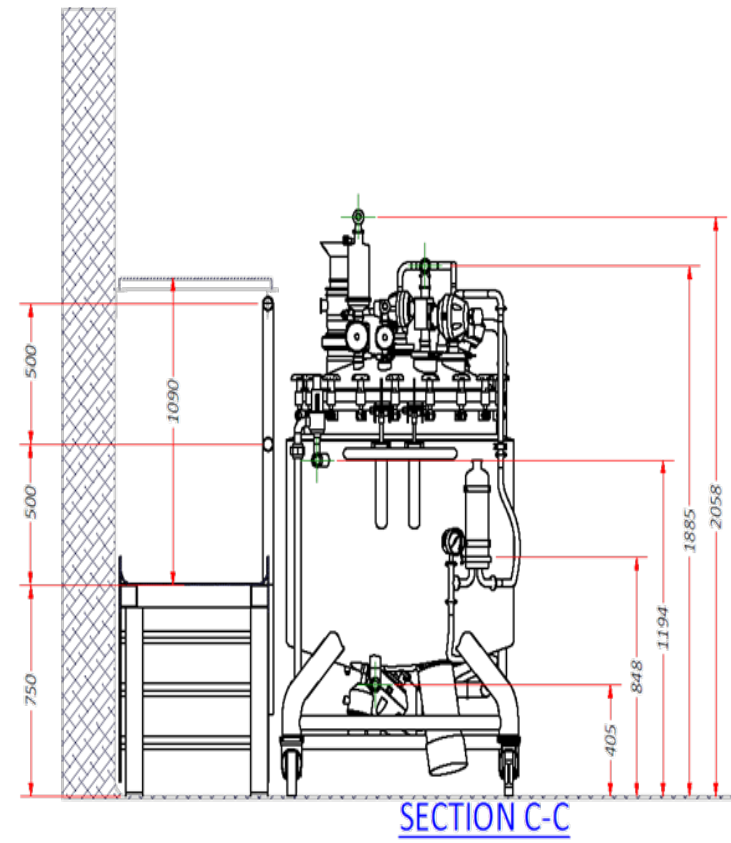
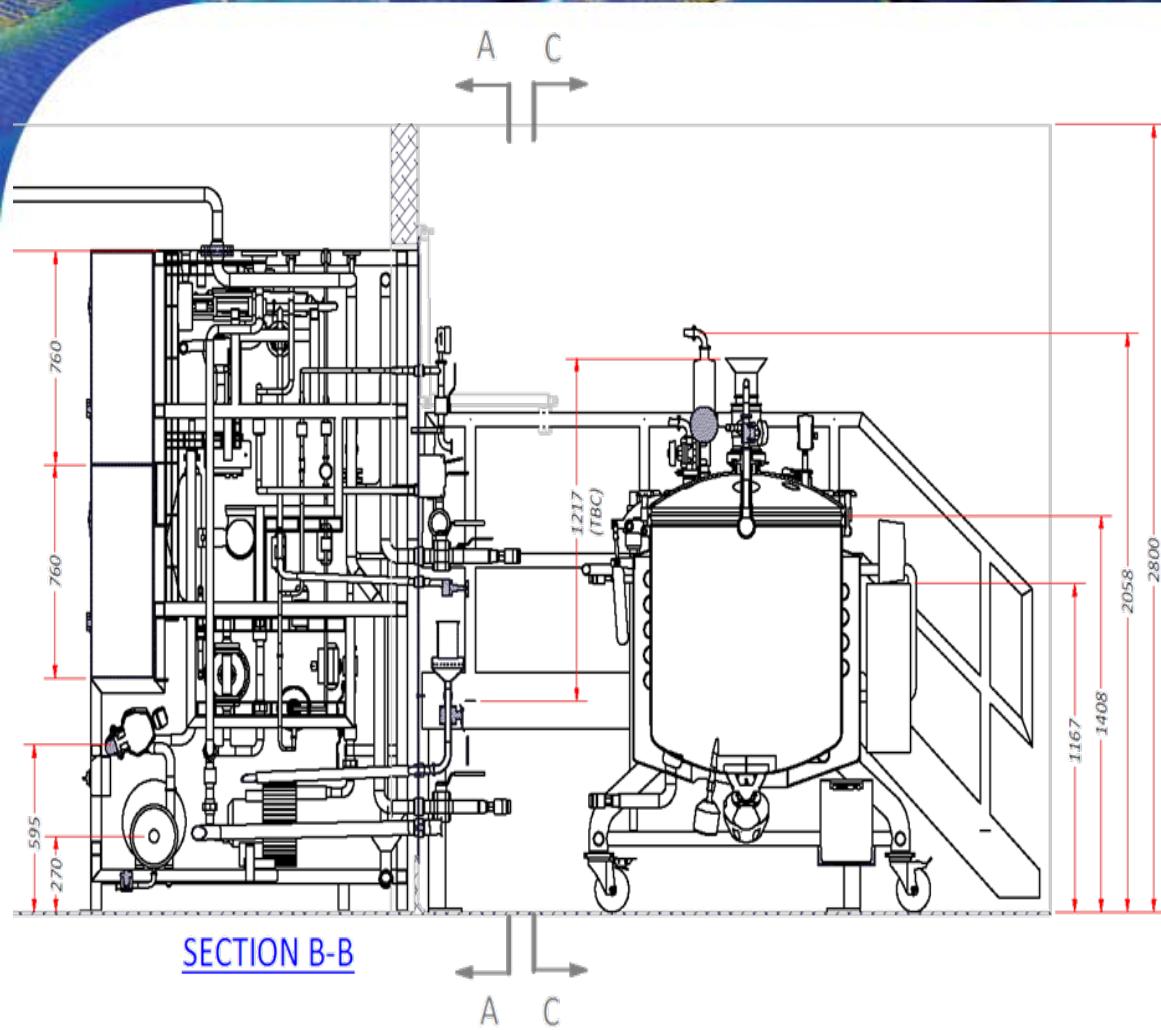
COMPOUNDING SKID PLAN

