

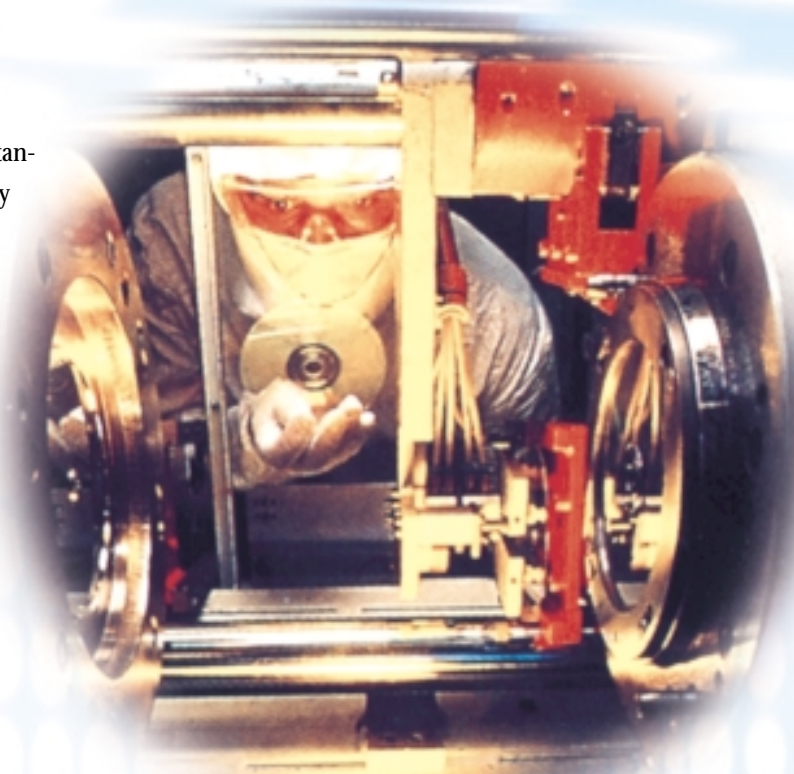
Laboratory control and clean-room technology: no place for experimenting

The living standards and quality of life we have achieved on our continent must be ascribed to the inventive genius of our researchers and innovative drive of our companies. With hi-tech production growing apace, the demands made on researchers and production specialists have also increased. One of the central concerns in this development process involves the protection of consumers and products from harmful influences.

What do pain killers have to do with Sauter?

From the idea to the creation of a finished product the development of a new drug goes through many different stages. Perhaps the most important are basic laboratory research, then scaling up to pilot production and finally full-scale production. In every step from research and development to production, safety and indoor air prescriptions must be most scrupulously observed. While globalisation is opening up more and more markets to companies, it is also increasing the pressure on pharmaceutical producers to com-

ply with FDA and GMP standards. This makes it necessary to include specialists like Sauter that are familiar with international requirements and guidelines right from the planning stages.



