



AUSTAR Liquid Process System





MISSION & VISION



MISSION

To promote the development of the liquid process system in the pharmaceutical industry, to achieve synchronization with the level of Europe and America, to contribute for human health.

VISION

To provide the best solutions for liquid process system that meet industry standards for pharmaceutical enterprises.

ABOUT US

AUSTAR Liquid Process System department focuses on the pharmaceutical water system and liquid process system. With more than 20 years experience in pharmaceutical industry, we can provide professional services in design, manufacturing, construction, project management, validation and aftersales service.



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- CIP System



Quality Assurance

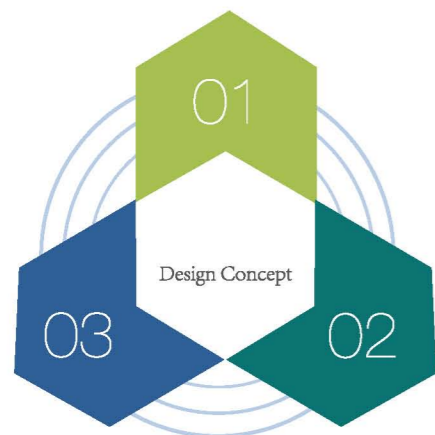
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PHARMACEUTICAL WATER SYSTEM

Pharmaceutical Water System

AUSTAR Liquid Process System Department provides the service in design, manufacturing, construction, testing and validation which are in conformance with the latest international standard, regulations of pharmaceutical industry and user's requirements.

Design Concept



- 01 Quality by Design
- 02 Inhibit Microbial Growth
- 03 Prevent Particles Contamination

Products & Services

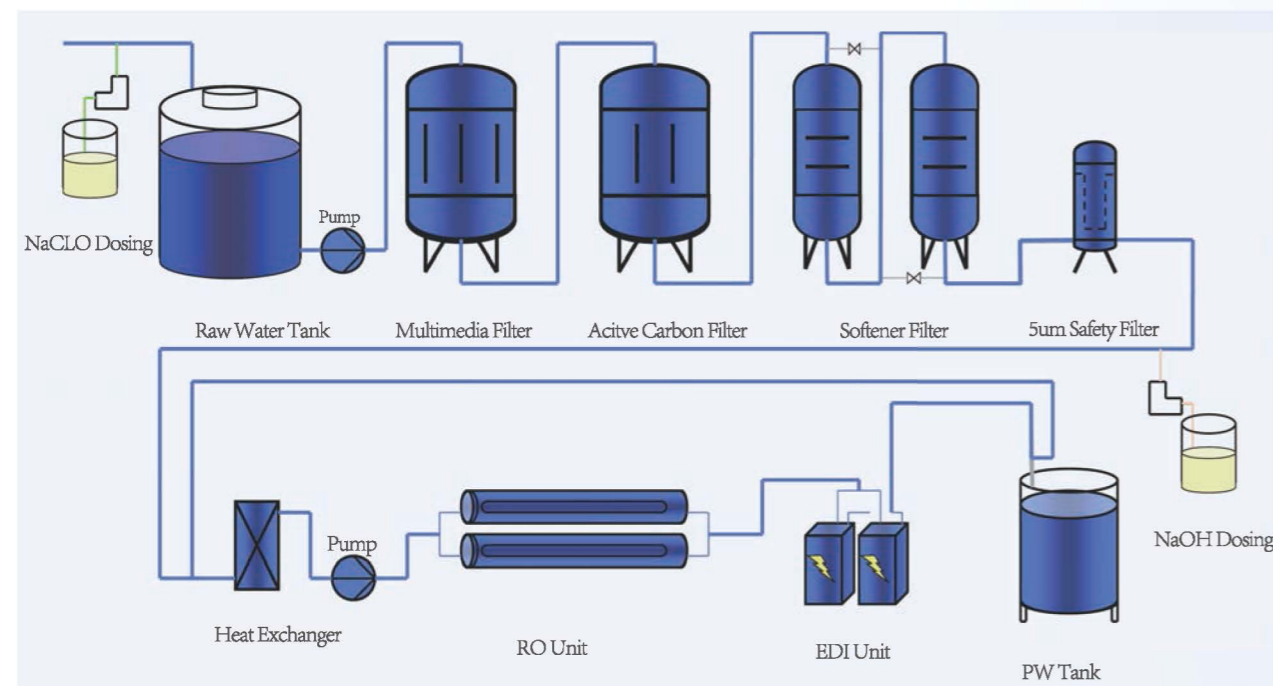


Purified Water Generator

According to quality of different raw water, AUSTAR provides customer with appropriate process design for ensuring long term stable generation of purified water which meets the pharmacopoeia standard.



