

BWT Pharma & Biotech



Systems, Solutions & Services for Clean Media Supply

For You and Planet Blue.





Water – Our Elixir of Life

According to UNO estimates, the world's population is set to increase from approximately 6.6 billion today to 9.2 billion by 2050. Due to the increasing average per capita consumption of water, currently 625m³ per annum, water consumption will also grow disproportionately. Globally, more than one billion people have no access to clean drinking water. In 25 years, up to 6 billion people will be experiencing water shortages because of poor hygiene. The demand for improved water quality has been a fundamental need since time immemorial and water quality is also a precondition for achieving the best results in a variety of work and home applications. The technological and legal requirements for optimal water treatment are becoming ever more stringent.

BWT – Best Water Technology Group was formed in 1990 and is now Europe's leading water technology company. The goal of the 2,800 employees in BWT's 70 subsidiaries and associate companies is to provide private, industrial, business, hotel, hospital and public sector customers with innovative, ecological and efficient technologies that deliver the highest levels of safety, hygiene and health in their daily contact with the elixir of life, water.

BWT Pharma & Biotech – your partner for clean media solutions

Water is the most widely used material in the Pharma & Biotech and related industries such as medical products and cosmetics. Most processes in these industries require water and other clean media that meet the legal standards as defined in international pharmacopoeias. The main quality definitions are for potable water, purified water (PW), highly purified water (HPW), water for injection (WFI) and pure steam. BWT Pharma & Biotech provides reliable systems to meet and exceed the defined qualities for clean media – from feed water supply to point-of-use.

BWT Pharma & Biotech, a division of BWT AG Austria with over 50 years experience, is a premium world-wide supplier in this market. With the industry-leading spectrum of technologies and products BWT is providing optimal solutions for all clean media applications.

Manufacturing facilities in Europe, Asia and the United States provide prequalified and performance-tested equipment skids that meet the highest quality standards. All critical engineering and production stages, such as process and automation engineering, quality and project management, welding and assembly, FAT testing, site commissioning and SAT testing, are fully controlled by experienced and well trained personnel.

Understanding Project Delivery

Evaluation, discussion and documentation of all relevant information during the tendering stage are the basis for a professional and seamless project execution and for providing the best solution to meet all requirements. We are passionate about working in partnership with our customers towards the common goal of a successful project that is delivered **on time and within budget**.

Markets and Partners

Projects are managed in partnership with pharmaceutical manufacturers, pharmaceutical plant designers and other leading specialist engineering companies. Our clients include leading international players like AstraZeneca, Bayer, CSL, Eli Lilly, GSK, Merck, Novartis, Novo Nordisk, Pfizer, P&G, Roche, Sanofi and many others, not forgetting the hundreds of smaller and medium-sized companies who are focused on high quality equipment and solutions.



Core Technologies

SEPTRON® & SEPTRON® BioSafe

BWT is the only European manufacturer of EDI modules. The unique, patented EDI spiral-wound module, SEPTRON®, has been specifically developed for both the pharmaceutical industry and the highest quality requirements. Today SEPTRON® is the core component of many modern water treatment systems.

- 316L stainless steel housing
- Seal-free, spiral-wound technology
- High-quality 'MADE IN SWITZERLAND'
- 100% factory tested and certified
- Various individual size modules from 150l/h up to 4,000l/h for optimal system configuration
- SEPTRON® BioSafe – unique and patented EDI with integrated UF – for increased microbiological quality and safety during PW generation and cost-effective HPW production in accordance with European Pharmacopeia

STERITRON

Unique and highly efficient sanitisation with electrolytic ozone generation.

STERITRON systems produce ozone from highly-purified water and, in combination with BEWADES ozone destruct units, guarantee automatic, continuous and cost-effective microbiological protection of distribution loops.

