

■ **Baxter, Austria**

Laboratory Upgrade

Siemens implemented a Simatic PCS 7 / Batch installation in Orth on the Danube; with the new process control system, Baxter's Pilot Plant I now meets the strictest documentation requirements.

The history of Baxter in Austria is also the history of Immuno AG, which was acquired in 1997. With it, in addition to other divisions, came the tick-borne-encephalitis-prevention business, which has been successful for 30 years, and the supply of therapeutic proteins manufactured biotechnologically or obtained from human blood plasma for patients

with serious illnesses. And Baxter is clearly committed to Austria as a research location. The location in Orth on the Danube is the company's largest research site today: approximately 500 employees work there in 17 buildings, 260 of them exclusively in research and development. The research team has grown by about 20 percent in the last two years alone.

470 employees work at the Baxter facility in Orth on the Danube in research, production, and quality control for the Viennese products



Multipurpose facility

Object number 17 – Pilot Plant I – has been modernized and is now a state-of-the-art facility. The fermentation plants have been equipped with a new process control system, Simatic PCS 7, as well as new measuring equipment and additional functions. Frederic Herzog, manager of Pilot Plant I, invested “a lot of theory in the plant” together with Siemens and its partner ISE. He refers to the upgrade of the process control system, which has been in operation since 1993, as a quantum leap: “We now have a fully validation-capable plant in accordance with GAMP and therefore meet the strictest requirements for work processes in the GMP-regulated environment. In practice, that means above all strictly controlled, hierarchically structured access rights and jobs with password protection; improvements to the control of production; cleaning and sterilization programs; and detailed, continuous recording of the process parameters.” Since the fermenters of Pilot Plant I produce both clinical material and material intended for sale, maximum flexibility is required. The plant units develop vaccines up to production maturity and at the same time perform normal production tasks. Exact and extensive documentation is an indispensable requirement for this.

Media without animal components

One of the greatest research successes at the Orth facility is the “vero cell platform,” with which Baxter is able to produce large quantities of vaccine without animal components. “Where earlier animal serums had to be added to the media, a mixture of salts, vitamins, and amino acids is now used,” Herzog explains. As a result, risks such as the transmission of the cattle disease BSE or certain viruses also dangerous to humans can be completely eliminated.

State-of-the-art automation technology

The upscaling of the production process from laboratory scale to production dimensions in Pilot Plant I required a sophisticated automation solution. The basic conditions such as sterile production, the use of very expensive raw materials, complex cleaning processes, great flexibility, production safety, and validation of the plant made high demands on the products used and on the know-how of the automation technicians.

Bernhard Baldaszti, head of automation technology at Baxter in Orth, cites “the impressive consistency, the intuitive operation, and the scalability of the system” as reasons for using Simatic PCS 7. Once they have been created, standards can be used throughout the system, from the laboratory fermenter to the large-scale plant.

The effects are demonstrated in a project that was handled extremely successfully in terms of budget and time scale. The ease of operation enabled the



All photos: Patrick Schaller

Simatic PCS 7 and Simatic Batch: the process control system and batch software ensure fully automatic recipes in research and production



Frederic Herzog during the commissioning phase: “The flexibility of Pilot Plant I has increased dramatically”

plant owners to begin production immediately. Via Profibus, about 1,000 distributed measuring points are processed and evaluated according to batch in the process control system. Documented and continuously traceable production parameters provide the necessary production safety and form the basis for a plant validated in accordance with GAMP.

The automation project was implemented by Siemens in cooperation with the Viennese company ISE GmbH. Baldaszti adds, “Another key success factor for the project was the excellent cooperation between the Baxter project team, the biotechnology professionals from ISE, and the specialists from Siemens.” ■

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