Purified Water Generator



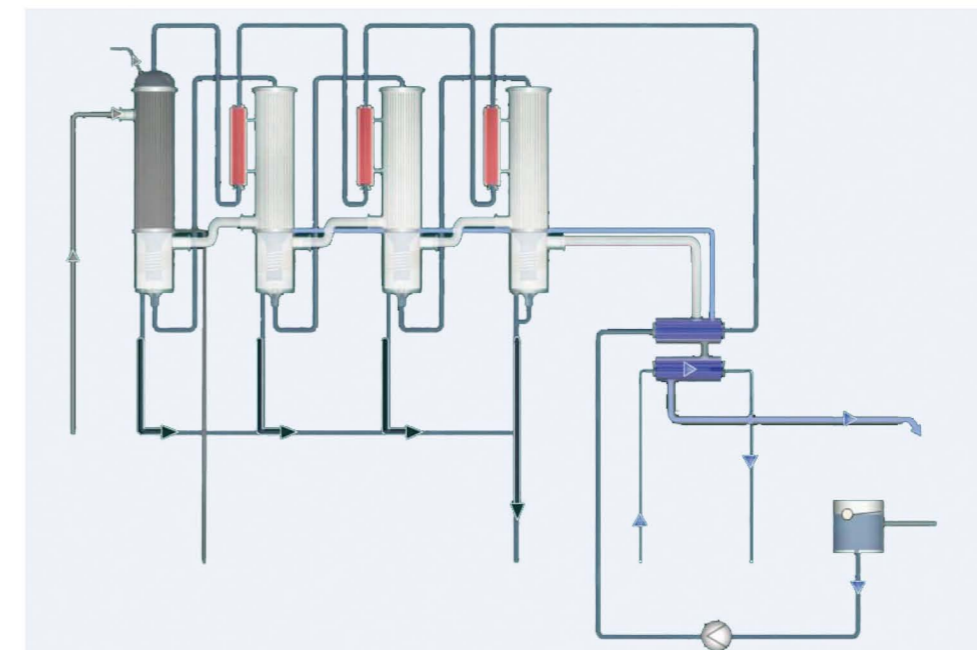
Schematic of Purified Water Generator

Multiple-effects Water Still

The multiple-effects water still is produced by Steris-Austar with the latest patented technology. Its design and fabrication complies with standards of cGMP, WHO, GAMP, HTM2010/EN285, ASME BPE, GB150 etc. (The index of endotoxin is lower than 0.01IU/ml.)



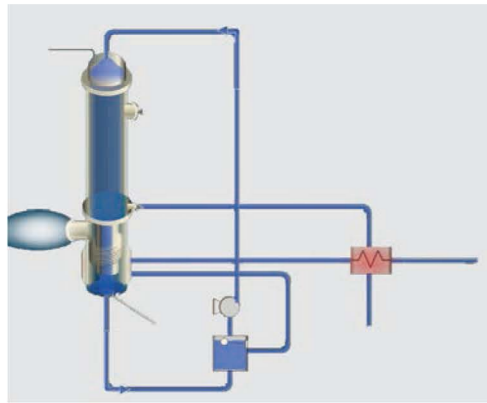
Multiple-effects Water Still



Schematic of Multiple-effects Water Still

Pure Steam Generator

The pure steam generator is produced by Steris-Austar adopting FINN-AQUA patented technology. It can produce pure steam within very short time which meets the requirements of pressure, flux, saturation and non-condensate gas. (The index of endotoxin is lower than 0.01IU/ ml.)



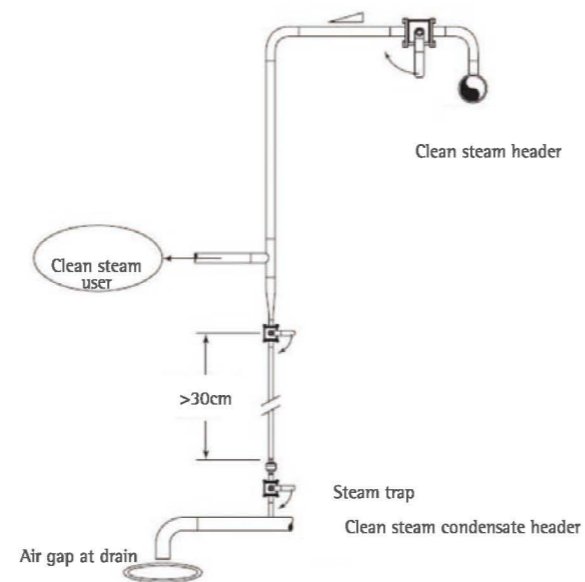
Schematic of Pure Steam Generator



Pure Steam Generator

Distribution Network System

The design of pure steam distribution system meets the POU's requirement for pure steam on non-condensate gas, superheat degree and dryness. (British standard EN285 and HTM2010)



Pure Steam POU's Design

Storage & Distribution System

Storage unit is to store the pharmaceutical water which can meet pharmacopoeia requirements and the maximum consumption of the system. Distribution system delivers the pharmaceutical water to each POU, and ensure its pressure, flow and temperature meet the requirements of POU. The flow, pressure, temperature, TOC, conductivity, ozone of pharmaceutical water can be monitored by the distribution system, and the bioburden in water can be controlled effectively by using periodic sterilization method.