- Highest microbiological safety and quality for clean media storage and distribution systems
- Energy-efficient continuous sanitisation
- Fully automated sanitisation of the entire storage and distribution system up to the point of use



Products & Applications

Pre-treatment

- ULTRASTIL – robust and reliable ultrafiltration systems
- ELITE RS – serial hygienic softeners with SANISAL regeneration salt

PW/HPW Generation

- SEPTRON® Line – compact and cost-effective standard integrated Reverse Osmosis / SEPTRON EDI systems with chemical sanitisation
- OSMOVISION – innovative high-efficiency open-skid softener / reverse osmosis / SEPTRON EDI systems with patented continuous chemical sanitisation
- OSMOLINE – hot-water-sanitisable compact and cost efficient standard open-skid reverse osmosis / SEPTRON EDI systems
- OSMOTRON – fully hot-water-sanitisable open-skid softener/reverse osmosis / SEPTRON EDI systems
- OSMOSTIL single and double-pass reverse osmosis systems with chemical or thermal sanitisation

PW/HPW Storage & Distribution

- LOOPO C – compact integrated distribution, sanitisation, monitoring and control systems with STERITRON electrolytic ozone and BEWADES UV technology

WFI generation

- MULTITRON – high-efficiency, multiple-effect distillation

Pure Steam generation

- VAPOTRON – fast pure steam generation in accordance with EN285

WFI & Pure Steam generation

- COMBITRON – space-saving and cost-effective parallel WFI and pure steam production in one compact system

WFI Storage & Distribution

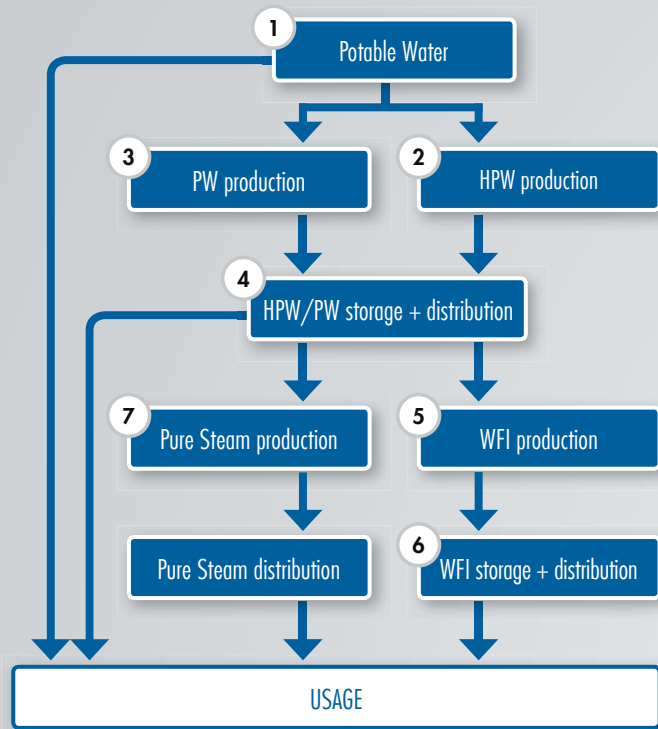
- LOOPO H – compact integrated distribution, sanitisation, monitoring and control systems with thermal sanitisation



Advantages of turnkey projects with BWT products

- Uniformly high product quality
- Direct communication with one project manager as single point of contact
- Seamless project delivery, without interfaces, creates shorter project cycles
- Overall warranty for products and quality
- Comprehensive support using AQU@SERVICE products
- Reliable supply and storage of spare parts
- Safe and easy to operate with validated AQU@VIEW automation products
- Compliant and uniform validation/documentation package
- Simplified acceptance by authorities and straightforward auditing

Products and Processes



1 ULTRASTIL

Pre-treatment

ULTRASTIL pre-treatment systems are used for difficult raw water conditions to protect downstream systems and ensure that the entire generation system operates reliably.



2 3 SEPTRON® Line, OSMOLINE OSMOVISION, OSMOTRON

PW/HPW generation

Invariably the best system and technology for every type of PW/HPW production need, project requirement and budget.



4 LOOPO C

PW/HPW storage and distribution systems

LOOPO C integrates high-quality pump with STERITRON electrolytic ozone generator, BEWADES ozone destruct UV and high-quality calibrated online analytical equipment for cGMP-compliant distribution, sanitisation, monitoring and control of ambient temperature PW/HPW loop systems.



5 **MULTITRON**

WFI generation

MULTITRON high-efficiency, multi-effect distillation systems with variable capacity control.



7 **VAPOTRON**

Pure steam generation

VAPOTRON fast-reacting pure steam supply in accordance with EN285 with optimal pure steam quality and precise pressure control.



