konradin mediengruppe

www.cpp-net.com

cpp

chemical plants & processes

3 2015

Processing pharmaceutical water efficiently

The elixir of life for pharmaceutical production

As in other industries, no aspect of pharmaceutical production can take place without water. However, not all water meets the same standards. We spoke with Stephan Stautmeister, CEO of BWT Pharma & Biotech, and product manager Andreas Minzenmay about the challenges of producing pharmaceutical water as well as new technologies for efficient production.

cpp: *Pharmaceutical water is produced from drinking water. Although the standards for pharmaceutical water have been clearly defined around the world, there are significant variations in the quality of drinking water. What does this mean for pharmaceutical water production?*

Stautmeister: The WHO has set minimum quality standards for drinking water, but in many countries these standards are not met. This is why pre-treatment technologies can differ significantly from region to region, according to what is necessary to ensure the safety of the main treatment technology. The drinking water supplied upstream must have the correct quality; otherwise, there is no way of being sure of a reliably high quality product at the end of the treatment process. This reliability is essential for our users, as many of them do not use a redundant process.

cpp: *In other words, there is only one unit for pharmaceutical water production at the customer site?*

Stautmeister: Yes, that is correct. Users often rely on a single unit to manufacture their ultrapure media. That is why the reliability issue has such high priority. If the production of ultrapure media is interrupted, it is only a matter of a few hours before the factory's entire production comes to a halt. Depending on the product, this can result in a loss of several hundred thousand euros. It is clearly important to prevent such a scenario.

cpp: *How do you achieve this?*

Stautmeister: We have more than 50 years of experience working with ultrapure media. We aren't satisfied with simply building good, reliable systems. We set the bar higher, working to provide corresponding services for the entire lifecycle of the systems. This means that customers don't need to worry about their ultrapure water systems and instead can completely focus on production.

cpp: *What level of demand is there for machine building services in the area of pharmaceutical water?*

Stautmeister: Manufacturer services are growing more and more important, because customers face the task of operating ever more complex systems with ever fewer employees. This is why we offer a full service for our systems, from the raw water to the point of use, including calibration and documentation updates – which are a particularly important consideration due to the high level of regulation in the field. Without proper documentation and validation, the user cannot operate the unit. In short, we used to be a machine builder. Now, we are on the path to becoming a service provider who also builds machines.

cpp: *Which products do you offer for PW/HPW production?*

Stautmeister: We have several complete product lines in this area ranging from Septron-line, the basic standard device, through Osmoline, a cost-efficient, hot-water-sanitised system, to Osmotron. These product lines cover different customers' specific requirements and, of course, different budgets. In

Stephan Stautmeister is CEO of BWT Pharma & Biotech GmbH

Andreas Minzenmay is product manager for the Osmotron and Osmovision product lines at BWT Pharma & Biotech

the end, the quality of the water always meets the quality level stipulated by the pharmacopeia.

Minzenmay: The only real difference between the systems lies in their quality gradation, ease of operation, materials and level of flexibility. A basic product such as Septronline comes as it is. There are no options for modifying it. On the other hand, these are standard units that can be delivered quickly.
An Osmotron, with its skid-mounted design, is of course another matter. There are many different aspects of this system, such as the instrumentation, that we can adapt and tailor to each user's requirements. That makes us very flexible. This is why it is important for us to receive the necessary basic data and specifications in advance, so that we can fine-tune the design to the customer's application.

cpp: *BWT presented an additional system for PW/HPW production at Achema – the Osmovision. How is the Osmovision designed?*

Minzenmay: With its compact, skid-mounted design, the Osmovision is similar to the Osmotron. All necessary process steps plus the control system are preassembled on a supporting frame. This means that a complete function and performance test can be carried out under operating conditions before the system even leaves the factory. The same applies to the preliminary qualification (IQ/OQ). This cuts the time required for on-site assembly and setup and significantly simplifies the qualification. The system is delivered to the customer exactly as it was during the acceptance. The Osmovision is rated for 500 to 10,000 l/h, in other words 80 to 90 % of the applications we see in the pharmaceutical industry.

cpp: *How is this different from your previous product, the Osmotron?*

Minzenmay: The Osmotron is our classic and it is state of the art. The raw water is pre-treated by softening, safety filtration, reverse osmosis, CO_2 gassing and electrode ionisation before entering a tank for temporary storage. Around 75 % of the water is converted. With an additional reverse osmosis concentrate stage, it is possible to achieve up to 85 to 90 % water conversion. Around 80 % of these systems feature hot water sanitisation. In other words, the water is heated to over +80 °C and then circulated through the system, to keep the microbiological status as low as possible.

