werner

Purified *Water*

Highly Purified *Water*

Concepts
Development
Engineering
Construction
Qualification
Service

Pharmaceutical *Water* . . . . . .

Quality and Diversity.

The quality and diversity our technologies ensure detailed and total solutions to meet specific customer needs.

This standard has enabled us to expand our business for pharmaceutical water systems in more than ten years to our strongest segment. As a result, Wilhelm Werner GmbH has become a leading provider for pharmaceutical water solutions, particularly for small and medium-sized companies.

Based on many years of experience in ultra clean processes, such as those in microelectronics and extensive engineering expertise, we are able to serve all fields of sterile production along with the conventional pharmaceutical industry, including food production, cosmetics manufacture, biotechnology and all other fields in the life science area. Production companies working upstream or parallel to these processes, such as suppliers of pharmaceutical packaging or research companies involved with scale-up, are also individually supplied by us with their own purification systems.

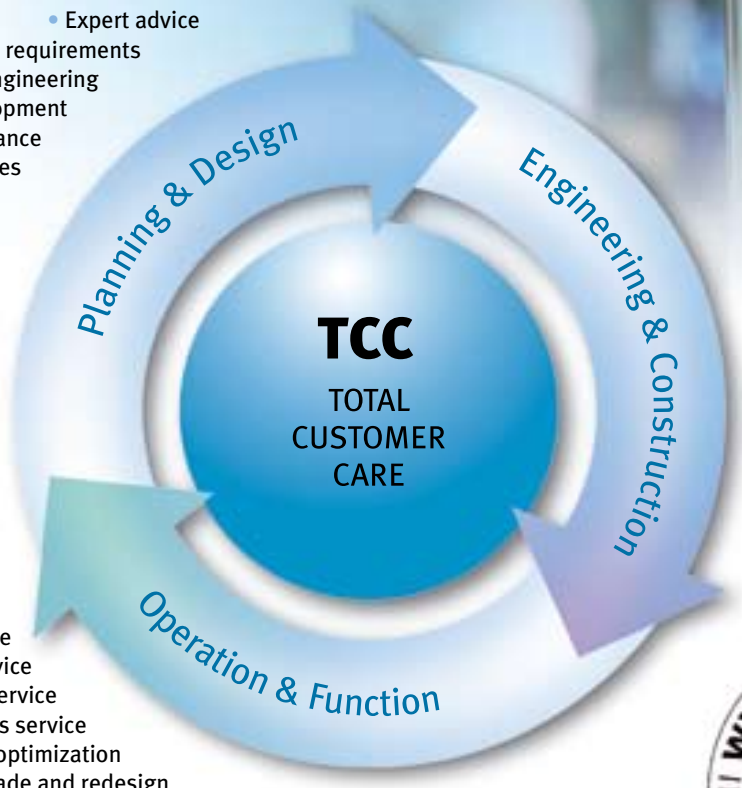
We understand how to harmonize customer expectations and requirements in an appropriate way:
we always combine statutory requirements (such as EP, USP, JP) and FDA and GMP guidelines with individual needs for plant safety, space considerations and the latest technology. This has brought us great success so far, not the least because we are a small, quality-focused, owner-operated company. Every customer always has a single point of contact in our team who knows what is needed. Flexibility, friendliness and special expertise are ordinary characteristics for all of our employees. Our customers appreciate this at the highest level.

Total Customer Care.

All plant development processes including after-sales service are documented and certified: since 1996 a quality management system in accordance with DIN EN ISO 9001:2000 has been in successful use. Customer audits by major companies have continuously verified the effectiveness and reliability of the QM system.

We provide you with support for each phase of your project and guarantee the best implementation and comprehensive service.

- Expert advice
- Determination of basic requirements
- Basic engineering
- Individual concept development
- Detailed engineering in accordance to FDA and cGMP guidelines
- Individual creation of test documentation (DQ, IQ, OQ)
- Design qualification (DQ)
- Plant construction
- Automation
- Installation and FAT
- Operational startup
- Installation qualification (IQ)
- Operational qualification (OQ)
- SAT and training
- Documentation for later validation
- Support during PQ
- Customer service
- Maintenance service
- Spare parts service
- Hotline service
- Calibration service
- After-sales service
- Plant and process optimization
- Upgrade and redesign of existing plants



Purified *Water* . . . . . .

Purified Water Made to Measure.
Custom Designed WERNER PW Systems.