配料模块的平面图



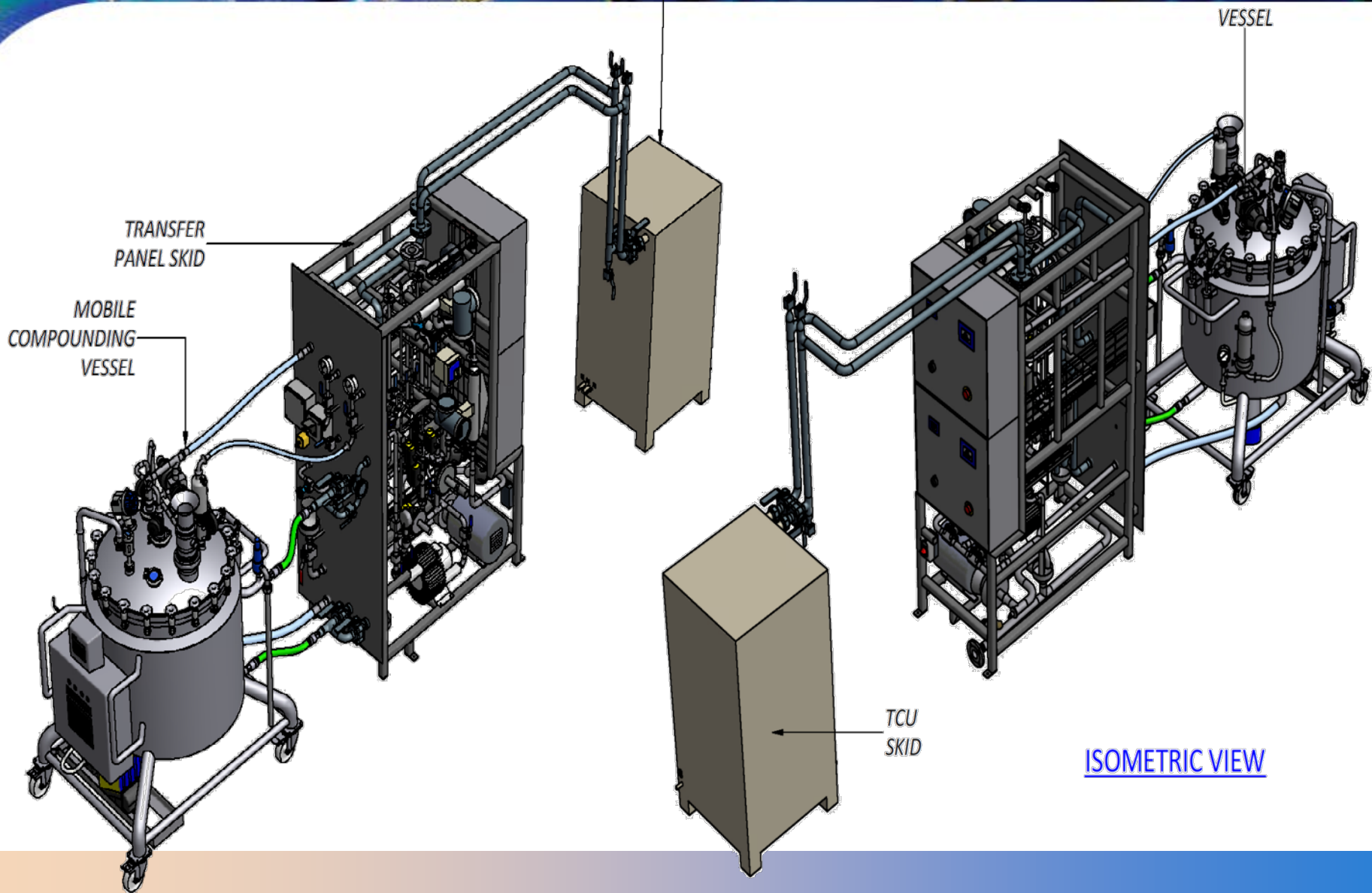
COMPOUNDING SKID ELEVATIONS

配料模块的立面图



COMPOUNDING SKID 3D MODEL

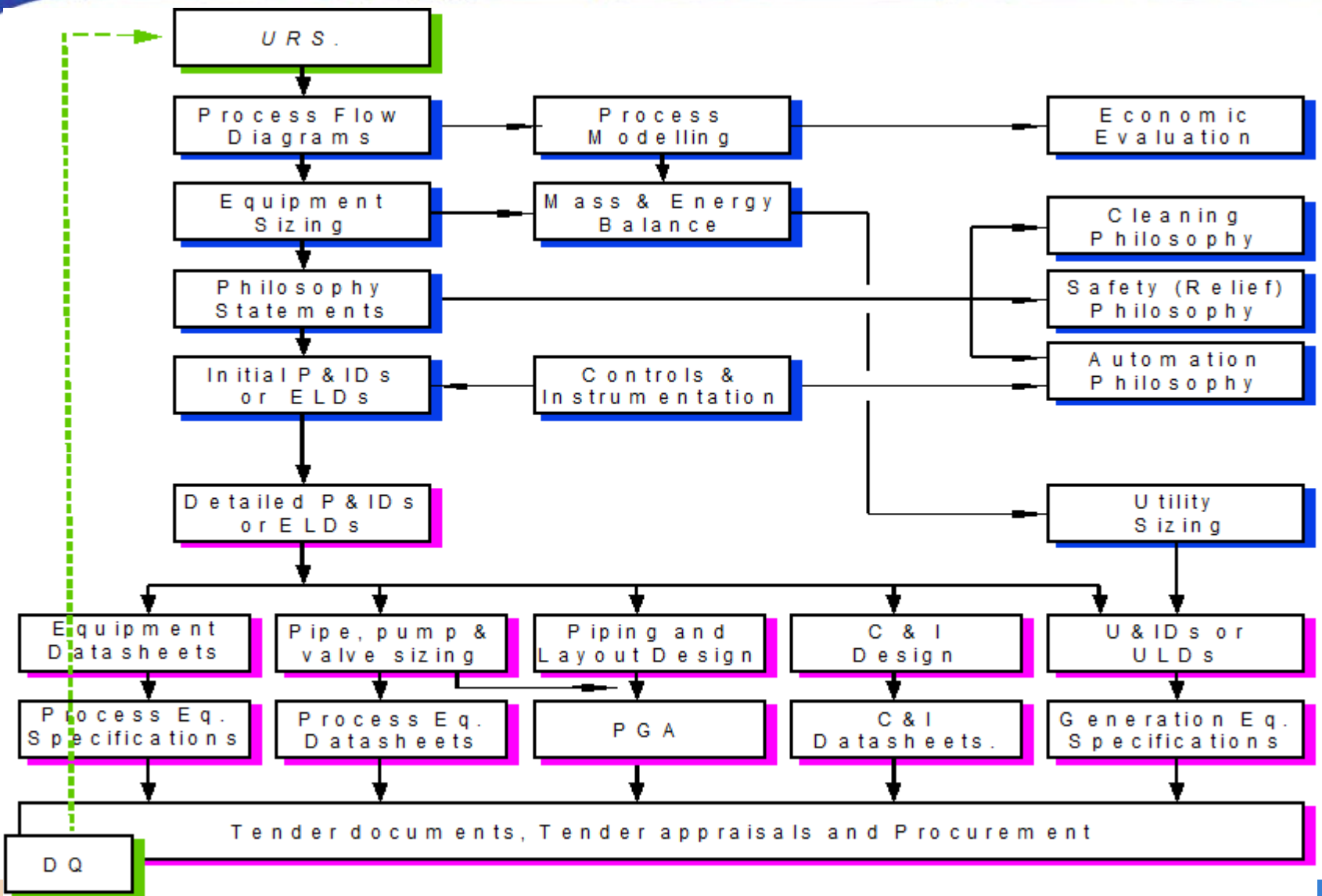
配料模块3D模型



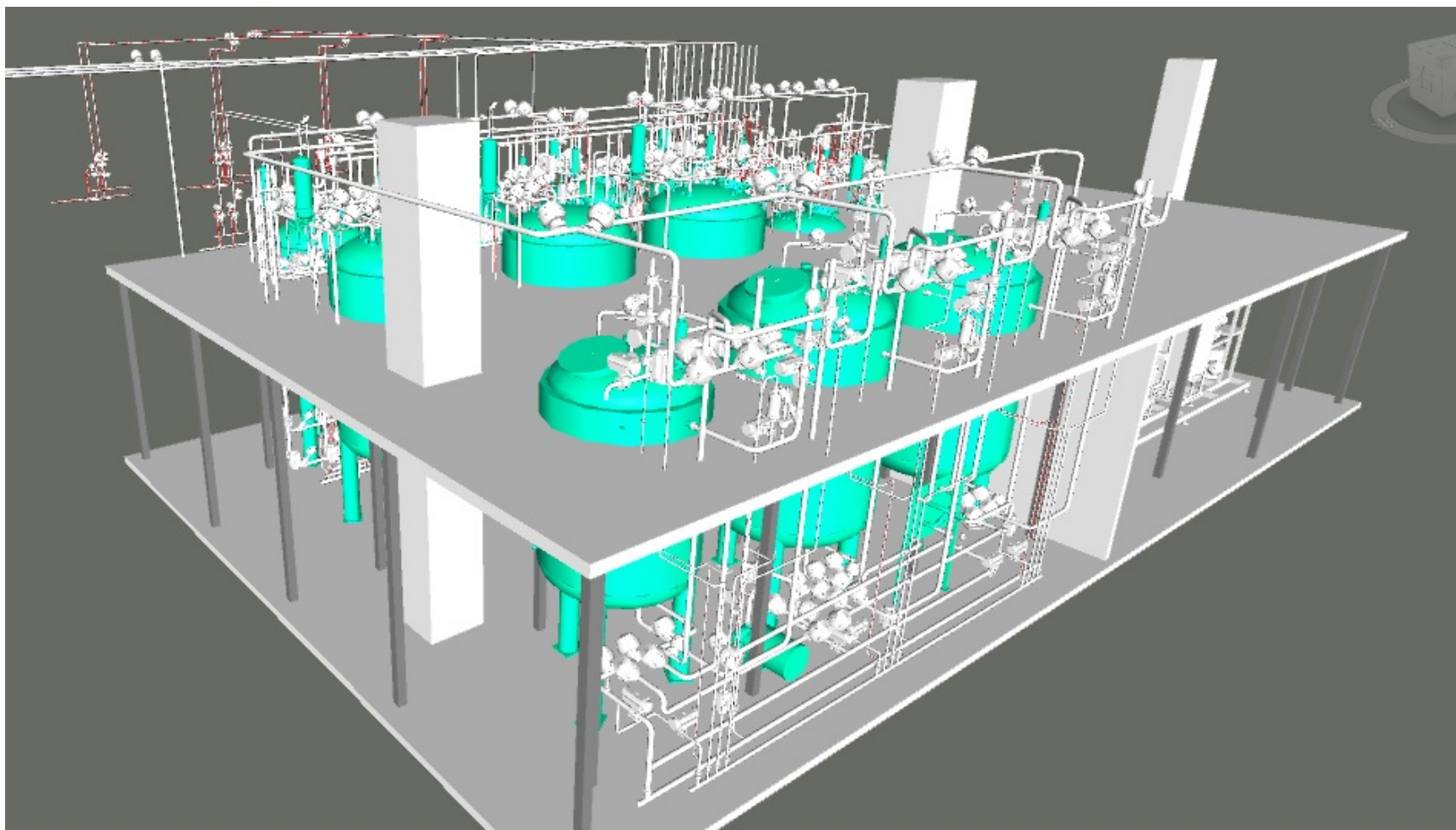
COMPOUNDING SKID PHOTO 配料模块的照片



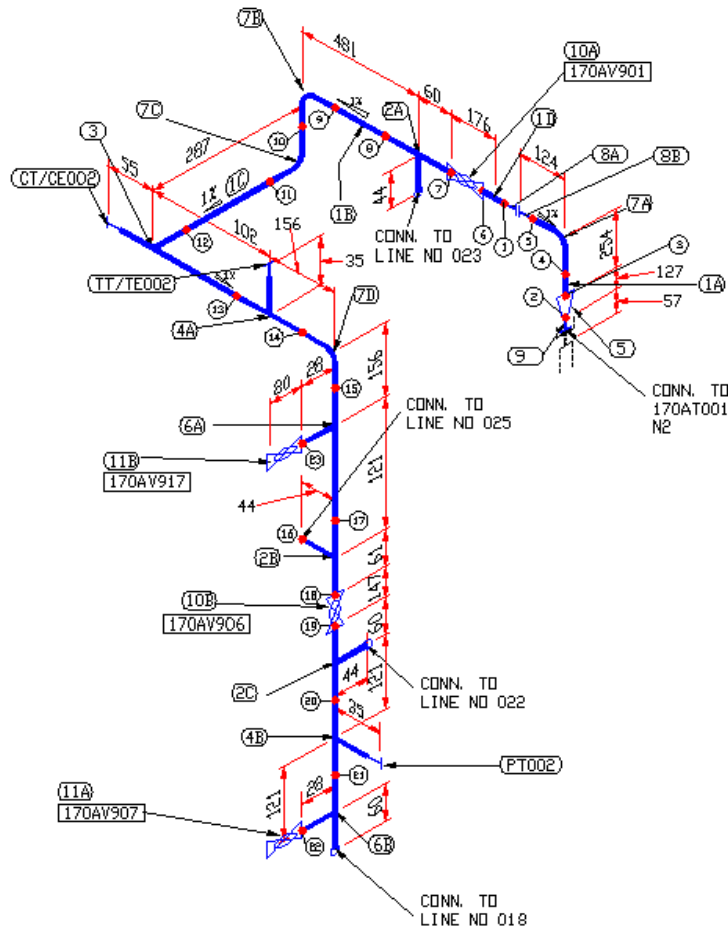
Process Design 工艺设计



设计图2 3D 三维模型



设计图3 Isometric drawing



FABRICATION MATERIALS

BILL OF MATERIAL

MARK	SIZE	DESCRIPTION	QTY	WEIGHT
PIPE				
1	40	TUBE, BUTT WELD, ASME BPE, SS316L	633	MM
FITTINGS				
2	40X40	TEE EQUAL, SHORT BUTT WELD, ASME BPE, SS316L	3	
3	40X40	Tee Equal BW / BW / CL	1	
4	40X40	Tee With Tri clamp End Types	2	
5	40X25	CON REDUCER, BUTT WELD, ASME BPE, SS316L	1	
6	40X15	TEE REDUCING, SHORT BUTT WELD, ASME BPE, SS316L	2	
7	40	90_ELLBOW, BUTT WELD, ASME BPE, SS316L	4	
8	40	FERRULE, BUTT WELD, ASME BPE, SS316L	2	
9	25	FERRULE, BUTT WELD, ASME BPE, SS316L	1	
VALVES / IN-LINE ITEMS				