5 7 **COMBITRON**

Combined pure steam/WFI generation

COMBITRON reduces investment costs and footprint by up to 30 % more than individual WFI and PSG systems.



6 **LOOPO H**

WFI Storage and distribution systems

LOOPO H integrates sanitary distribution pump, fail-safe DTS heat exchanger and high-quality calibrated online analytical equipment for cGMP compliant distribution, sanitisation, monitoring and control of hot WFI loop systems.



Comprehensive Services for Successful Projects

Concept studies and basic engineering

Key to overall concepts is compliance with the most recent regulations and official guidelines, design quality, system reliability and efficiency and total cost of ownership, whether high-quality standardised systems or customised solutions are deployed.

The spectrum of engineering services includes mass balance and energy efficiency considerations, pressure drop calculations in distribution systems, pipe routing, point-of-use (POU) solutions, layout and 3D design, P+I diagrams and corresponding parts lists, on-site inspection of the planned location and specific requirements and cost of ownership calculations – all of which are provided by experienced engineers working with the latest tools and software.

BWT Pharma & Biotech also has novel approaches to process design and configuration, and to controlling and operating systems. All are aimed at reducing a system's power consumption and the amount of water it wastes, thereby making the generation and distribution of clean media more economical.

Validation and documentation

International and experienced staff members, who are familiar with the latest regulations and directives of all the relevant authorities, ensure implementation of the current FDA, ISPE and GMP, GAMP requirements and guidelines.

Validation and documentation engineers are assigned to each project at every stage of the V-model, starting with the URS and ending with FAT, IQ/OQ and SAT. At the beginning of a project, a Quality & Project Plan (QPP) is created to show the project's Quality Control system, together with scope, responsibilities, communication routes, submissions etc. This document is given to the customer for approval.

The water treatment systems are validated against FDA, cGMP, cGAMP, USP and Ph. Eur. requirements. BWT Pharma & Biotech also follows the ISPE Engineering Baselines for Water and Steam Systems, Commissioning and Qualification.

Assembly and full production facilities

All BWT factories use the latest technology and operational procedures for systems production.

All systems are manufactured as far as possible, and where feasible, with the aid of orbital welding machines (for stainless steel (316L) applications), if necessary under clean room conditions. Strict material handling and documentation, from the incoming inspection to the final product, together with high-performance inspection equipment used by certified inspectors, ensures the highest quality products.



Factory Acceptance Test (FAT)

Skid-mounted systems leave the factory after a FAT has been successfully executed in order to shorten on-site commissioning and validation. In general, the FAT is carried out under real conditions in the presence of the customer. Partial IQ and OQ tests are already carried out, where possible, during the FAT to reduce on-site implementation time and risk. For turnkey projects, the required equipment skids are installed as a complete system. Commissioning and qualification are then performed and documented in the SAT (Site Acceptance Test) for the complete installation before the final handover to the customer.

IQ, OQ, SAT and training

After the systems have been built, the IQ (Installation Qualification) verifies the installation while the OQ (Operational Qualification) verifies the correct functionality. After completion of IQ/OQ the SAT is carried out and documented in the presence of the customer.

Certified training for the operators and engineers provides quality know-how on all system requirements and functionalities to ensure trouble-free operation.

AQU@VIEW automation technology

The critical area of automation is handled by in-house resources only. Unlike many suppliers, BWT Pharma & Biotech employs its own specialist departments for the design of control cabinets and for software development and programming. Validated software modules are used for fail-safe operation in accordance with cGAMP guidelines.

HMI visualisation (employing modern touch-screen panels at the unit level), process visualisation via networked PLC structures and PC visualisation of the entire turnkey project are implemented on a wide range of platforms. With validated AQU@VIEW automation products, BWT offers easy-to-use, cGAMP-compliant control and monitoring of clean utility systems, based on the current, most internationally recognised hard and software products, such as Siemens and Rockwell.

Quality and Passion

A knowledge of customer requirements and expectations; an understanding of legal requirements such as USP, Ph. Eur. and JP; an appreciation of the demands of inspection authorities, such as the FDA and various local authorities; compliance with GMP standards; and familiarity with state-of-the-art processes and technologies – all these combine to characterise BWT Pharma & Biotech as a competent specialist supplier and partner for clean utility systems.

