

CHEMION PURIFIED WATER GENERATION, STORAGE AND DISTRIBUTION SYSTEM

**“YOUR PARTNER FOR TURNKEY SOLUTIONS IN PHARMA &
BIOTECH INDUSTRY”**

AN ISO 9001:2008 CERTIFIED COMPANY



“WE CAN MAKE WATER WORK EFFICIENT FOR YOU”

CHEMION ENGINEERING – THE COMPANY

- ❖ The demand for improved water quality has been a fundamental need since time immemorial and also a precondition for optimal results in various aspects of work and life. The technological and legal requirements for optimal water treatment are constantly rising .
- ❖ As a leading supplier to this market, Chemion Engineering has many years of experience and possesses a comprehensive range of technologies for producing all the grades of water required in Pharma and Biotech industry.
- ❖ When it comes to water ,whether at the point of entry or to the point of use , the trend setting products by Chemion Engineering are in use and have proved their quality several times.
- ❖ Extensive innovations enable us to provide our customers and partners with the best products ,systems ,technologies and services in all areas of water treatment.
- ❖ Our projects are constructed on time and within budget also. We also monitor all aspects of the project on regular basis . We continually work with our customer ,ensuring that their requirements and expectations are met within line with the project programme.

TURNKEY SYSTEM –COMPONENTS

Our turnkey services and products includes,

- ✓ Concept design, basic design, case studies and consultancy services.
- ✓ Complete assistance for User Requirement Specification (URS).
- ✓ Detailed design and engineering.
- ✓ Raw water Disinfection
- ✓ Purified Water Generation System.
- ✓ Storage and Distribution System.
- ✓ Ozone and heat sanitization for distribution system.
- ✓ PLC Systems .
- ✓ Design ,maintenance and consultancy service.
- ✓ Qualification, Validation and full documentation packages to CGMP.

ADVANTAGES – TURNKEY PROJECTS.

- ✓ Single roof Warranty for products and quality.
- ✓ Uniform high product quality with high end components.
- ✓ Seamless project execution without interfaces, one communication for customers.
- ✓ Shorter project cycle.
- ✓ Simplified spares part storage
- ✓ Cost efficient service and recalibration.
- ✓ Consistent documentation and validation package.

PROCESSES AND PRODUCTS

- ✓ Raw water disinfection systems
- ✓ Dosing Systems .
- ✓ Fully Automatic “TWIN RAPID “ DM Plant with regeneration duration-25-30 minutes, providing mixed bed quality without Mixed bed .
- ✓ Fully automatic Filtration system.
- ✓ Fully Automatic “TWIN SOFTENERS” with salt saving technology.
- ✓ Fully automatic Ultra filtration system-Pretreatment.
- ✓ Fully Automatic Chemically sanitisable /Hot water sanitisable RO systems .
- ✓ Fully Automatic CEDI systems.
- ✓ UV systems for disinfection.TOC reduction and destruction of ozone .
- ✓ Storage and distribution systems for ultrapure water , made of SS 316L OR PVDF.
- ✓ CIP/SIP for solution preparation systems .
- ✓ PLC and point of use management systems.
- ✓ Data archiving and remote monitoring system.