10	40	AUTOMATIC SANITARY 2-WAY DIAPHRAGM VALVE, SHORT BUTT WELD, ASME BPE, SS316L	2	
11	15	MANUAL SANITARY 2-WAY DIAPHRAGM VALVE, SHDRT BUTT WELD+TRI CLAMP, ASME BPE, SS316L	2	

合同签订后，2周提供罐子确认图纸及材料清单
1个月提供最终流程图及材料清单

图纸及清单确认后，3个月 罐子加工完成
2个月 净泽公司3D模块设计图完成递交

2个月进行钢平台拼接及管道焊接
2个月电气接线

1个月FAT

现场设备安装调试2个月

SAT

WORKSHOP TEMPORARY PLATFORM



某疫苗厂设备工厂FAT现场



CIP, SIP问题

清洗设备的分类

- ❖ 固定系统
- ❖ 管线系统
- ❖ 移动系统
- ❖ 规则零部件
- ❖ 不规则零部件
- ❖ 特殊设备

配料罐的设计考虑问题

1. 有效容积
2. 设计压力
3. 洗球的类型和角度
4. 人孔的类型和安全性
5. 封头的选择与死角和排水的问题
6. 内部抛光的选择
7. 伸入管的清洗问题
8. 搅拌器选型
9. 机械密封的选择
10. 夹套设计和冷冻及加热的切换。

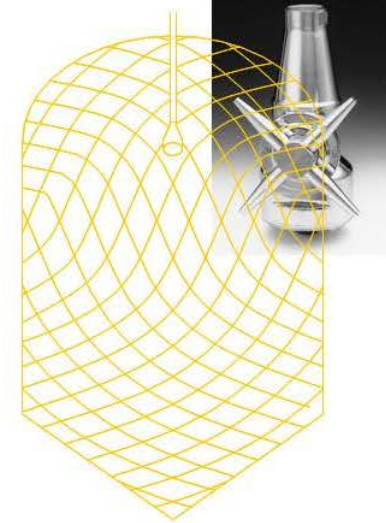
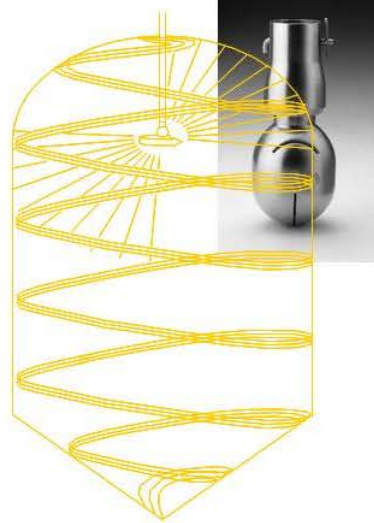
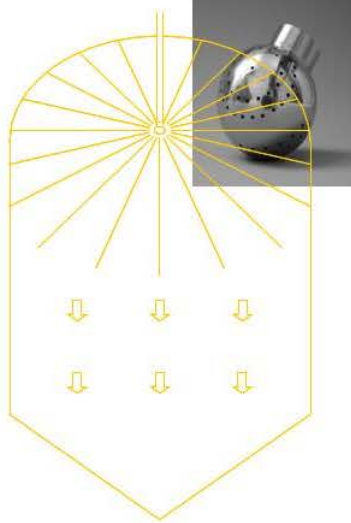
清洗的效果

- ❖ 清洗时间
- ❖ 清洗液的组成
- ❖ 清洗液的温度
- ❖ 清洗液的速度
- ❖ 是否覆盖到了所有表面
- ❖ 机械的打击力

清洗面临的问题

- ❖ 多长时间和什么情况需要清洗？
- ❖ 洗多长时间？
- ❖ 同时可以洗几个设备？
- ❖ 如何省水？
- ❖ 大循环还是小循环
- ❖ 如何解决死角问题达到完全清洗？
- ❖ 多系统清洗时如何防止交叉污染？
- ❖ 清洗排水（反串和溢出）
- ❖ 如何设置Air Gap
- ❖ 如何取样，如何清洁验证

