
Pharmaceutical Liquida From generation to the final product	page 02
Pure media PW-generation Generation of Aqua Purificata	page 04
Ultra pure media PW-/WFI-/PS-systems Storage and distribution systems for ultra pure media	page 05
Formulation systems High quality formulation systems for liquid and semi-solid products	page 06
CIP/SIP/WIP cleaning systems Solutions for highest product quality	page 07





PHARMACEUTICAL LIQUIDA

From generation to the final product

Wellmann Engineering designs and delivers products and systems for the pharmaceutical industry with the highest standards in function and quality. All concepts are developed together with our customers, always focussed on their individual needs.

To ensure the effectiveness and safety of pharmaceutical products the qualification of the process equipment is essential, as defined in the EC-GMP-Guide. The individual risk analysis results in a catalogue of specific measures to optimise the production process. This aims are reached through consistent state-of-the-art engineering.

Qualification has the highest priority in the pharmaceutical industry. We create all requisite documents for the qualification of the customers production plant. This forms the basis for the prospective validation system according to the V-mo-dell of the FDA.

In order to reliably comply with the desired process and system parameters, we cooperate with all considerable and well-known component suppliers.

Specific requirements and customer standards are always carefully considered and integrated in an individual solution. For an integrated and continuous quality management, we support you in the instruction and training of your employees.

Engineering service

- Basic engineering: concept development and process design
- Process analysis for optimizing existing plants
- Detail engineering: project management from specification to commissioning and production assistance
- Software engineering according to GAMP 5
- Concepts for online monitoring and batch traceability
- Creation of specification sheets (URS, FS) and the implementation of plant qualification
- Documentation in accordance with international standards
- Creation of maintenance and calibration measures and SOPs
- Change control: implementation and maintenance
- Assessment and documentation of maintenance work
- Rapid procurement of spare and wear parts

Our products

- Systems for generating, storing and distributing ultra pure media, especially water (AP, WFI), pure steam and process gases like compressed air and nitrogen
- CIP, WIP and SIP systems
- Formulation systems for liquida
- Sterile filtration systems for the production of suspensions or emulsions
- Systems for cleaning and sterilization with ozone, steam or pressurized overheated water
- Derouging

Pharma specific installation services

- Orbital welding
- Ferrite measurements
- Check of surface roughness
- GMP conforming welding documentation including isometric drawings and endoscopy images
- Hygienic design without dead legs to ensure complete cleaning and drying
- Maintenance and repair of existing plants





PURE MEDIA PW-GENERATION

Generation of Aqua Purificata

The generation of purified water from drinking water requires technical processes according to highest hygienical standards. Wellmann Engineering provides PW-generation units from 0.5 m³/h up to several thousand liters per hour.

Purified water is produced through water softening, reverse osmosis and electrodeionization. Orbital welded plants in stainless steel ensure highest product quality.

The plant control systems developed by our automation experts ensure continuous monitoring and analysis of performance and water quality even after long-term use.

All plants are qualified and documented according to international standard.



ULTRA PURE MEDIA PW-/WFI-/PS-SYSTEMS

Storage and distribution of ultra pure media

Wellmann Engineering supplies high quality systems for the distribution of AP („Aqua Purificata“), WFI („Water for Injection“) and pure steam.

The freshly generated ultra pure media is stored and then transported in a distribution system up to the tapping points.

Wellmann Engineering develops individual process systems according to each customer's requirements always with product safety in focus. We offer solutions for cold and hot storage. The distribution through ring pipe systems (Loops) ensures a turbulent flow and the hygienic design without dead legs prevent the formation and growth of microorganisms and biofilm.

Our systems are completely made of stainless steel and are orbital welded. In combination with control systems developed by our automation experts this ensures the highest level of product safety.

Scheduled sanitisation of the entire storage and distribution systems is processed either cold (by addition of ozone) or hot (by heating to >85°C).

Our services

- Project support/project management from the concept study through implementation to commissioning and production support
- Requirement analysis and development of tapping concept for flow and amount
- Design and dimensioning of the storage and distribution systems
- Software development for process automation and connection to process control systems
- Construction completely made of stainless steel 1.4404, 1.4435
- Hygienic, dead leg free design
- GMP-compliant welding documentation incl. isometric drawings and endoscopy images
- Manufacturer and product neutral qualification of your plants as well as preparation of qualification plans and reports



FORMULATION SYSTEMS

High quality formulation systems for liquid and semi-solid products

In the production of active ingredients in formulation systems sterility is a crucial factor for product quality.

Wellmann Engineering offers high-quality formulation systems for liquid or semi-solid products as liquid drugs or cosmetics. The vessels are completely manufactured in high quality stainless steel.

A hygienic design without dead legs ensures highest product safety.

Our services

- Complete manufacturing in stainless steel 1.4404 or 1.4435, special materials available on request
- Construction in hygienic design without dead legs
- Surface roughness e.g. Ra <0,8µm
- Complete cleaning and drying without manual intervention
- Compressed air or nitrogen atmosphere
- Systems with stirrer, powder wetting or dispersing machines for the dissolving or suspending of solids
- Precise recipe based dosing
- In compliance with legal regulations: Federal Water Act (WHG), machinery & ATEX directives and operational safety according to SIL standards (Safety Integrity Level)
- Qualification and documentation according to international guidelines
- Software for process control including recipe management, dosing and weighing system, connection to production management systems or SADA systems



CIP/SIP/WIP CLEANING SYSTEMS

Solutions for highest product quality

Wellmann Engineering brings unlimited flexibility to its customers and offers customized CIP/SIP/WIP solutions.

The scope of service includes planning services, developing of automation concepts as well as the installation, qualification and validation of the system.

Our services

- Validation and traceable cleaning processes for highest product quality
- Specific measurement and control technology ensure a constant cleaning effect
- Design of cleaning systems according to latest GMP requirements (DQ, IQ, OQ, PQ)
- Planning in accordance with all regulations, such as DIN, ASME, GMP, FDA
- Manufacturing in stainless steel
- Specification of the necessary cleaning steps, using validated software modules
- Recipe-controlled and editable cleaning programs
- Recording and archiving cleaning cycles for tracking purposes
- Controlling and visualization depending on customer requirements by Simatic, Allen Bradley, etc.

CIP: Cleaning in place

- Highly efficient level of cleaning using fully-automated, recipe-controlled cleaning programs
- Removal of anorganic and organic adhesions and residues (e.g. biofilm)
- Cleaning with acid or caustic (up to 90°C)
- Dosage of specialised detergent

SIP: Sterilization in place

- Usually following on CIP cleaning using the same system
- Additional to CIP, the destruction of microbiological germs by sterilization using hot water or pure steam (>121°C)
- Prerequisite for highest product quality

WIP: Washing in place

- Less manual effort using fixed installed units
- Automated cleaning paths for complex process plants
- High energy efficiency and perfect cleaning results through fully automated cleaning programs

Certified specialized welding company in accordance to DIN EN ISO 3834-3
Certified company according to DIN EN 1090-2 EXC2 supporting components and kits for steel carriers
Quality management according to DIN EN ISO 9001:2015
Certification of welding processes according to DIN EN 15614-1
Specialized company according to § 19 WHG (German Water Resource Act)

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