

Product application for sterile technology

Fully automated multifunctional system for preparation, bottling and freeze-drying



Application

The system is used for manufacturing, portioning and packaging biotechnological active pharmaceutical substances. The operations of weighing the substance matter, preparing the recipe, treating the plugs, sterilisation of the portioning tanks, bottling the medicament, freeze-drying it, sealing bordering and visual inspection are combined fully automated in this sterile system. Moreover, the complete handling of the frames (container pallets) including the transfer and magazing, cleaning and sterilisation is integrated fully automated in the system. The entire area is hermetically sealed and separated from the rest of the cleanroom by glass walling and superposed with a laminar flow. It is only possible to intervene in this room using the gloves which are integrated in the partition walls. The respective parts of the system are integrated in a CIP / SIP cycle. The room surrounding the aseptic operations is equivalent to a conventional cleanroom installation and it is designed according to the current EU GMP and FDA directives.

Plant design

In principle, the direct intervention of operating staff in process control was eliminated where it makes sense and is economically justifiable. This reduces the process risks considerably. Preparation and sterile filtration take place process-controlled via a touch-screen interface. First, the system is cleaned and sterilised inline. High-quality stainless steel alloys are used for the containers, the pipes and the valves. The individual components are orbitally welded into the piping system and integrated using sterile clamps.

Solution

The parts of the plant covering the media are equipped with GEMÜ 650 BioStar valves. The valves are activated pneumatically and are available with all normal control functions. The use of these devices which are manufactured using stainless steel only makes allowance both for the high technical requirements and the noble appearance of the plant. As well as the interior cleaning and sterilisation of the valves, it is easy to clean the exterior. The electro-polished outer surfaces minimize unwanted residual material. The interfaces between the water and process circulation and the CIP / SIP cleaning are equipped with GEMÜ M600 multi-port valves. The valve blocks which are manufactured from a single piece and adapted individually to meet the requirements serve to avoid inoperative areas in the medium, realise a highly compact construction style and save unnecessary welding seams.

GEMÜ® VALVES, MEASUREMENT AND CONTROL SYSTEMS

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