Each plant for the production of purified water is custom work, whether its capacity is 100 l/h or over 25 m^3/h. After all, each customer has individual system requirements: An SME engaging in contract manufacture has needs which differ from an international conglomerate. Thus no plant is entirely like any other. All WERNER PW basic systems meet EP, USP and JP guidelines and ensure the production process, product quality and profitability. The GMP-compliant design confirms to FDA and ISPE requirements.

PW Basic System.

Ready-to-connect, pretested compact systems for purified water production.
The compact, package unit design on a stainless steel frame offers all purification technologies, which are specifically adapted to the present tap water quality, such as

- automatic backwash pre-filters
- pipe separators
- duplex softening units, serially connected, quality-controlled, optional sanitisation with hot water > 80 °C
- alternative conditioning
- UV+Plus recirculation system
- one- or two-pass reverse osmosis
- membrane degassing for CO_2 reduction
- CEDI continous electrodionisation
- chemical sanitisation or optional hot water sanitisation > 80 °C
- pipework made of PVDF-HP by BCF welding technology or AISI 316L orbital welded
- state-of-the-art PLC technology with Siemens S7 PLC, touch panel or panel PC
- data storage in compliance with 21 CFR Part 11

Custom Work in the Details. Custom Overall.

We are the right partner for large production capacities even well above 25 m^3/h as well as for difficult conditions, such as intermittent use, seasonal variations in production, reconstruction projects with ongoing production or critical tap water. All the expertise gained from customer-specific solutions and the latest developments in technology contribute to creating the individual WERNER PW system solution for every requirement.

Pre-treatment
- alternative preconditioning technologies
- serial softening systems with chemical or hot water sanitisation

Recirculation system UV+Plus
- continuous circulation of RO and CEDI
- 100 % recycling of CEDI wastewater in all operating modes
- 100 % recycling of RO concentrates in the recirculation mode
- UV disinfection in the RO feed (1,250 to 3,000 J/m^3)

Sanitisation
- dialog-supported chemical sanitisation program
- optional hot water sanitisation > 80 °C

Expandable plants
- modular system concept
- subsequent capacity expansion up to 100 %

EEx
- systems for EEx Zone 1 with EEx-p encapsulation

Highly Purified *Water* . . . . . .

Highly Purified Water. Costs to Fit Your Budget.

The inclusion of the quality “highly purified water” (HPW) in the European Pharmacopeia on June 1, 2002 enables a new plant design with an additional depyrogenation step after the purified water production. This allows considerable savings of capital expenditures and operating costs for the final rinse of parenteral containers and equipment which previously had to be cleaned with WFI.

HPW Basic System.

Ready-to-connect, pretested compact systems for highly purified water or WFI (USP/JP) production. The compact, package unit design on a stainless steel frame offers all purification technologies, which are specifically adapted to the tap water quality present, such as

- automatic backwash pre-filters
- pipe separators
- duplex softening units, serially connected, quality-controlled, optional sanitisation with hot water › 80 °C
- alternative conditioning
- UV+Plus recirculation system
- one- or two-pass reverse osmosis
- membrane degassing for CO_2 reduction
- CEDI continous electrodionisation
- ultrafiltration, 6,000 Dalton cut-off
- chemical sanitisation or optional hot water sanitisation › 80 °C
- pipework made of PVDF-HP by BCF welding technology or AISI 316L orbital welded
- state-of-the-art PLC technology with Siemens S7 PLC, touch panel or panel PC
- data storage in compliance with 21 CFR Part 11

Custom Work in the Details.
Custom Overall.

Werner HPW systems can be combined with existing PW production systems or will be designed directly as a complete HPW system. The unit includes all the important purification steps for producing HPW; entire design and construction are in accordance with all guidelines and recommendations of the FDA, GAMP and ISPE. Based on the Werner PW basic systems, Werner provides HPW systems with the following features:

- sealless ultrafiltration unit with a cut-off of 6,000 Dalton
- optional recirculation pump
- optional hot water sanitisation at > 80 °C
- compact, modular construction, also as a single-stage unit downstream from existing PW systems
- optional EEx execution

Storage.

