

New room decontamination system at Lactosan

## Automatically germ-free

Ortner Reinraumtechnik has implemented a fully automated cleanroom decontamination system with H<sub>2</sub>O<sub>2</sub> in Lactosan's cleanroom production facilities.

### Cleanroom

decontamination plays an important role in cleanroom technology.

During commissioning and after maintenance work or process modifications, it is necessary to ensure that all microorganisms – be they bacteria, viruses or spores – are destroyed. A number of technologies are used for this task. In many of these, an aqueous solution of hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>) is evaporated and delivered into the rooms.

“We have studied the H<sub>2</sub>O<sub>2</sub> decontamination situation intensively,” Josef Ortner, founder and CEO of Ortner Reinraumtechnik GmbH, says. But since there was no reliable information available about many of these systems, Ortner initiated a research project in collaboration with Graz University of Technology and the Competence Center for Pharmaceutical Technology, RCPE. The result was a calculation program which simulates room fumigation even under difficult conditions. “This is particularly important for complex processes where you need to know in advance what should be installed,” Ortner explains.

Ortner Reinraumtechnik GmbH successfully used the know-how gained in this way for a contract from a Swiss Pharmaceutical company in which a vaccine production facility in Basel was fitted with an H<sub>2</sub>O<sub>2</sub> fumigation system. According to Ortner, “Based on the calculations, the system could be designed to meet the requirements of pharmaceutical cleanroom production exactly.”

Building on this, the system was continuously improved and expanded with separately controllable injectors. The gas can be delivered either by means of small devices installed in the room or through the ventilation system. This technology was also used recently in a project by the company Lactosan in Kapfenberg.

#### Biotech pioneer from Kapfenberg

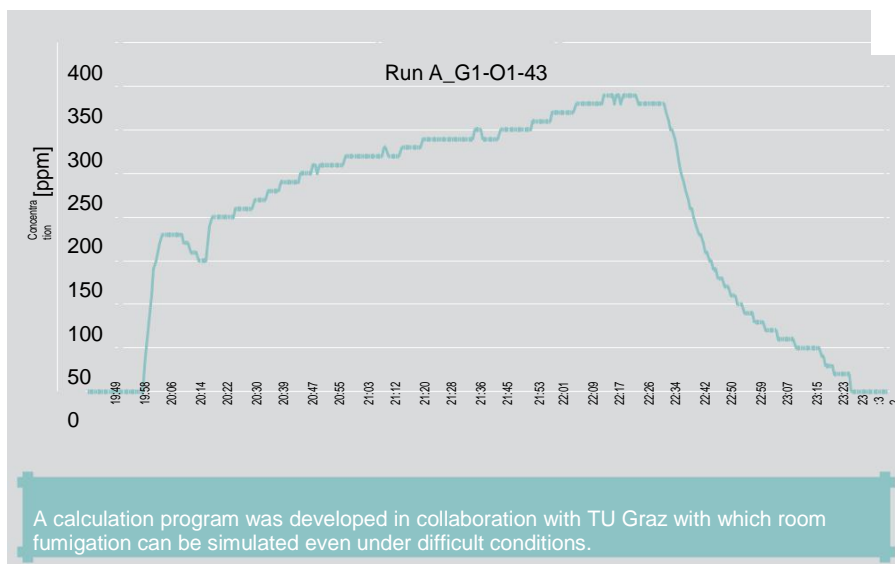
Lactosan was founded in 1989 and initially concentrated on biotechnical manufacturing of lactic acid bacteria.



The H<sub>2</sub>O<sub>2</sub> gas can be delivered by means of small devices installed in the room or throughout the ventilation system.

Today, continuous growth and investments in new technologies and systems have allowed the company to offer a portfolio of around 600 products, including live lactic acid bacteria for the production of silage, as animal feed or energy crops for biogas generation, and as probiotics for humans and livestock as well as starter cultures for the food industry. In addition, more than 40 enzymes are being produced on contract for the food and pharmaceutical industries. Since 2011, the company has also been able to produce lactic acid bacteria in a production facility that operates in accordance with GMP [Good Manufacturing Practice] conditions.

During the last upgrade, additional capacities for freeze-drying, pulverization, filling, mixing and storage were created. An existing raw materials warehouse was converted into a clean room for this purpose; Lorenz Consult Ziviltechniker GmbH was the general planner for this conversion. “We were in charge of all of the planning and monitoring activities from initial conception to submission, tendering and execution all the way to approval,” Christian Lorenz says. It was especially important to install all of the pipe runs for the operation of the clean room into the existing rooms in coordination with the plant technology of the client.



A calculation program was developed in collaboration with TU Graz with which room fumigation can be simulated even under difficult conditions.

► A 3D scanner was used during this for inventory control. “In highly specialized areas, it is especially important to find room for all of the necessary systems and pipes,” Lorenz emphasizes.

### Fully automatic cleanroom decontamination

There were special requirements for room decontamination: “Several rooms needed to be contaminated with the help of a fully automated fumigation system,” Josef Ortner explains. The room situation in the advance simulation was updated to include all of the systems contained therein in order to adjust the system to be installed to the current conditions. “One characteristic is that aggressive gas is not produced directly in the room but rather centrally, and is delivered by pipe into the rooms to be fumigated,” Ortner goes on. Lorenz designed a separate pipe system for this with process valves and attendant control. All of the materials selected to be used cannot be corroded by hydrogen peroxide.

The system is fully automated and can be activated on a room-by-room basis. Different processes would be required for different rooms so that, for example, decontamination can take place more quickly or over a longer period of time.

The whole system is controlled centrally; every valve position is monitored. “This ensures that data is available in real time and that the client knows what happened at all times,” Ortner explains. Lactosan is thus operating a state-of-the-art system: “This is one of the *largest* fixed-installation decontamination systems that I know of,” Lorenz notes. ■

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### The participating companies

#### Lorenz Consult Ziviltechniker GmbH ...

... is a general planning company with a special focus on the pharmaceutical and health fields and a great deal of GMP experience. Its services are comprised of building construction, static and building services planning using building information modeling technology, and project management as well as construction coordination.

#### Ortner Reinraumtechnik GmbH ...

... is an Austrian pioneer in cleanroom technology and has concentrated completely on cleanroom device construction for the past decade. It specializes in special solutions for the pharmaceutical and health fields such as room decontamination, lock systems, isolator technology, etc.