



From ultrapure steam to wastewater treatment: a wealth of expertise in pharmaceutical water

The sustainable and efficient use of water is also a key topic for the future in the pharmaceutical industry. Suitable plant solutions allow companies to overcome the complex array of challenges here. The EnviroWater Group is their reliable partner in this task. With its flagship project for a Brazilian vaccine manufacturer, Enviro Water Group has devised a complete solution.

The pharmaceutical market is growing dynamically thanks to a continuous stream of new active ingredients and products developed by the industry. The factors driving this include demographic change, which is increasing the consumption of pharmaceuticals, and new pathogens such as SARS-CoV-2. Water is one of the most frequently used raw materials in the development and production of medications.

"Water is a particularly challenging topic in the pharmaceutical industry, as patient safety is paramount," says Elmar Billenkamp, department manager at EnviroChemie. "Throughout the production process we have ultrapure water that needs to be provided at a consistent quality, as well as process water and wastewater, which has to be treated thoroughly," comments Billenkamp, adding that pharmaceutical and environmental specifications also have to be adhered to reliably.

A wealth of expertise in pharmaceutical water

Companies in the expert network of the EnviroWater Group have gained experience in numerous projects for the pharmaceutical industry over the years. The companies EnviroFALK PharmaWaterSystems, EnviroDTS and EnviroChemie are all members of the Group and are long-standing actors on the pharmaceutical market.

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According to Billenkamp, all three companies contribute their specific competencies and work hand in hand on joint projects: EnviroFALK PharmaWaterSystems provides solutions for generating pure and ultrapure water as well as water for injections (WFI) and ultrapure steam for applications in pharmaceutics, biotechnology and life sciences; EnviroDTS specialises in wastewater sterilisation and decontamination for laboratories, institutes, hospitals and industry; and finally, EnviroChemie develops customised plant solutions for treating cooling water and wastewater and for water recycling for companies in the pharmaceutical industry and life sciences sector.

Innovations for the pharmaceutical industry

Pharmaceutical companies thus receive complete solutions encompassing everything from the drinking water inlet, through the generation of ultrapure water and water for injection purposes, all the way up to wastewater treatment from a single source. Joint research and development projects are also in planning.

According to Fabian Stapper, sales director at EnviroFALK PharmaWaterSystems, pharmaceutical companies benefit from the synergy effects: "A general project manager coordinates all activities." This ensures that a single contact is available to pharmaceutical companies for all disciplines. "This is an added plus that we as a Group can offer our customers," emphasises Stapper.

The fact that one person at the EnviroWater Group holds the reins also makes project management easier. "In case of problems or delays, we use our short paths and solve issues internally," states Stapper. "This means we can work efficiently and profitably. In turn, the customer can rely on our adherence to deadlines, saving time, money and stress."

Solution concept for vaccine production in Brazil

One example of this concept can be found in Brazil, where a vaccine manufacturer is planning a new, large-scale pharmaceutical production facility. The company plans to produce vaccines against yellow fever and COVID-19 in Rio de Janeiro. Three buildings are planned, each with its own focus. The production processes are very complex and pose high requirements for the water technology.

The EnviroWater Group is contributing to this with a modular solution concept for water treatment along the entire process: all three buildings will require different ultrapure media for production and has to be developed by EnviroFALK PharmaWaterSystems. Engineers and technicians from EnviroDTS will thermally inactivate the resulting wastewater before it progresses to the final step of the process, the wastewater treatment plant to be projected by EnviroChemie.

Production of ultrapure media

The individual subprocesses look like this: to produce its vaccine, the company requires three different media qualities in each of the three buildings: purified water (PW), water for injection purposes (WFI) and ultrapure steam. In this case, the purified water is required for producing the other two media.

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PW is demineralised water that is made from feed water and from which the salts have been removed using various processes. The most important methods are filtration, softening, reverse osmosis and electro-deionisation. Because the production of purified water is subject to strict regulations, it is vital that the microbiological quality of the feed water remains constant.

