

Sauter Iberica S.A. – system partner of leading pharmaceutical companies

Sauter Iberica S.A. and INMAK S.L. (an engineering and building company that is a contracting partner of STE) were awarded the contract for the construction of Cinfa Laboratories. This new pharmaceutical complex will have a total surface of 2.500m² and serve as production site of chemical solids. The project was realized in two stages involving some 2.800 data points.

The new complex features six heating, ventilation and air-conditioning (HVAC) systems. These will all need to pass the muster of pharmaceutical industry regulations. Sauter Iberica S.A. takes the increasingly stringent conditions in this industry and the need to comply with international

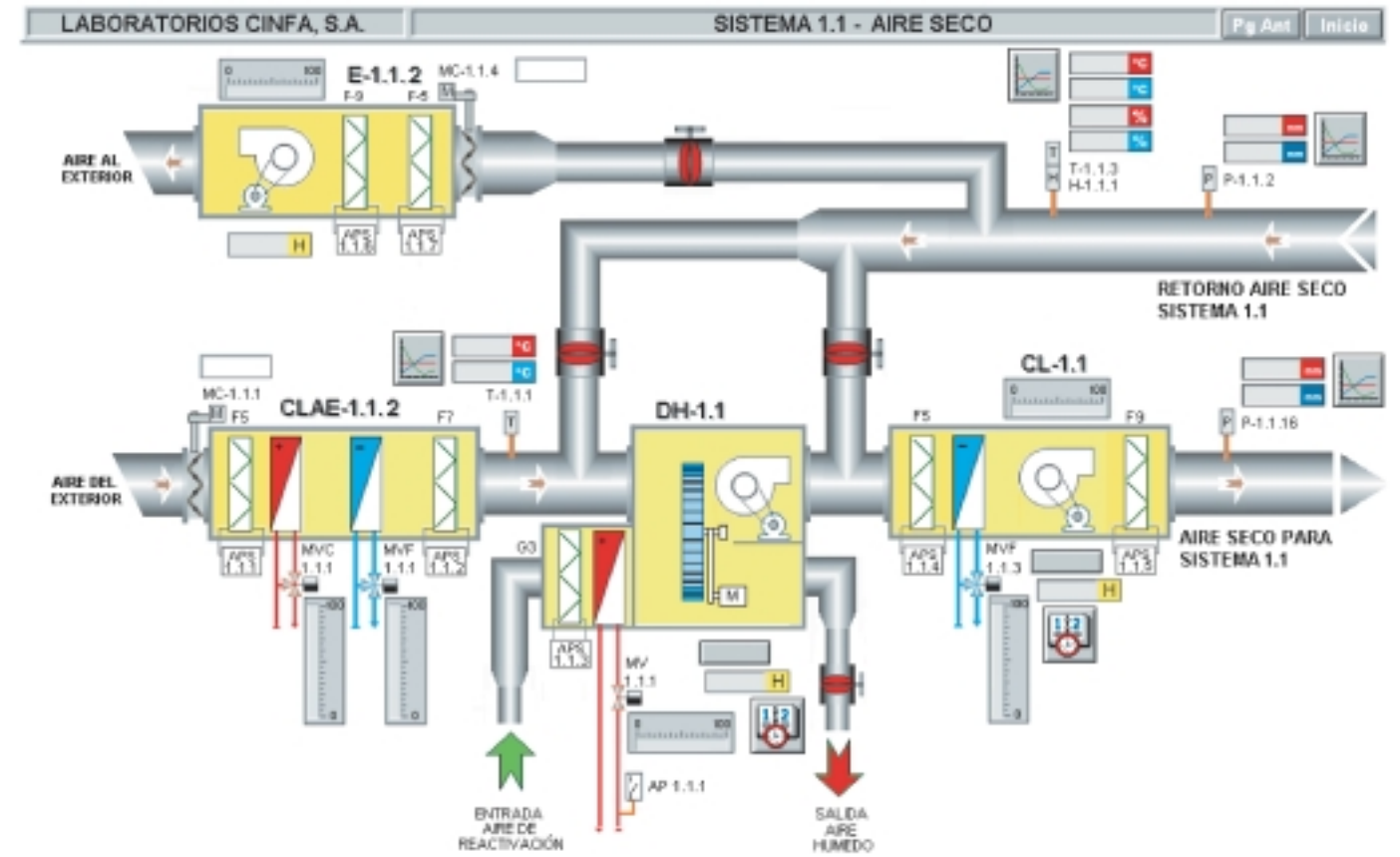
legal prescriptions like Food and Drug Administration standard CFR 21 very seriously. And understandably so since growing demands for the comprehensive control of pharmaceutical products and globalisation of standards are constantly translating into more stringent application of these regulations.

At Cinfa Laboratories quality systems have been installed in the main and secondary production centres. These ensure perfect production conditions and the acceptance of their products on international markets.

Sauter Iberica S.A. very closely cooperated with the engineers of INMAK (who acted as Cinfa site managers). Even prepara-

tion of the check plan and corresponding GMP-based check reports were carried out in close cooperation with INMAK. From the start both Cinfa Laboratories and the INMAK engineers required a checking protocol. To meet with this requirement Sauter Iberica S.A. performed a single calibration for each sensor (temperature, pressure and humidity) and drew up a certificate for the sensors and all other control elements at Cinfa Laboratories. The main purpose of this is subsequent FDA certification.

The labs in pharmaceutical institutions fall into one of the most demanding sectors of human activity. Which also explains why they are subject to the most stringent series of tests and check-ups. Lab clean rooms serve either to prepare intermediate or end products. These rooms



must thus enable very specific work conditions that comply with all legal prescriptions. Only in this way can optimum production be guaranteed.

In view of meeting such stringent conditions, Sauter Iberica S.A. opted for the

EY3600 building management system. The EY3600 offers high communication speeds between all automation stations and is capable of operating fully independently

(i.e. it needs no host computer). The EY3600 is the system offering the highest degree of unifying technology for pharmaceutical facilities like those of Cinfa Laboratories. At the same time EY3600 meets FDA standard CFR21, Part 11.

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