PRODUCTS



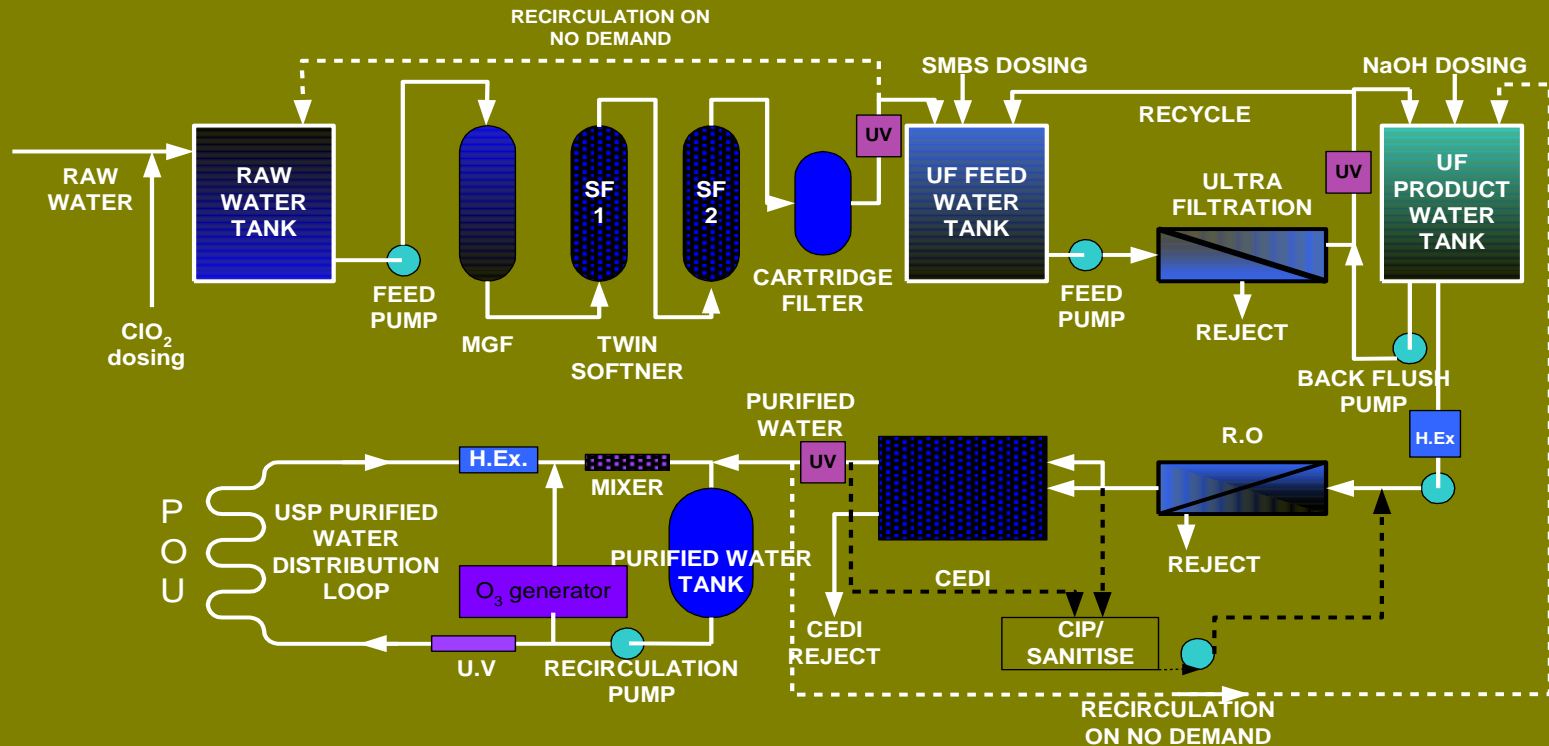
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PROCESS FLOW DIAGRAM



PROCESS FLOW DIAGRAM
PURIFIED WATER GENERATION/STORAGE/DISTRIBUTION SYSTEM

NOTE: VALVES & INSTRUMENTATION NOT SHOWN

TOTAL SERVICE FOR SUCCESSFUL PROJECT

1) Proper Study of Concept:

- Staff members who are familiar with latest regulations and directions of all applicable authorities ensure that the current requirements are implemented.

2) Proper Planning :

- The spectrum of service includes mass balance considerations with the aid of modern tools , calculations, P&ID with the generation of corresponding parts list ,on site inspection of the site.

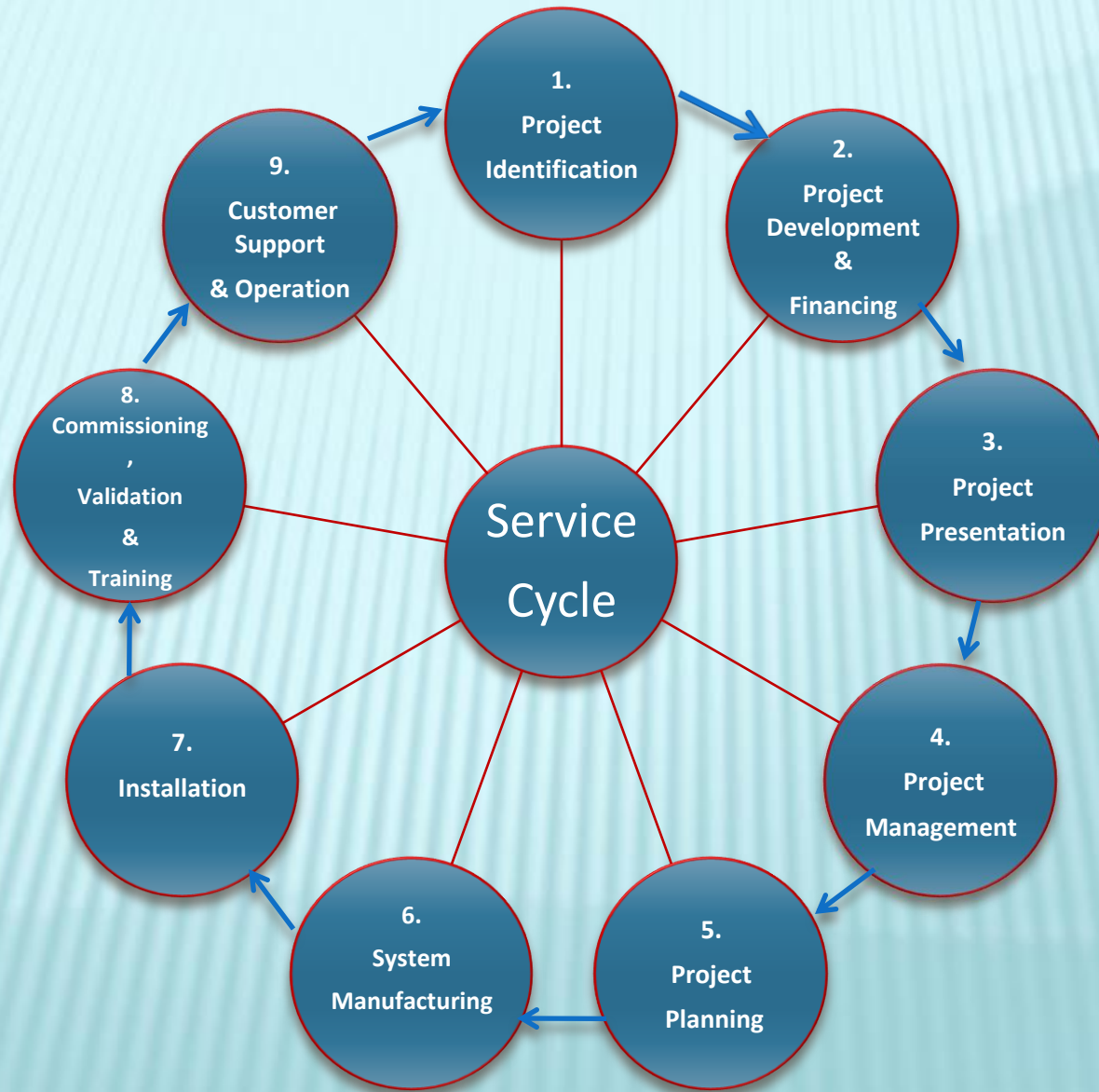
3) Validation & Documentation :