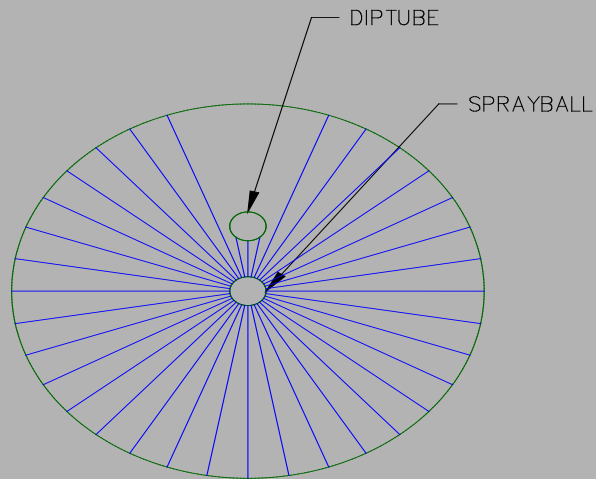
洗球覆盖形式



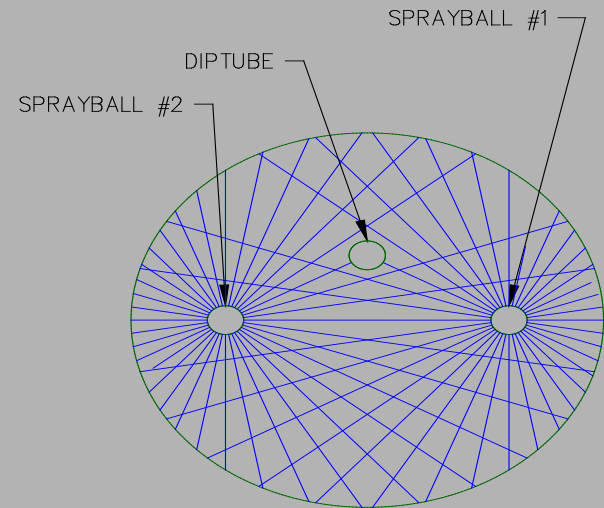
三类喷淋设备全面比较

三类洗球	固定洗球	旋转洗球	洗罐器
应用范围	多数6米直径以下，容易清洗的罐	6米以下，相对容易清洗的罐	洗大罐或相对难清洗的罐或者对清洗要求高的罐
覆盖率:	小股液体从喷球的每个孔中持续喷向罐壁上固定的点，简单地将清洁液体分配至储罐和容器表面	扇形涡流以振动的模式均匀地喷向容器表面	通过旋转的喷嘴将清洗液体喷射在储罐的整个内部表面上并形成逐步密集的网状覆盖
特点	大流量或高浓度清洗液体通过层流的方式完成清洗	振动模式与物理冲击力的结合	水平旋转与垂直旋转相结合形成的高速射流以及由储罐壁上反射回的水流可以作用于最难达到的位置
冲击力:	10%	70%	100%
优缺点	温度相对要求高，冲洗时间长，颗粒会阻塞喷淋球，冲击力极低，水浪费很多。	相对较大的冲击力，浪费较少的水和较短的清洗时间。	强大的冲击力，清洁时间最短，降低耗水量和清洗剂用量，同时降低能颗粒会阻塞喷淋球耗。增加产品的生产时间，减少产品损失
流量 + 时间 :	100%	70 to 75 %	40 to 50 %

洗球数量的确认

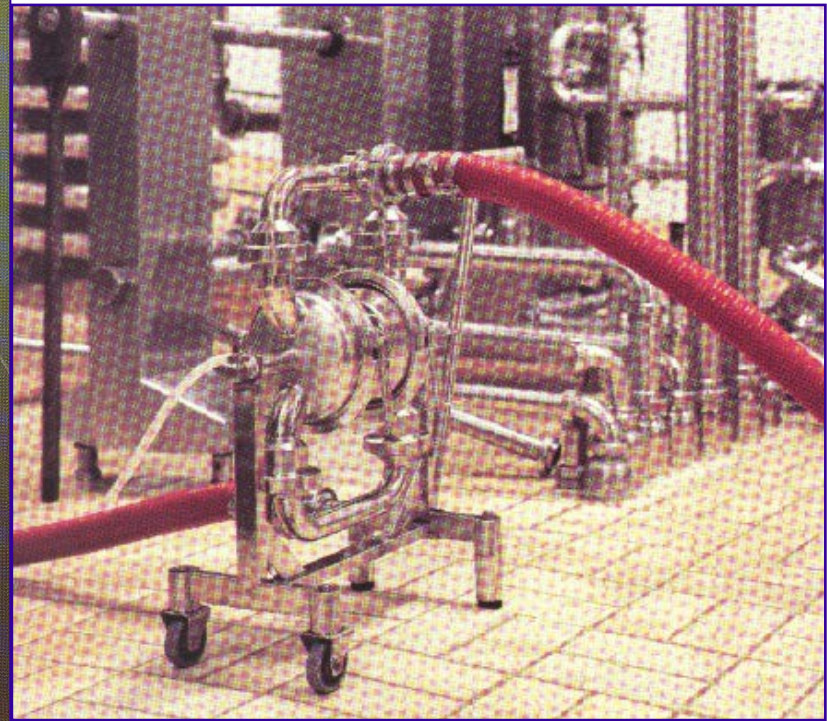


TANK WITH 1 SPRAYBALL



TANK WITH 2 SPRAYBALLS

现场的回流泵 保证流速



CIP设计中考虑的问题

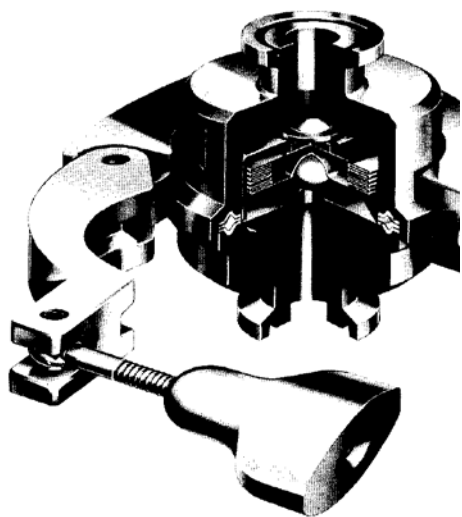
- ❖ 公用设施的连接(包括洁净室内的排放)
- ❖ 生产工艺才是关键,如何来配合有效清洗,防止交叉污染和死角残留
- ❖ 检测和取样
- ❖ 吹干功能必要性
- ❖ 罐和管道的分别洗净的能力
- ❖ 回流的动力
- ❖ 回流和供应流量的平衡
- ❖ 核心清洗工艺参数的确认.如酸碱的使用和浓度.
- ❖ 监控仪表的选取.程序的打印

报表数据

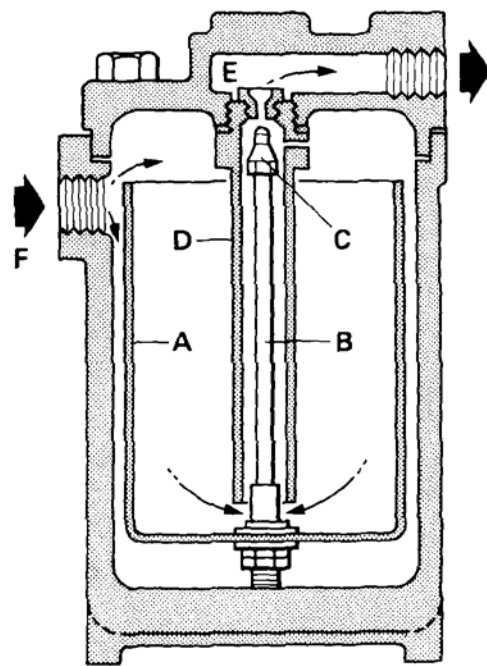
- ❖ 数据的信息越复杂，对于控制系统要求就越复杂
- ❖ 核心工艺参数才是关键
- ❖ 实时监控数据的问题
- ❖ 项目的步骤设计与报表
- ❖ 报警和数据的完整新确保了，如何确保工艺数据的稳定性，还有异常情况下如何进行进一步的工艺操作。退出机制，和故障机制。
- ❖ 仪表的维修维护，校验对于数据记录至关重要。尤其是对于精度的定义，而又仪表本身的缺陷和限制必须考虑到位。
- ❖ 报表应该在满足以上条件的情况下尽量简化。方便审核和递交。

