

REQUEST FOR QUOTATION (RfQ)

Purified Water (PW) Production and Distribution System

1. Purpose of the Request

The purpose of this Request for Quotation is the turnkey supply of a system for the production, storage, and distribution of Purified Water (PW), including design, manufacturing, installation, testing, qualification, and start-up support, in compliance with current GMP regulations.

2. General Description of the Supply

The system shall include at least the following subsystems:

- PW production system
- PW storage system
- PW distribution pumping group
- PW distribution loop with approximately 10–15 user points
- Control and supervision system
- Mechanical and electrical installations
- Engineering, commissioning, and qualification services

3. PW Performance Requirements

The system shall guarantee the following minimum performance:

- Total flow rate: 600 L/h (0.6 m³/h)
- Conductivity: < 1.0 µS/cm
- TOC: < 500 ppb
- Nitrates (NO₃): < 0.2 ppm
- Microbial count: < 10 CFU / 100 ml

4. PW Production System

The production system shall consist primarily of:

- City water storage and recirculation tank
- Primary booster pump
- Scale reduction skid
- Dechlorination skid
- Multistage high and very-high-pressure pump

- Double-stage reverse osmosis skid
- EDI system

The system shall be sanitizable with hot water ($T > 80^{\circ}\text{C}$).

If applicable, it shall be predisposed for future upgrade to cold WFI production.

5. PW Storage System

- PW tank: usable volume 5,000 L
- Design: Horizontal, tank-in-tank configuration
- Materials:
 - Product contact parts: AISI 316L
 - Other parts: AISI 304
- Internal surface finish: $R_a \leq 0.5 \mu\text{m}$ + passivation
- Design temperature: $0 \div 90^{\circ}\text{C}$
- Design pressure: 0.49 barg
- Seals: PTFE FDA
- Equipment: CIP spray ball, temperature, pressure, and level sensors

The tank shall be inertized with pharmaceutical-grade nitrogen at approximately 0.2 bar.

6. PW Pumping Group

- No. 2 pumps (1 in operation + 1 standby) mounted on a skid
- Flow rate: $10 \text{ m}^3/\text{h}$
- Operating pressure: 4 bar
- Product contact surface roughness: $R_a < 0.5 \mu\text{m}$
- Mechanical seals: Tungsten carbide / silicon carbide
- Gaskets: EPDM FDA – USP Class VI
- Connections: Clamp OD
- Certifications:
 - Materials EN 10204 – 3.1
 - Gaskets EN 10204 – 2.1
 - Surface roughness certificate

Instrumentation included:

- Conductivity

- Temperature
- Pressure

7. PW Distribution Loop

- Main loop: DN40, AISI 316L ASME BPE SF1
- Maximum length: 250 m
- Welding: Orbital TIG (manual only if strictly necessary)
- User points: No. 12
 - Pneumatic diaphragm valve
 - Tandem sampling valve for critical POU
- Insulation:
 - Pipe-in-pipe for POU
 - Armaflex for other sections
- Heat exchangers:
 - Cooling (AISI 316L)
 - Electric heating for sanitization

Instrumentation:

- Conductivity
- Temperature
- Pressure
- Flow
- TOC analyzer

8. Control System

Hardware:

- Power and control panel
- Siemens PLC
- 12" HMI
- Emergency stop buttons
- Inverters
- Communication protocols (Modbus / Profinet / Profibus)

Software:

- Compliance with 21 CFR Part 11
- System Start/Stop
- Monitoring of critical parameters
- Alarm management
- Access control and user profiles
- Process parameter modification capability

9. Required Services

9.1 Engineering and Documentation

- Mechanical and electrical manuals
- Construction drawings
- P&ID
- Datasheets
- Material and weld certificates
- Boroscopies
- Test reports and inspection results

9.2 Project Management

- Dedicated Project Manager
- Coordination of activities and reporting to the Client

9.3 Commissioning and Qualification

- FAT (with protocol)
- SAT (optional)
- IQ / OQ
- Final qualification reports

10. Applicable Standards and References

The system shall comply with, among others, the following standards and guidelines:

- EU GMP – Vol. 4 – Annex 1
- WHO QAS/10.379
- ISPE – Water & Steam Systems

- European Pharmacopoeia (latest edition)
- ASME BPE
- Applicable ISO standards
- 21 CFR Part 11, 210–211
- ATEX Directive 2014/34/EU (if applicable)

11. Warranties

The supplier shall guarantee:

- Compliance with GMP requirements
- Execution by qualified personnel
- Free correction of any supplier-attributable non-conformities within 12 months from final delivery.