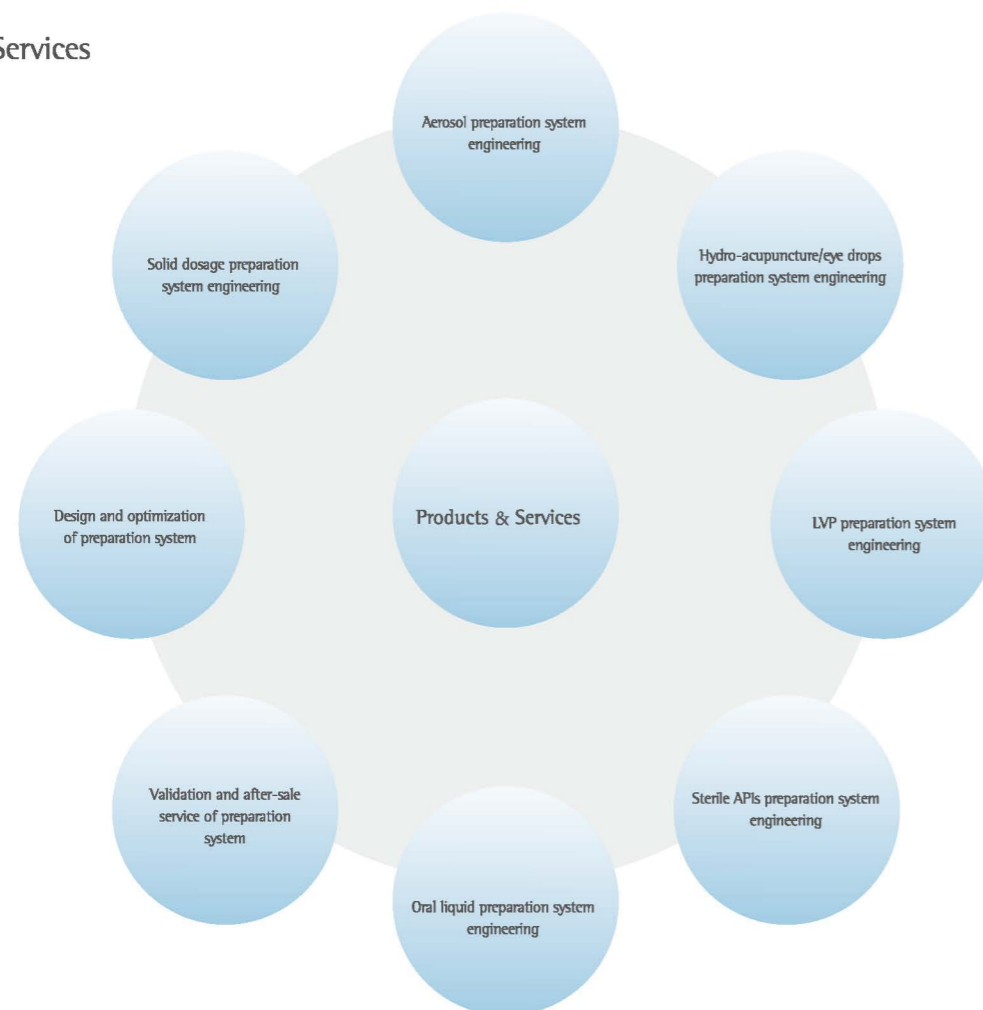
Water for Injection Distribution Module

PHARMACEUTICAL PROCESS SYSTEM

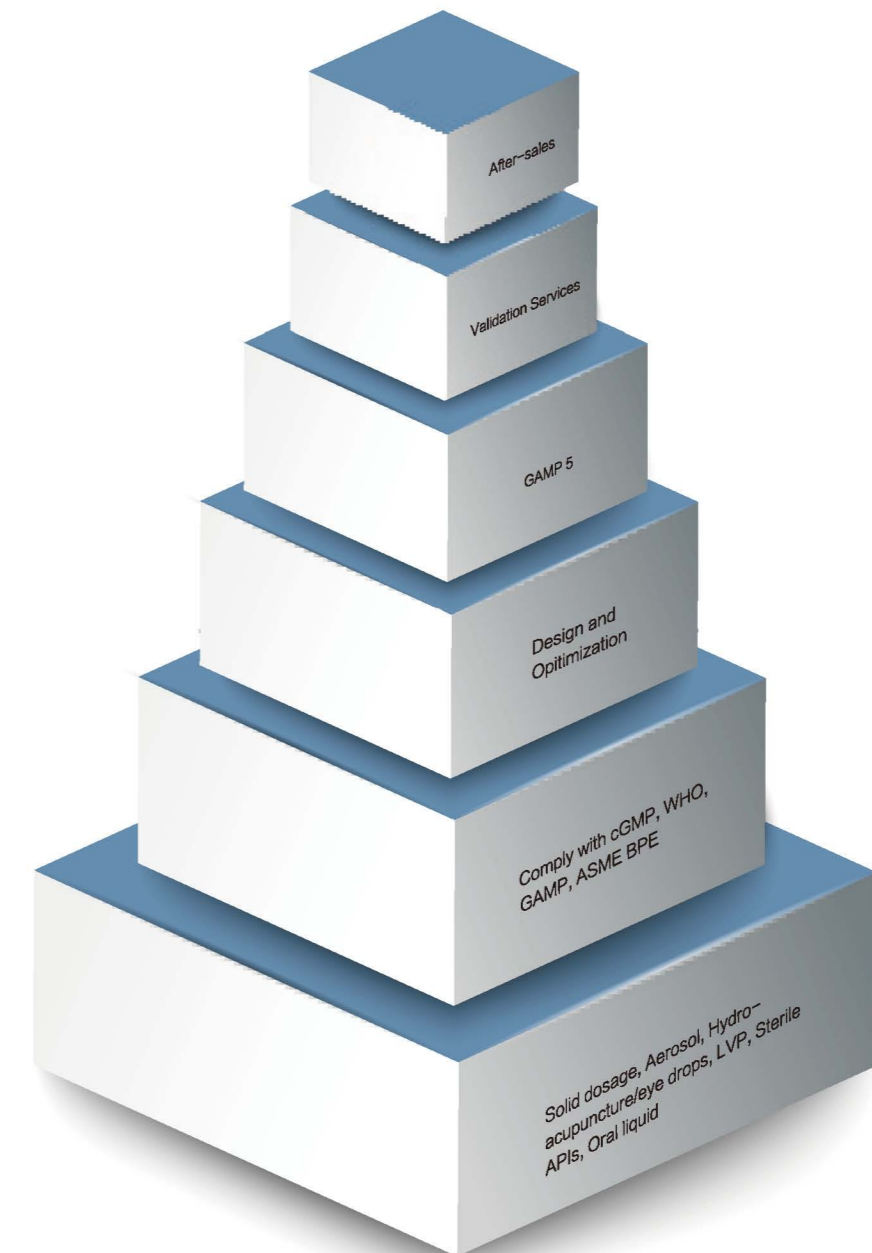
Pharmaceutical Process System

Pharmaceutical process system can be defined as the production system with multiple operation functions including heating, cooling, mixing, stirring, constant volume, filtering delivery, CIP and SIP.

