



In the pharmaceutical industry, the production of complex-structured active substances, or biocatalysts, using biotechnological methods has been increasing in significance for a number of years.

With its many years of experience in the production of pharmaceutical process systems, Pharmatec, a Bosch Packaging Technology company, offers tailor-made solutions for the fermentation of microorganisms. Pharmatec is known throughout the pharmaceuticals industry for its high-purity media production systems, plus process and CIP systems. The development of bioreactors and their relevant upstream and downstream processes will be increasingly pushed forward by Pharmatec in the future.

To create the optimum environment for live cells and bacteria, the challenge lies in designing systems which firstly offer conditions under which the desired organisms can grow optimally and secondly meet the high cGMP regulation standards prevalent in the pharmaceuticals industry.

New fermenter for multipurpose use in pilot plant stations



Fermentation system – various perspectives

The success of such a project is dependent on a number of technical and biological process details. Diverse process parameters, such as the pH value, oxygen content, foam formation and temperature control plus their time lapses, have to be constantly monitored and corrected throughout the entire fermentation process in case deviations arise. Perfectly coordinated measurement and control technology is therefore essential for successful cultivation. More extensive deviations from the specifications may significantly impair the process and, under certain circumstances, render an entire batch useless.

Last year, a well known pharmaceutical company based near Frankfurt commissioned Pharmatec to supply a fermentation system to investigate long-term cultivation involving streptomycetes, filamentous fungi, bacteria or yeasts for the production of natural substances or recombinant proteins. Different proce-

dures, such as the batch or fed batch process and scale-up trials, were to be tested. Various demands were also made concerning CIP cleaning, continuous sterilization capability and the temperature control of the unit. The specialist's innovations and wealth of ideas were required to achieve this. Together with the customer, the Pharmatec team developed a concept which was successively implemented within seven months in Dresden. After commissioning and a successful Factory Acceptance Test by the customer, the system was installed precisely in its target location, started up and transferred to the customer following IQ and OQ.

The first trial for the new system was a long-term sterility test called media-run. Following full sterilization of the system, complete fermentation is undertaken with all of the media. Inoculation with a cultivated strain additionally took place. The sterile tests were verified with

outstanding results. The requirements made on the fermenter were optimally met and the Site Acceptance Test was also successfully completed. Commissioning of the Pharmatec bioreactor was therefore judged to be an unqualified success. Further operation of the system under production conditions proceeded to our customer's satisfaction.

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