- During initial stage of a project, a project plan is setup to ensure quality control in the project, together with scope submittals etc. The documents shall be submitted to customer for approval.
- The water treatment systems are validated according to FDA,cGMP,USP requirements.

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- Our complete system will be skid mounted and leaves the factory after properly executed FAT, done in the presence of customer under real conditions. Commissioning and handover will be performed before final hand over to the customer.
- After erection of the system IQ(Installation Qualification) which verifies the installation , the OQ(Operation Qualification) which verifies the correct functionality will be performed. Once IQ and OQ is completed SAT (Site Acceptance Test) will be done in the presence of customer.
- Proper training will be imparted to the operating personnel , makes it easier to handle the system and ensure trouble free and reliable operation.
- Services during the entire project cycle :
 - ❑ Project & Validation Plan
 - ❑ Design Verification
 - ❑ Execution of FAT,SAT
 - ❑ SOP Preparation
 - Validation Strategy
 - Validation of Protocols
 - DQ,IQ,OQ Validation
 - Review of certificates, tests

OUR SERVICE CYCLE



PHARMACOPOEIA REQUIREMENTS

Pharmacopoeia requirements for 'purified water'

Properties	Ph Eur	USP
Conductivity	<4.3 $\mu\text{S}/\text{cm}$ at 20°C	<1.3 $\mu\text{S}/\text{cm}$ at 25°C*
TOC	<500 $\mu\text{g}/\text{l C}^{**}$	<500 ppb
Bacteria (guideline)	<100 CFU/ml	<100 CFU/ml
Nitrates	<0.2 ppm	-
Heavy metals	<0.1 ppm	-

Pharmacopoeia requirements for 'water for injection' & 'highly purified water'

Properties	Ph Eur	USP
Conductivity	<1.1 $\mu\text{S}/\text{cm}$ at 20°C***	<1.3 $\mu\text{S}/\text{cm}$ at 25°C*
TOC	<500 $\mu\text{g}/\text{l C}^{**}$	<500 ppb
Bacteria (guideline)	<10 CFU/100ml	<10 CFU/100ml
Endotoxins	<0.25 IU/ml	<0.25 EU/ml
Nitrates	<0.2 ppm	-
Heavy metals	<0.1 ppm	-

Stage 1: Temperature/Conductivity Requirements (for USP)

(for non-temperature compensated conductivity measurements)

Temperature °C	Conductivity $\mu\text{S}/\text{cm}$	Temperature °C	Conductivity $\mu\text{S}/\text{cm}$
0	0.6	55	2.1
5	0.8	60	2.2
10	0.9	65	2.4
15	1.0	70	2.5
20	1.1	75	2.7
25	1.3	80	2.7
30	1.4	85	2.7
35	1.5	90	2.7
40	1.7	95	2.9
45	1.8	100	3.1
50	1.9	-	-

Stage 3: Conductivity Requirements (for USP) as a Function of pH

pH	$\mu\text{S}/\text{cm}$	pH	$\mu\text{S}/\text{cm}$
5.0	4.7	6.1	2.4
5.1	4.1	6.2	2.5
5.2	3.6	6.3	2.4
5.3	3.3	6.4	2.3
5.4	3.0	6.5	2.2
5.5	2.8	6.6	2.1
5.6	2.6	6.7	2.6
5.7	2.5	6.8	3.1
5.8	2.4	6.9	3.8
5.9	2.4	7.0	4.6
6.0	2.4	-	-

THANK YOU

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