询价函 (RfQ)

纯化水 (PW) 生产及分配系统

1. 询价目的

本询价函旨在采购一套纯化水 (PW) 生产、储存及分配系统的交钥匙工程，包括系统的设计、制造、安装、测试、确认 (Qualification) 以及启动支持，系统须符合现行 **GMP** 法规要求。

2. 供货范围总体说明

系统至少应包括以下子系统：

- 纯化水生产系统
- 纯化水储存系统
- 纯化水分配泵组
- 纯化水分配回路 (约 10–15 个用水点)
- 控制与监控系统
- 机械与电气安装
- 工程设计、调试及确认服务

3. 纯化水性能要求

系统应至少保证以下性能指标：

- 总流量：600 L/h (0.6 m³/h)
- 电导率：< 1.0 μ S/cm
- TOC：< 500 ppb
- 硝酸盐 (NO₃)：< 0.2 ppm
- 微生物：< 10 CFU / 100 ml

4. 纯化水生产系统

生产系统主要包括：

- 市政水储罐及循环系统
- 初级增压泵
- 阻垢装置撬装系统
- 脱氯装置撬装系统
- 多级高压及超高压泵
- 双级反渗透（RO）装置
- EDI（连续电去离子）系统

系统应可进行热水消毒（ $T > 80^{\circ}\text{C}$ ）。

如适用，系统应预留未来升级为冷法注射用水（WFI）生产的可能性。

5. 纯化水储存系统

- 纯化水储罐有效容积：5,000 L
- 设计形式：卧式，罐中罐结构
- 材质：
 - 与产品接触部分：AISI 316L
 - 其他部件：AISI 304
- 内表面粗糙度： $Ra \leq 0.5 \mu\text{m}$ ，并进行钝化处理
- 设计温度： $0 \div 90^{\circ}\text{C}$
- 设计压力：0.49 barg
- 密封件：PTFE，符合 FDA 要求
- 配套设备：
 - CIP 喷淋球
 - 温度、压力及液位传感器

储罐应使用药用级氮气进行惰性保护，压力约为 **0.2 bar**。

6. 纯化水泵组

- 数量：2 台（1 用 1 备），安装于撬装底座
- 流量：10 m³/h
- 工作压力：4 bar
- 与产品接触表面粗糙度：Ra < 0.5 μm
- 机械密封：碳化钨 / 碳化硅
- 垫片：EPDM, FDA 认证 – USP Class VI
- 连接方式：卡箍式（Clamp OD）

证书要求：

- 材质证书：EN 10204 – 3.1
- 垫片证书：EN 10204 – 2.1
- 表面粗糙度证书

配套仪表：

- 电导率
- 温度
- 压力

7. 纯化水分配回路

- 主回路：DN40, AISI 316L, ASME BPE SF1
- 最大长度：250 m
- 焊接方式：轨道 TIG 焊接（仅在必要时允许手工焊接）

用水点（POU）：

- 数量：12 个
- 气动隔膜阀

- 关键用水点配置双联取样阀

保温方式:

- 用水点采用管中管结构
- 其他区域采用 Armaflex 保温

换热设备:

- 冷却换热器 (AISI 316L)
- 用于消毒的电加热系统

仪表配置:

- 电导率
- 温度
- 压力
- 流量
- TOC 在线分析仪

8. 控制系统

硬件:

- 动力与控制柜
- 西门子 PLC
- 12 英寸 HMI
- 紧急停止按钮
- 变频器
- 通讯协议 (Modbus / Profinet / Profibus)

软件:

- 符合 21 CFR Part 11

- 系统启动 / 停止控制
- 关键参数监控
- 报警管理
- 权限管理及用户分级
- 工艺参数修改功能

9. 所需服务

9.1 工程设计与文件

- 机械及电气操作手册
- 施工图纸
- P&ID
- 设备数据表
- 材料及焊接证书
- 内窥镜检测 (Boroscope)
- 测试报告及检验结果

9.2 项目管理

- 指定项目经理
- 活动协调及向客户汇报

9.3 调试与确认

- FAT (含测试方案)
- SAT (可选)
- IQ / OQ
- 最终确认报告

10. 适用标准与参考规范

系统应符合但不限于以下标准与指南：

- EU GMP – 第 4 卷 – 附录 1
- WHO QAS/10.379
- ISPE 《水与蒸汽系统指南》
- 欧洲药典（最新版）
- ASME BPE
- 相关 ISO 标准
- 21 CFR Part 11, 210–211
- ATEX 指令 2014/34/EU（如适用）

11. 质量保证

供应商应保证：

- 系统符合 GMP 要求
- 由具备资质的人员执行
- 自最终交付之日起 **12** 个月内，对因供应商原因造成的任何不符合项进行免费整改