However, feed water quality varies in regions such as Brazil, which is in part due to natural events such as the heavy rainfall during the rainy season. Therefore, water quality must be analysed particularly frequently and precisely. "This requires experience and regional expertise," explains Stapper. "The right selection of process technology plays a significant role in the reliable functioning of the systems." In the plant in Rio de Janeiro, five PW generators from EnviroFALK PharmaWaterSystems with a total output of about 18 cubic metres per hour (m³/h) are to ensure that production is supplied with sufficient purified water.

Of this, about 13 cubic metres of water per hour is distilled for injection purposes in a total of four generators, which then needs to be stored safely and distributed. This very pure water is subject to the

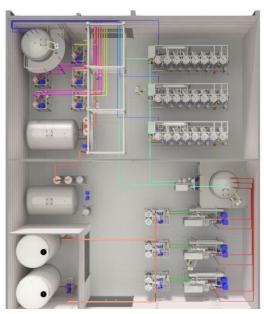


Image: All components of the plant are designed redundantly to make processes more secure.

very highest international standards in pharmacopoeias, which means special care must be taken here.

Similar standards apply for ultrapure steam, which is used for sterilisation at over 121°C. Here, five UPS generators with a total capacity of about eight tonnes per hour (t/h) ensure a sufficient quantity. The concept of the EnviroWater Group entails the redundant construction of all generators in order to ensure the supply of ultrapure media at all times.

Thermal inactivation

Wastewater from medical production generally needs to be thermally inactivated due to strict hygiene regulations. In the project in Brazil, each building produces about ten cubic metres of wastewater every hour. Here, it is important to guarantee a temperature of 135°C and a retention time of at least two minutes in order to kill all microorganisms and inactivate viruses.

EnviroDTS therefore plans to equip each building with a Sterifix E10200 continuous flow system, which continuously processes the generated wastewater. "Heat exchangers ensure efficiency here, thus lowering operating costs," explains Billenkamp. An integrated CIP system cleans the exchanger and the retention stage on a cyclical basis.

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Image: EnviroDTS SteriFix E15000 wastewater sterilisation plant for safe inactivation of active components in wastewater.

Wastewater treatment

According to the plan, about 380 cubic metres of sanitary wastewater and around 440 cubic metres of industrial wastewater will be left over every day from the entire site and will have to be treated in the wastewater treatment plant. This organically contaminated wastewater is to be collected in a mixing and expansion tank and continuously fed to the wastewater treatment plant.

The treatment concept by EnviroChemie proposes a membrane-biological Biomar OMB process with nitrification, denitrification and downstream reverse osmosis.

The permeate resulting from the reverse osmosis is to be sterilised via a UV system so that it can be utilised again in production. "The entire plant is designed in such a way that the concentrate from the reverse osmosis complies with the discharge values," explains Billenkamp. This applies in particular for the COD limit value of 150 milligrams per litre.



Image: Example of a biological Biomar membrane wastewater treatment plant with mixing and expansion tank, aerobic cleaning step and membrane filtration unit.

Water experts on site

Some of these large wastewater treatment systems are built in Germany and tested before being shipped, while others are constructed locally. "We also have local representatives and work with the engineers on site," says Stapper. He adds that it is especially important to know the regulations, which differ from one region to the next, and to always remain up to date with them: "To this end, we stay in contact with local authorities and take care of planning applications and permits."

As the example shows, the treatment of water and wastewater in the pharmaceutical and life sciences industry is demanding and location-specific. If a pharmaceutical company decides to entrust a single source with the planning, construction, commissioning and outsourcing of the operation of

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its entire water and wastewater management, it enjoys a multitude of benefits: the holistic concept helps it use resources efficiently and work sustainably throughout the entire process and save on operating costs through plant optimisation measures.

"Ideally, we are involved in the new construction of plants right from the beginning," says Billenkamp. "The planners know the customer's range of services and we contribute our water expertise."

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