SIP中疏水器的选用

热静力型

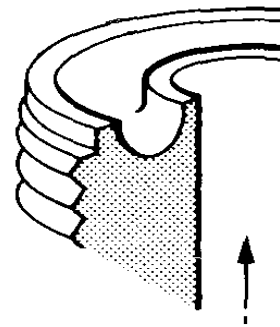


机械式



Open Top Bucket Trap

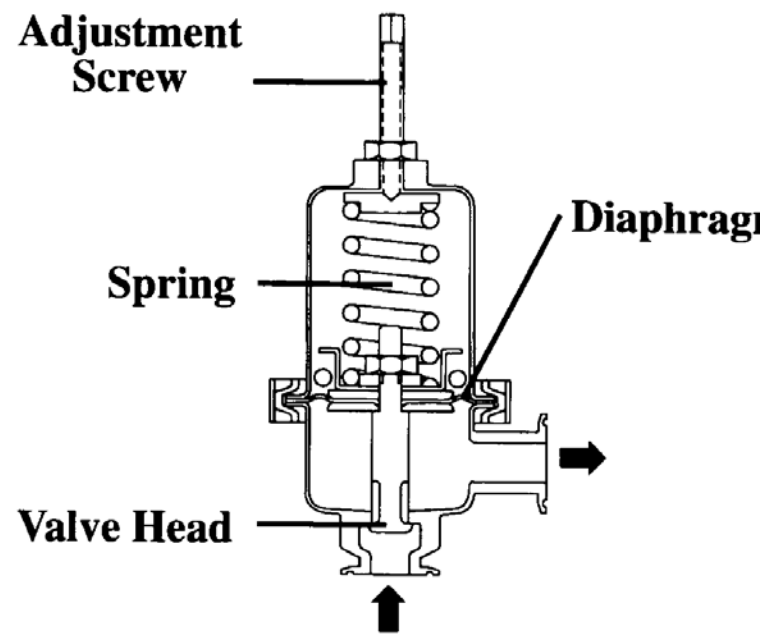
热动力型



Thermodynam

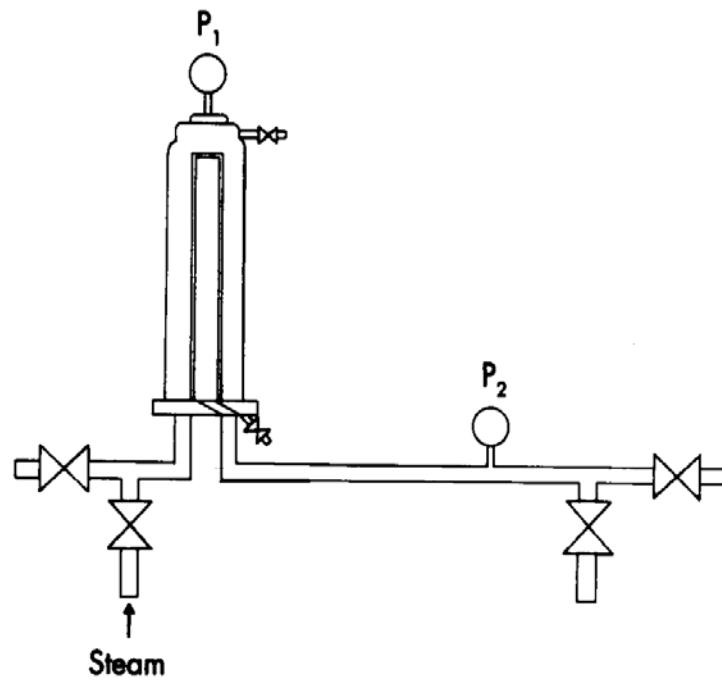
减压阀选取

减压阀



SIP中最担心问题

正向SIP



SIP的要求

- ❖ 饱和蒸汽
- ❖ 系统除气除水
- ❖ 最低点确认.
- ❖ 有效调节压差
- ❖ 在线SIP,完整性检测
- ❖ 有效疏水和温度监控
- ❖ 无菌性的保证，补充WFI，PA的无菌性
- ❖ SIP和CIP带来的一个问题是生产时间比原来手动模式加长了。并且如果不稳定那么就会导致不断重复步骤。所以工艺稳定性测试尤为重要

WFI ROUGING(红锈)

ROUGING的种类

目前分为三类

1. 颗粒装可擦去, 会脱落, 比较常见
2. 比较稳定的黑色氧化层, 擦不去, 多见于一直不进行酸洗处理的系统, 可通过较强的酸去除.
3. 深层也有所氧化的, 不易去除

ROUGING的引起原因

目前没有完全的研究结果

但是以下因素会影响

- 1.运行温度,主要原因
- 2.CO₂ 的含量
- 3.表面原始的干燥度和焊接影响

ROUGING的抑制方法

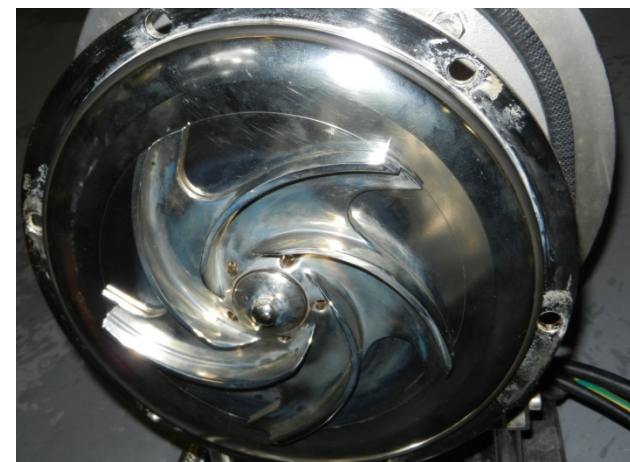
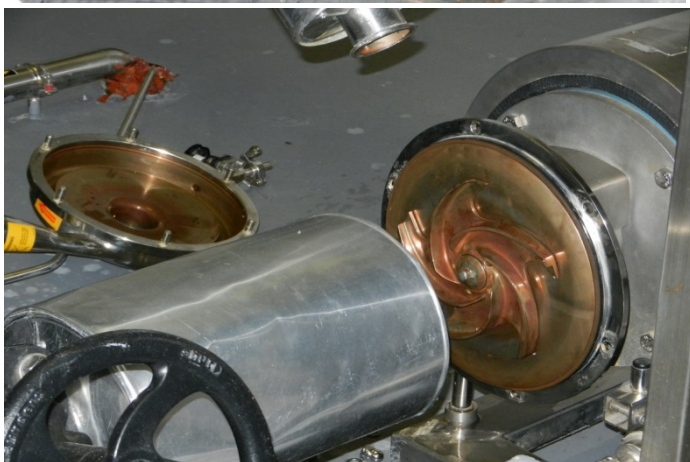
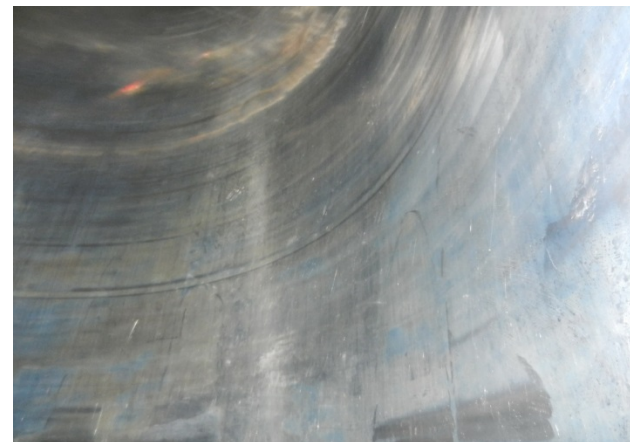
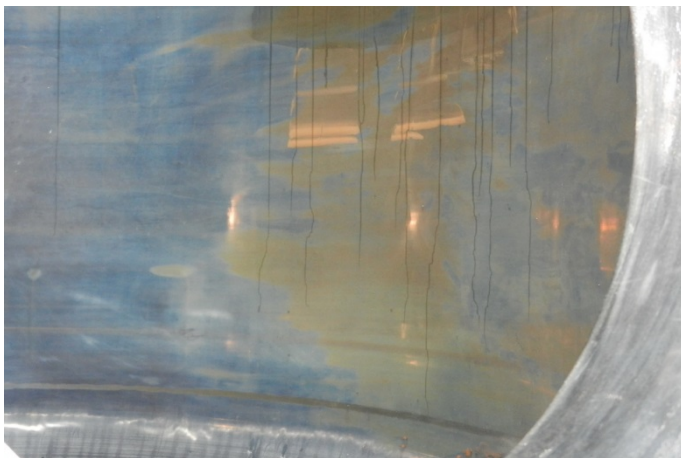
- 1.运行温度尽量低
- 2.对于进水和运行时的CO₂ 要采取隔绝状态,通氧气等.
- 3.使用电抛光管道,严格控制焊接过程中的氧化.
- 4.定期对系统进行专业清洗。

ROUGING的专业清洗案例

使用产品 deconex®DEROUGING system

- ◆工作溶液浓度 3.5 - 3.9% (采用了低水量, 高浓度的方法)
- ◆工作溶液温度 主清洗步骤73.1-75.9°C
- ◆去除作用时间 4小时
- ◆漂洗次数 钝化后漂洗4次
- ◆使用水质 纯化水

ROUGING的专业清洗案例



项目施工的复杂性

cGMP Perspectives

cGMP Perspectives

For single line

- Material
- Deadleg
- Drainability
- Welding
- Calibration
- Marking & Labeling
- Insulation
- Pickling & Passivation
- Decontamination
- Valve Angles
- Air Break
- Filter Integrity
- Etc.

For System

- Surface Finish test
- Sprayball Coverage Test
- GAMP5 & Part 11
- Minimum Flow Rate
- Wiring Test
- System Alarm
- Interlock
- P&ID Verification
- Critical Process Parameter
- Critical Quality Attributes
- Etc.