Products and Services

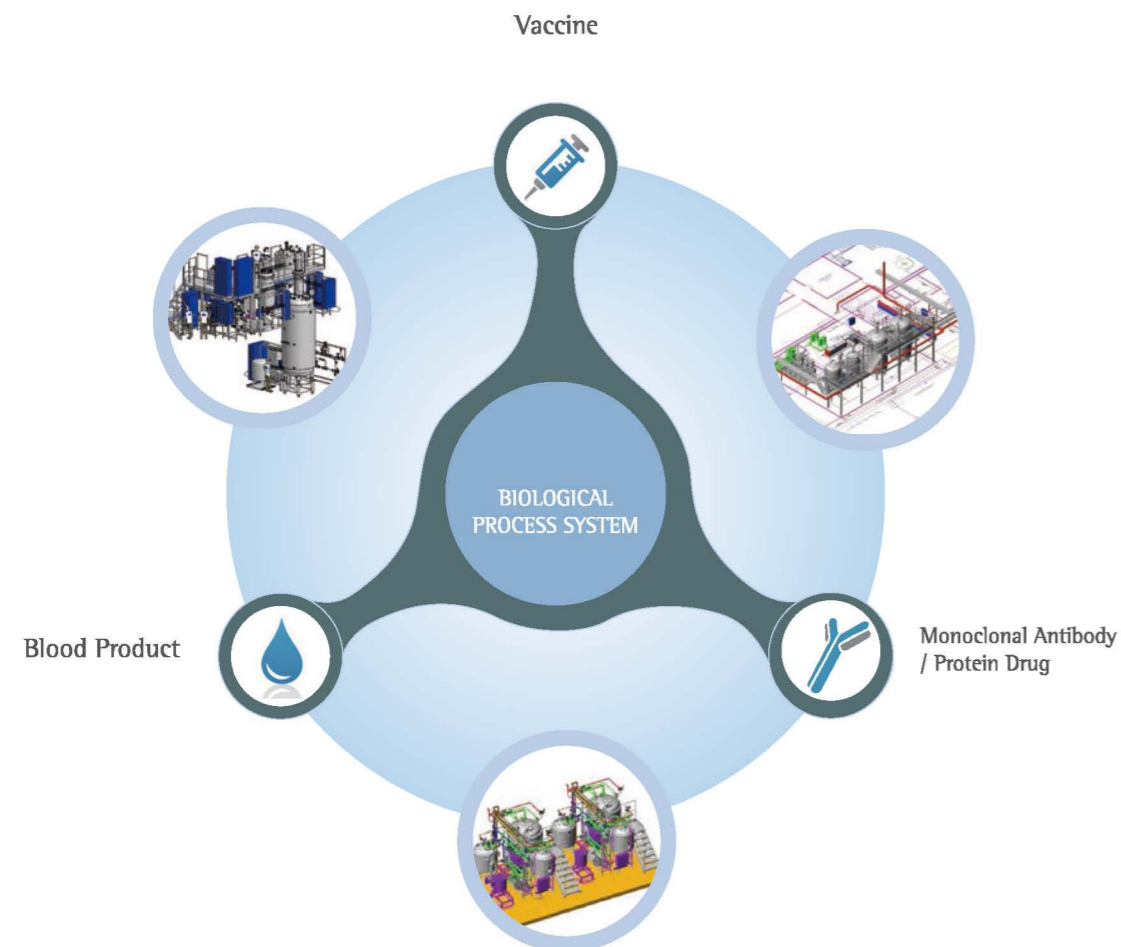


Design Concept



Bioprocess System

AUSTAR provides complete Bioprocess Systems including upstream and downstream process system, which are widely used for the production of insulin, monoclonal antibodies, vaccines and blood products. AUSTAR provides integrated solution from drug R&D, pilot test to scale-up production for biopharmaceutical industry. Upstream process system includes: medium and buffer preparation system, fermenter/bioreactor, harvest system etc.. Downstream process system includes: filtration system, chromatography, ultrafiltration system and so on. AUSTAR is capable of providing independent equipment and owns rich experiences in bioprocessing integration engineering system.