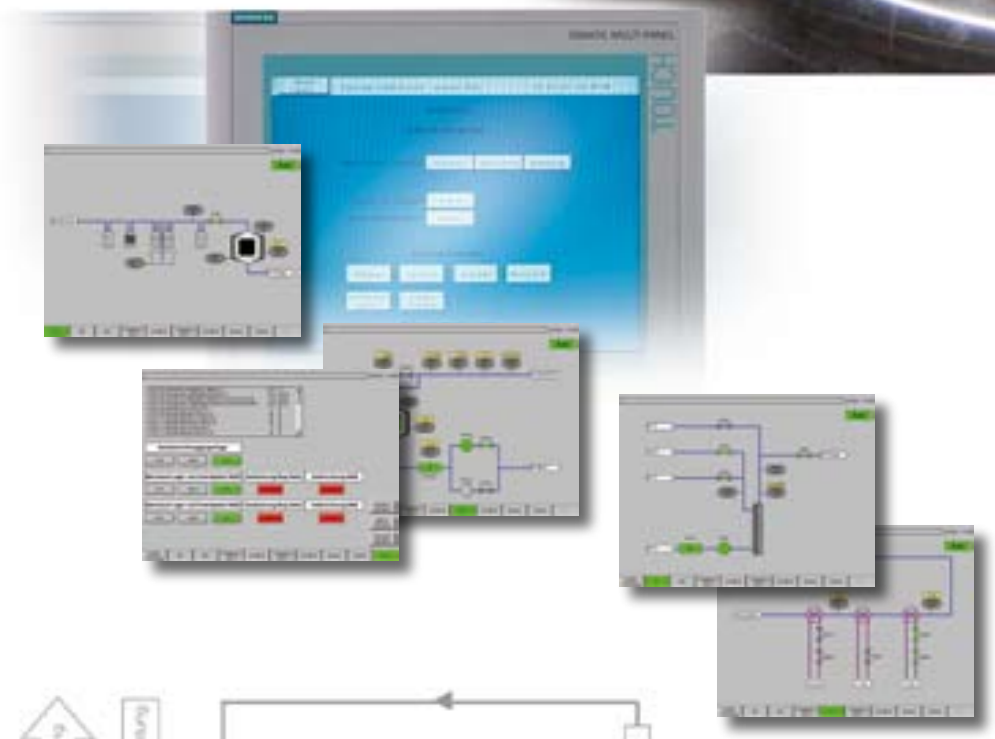
After the purification of PW or HPW, engineering of the customer-specific storage and distribution system takes place so product water can be delivered to each point of use in the sterile distribution system without recontamination. Here too we consider the customer's specific conditions and produce an individually engineered design.

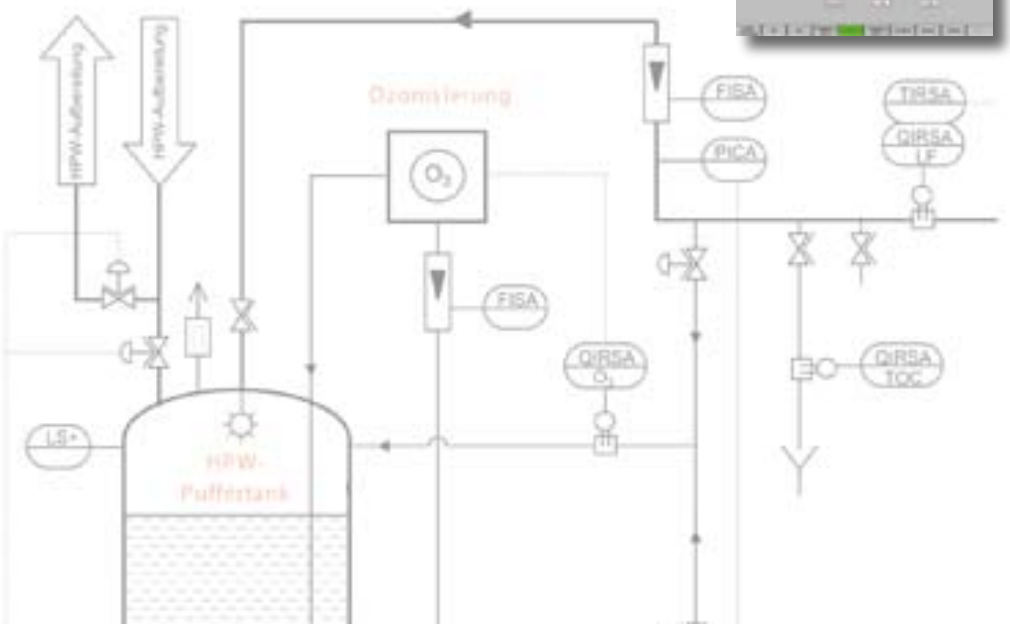
- 316L SS storage tanks for PW and HPW
- frequency controlled distribution pump
- optional dual pump station, continuous flow-through
- UV disinfection / ozone reduction
- tap management
- uncompensated conductivity measurement
- flow management
- ozonation
- online TOC measurement
- optional thermal sanitisation at > 80 °C
- cooling with DTS heat exchanger

Distribution.