施工管理对于GMP的重要性

- ❖ 材料的抗腐蚀性能
- ❖ 安装的规范性
- ❖ 死角的控制
- ❖ 文件的真实有效性。
- ❖ 焊接对于使用寿命的影响。
- ❖ 设备的正确安装决定了系统的稳定性。
- ❖ 在线控制的重要性

预制间及仓库



配管及预制间



Welding Quality Control

焊接质量控制

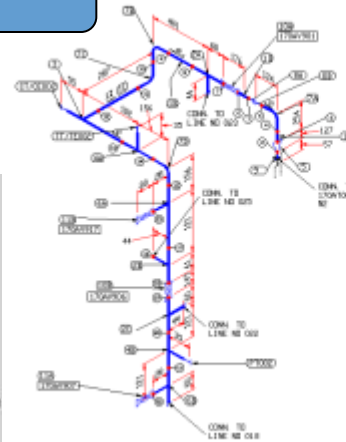
预制配管及准备

The Approved Isometric Drawing 被批准的轴测图

Pipe cutting and facing 管道切割及切口平口

High purity Ar and PTFE pipe 高纯氩气及PTFE焊接气管

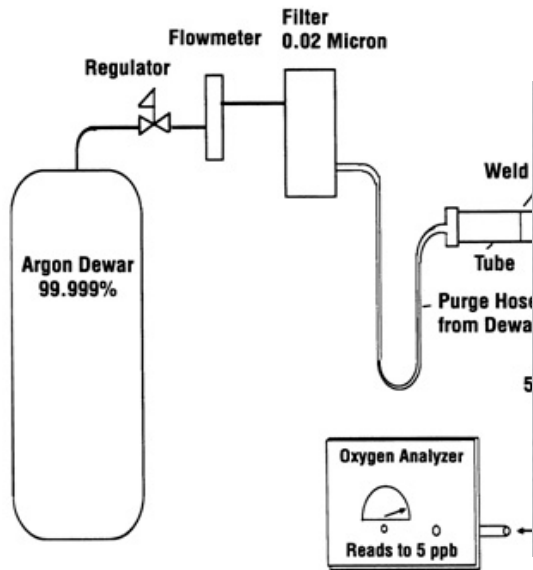
Spot Welding 焊接管对口及三点式点焊



FABRICATION MATERIALS		BILL OF MATERIAL	
NO.	QTY	DESCRIPTION	UNIT
1	40	PIPE, BUTT WELD, 40# 3/4" SCH. 40	633 MM
FITTINGS			
2	40	TEE, 40# 3/4" SCH. 40	3
3	40	90° ELBOW, 40# 3/4" SCH. 40	1
4	40	45° ELBOW, 40# 3/4" SCH. 40	1
5	40	FLANGE, 40# 3/4" SCH. 40	1
6	40	VALVE, 40# 3/4" SCH. 40	1
7	40	WELDED END, 40# 3/4" SCH. 40	4
8	40	FLANGE, BUTT WELD, 40# 3/4" SCH. 40	2
9	40	FLANGE, BUTT WELD, 40# 3/4" SCH. 40	1
VALVES / IN-LINE ITEMS			
10	40	AUTOMATIC SHUT-OFF 2-WAY BALL VALVE, 40# 3/4" SCH. 40	2
11	15	MANUAL SHUT-OFF 2-WAY BALL VALVE, 40# 3/4" SCH. 40	2



Welding Quality Control 焊接质量控制



Oxygen content test machine
含氧量测试设备



Weld Oxidation Color
焊缝氧化颜色

Boroscope ratio在焊缝检查中，内窥镜检查比例:

Module模块部分 检查比例为100%

Site现场部分 Pre-fabricate 100%预制检查比例为100%， site piping 30-50%现场管道安装检查比例为30~50%

Equipment & Welder certificate 施工设备及焊工资质



Imported endoscope
进口手持式内窥镜3pcs



spectrum analyzer
手持式光谱分析仪1pcs



Imported Automatic welder
进口自动焊机



Oxygen content test machine
含氧量测试设备

SGS

WELDING OPERATOR QUALIFICATION CERTIFICATE
(To ASME Code Section IX, 2013 Edition)
Certificate No.: IN-SH-5805-1-563-102

Company:	Winatech Process Engineering (Shanghai) Co., Ltd		
Address:	Building E, No.568, Huaxu Rd., Qingpu District , Shanghai, China		
Welder:	沈九波 (Fanlong Zhang)	ID:	J46322199405047837
Stamp No.:	WD1	WPS No. Followed:	WPS-001 Rev.0 <input checked="" type="checkbox"/> Test Coupons <input type="checkbox"/> Production weld

Specification and typegrade	ASTM A270 316L	Thickness	1.5mm
Base metal P or S Number	R	Ta P or S Number	R
<input type="checkbox"/> Plate <input checked="" type="checkbox"/> Pipe (enter diameter, if pipe or tube)		Position (2G, 6G, 3F, etc.)	2G
Filler metal (SFA) Specification	None	Filler metal or electrode classification	None

Testing Conditions and Qualification Limits When Using Automatic Welding Equipment		
Welding Variables (QW-361.1)	Actual values	Range qualified
Type of welding (Automatic)	NA	NA
Welding process	NA	NA
Filler metal used (EBW or LBW)	NA	NA
Type of laser for LBW (CO ₂ or YAG, etc.)	NA	NA
Continuous drive or inertia welding (F/W)	NA	NA
Vacuum or out of vacuum (EBW)	NA	NA

Testing Conditions and Qualification Limits When Using Machine Welding Equipment		
Welding Variables (QW-361.2)	Actual values	Range qualified
Type of welding (machine)	Machine	Machine or auto
Welding process	GTAW	GTAW
Direct or remote visual control	Direct	Direct
Automatic arc voltage control (GTAW)	Yes	Yes
Automatic joint tracking	Yes	Yes
Position qualified (2G, 6G, 3F, etc.)	2G	2,4
Consumable inserts (GTAW or PAW)	None	None
Racking (metal, weld metal, etc.)	Yes	Yes
Single or multiple passes per side	Single	Single

RESULTS

Visual Examination of Completed Weld (QW-462.4) Acceptable Retest required (see basis) (QW-462.3 (a));

Longitudinal root face bend test (QW-462.3 (b)) Side bend tests (QW-462.3) Plate bend specimen, compression-tension overlay (QW-462.5 (c))

Pipe Macro test for fusion (QW-462.5 (d)) Plate Macro test for fusion (QW-462.5 (e))

Type	Result	Type	Result	Type	Result
Face	accepted				
Root	accepted				

Alternative radiographic examination results (QW-461) NA [Length and percent of defects NA
Fillet weld in pipe (QW-462.4 (b)) NA [Fillet weld in pipe (QW-462.4 (b)) NA
Mechanical tests (QW-464) NA [Fillet size (in.) NA Compressive strength (ksi.) NA

Other tests: NA
Fits or specimens evaluated by: NA Film No: NA
Mechanical tests conducted by: SGS Lab Laboratory Test Number: **NM150500778**

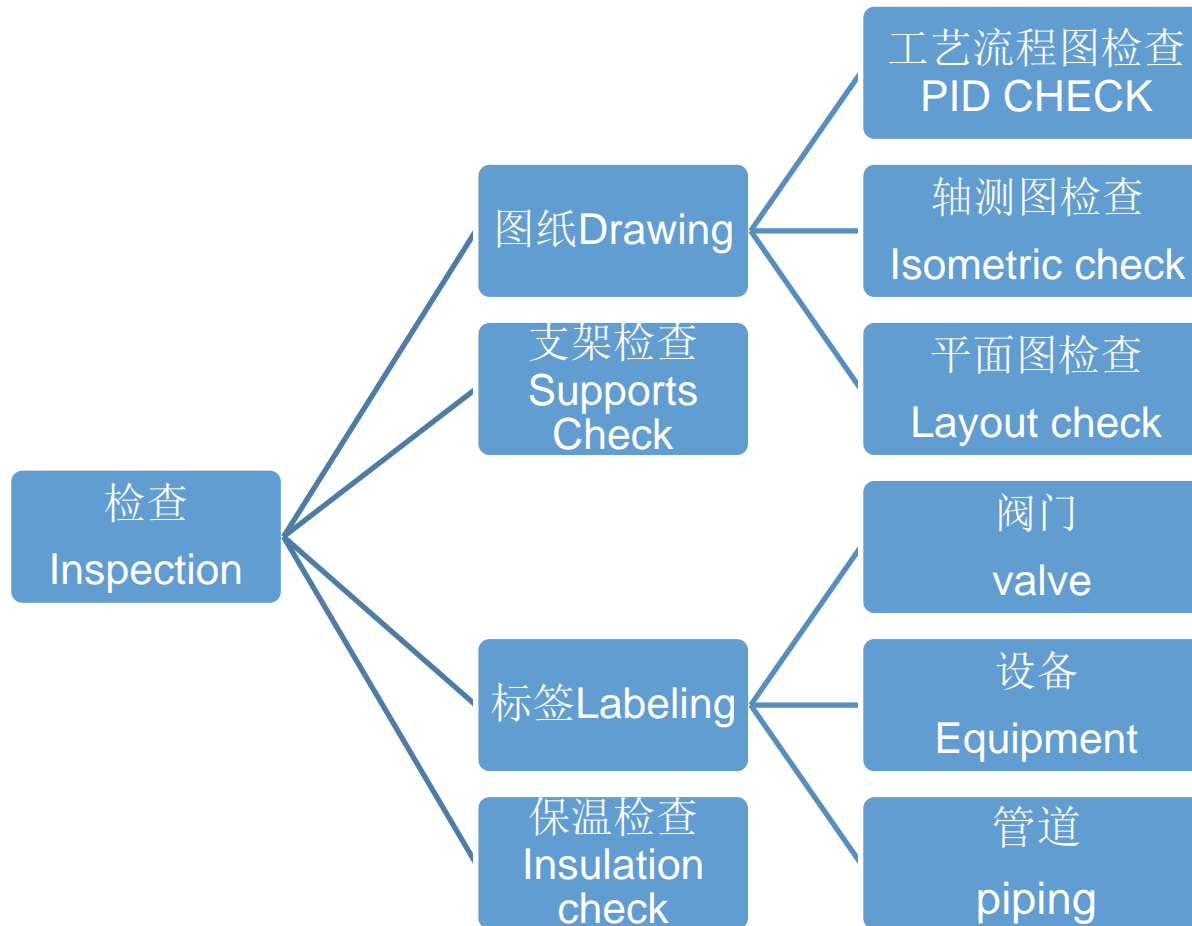
We hereby certify that the undersigned surveyor(s) witnessed the welder performance qualification on the city of **Apr 26, 2015** at **Winatech Process Engineering (Shanghai) Co., Ltd, Located at Building E, No.568, Huaxu Rd., Qingpu District , Shanghai, China.** And statement is this record is correct and that the qualification test coupons were prepared, welded and tested in accordance with requirement of **To ASME Code Section IX, 2013 Edition.**