Biological Preparation



Fermenter/Bioreactor



Pilot Fermenter/Bioreactor



Ultrafiltration System



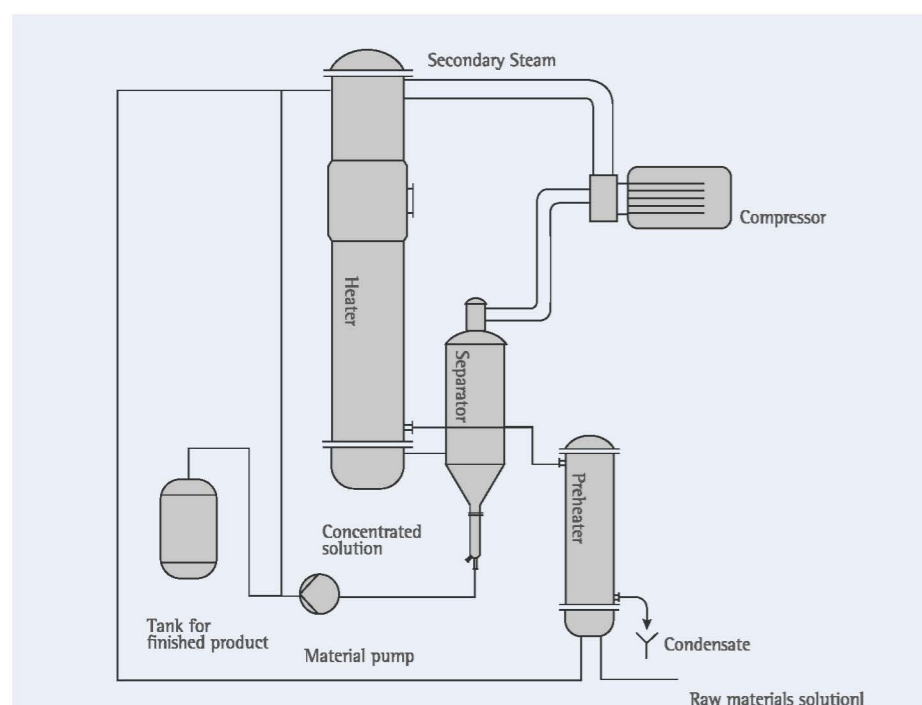
Chromatography System

Traditional Chinese Medicine Process System

AUSTAR provides traditional Chinese medicine customers with comprehensive solutions of optimization design, automation control system and pipeline installation of extract workshop, liquid formulation production line and Semi-Fluid formulation production line. AUSTAR owns rich experience in the automatic control of Chinese medicine extraction process. AUSTAR can effectively solve the problem of clarity in liquid formulation production of traditional Chinese medicine, the problem of fusion and inhomogeneous mixture in the Semi-liquid formulation production.

MVR Energy-Saving Evaporator for Traditional Chinese Medicine

The MVR evaporator is a high-end device of AUSTAR which is tailored for traditional Chinese medicine companies. This MVR evaporator has changed the status of high consumption and low efficiency of traditional evaporator, and also avoided material escaping and scaling in the evaporating pipeline during traditional Chinese medicine extract process.



Mechanical vapor recompression

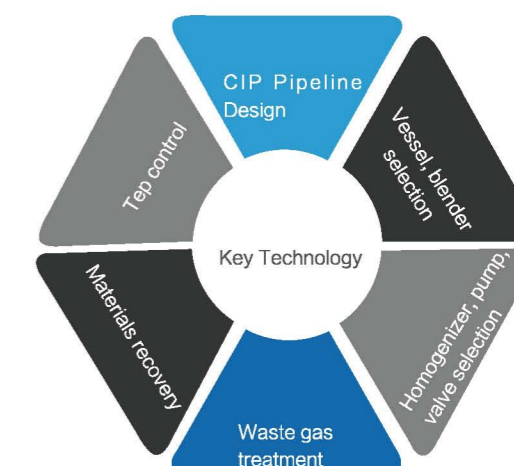
Emulsion Process System

Fat Emulsion Process System

AUSTAR develops a complete set of automatic control solution of fat emulsion production based on abundant theoretical research, combining with onsite commissioning and customer's production experience. The core process of fat emulsion production includes proportional feed control of oil phase and aqueous phase, the control of system residual fluid, the protection of homogenizer and the process control of homogenization, cleaning and sterilization of production system.

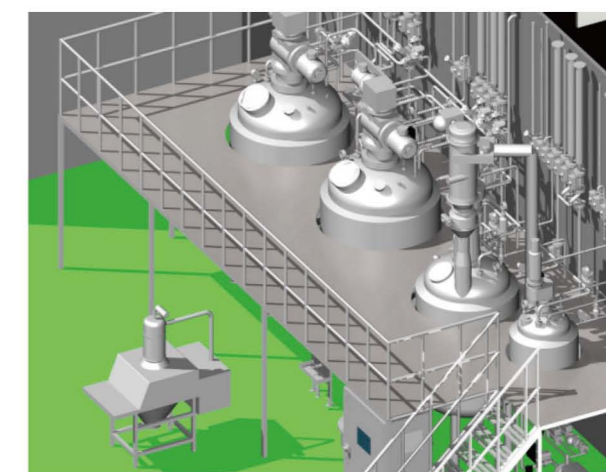


Fat Emulsion Process System



Ointment/Suppository System

Ointment/Suppository system mainly includes raw material pretreatment, sterilization, homogenization and emulsification, storage and transmission, CIP etc. AUSTAR is capable of providing first class product preparation system in the industry, such as modular equipment with appropriate layout, automatic and semi-automatic control system. AUSTAR also provides differential solutions considering characteristics of different products.



Ointment / Suppository Process System

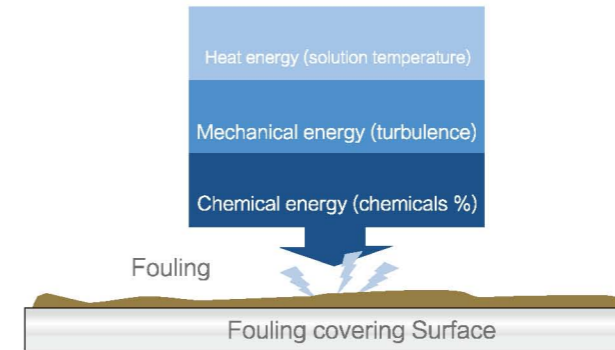
CIP System

AUSTAR's CIP/SIP system follows the latest international standards and complies with requirements of the pharmaceutical industry laws and regulations. AUSTAR designs, manufactures and tests system according to the actual need of users in order to ensure the cleaned process system meet the requirements of cleaning validation and sanitation validation. The whole system including all the interconnected pipelines and cables is installed on an independent holder.

