



## Reliable and economic production processes: Knowing, evaluating, and using success factors.

Good service for clean utility systems covers the whole lifecycle, takes individual requirements into account, and is as transparent as pure water.

#### Success factor management of fixed assets

The world of pharma & biotech production is complex: expensive production facilities, comprehensive regulatory laws, and complicated value creation processes place great demands on those responsible for production and machinery. This is also reflected in the high degree of automation and the expensive process technology involved.

The economic success of every production plant is therefore inseparable from the optimal management of fixed assets. This means that securing the availability, economic operation and minimizing weak points is of paramount importance. An important part of this plant management is proactive maintenance and risk management of all product critical plants and systems.

#### **Production factor clean utilities**

Integral parts of production facilities are also clean utility systems. Their availability is a basic requirement for trouble-free, reliable, and economic operation of the whole production process.

AQU@SERVICE is the solution to guarantee operational readiness of clean utility systems, to minimize downtimes, and to avoid cost-intensive, unplanned down-time. Along with operators, the ideal-fit maintenance package and premium, validated replacement parts maximize overall availability, increase longevity, and the quality of clean utilities is always achieved at the optimum level.

The expense of administration and coordination is reduced, because a competent contact person takes on the responsibility for all topics relating to the supply of clean. Ongoing, comprehensive, and consistent service documentation of all measures carried out in accordance with the valid guidelines and GMP standards make for maximum confidence with audits and inspections.

The comprehensive service offering AQU@SERVICE is available for all premium plants from BWT Pharma & Biotech as well as for all systems from third parties.

- Production safety
- Plant safety
- Audit / Inspection safety
- Profitability
- Planning security
- Lifecycle

- Manufacturer-independent
- Comprehensive
- Modular

### Convincing arguments for AQU@SERVICE from BWT



#### Global

Global service, with branches and partners focusing on clean utilities.



#### **Experts**

Decades of experience, with welltrained employees constantly engaged in further training.



#### All manufacturers

Service for the whole clean utility supply for all manufacturers.



#### Value preservation

Preserved value of machinery and performance in the long run, and extended lifecycles.



#### Costs

Taking account of overall operating costs shows that trust in AQU@SERVICE pays off in hard cash.



#### **Partnerships**

Long-term, trusted, and honest relationships are more important than short-term gains.



### Freedom of choice

AQU@SERVICE allows for customized service packages.



#### Safety

Preventive protection against problems with quality and for long-term high availability.



#### **Documented**

All measures are documented in line with guidelines



#### **Time**

Time saving with only one single contact partner for comprehensive service.



#### Modular

Because individual services are matched perfectly to each other, plant responsibles have less work.



#### Quality

Outstanding quality at the highest level are the hallmarks of BWT Pharma & Biotech.



### Good service is more than emergency assistance

Four building blocks form the right basis for long-term and safe system operations by AQU@SERVICE.



#### Service on demand

Service on demand from qualified service technicians.



#### **GMP** maintenance

Planned and documented pharma-approved maintenance.



#### **Calibration**

For quality and process critical measurements for all manufacturers and makes.



#### **Parts**

Customer- and device-specific replacement parts concept, higher availability.

### The right service makes everyone happy

The comprehensive AQU@SERVICE covers every regulatory requirement and, therefore, secures for safe audits and inspections.



#### Pure steam

Testing the steam quality for sterilizers in accordance with DIN EN 285.



#### **Documentation**

Always up-to-date.



#### **Replacement of seals**

Pharma-certified membrane and seal changes in product-relevant area.



#### Sterile filter integrity

Proof of integrity of sterile barriers.

### Nothing can replace knowledge

That's why AQU@SERVICE is so keen to share it.



#### **Remote Assistance**

Internet-based analysis of operation and system data.



#### 24/7 Hotline

Qualified technical support hotline at any time.



#### **Training**

Expert knowledge for owners and operators.

### Optimal set-up of lifecycles for all systems

Operators aren't left alone with their plants. AQU@SERVICE ensures a long, productive and economic life time. Regardless of manufacturer and current status of the clean utility system.



#### **Audit**

Qualified and manufacturerindependent system audits.



#### **Optimization**

System and software updates keep systems up-to-date.



#### Upgrade

Tailored adjustment of plants with minimal downtime.





### AQU@SERVICE makes everyday better









Tailored service, inspection and maintenance, calibration and replacement parts are a part of our service for plants: BWT goes above and beyond.

Maximum plant availability through optimum operation and minimal downtime, planned where possible, are every production managers goal. For this reason, BWT Pharma & Biotech does not do things by half-measures with AQU@SERVICE. With an experienced and well-trained staff, precision tools and instruments, instinct, a lot of experience, and high demands on quality. For the benefit of all customers who have discovered AQU@SERVICE.

#### **AQU@SERVICE BASIC**

When it comes to breakdowns, problems, or abnormalities, more than 100 qualified service engineers from BWT help worldwide on-site. They are positioned geographically in Europe, North America and Asia in the right place for the customers. In emergency situations, response time, analysis and repair are paramount in ensuring customer downtime is kept to a minimum.