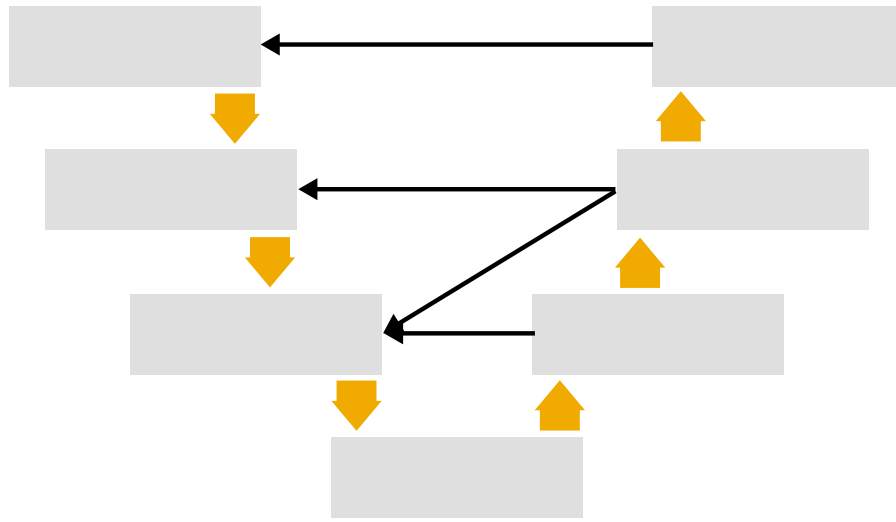
One for all

In this process Sauter offers its customers an 'all-round carefree package' covering every need involved in building automation in laboratory and pharmaceutical facilities. This includes system designing of high-precision room pressure controls or laboratory vent controls, comprehensive measurement detection by means of calibrated sensors, monitoring and provision of all relevant functions as well as the control and regulating of air installations through building management system EY3600 novaPro Open. In addition all DQ, IQ and OQ documents for field automation and management level must be provided, when necessary. Thus vertical integration through all building automation and room technology systems is no marketing gag for Sauter, but a sign of our responsibility vis-à-vis users and the products they want. Sauter meets the demand for these complex systems by means of a specialist Swiss team co-operating with specialists in each of the regions we are active in.

Taking no risks – Sauter laboratory systems

Laboratories are not places where you can afford to experiment with safety installations. Ventilation facilities and the choice of components used to control and monitor the flow of air is a task that must be left to specialists. Laboratory ventilation systems must be planned to exclude any risk of contaminating laboratory personnel or the surrounding rooms. This is done by observing series of predefined pressure relations ranging from critical to less critical areas. In practice it means that laboratory rooms must be kept at a pressure lower than that of the adjacent corridors. However, comprehensive system solutions must also integrate the non-critical areas, thus ensuring optimum cost-efficiency for the entire complex. Vertical integration of all these systems will guarantee the lab operator a harmonious overall setup.





When Sauter develops laboratory ventilation systems, it focuses in particular on providing the highest possible level of safety to users, while keeping construction and installation flexible and neutral for laboratory manufacturers coming from any imaginable horizon. By adjusting every control and monitoring system to all laboratory equipment currently available on the market, Sauter avoids interface problems on control and bus systems level. This enables us to ensure the correct interplay between every component of all systems. This is our unique contribution to safe, cost-efficient and readily-available laboratory aeration and ventilation systems. We are even capable of equipping laboratories in need of explosion protection with pneumatic laboratory ventilation equipment without any particular problem.

Perfect pressure in clean rooms

The pharmaceutical industry is subject to a very wide spectrum of the most varied of room climate requirements. To meet very precise room requirements in terms of temperature, humidity and pressure you need flexible, safe but also very rugged systems. Sauter produces the world's most advanced equipment in this field, in particular when it comes to our pneumatic room-pressure control system. This equipment is capable of maintaining room pressure of 'tight rooms' at +/-1.5 Pa throughout. It is only at this high level of control that it becomes possible to perform tasks with pressure levels of 6 Pa compared to adjacent rooms without running the risk of cross contamination. A spin-off benefit of this is smaller systems at a much lower input and maintenance cost.

At the same time this system meets all new ATEX requirements for areas presenting explosion risks.

Sauter also meets all other airflow, air speed, humidity and temperature requirements predefined in co-operation with the customer in project groups. In practice monitoring and control of these param-

eters are mostly performed as independent systems for safety reasons. This ensures double control of the system, and ensures maximum safety. And, naturally, monitoring of all parameters through calibrated sensors and long-term archiving of measuring data (in accordance with legal requirements of proof) using monitoring systems in the EY3600 novaPro Open system are all part of the services provided by Sauter.

FDA and GMP – household terms for Sauter

GMP (Good Manufacturing Practice) has been serving as textbook to the pharmaceutical industry for all drugs subject to registration for years. The aim of a quality management system like GMP is to ensure that patients be subjected to no indeterminate quality, safety or efficiency risks. This requires comprehensive control and monitoring of all systems directly or indirectly related to the manufacturing process, the responsibility of which is shouldered by Sauter's MCR heating, air-conditioning and ventilation facilities. The GAMP 4 documents required for the DQ (Design Qualification), IQ (Installation Qualification) and OQ (Operational Qualification) validation processes are generated in the course of the project. The

EY3600 novaPro Open building management system also meets all specifications in FDA CFR Title 21 Part 11 (electronic signatures & electronic records). In general, Sauter's specialist teams provide our international clients with advice right from the planning stages. This ensures that even the smallest details necessary for the successful implementation of a project will be met. For more information, please contact our specialist department in Switzerland at:

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Glossary

- ATEX** Atmosphere Explosive
- FDA** Food and Drug Administration
- GMP** Good Manufacturing Practices
- CFR** Code of Federal Regulations
- GAMP 4** Good Automated Manufacturing Practice, Version 4.0
- DQ** Design Qualification
- IQ** Installation Qualification
- OQ** Operational Qualification