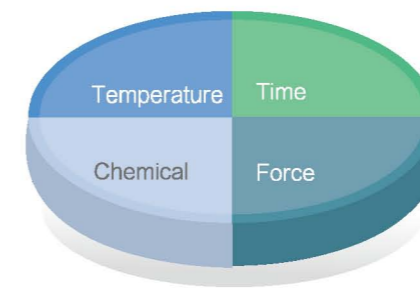


CIP System

Design Concept



The principle of cleaning



TACT model

$$CR = Ti + A + C + Te = 100\%$$

- CR : Cleaning criteria (acceptable cleaning results)
- Ti: Time (full contact time and action time of the cleaning process)
- A: Mechanical action (flow velocity, flow rate and pressure of cleaning process)
- C: Chemical action (The type and concentration of cleaning agent)
- Te: Temperature (The temperature of cleaning water and cleaning solution)



CIP100 / CIP200

Modular Design

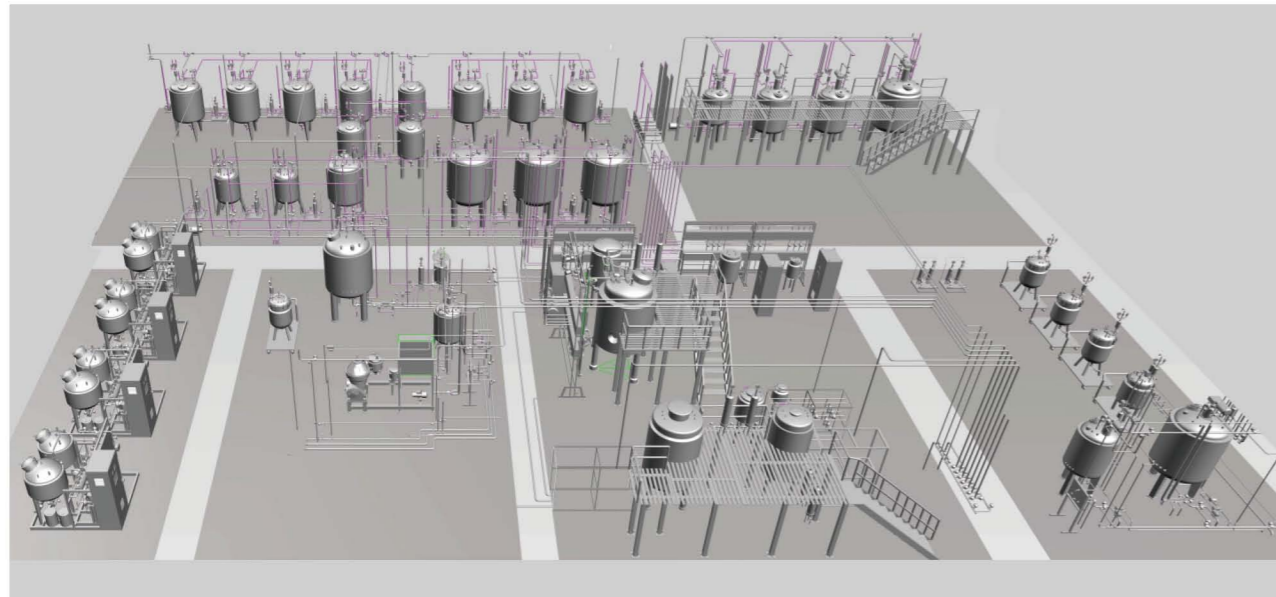
Modular design bases on professional 3D software, which makes cost, design, assembly, project duration more predictable. Its advantages are as follows:

Better quality assurance—Assembled in factory, high quality, conducive to the realization of FAT, predictable quality.

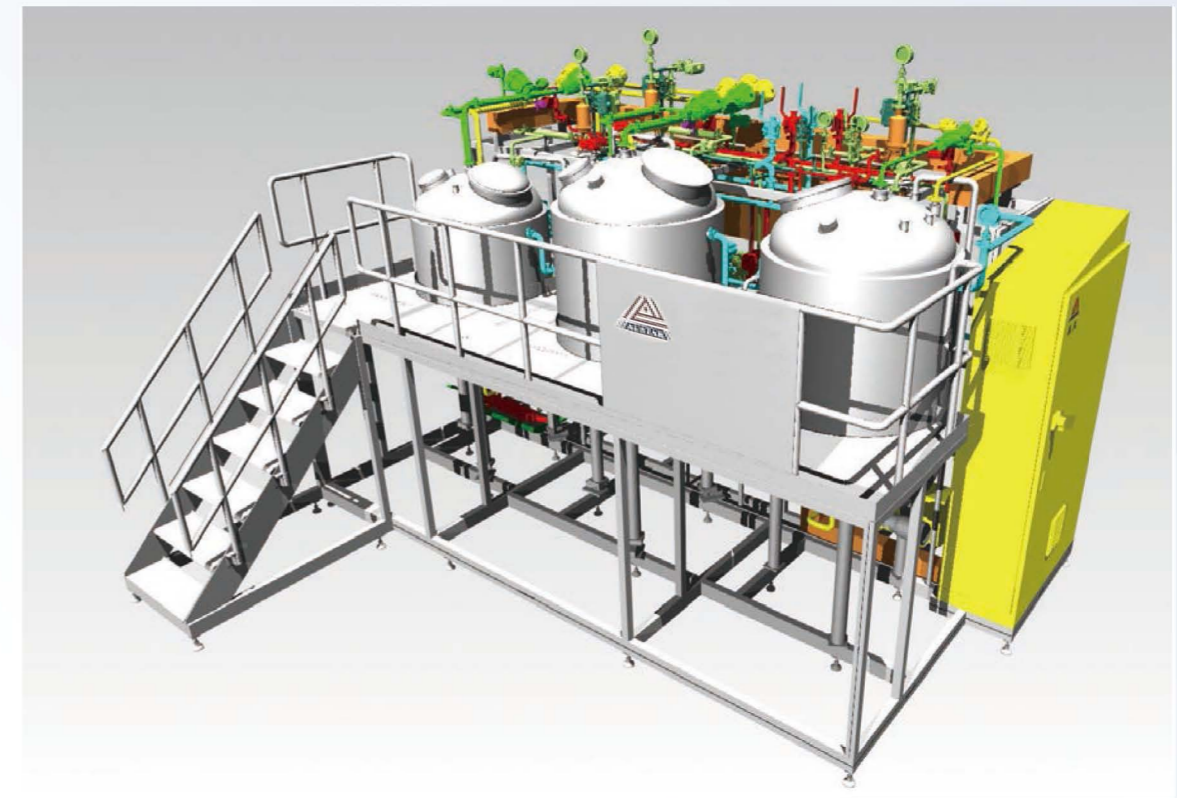
Lower project cost—High-efficient assembly avoid repetitive work.