PVDF-HP has established itself as a material for all distribution systems particularly because of its high surface quality, with an average Ra < 0.20 µm, and low ion and TOC leach-out. With its temperature resistance up to 140 °C, a corresponding piping calculation can be performed and permanent hot storage at 85 °C or periodic heat sanitisation implemented.

Likewise the entire distribution system can be made of 316L stainless steel, with the option to improve the surface quality from Ra < 0.80 µm to Ra < 0.40 µm.





Automation.

Planning and producing of the entire automation system requires experience and knowledge of the overall process. A team consisting of a project leader and automation engineer supports the project from the design phase through its conclusion, enabling this sensitive field to be covered with complete competence.

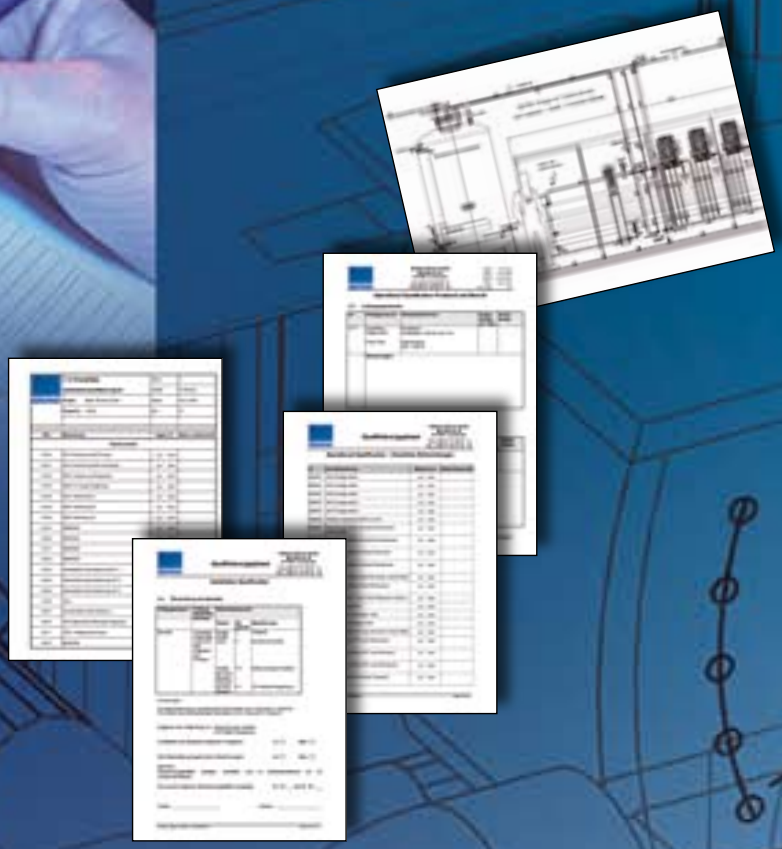
- project coordination
- one-stop implementation
- hardware design
- software design
- control technology system design
- software validation
- design and implementation with EPLAN/WSCAD, ProTool/WinCC

Validation is Teamwork.

Together with the customer, we develop a basis for the entire qualification. Each customer has different benchmarks for the internal validation process.

We accept the requirements of the qualification management, couple these with our experiences and in this manner define a common path for the validation process right at the start of the project based on teamwork with the customer from the beginning.

The validation of the PW and HPW systems is performed in accordance with FDA, cGMP, GAMP, USP and PharmEUR regulations as well as ISPE baselines.



Service is Teamwork.

As we understand it, customer relations even after operational startup is also teamwork, because only thorough instruction and training of operating personnel ensure high customer satisfaction and a long service life for the system.

The associated maintenance service is defined in parallel to the time for startup. Numerous optional services are offered as part of the standard basic and primary maintenance; these can also be combined in a complete service package:

- basic and primary maintenance as a customer-specific service
- user training of operating personnel
- critical tap water analysis by in-house or contract laboratory
- calibration service for all measurement points subject to calibration
- certified reference measurement using ASTM standards
- provision and management of system-specific test equipment
- remote maintenance via modem
- development of operation models
- customer-specific spare parts provision

