

Validation, qualification and documentation

Engineering and Project Execution

From concept studies to planning and dimensioning to detail engineering and project execution. The specialists and experts of BWT Pharma & Biotech cover all fields of engineering. Process engineers, automation engineers, mechanical engineers, validation engineers, project managers among others take care of our customer's projects and bring them to a successful conclusion.

Validation and documentation

Consistent documentation and compliance with the regulations and guidelines like cGMP, GAMP, USP and Eur. Ph. Requirements, ISPE Engineering Baseline Guide, Vol. 4 "Water and Steam Systems". We create the conditions to make sure you experience a successful inspection of your system.

Qualification of each project follows the "V-model", from URS to the final FAT/SAT which is carried out before the system is finally handed over to the customer.

Full Production Facilities and Quality Assurance

All factories of BWT Pharma & Biotech use the latest technology for production of the systems. The final assembly of the systems in the factory, including commissioning and the FAT, results in pre-qualified complete systems. In combination with our Quality Assurance System we can ensure the highest quality is delivered for our customer's satisfaction.

IQ, OQ, SAT and Training

The on-site services include commissioning, start up, IQ/OQ, SAT execution and training. Training of the operating personnel by experienced service engineers is one key to ensure reliable and trouble-free operation. Even after handover of the system BWT Pharma & Biotech remains your reliable partner for various service and maintenance packages with individual levels of support, based on your needs.

