

# WEDECO UV and Ozone systems sanitize purified water loop

A leading pharmaceutical manufacturer and leading biotechnology company in Germany, has chosen Wedeco ME Pharma UV and WEL ozone systems for a biopharmaceutical production plant in southwest Germany.

The plant is Europe's largest manufacturing location for biopharmaceutical active ingredients derived from mammalian cell cultures.

**“The Wedeco equipment was fully documented for qualification and validation”**

The biopharmaceutical active ingredients production plant started operation in September 2003 and received the official approval by the FDA (US Food and Drug Administration) in July 2004. The company closely examined their ability to manufacture the product applying state-of-the-art technology and cGMP rules recognized in the United States.

## **Purified Water Systems Sanitation with Ozone and UV**

One of the biggest challenges in the production of human proteins lies in the sterile process management. A special emphasis for the company is the purified water which is used for several production and cleaning purposes. Total there are four different ozonated loops equipped with UV systems.

In addition to periodical thermal sanitation/sterilisation up to 130 °C ( 1 - 2 times per year) the end client decided to incorporate cold sanitation with a combination of ozone and UV, which is highly effective against a multitude of micro-organisms and bio-films. An ozone dose of 30-40 ppb is constantly achieved by the Wedeco WEL systems, which stabilizes the water and protects against microbiological growth.



The production takes place in accordance with “current Good Manufacturing Practises” (cGMP) and the plant has to follow the requirements of FDA and European regulations.

The Wedeco ME Pharma systems also disinfect the water and ensure destruction of residual ozone before the point of use.

### Reasons for Wedeco's success

The end client has had favorable experiences with existing Wedeco ME installations in other production facilities. Reliable disinfection and ozone destruction results were two reasons for choosing Wedeco. The direct ozone generation in the water without any air or oxygen injection was a deciding factor for the German company. The contractor also appreciated the relationship with Wedeco, as well as a packaged solution that includes ozone generators, UV systems and ozone monitors.

### Scope of supply:

- 4 pcs. Wedeco ME 450 Ph for 2 x 45 m<sup>3</sup>/h with 850 J/m<sup>2</sup> and 2 x 35 m<sup>3</sup>/h with 1120 J/m<sup>2</sup>
- 2 pcs. Wedeco WEL 4-4 with 3-4 g/h ozone directly produced in the water
- 1 pcs. Wedeco ozone destructor for off-gas treatment
- 1 pcs. Ozone Monitor type Orbisphere

The Wedeco equipment was fully documented for qualification and validation (certificates for materials, seals, surfaces, weldings and pressure).



WEDECO ME Pharma



WEDECO WEL cell with stainless steel cabinet