#### **AQU@SERVICE GMP**

Regular care and preventive maintenance are important for safe and durable permanent operation, and maximum value preservation. Based on the recommended intervals set out in technical documentation, there are professional, mutually planned and agreed, pharma-compliant maintenance works and inspections by specialists, with documentation according to cGMP rules and current ISPE guidelines.

#### **AQU@SERVICE Calibration**

To guarantee that product quality remains constant, all quality and process critical measurements in clean utility systems must be periodically calibrated according to standardized cycles. Service technicians from BWT fulfill this pre-determined calibration of sensors independent of manufacturer and model and according to manufacturer guidelines. All calibration are traceable to international standards (such as NIST, DKD) and are supported by certificates and relevant documentation.

#### **AQU@SERVICE Spare Parts**

Good systems for clean utilities are built for permanent operation and can withstand a lot. The experts in our replacement parts service know our customers' plants and operating requirements, help with the selection of parts, offer alternatives, suppor in case of premature wear or recurring faults and create customer-specific concepts for spare and wear parts based on Failure Mode and Effects Analysis (FMEA). Access to multiple, comprehensive warehouses on every continent with global logistics increases the security and availability of clean utility systems.

- Expert staff
- Fast reaction time
- Global
- Preventive maintenance
- Planned maintenance window
- Experience exchange on site
- For all sensors, independent of manufacturer and model
- Low expense
- Safe processes and products
- For all systems
- Original parts or first-manufacturer quality
- Validated wear/replacement parts
- Advisory recommendation
- Parts recommendation

# More time for other tasks









Everything that has to do with the clean utility system is done by BWT - for you.

It is certainly worth more than a degree of attention to note how you can make work and life easier for your customer. Because it is easy and better, AQU@SERVICE covers the whole spectrum of customer-friendly services for clean utility systems. That means, you can calmly and intensively dedicate yourself to the other tasks and production plants in the time remaining.

#### **AQU@SERVICE Replacement of seals**

In the product-related area, there are planned seal-change intervals. Each individual seal is packed to comply with pharma norms, is provided with a sticker that clearly displays the installation location and all commercial information in text, and is contained within a QR code. In the LOC and R+I guidelines, all replaced seals are documented clearly.

#### **AQU@SERVICE Documentation**

Adaptions are constantly made to clean utility systems. So that current as-maintained documentation is readily available in data carriers, technical documentation is continuously managed and adapted by BWT. In so doing, the delivery of replacement and wear parts, material and calibration certificates and service activities are updated.

#### **AQU@SERVICE Pure steam quality**

To guarantee reliable sterilization and safety, the DIN EN 285 guideline "Sterilization - steam sterilizers - large sterilizers" describes the requirements and test of steam quality in steam sterilizers and pure steam generators. The recommended measures of dryness, overheating, and non-condensable gases are carried out ideally in the course of maintenance.

#### AQU@SERVICE Integrity of sterile filters

Proof that sterility barriers are free from damage is a critical and urgently prescribed step in the context of bio-pharmaceutical production processes. Inspectors and auditors often ask questions, for example, to check the integrity of ventilation filters on tanks. With AQU@SERVICE, the measurement is taken as part of regular maintenance. In one go the so far installed filter candle which is regularly replaced and the newly installed one are tested. Thus the continuous integrity is proven.

- Efficient plannina
- Clearly traceable
- Safe
- Premium documentation quality
- Safe audits and checks
- Minimal expense
- Trouble-free process
- Experienced technicians
- Safe inspection
- Preventive maintenance
- Predictable maintenance window
- Experience exchange on-site











Specialized and competent Experts from BWT Pharma & Biotech assist over the phone and the internet

### **AQU@SERVICE DIRECT HELP**





Expert service and quick response.

#### **AQU@SERVICE Hotline**

Should a breakdown occur, or a clean utility system fail to function, there can be different causes such as operator fault, failure of components, or material failure. The technical hotline is open for all questions and problems. Experienced service technicians from BWT Pharma & Biotech are available 24 hours a day, 365 days a year, to provide telephone support right away. Often, problems can directly be solved by the operator, and there is no need for an on-site appointment.

#### **AQU@SERVICE Remote Assistance**

With plants from BWT, optional hardware for remote assistance can be installed or retrofitted. Remote access occurs via safe VPN link and enables the analysis and diagnoses of systems on a solid data basis. Questions are clarified and problems solved without having to wait for a technician and cover their travel costs. Plant operators have full control at all times, and AQU@VIEW Remote wins over every IT department in all aspects of security.

- Expert staff, no call center
- 24 hours a day, 365 days a year
- Immediate support
- 100% access control for operators
- Qualified diagnosis and analysis
- Quick problem solving

### BWT - For You and Planet Blue. | 13

## The benefit of years, performance and efficiency for all devices







AQU@SERVICE is available for BWT Pharma & Biotech systems and all other manufacturers. And if a larger expansion becomes necessary, we can include that too.