BWT's global presence and experience demonstrate our competence, which is reflected in repeat business and long-term customer satisfaction. Research and development, future-oriented thinking and the flexibility and innovative power of our staff ensure that BWT can meet the continually increasing demands of the latest quality standards, while taking responsibility for sustainable actions and the protection of our environment.

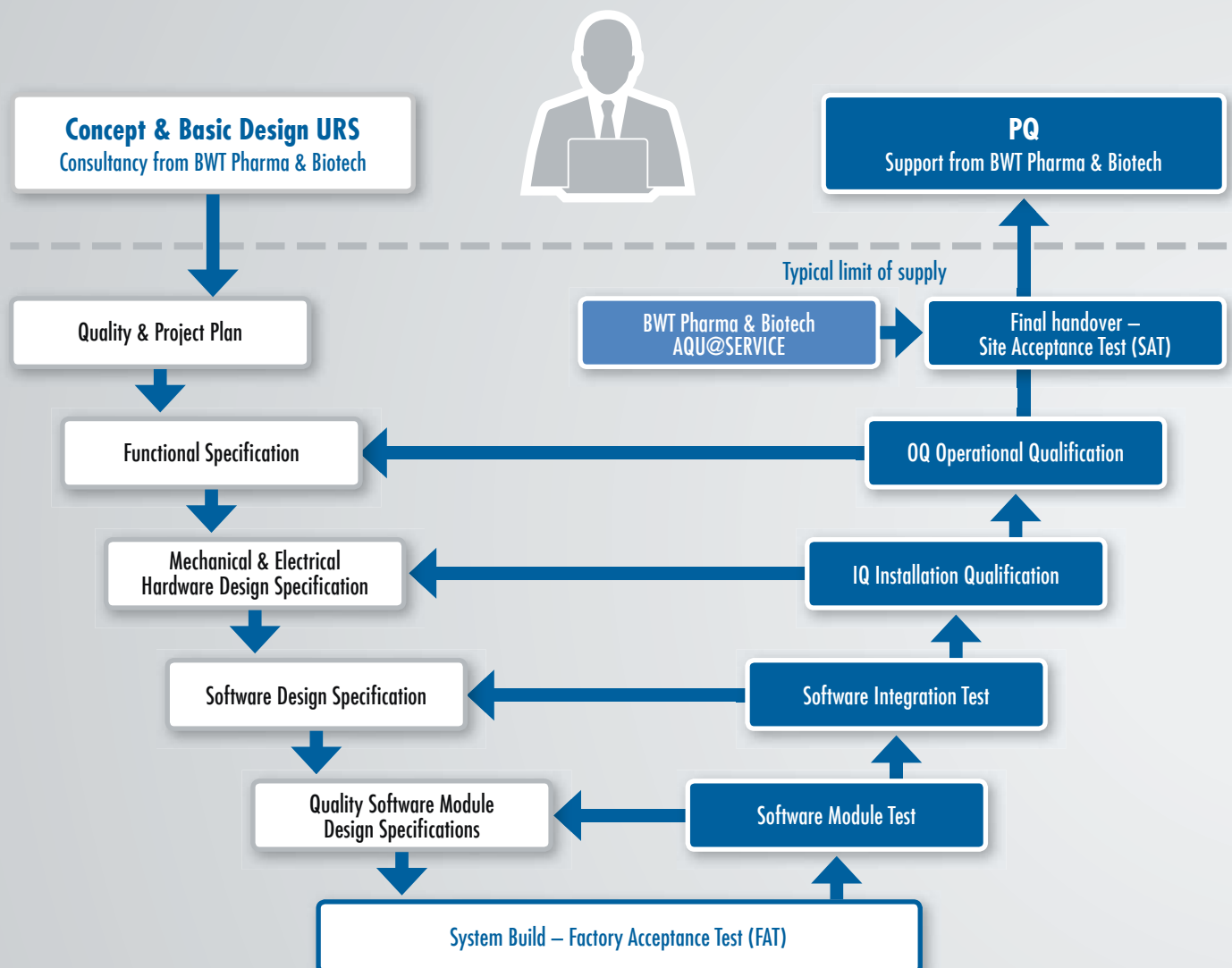
BWT Pharma & Biotech is therefore ISO 9001 certified.