Welding Test Witnessed By: **SGS-CSTC**

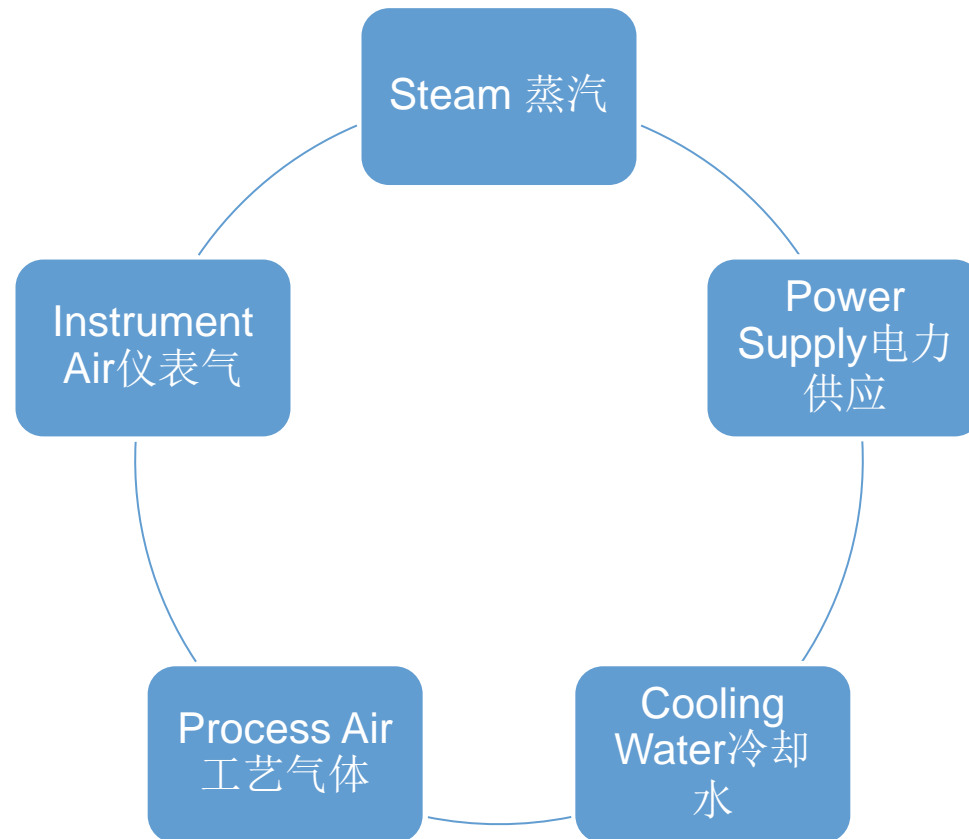
Certified By: Date: **May 14, 2015**

SGS certificated welder
国际第三方认证焊工

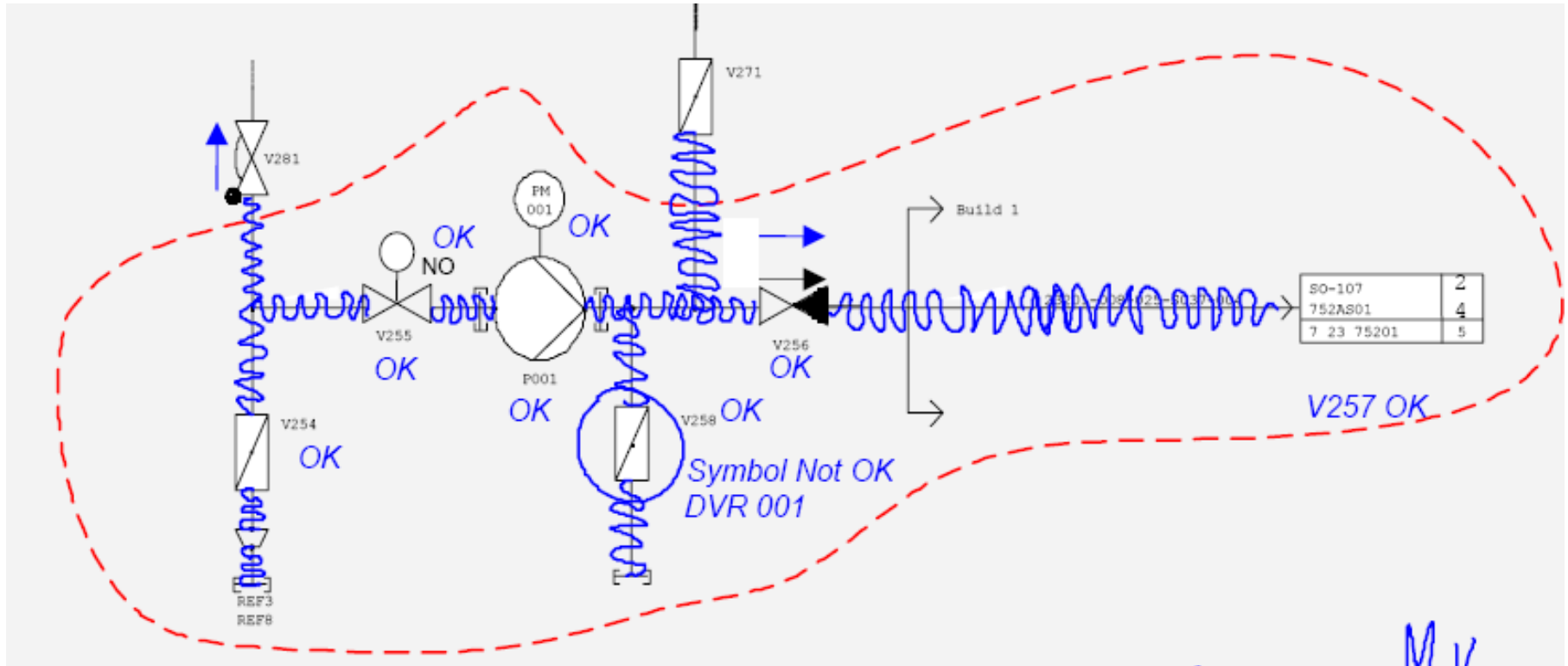
机械完成性检查 Mechanical Completion Inspection