#### **AQU@SERVICE Audit**

All machine operators can benefit from AQU@SERVICE. Manufacturer-independent. In such cases, an experienced BWT service engineer will carry out a qualified system audit and deduce the status, output, and potential of the plant. Based on these results and the requirements of the operator, specific measures are recommended and possibilities for their implementation suggested. The expenses involved and application expected are considered realistically.

#### **AQU@SERVICE Optimization**

Optimization and software updates make sure that systems always correspond to current technical standards and the up-to-date GMP regulations. The productivity, efficiency, and process safety are therefore maintained or even improved, while operating costs are saved at the same time. The lifetime and availability are increased. The newest components ensure long-term availability of replacement parts.

Of course, BWT also takes on the responsibility for the qualification, validation, and documentation of modifications.

#### AQU@SERVICE Upgrade

When regular need for clean utilities reaches the limits of production and buffering capacity, an expansion of capacity within the existing works, or an installation of a completely new system must be considered. Similar considerations are necessary when individual critical components such as automation, no longer meet the latest technology and pose a risk to reliability.

As systems are generally not permitted to go offline, or only for as short a time as possible, many parameters must be considered when making such decisions. In these cases, the experience, competency, and speed of project leaders, engineers, and technicians from BWT Pharma & Biotech are especially important. We look for, find, discuss, and implement an individually tailored solution.

- Simple status analysis
- In-depth planning basis
- Independent of manufacturer
- Optimized systems and processes
- Increase in productivity and efficiency
- Increased machine, production, and process security
- Qualification/validation and reconstruction documentation
- Extended total lifespan
- Complete portfolio of platform solutions
- Minimal impact on ongoing operation
- Scheduling
- Future security regarding quality and performance







**AQU@SERVICE Training** 



Efficient and secure pharmaceutical production relies on a manufacturing process that conforms to the guidelines. A determining factor in that is personnel.



#### Qualified production staff for safe production

During production at pharma and biotech businesses, observing the guidelines and regulations is of utmost importance. In order to attain safe and efficient production, not only reliable technology, but also staff who are capable of carrying out their tasks with the systems are required.

The better the staff on-site understand the plant and the overall system and know the ropes, the safer the routine work on the plant can be carried out and the downtime minimized.

Training owners and operators allows for better operating safety. It makes sense for the entire core team when bringing up new plants, for new staff, and for regular refreshers and deepening of knowledge for the expert staff on location.

#### Individual content delivered worldwide

Theoretical and practical content is adapted individually to suit customer needs, and supplied in the BWT Pharma & Biotech classrooms or at the plant on-site. Tailored content and processes go from practical, basic briefings for novice operators to multi-activity, structured, and combined theory/practice lessons for larger groups. Participants benefit from the experience and expert knowledge of clean utility experts from BWT Pharma & Biotech.

BWT Pharma & Biotech provides qualification to staff globally according to the same quality standards. That means that AQU@SERVICE Training can bring the relevant knowledge and skills for the whole clean utility system to your business. Regulatory requirements for proof of qualification of staff are therefore also fulfilled



#### **Better-qualified staff**

The value of well-educated staff is very high, all over the world. However, level of qualification is very different, ranging from well-educated experts with regularly continuing education to temporary workers who have learned on the job. Through regular, structured training, obligations are met and plant efficiency is raised.

- Operations safety
- Error prevention
- Optimal plant utilization



#### The right content

Based on existing requirements, the content of training is defined and carried out for owners and operators. From basic training for novice or new staff to expert training for professionals with years' experience, the content is individually prepared and supplied.

- Success review
- Modular structure
- Relevant to work



### Expert knowledge, first-hand

BWT's trainers are experts in theory and practice. For successful supply of knowledge, they are trained both as educators and speakers. There is nothing worse than training of theory without reference to practice, or experts with enormous amounts of experience, but no ability to convey this knowledge.

- Short and entertaining
- Flexible regarding questions
- By professionals, for professionals



#### **Practical exercises**

People learn most effectively when newly learned information can then be used in practice right away. Practical exercises on plants are therefore an integral part of almost every Training.

- Improved learning success
- Theory-practice transfer
- Avoidance of errors and clarification of questions



#### **Small groups**

During trainings, individual learning requirements and questions from every participant are considered. In small groups, the trainers can react better to the situation and offer the best training for every participant.

- Quicker and better progress
- Personal learning environment
- Modular structure



#### Online training

Nothing can beat personal training by BWT experts, but it's sometimes not possible for organizational reasons. Because good training simply can't be overlooked, there are webinars and video seminars over the internet.

- Simple organization
- Flexible time and location
- By professionals, for professionals



# 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

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 🄉 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.

resulting minimisation of CO<sub>2</sub> emissions.

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.

signifies that our mission is to take ecological, economical and s ocial 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.



For You and Planet Blue

Find us on www.bwt-pharma.com