Scope of Services

By integrating all process stages, BWT Pharma & Biotech can offer its customers a complete design and solution, ranging from project identification and optimisation, process and automation engineering, production, validation and documentation through to commissioning, training and full customer support for all clean utility applications.

Validation and Documentation services during the entire project cycle

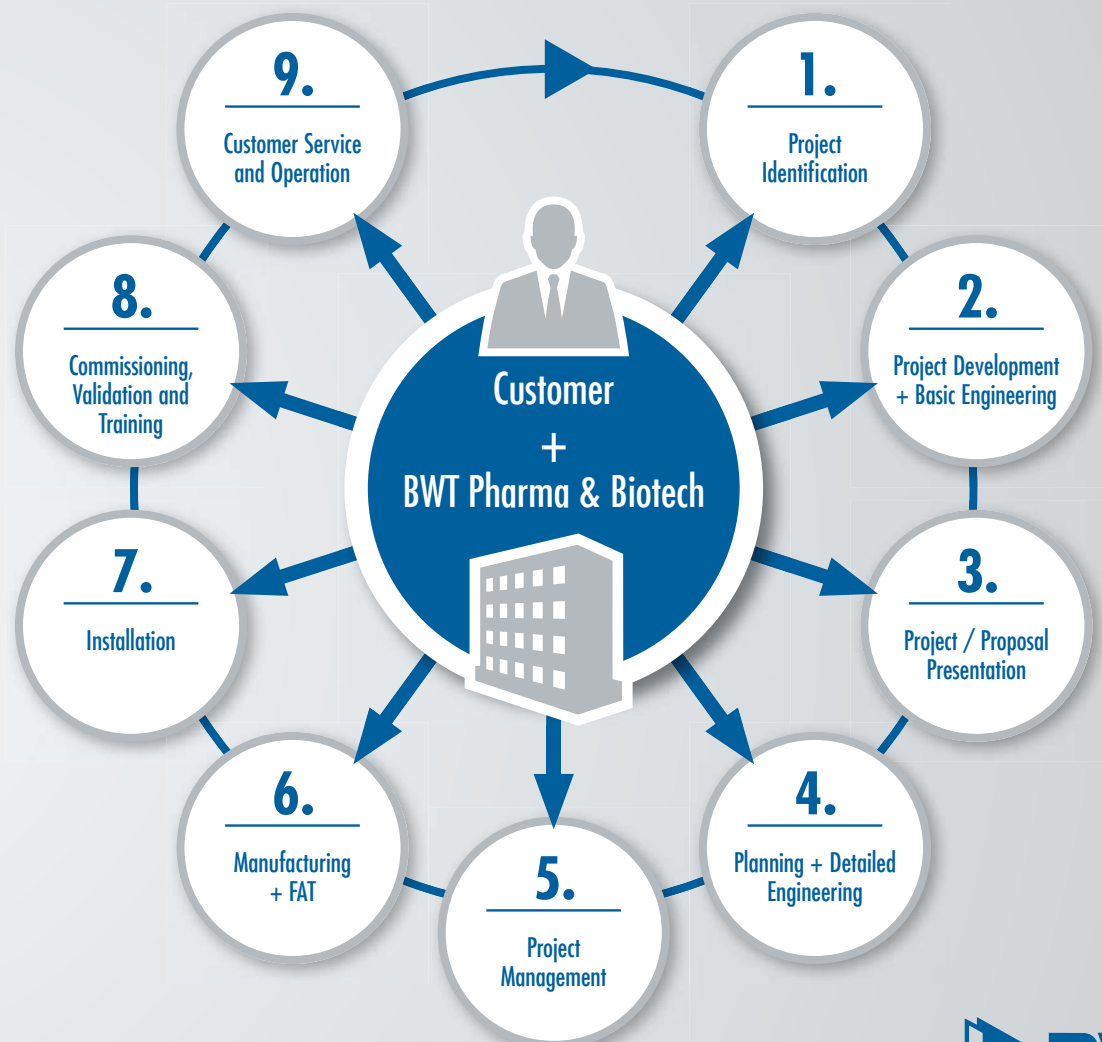
- Quality & Project Plan
- Validation Plan
- Traceability matrix
- Risk analysis
- Validation protocols
- Factory and site acceptance test (FAT and SAT)
- IQ, OQ execution
- PQ support
- Comprehensive technical documentation
- Operating instructions
- As built document revision
- Change control procedure