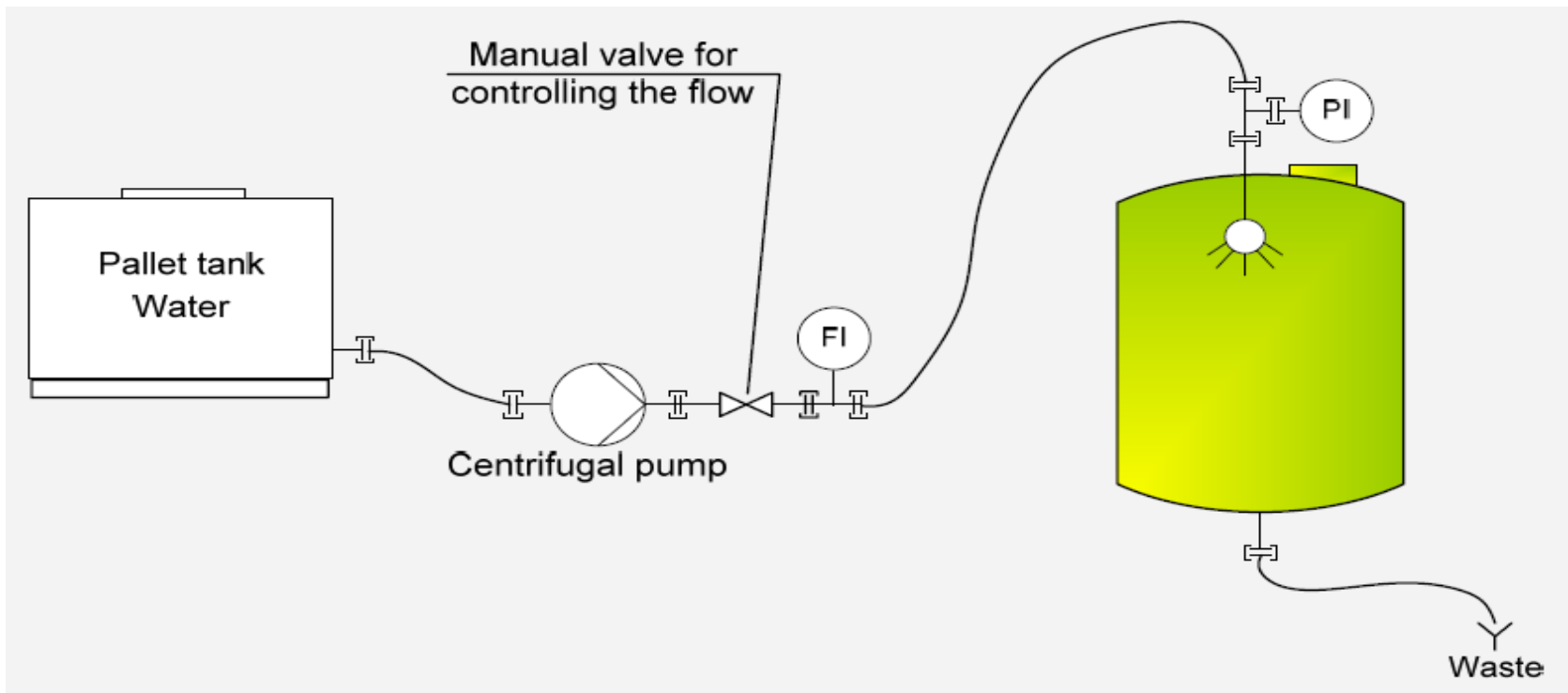
Utilities Confirmation 公用设施的确认



工艺流程确认 PID check



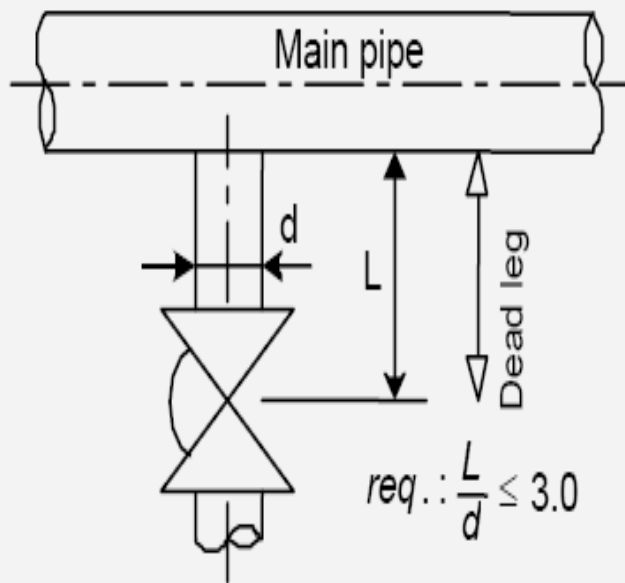
喷淋球覆盖范围测试 Spray ball coverage test



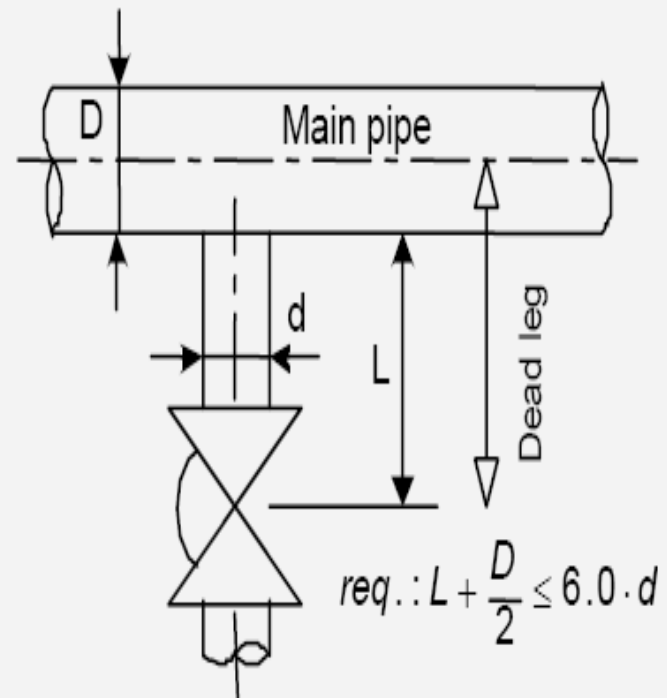
喷淋测试流程示意图
Introduction of spray ball coverage test

死角接受标准 Deadleg Acceptant Criteria

3.0 x d norm: Acceptance criterion 1

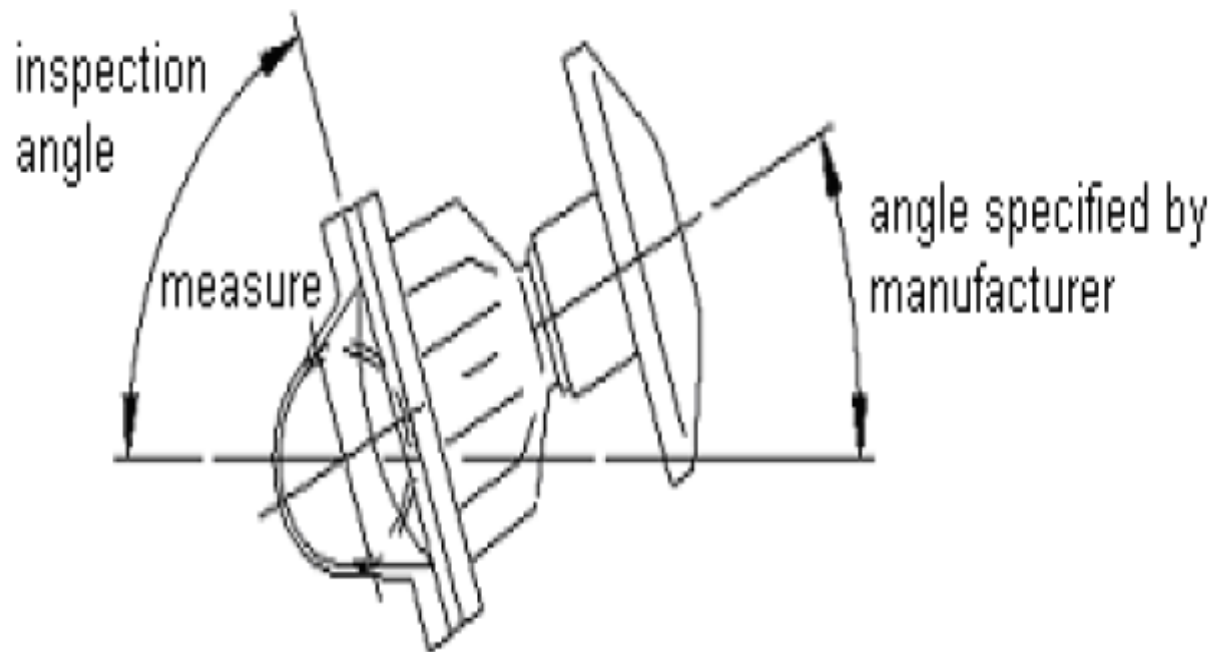


6.0 x d norm: Acceptance criterion 2

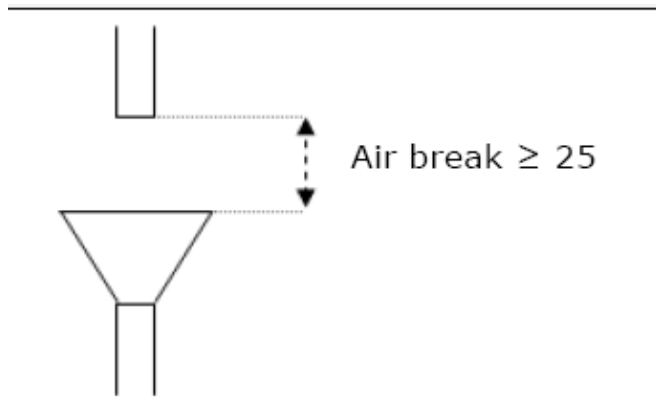


阀门角度检查 Diaphragm Valve's Angle Inspection

在水平管路上安装的隔膜阀，生产商必须明确需要安装的角度（如果不能以其他方式排水）。测量的误差不需考虑。



空气隔断的检查Air break inspection



Our Client 我们的客户



Questions?

Thank You!

More information please contact
William Wang
williamw@winatech.com.cn