Shorter lead time—Factory assembly is implemented simultaneously with onsite construction and project duration is shortened.

Compact layout and convenient operation—Integrated with the concept of ergonomics, more convenient and efficient operation and maintenance, more compact aspect design and improve space usage.



Layout of Biological Preparation Workshop



3D Drawing of Pharmaceutical Preparation System



Pharmaceutical Preparation System

DEROUGING AND PASSIVATION SERVICE



Rouge is a kind of common phenomenon in clean fluid system. The formation rate and extent of rouge in the high temperature system is much higher than that in the normal temperature system. AUSTAR can provide pharmaceutical companies with perfect derouging integrated solutions by relying on professional execution team and reliable cleaning and derouging agent.

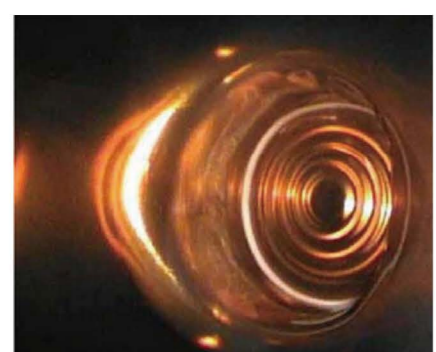
Harm of Rouge

Affecting the quality of pharmaceutical water; Disturbing the clarity of liquid; Physicochemical reaction with the product; Increasing the workload of the filter; Affecting the production capacity of MWS; Weakening the anti-pressure capacity of the container; Inducing the pipeline leakage; Affecting pipeline's surface finish; Increasing energy consumption of production; Reducing operating life of system; Increasing maintenance cost

Level of Rouge

	(Ingredient)	(Color)	(Characteristic)
Primary	FeO; Fe(OH) ₂	Yellow or orange	Easily forming, Easily removing, Easily recurring
Moderate	Fe ₂ O ₃	Red	Appearing in various forms of corrosion pit and crevice etc. , more difficult to be removed
Severe	Fe ₃ O ₄	Black	Close to the inner wall of the system and difficult to be removed

Before and After Comparison



Before derouging



After derouging

Professional Cleaning and Inspection Equipment



Derouging Equipment



Endoscope



Iron Ion



Alloy Analyzer



Certification

Certificate

Standard **ISO 9001:2008**

Certificate Registr. No. 01 100 064539

TÜV Rheinland Cert GmbH certifies:

Certificate Holder: Shanghai Austar Pharmaceutical Technology Equipment Ltd.
No. 799, Yuyang Road, Cangqiao Industrial Zone, Songjiang District, Shanghai 201600, P. R. China

Scope: Manufacturing of Purified Water System Equipments, Multi-Effect Water Still, Pure Steam Generator, Cleaning and Sterilizing Equipments, Powder Filling Machine for Pharmaceutical Use

An audit was performed, Report No. 064539. Proof has been furnished that the requirements according to ISO 9001:2008 are fulfilled.
The due date for all future audits is 01-11 (dd.mm).

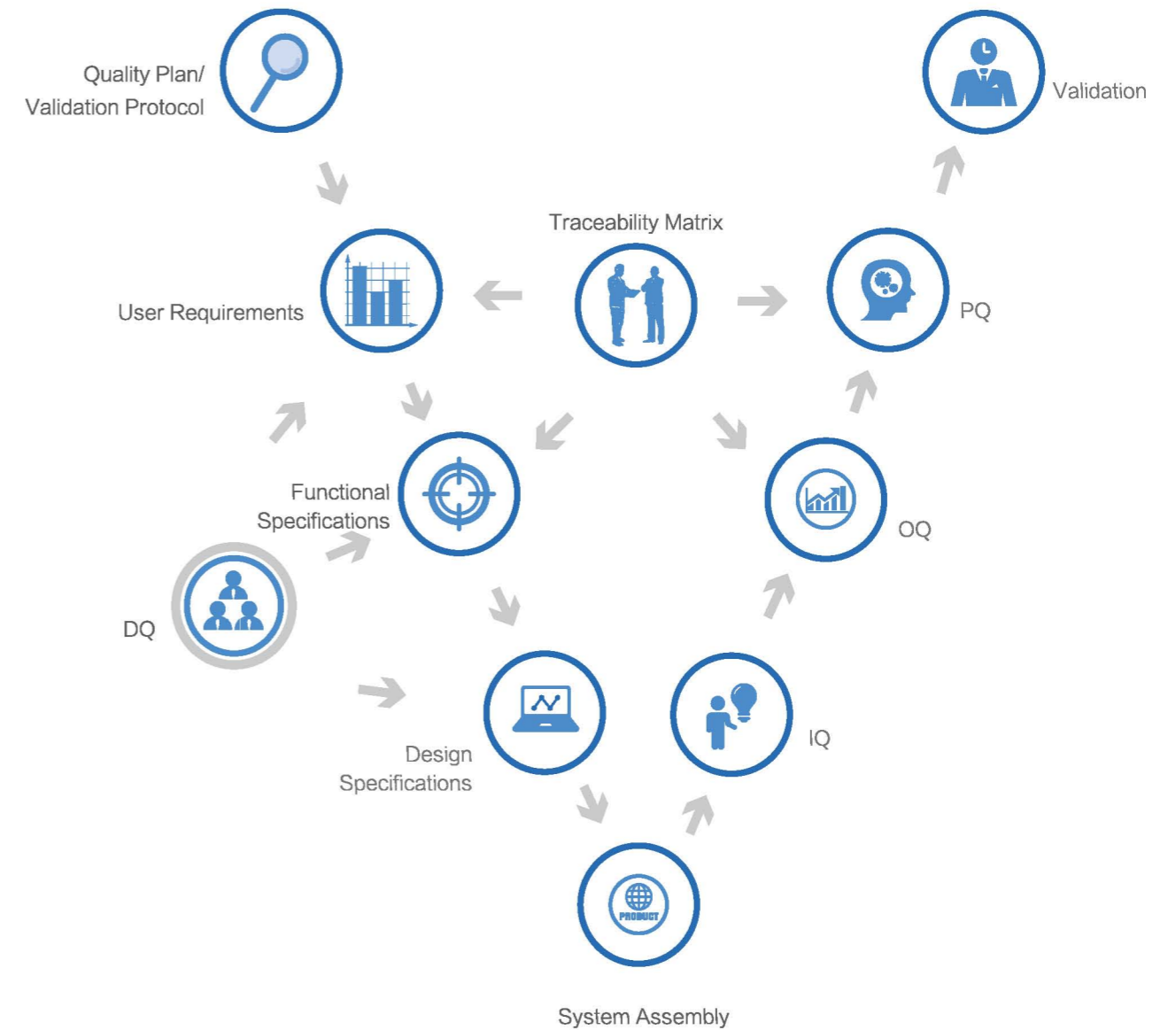
Validity: The certificate is valid from 2013-01-10 until 2016-01-09.
First certification 2007