Scope of our AQU@SERVICE customer services

- Short-, medium- or long-term maintenance agreements
- Calibration agreements for measuring devices (such as conductivity, pressure, flow, temperature, TOC, ozone)
- Special services, such as sterile filter integrity testing, pure steam quality verification in accordance with EN 285, lab analysis services for water samples, resin qualities and membrane analysis
- Qualified Technical Service Hotline (24 hours, 365 days a year)
- Spare parts services and management
- Remote plant maintenance and control assistance
- Training of operating personnel
- Plant audits for system and process optimisation
- Modernisation and upgrade services
- Change control documentation
- Validation services, including retrospective validation

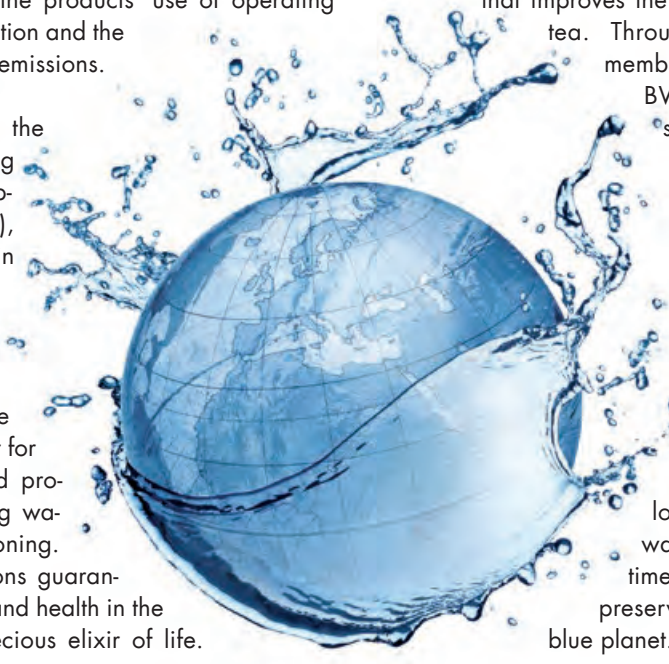
Maintaining the highest system reliability, availability and asset value with AQU@SERVICE during the entire system life cycle.



BWT – the Company

Best Water Technology Group (BWT) is Europe's leading water technology company. Our water partner network comprises the group's 3,300 employees and thousands of plumbers, planners, architects and hygiene experts. Our Research & Development teams, using state-of-the-art methods, work on new processes and materials to create products that are both ecological and economical. Looking ahead, a key development issue is a reduction in the products' use of operating resources and energy consumption and the resulting minimisation of CO₂ emissions.

Whether at the place where the water pipe enters the building ('point of entry') or at the tapping point ('point of use'), BWT's trend-setting 'Made in Europe' products have proved their quality millions of times over in the treatment of: drinking water, mineral water and ultrapure water for the pharmaceutical industry; water for swimming pools; heating and process water; boiler and cooling water; and water for air-conditioning. BWT's wide-ranging innovations guarantee maximum safety, hygiene and health in the daily use of water – that precious elixir of life.



These innovations, among others, include: SEPTRON®, the world's first electrodeionisation module (EDI) with spiral wrap; manganese oxide activation (MDA) – a method for effective manganese removal; AQA total bipolar technology for chemical-free limescale protection; SANISAL – the world's first regeneration salt for softening water systems, which also works as a disinfectant; and the new, revolutionary Mg²⁺ technology that improves the taste of filtered water, coffee and tea. Through its unique, high efficiency membranes for fuel cells and batteries, BWT is creating a cleaner, more sustainable energy supply for the 21st century.

BWT – For You and Planet Blue signifies that our mission is to take ecological, economical and social responsibility, to provide our customers and partners with the best products, systems, technologies and services in all areas of water treatment and, at the same time, to make a valuable contribution to preserving the global resources of our blue planet.



Find us on www.bwt-pharma.com