Stautmeister: This is also a small weakness of this type of system: all in all, hot water sanitisation takes around three hours. During this time, the system is not available for production. With single-shift operations, this is no problem. For round-the-clock production, the only workaround is to increase the storage tank volumes or reduce consumption during the sanitisation phase. An alternative solution would be to switch to a different technology, such as Osmovision.

cpp: *And how does the Osmovision solve the problem?*

Minzenmay: The design of the Osmovision features continuous chemical sanitisation. Various oxidation products are created on the EDI concentrate side – products that we then use for chemical sanitisation. Up to now, these have been disposed of with the waste water. By recycling them back into the Sanitron reactor, it is now possible to put the oxidation products to good use. There is no need for an additional dose of chemicals. Sanitisation is continuous and the system can work without any interruptions.

The BWT-designed and patented EDI module was specially developed for the pharmaceutical industry and is used for the demineralisation of water with a low ion content

cpp: *Which oxidation products are created in the EDI module?*

Minzenmay: As a rule, the products that can be present in the EDI concentrate are hydrogen peroxide and free chlorine. The composition of these oxidation products can be controlled by altering the type of electrode material in the EDI stage and the operating mode. There are always more oxidation products created in the EDI stage than are actually required for sanitising the feed water in the Sanitron reactor. As a result, there is an excess of oxidation products at the outlet of the reactor. Since these would destroy the membranes, they must be eliminated in the downstream process stage. In the past, in systems with excess hydrogen peroxide, this was carried out using a catalyst in the form of manganese dioxide. At Achema, we presented an optimised system which operates with an excess of free chlorine. The free chlorine is eliminated using highly efficient UV technology.

The Osmovision is a high efficiency PW/HPW system which can keep operating 24 hours a day in continuous production

cpp: *In this sense, the Sanitron reactor is the core component of the Osmovision. Which processes take place in the reactor?*

Minzenmay: In the Sanitron reactor, the water from the softening stage is atomised together with the EDI concentrate due to the introduction of air. This allows the carbon dioxide in the feed water to escape and the carbon dioxide level drops below the required values, eliminating the need for additional degassing. At the same time, if free chlorine is present in the feed water, it reacts with the hydrogen peroxide. The excess is removed in the downstream process stage. Active carbon filters are no longer necessary – a fact greatly appreciated by users, as active carbon is problematic for the pharmaceutical industry from a microbiological perspective. Added to this, oxidation products from the EDI stage also result in a permanently lower level of germs in the Sanitron reactor.

A small system in continuous operation is not only far less susceptible to faults but also much more cost-efficient than a large system that is only in operation for a few hours a day.

cpp: *How efficient is the Osmovision?*

Stautmeister: Our goal was to make the system as efficient as possible. It is always possible to achieve 80 to 90 % conversion with the Osmovision. At the same time, we worked to keep the operating costs low and this goal has been met. We also managed to avoid many of the weaknesses of state of the art treatment systems. By integrating the concentrate stage in the reverse osmosis, skillfully exploiting different water currents – for instance, we use the permeate from the integrated concentrate stage to rinse the electrode ionisation on the concentrate side – and implementing the continuous sanitisation process in the Sanitron reactor, we have realised an efficiency level in the premium range.

cpp: *You mentioned the operating costs. What is the breakdown?*

Stautmeister: The most important costs when operating a pharmaceutical water production system are those for feed and waste water. These can make up as much as two thirds of the total. In addition, there are the power costs and the costs for replacement parts. Each of these items accounts for around 10 %. The costs for maintenance and repairs are minimal at just 1 to 2 %. The remaining costs are for chemicals as well as additional costs incurred by the user.

cpp: *One last question: what about automating the Osmovision?*

Stautmeister: Automation is an increasingly important consideration in machine building. Nowadays, almost all functions are automated and feature intelligent control. We offer convenient, cGAMP-compliant control and monitoring for our systems in the form of validated Aquaview automation products. The hardware and software components we use for this come from Siemens or Rockwell. Due to the regulations that apply in our field, we only use our own, validated software modules. These are open and transparent for customers around the world. After all, you need to be able to control the brain of your own system. We also offer opportunities for networking with customers or process control systems, remote maintenance and options for accessing the system using a tablet computer. It goes without saying that this data is encoded for security. As you can see, Industry 4.0 has found its way to us as well.

» **www.cpp-net.com**
Online search: cpp0315bwt

Author

Dr. Bernd Rademacher
Editor,
cpp chemical plants & processes