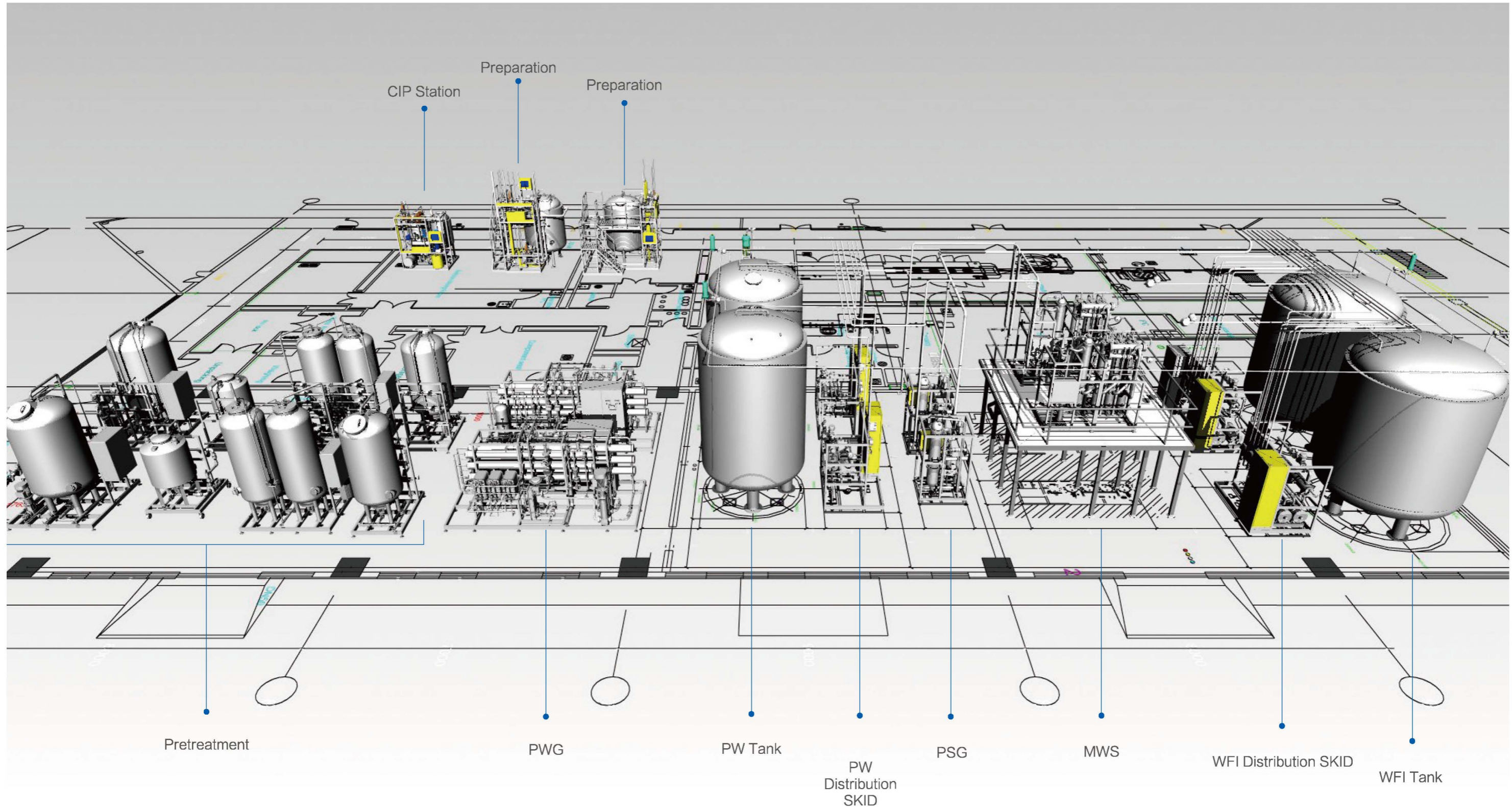
2012-12-28

TÜV Rheinland Cert GmbH
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Precisely Right.

Project Management





Liquid Process System



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