References

international

Alkaloid AD · Skopje Macedonia
Arabio · Jeddah · Saudi Arabia
AC Helcor · Baia Mare Romania
Alsficom · Cluj-Napoca Romania
Ardea Pharma · Sevetin Czechoslovakia
Beiersdorf Thailand Co. Ltd. · Bangkok Thailand
Esco France S.A. · Dombasle France
Farmex Companx S.R.L. · Bucharest Romania
Pharmex Rom Industry S.R.L. · Ilfov Romania
Farmacon S.R.L. · Brasov Romania
FDS Pharma ASS · St. Petersburg Russia
Galex d.o.o. · Murska Sobota Slovenia
Gematek OOO · Tver Russia
Hoechst Biotika spol.sr.o. · Martin Slowakia
ICN-Farm AD · Skopje Macedonia
ICN Czech Republic A.S. · Roztoky Czechoslovakia
Institute of Virology · Vaccines and Sera Torlak · Belgrade Serbia
Institute Apicol · Bucharest Romania
Medipharm (Pvt) Ltd· Lahore Pakistan
MTH (Binnopharm) · Zelenograd Russia
Nivea (Shanghai) Company Ltd. · Qing Pu China
PharmaConstruct Ltd. · Orgsintez Russia
Shifa Pharmazeutical Industries · Aleppo Syria
University Pharmacia · Prag Czechoslovakia

national

Altana Pharma AG · Konstanz, Singen
Ascalon GmbH · Berggießhübel
BASF AG · Minden
Baxter Oncology GmbH · Halle Westf.
Bayer AG · Dormagen
Bayer Bitterfeld GmbH · Greppin
Bela-pharm GmbH & Co. KG · Vechta
Boehringer Ingelheim Pharma GmbH & Co. KG · Biberach
Boehringer Ingelheim MicroParts GmbH · Dortmund
Braun GmbH · Bahlingen
C.P.M. Contract Pharma GmbH · Feldkirchen
Chemische Fabrik Lehrte – Dr. Andreas Kossel GmbH · Lehrte
Dade Behring Marburg GmbH · Marburg
Dolorgiet Arzneimittel GmbH & Co. KG · St. Augustin
Dr. August Wolff GmbH · Bielefeld
Dr. R. Pfleger GmbH · Bamberg
Excella GmbH · Feucht
GeneScan AG · Freiburg
Girindus AG · Halle
Hexal AG · Holzkirchen
Linde AG, Dresden
MAQUET Cardiopulmonary AG · Hechingen
Medtronic Sfamor Daneck · Deggendorf
Membrana GmbH · Obernburg
Merck KgaA · Darmstadt
Mibe GmbH · Brehna
NextPharma, Pharbil Waltrop GmbH · Waltrop
Nordmark Arzneimittel GmbH & Co. KG · Uetersen
Norbitec GmbH · Uetersen
Organon Development GmbH · Waltrop
Oxoid Biotech GmbH · Wesel
Pegasus Pharma GmbH · Hannover
Pharmazeutische Fabrik Lichtenheldt GmbH · Wahlstedt
Qiagen GmbH · Hilden
Roche Diagnostics GmbH · Mannheim
Roha Arzneimittel GmbH · Bremen
Rottendorf Pharma GmbH · Enningerloh
Sandoz Pharmaceuticals GmbH · Gerlingen
Sanorell-Pharma GmbH · Bühl
Solvay Pharmaceuticals GmbH · Nienburg
Temmler Pharma GmbH & Co. KG · Marburg
Trion Pharma GmbH · München
Tutogen Medical GmbH · Neunkirchen
Wacker Chemie GmbH · Nünchritz
Wala Heilmittel GmbH · Bad Boll

Uncompromising in Quality.
Consequent in Details.

Experience and innovation.

For more than two decades our name has stood for the highest quality in the purification of pure and ultrapure water. We are in demand as a partner internationally with dedicated sales organizations and subsidiaries in many European countries. With a focus on quality, an understanding of market needs, innovative drive and flexibility we have grown to become one of the leading providers of pure and ultrapure water purification systems on the German and international markets.

Products and service from a single source.

Increasingly precise and challenging analytical and production technologies in research and industry require innovative water purification methods.

We offer everything – from the smallest laboratory system with 0.5 l/min up to pilot plant systems with 25 m^3/h: precise, customized solutions from a single supplier. This is backed up by a highly motivated team which develops and produces practical solutions and covers the range from analysis and consulting to CAD design, in-plant manufacture, operational startup and maintenance.

Certified quality.

Since 1996 we have been certified as meeting the highest internationally recognized quality requirements. WERNER was one of the first providers of water purification systems to achieve ISO certification. This established a basis for future security for companies, customers and business partners.

Subject to technical changes without notice.
Last revised 04/2009

Wilhelm Werner GmbH
Reinstwassertechnik
Maybachstraße 29
D-51381 Leverkusen
tel +49 2171 7675-0
fax +49 2171 7675-10
e-mail: info@werner-gmbh.com
www.werner-gmbh.com