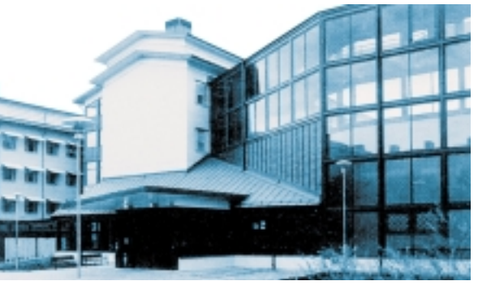
GIN Laboratories – a unique research centre in Uppsala



The GIN Laboratories complex in Uppsala is a unique facility for the production of compounds for G*ene-*, I*mmuno-* and N*uclide* therapy. The laboratory is an integral part of the newly erected Rudbeck laboratory complex administrated by the Medical faculty at Uppsala University.

Here some 250 doctors and medical scientists representing different disciplines like medical genetics, oncology, immunology and biomedical radiation science have joined forces in pursuit of a common aim: to improve cancer treatment.

The Rudbeck laboratory complex is a research centre on the mechanisms behind cancer and genetic diseases. Another important area of the Rudbeck laboratory is to translate basic research into applied cancer therapies.

Associate professor Mats Carlsson, who heads GIN Laboratories, says the laboratory has been built for the production of biological substances for early clinical tests on humans and to support further research and development of cancer therapies. These services will not serve purposes of academic research only but will also be offered to the biotechnological industry at large.

The GIN Laboratories comprise four different production areas. The section requiring the highest safety level produces viral vectors. Here replicant deficient modified viruses are cultured and further prepared for injection into patients undergoing modern genetic therapy. In the transfection unit patients´ cells are transfected, i.e. receive new genetic material before they are transplanted back into the patients. In the third section biological drugs based on proteins, RNA and DNA are produced. And in the last section – the nuclide conjugation module – GIN Laboratories tags all the substances mentioned above. A unique combination. As states a proud Mr. Carlsson, 'We have yet to find another GMP-approved laboratory demonstrating such broad competence in genetics, immunology and nuclide therapy. This makes us unique worldwide.'

The GIN Laboratories have been constructed to satisfy both national and international standards for pharmaceutical preparation and production. The international GMP standard (Good Manufacturing Practice), has formed the basis for all buildings and installations.

All technical installations including heating, ventilation and controls are located on or near to the top floor. Service personnel have easy access for maintenance and do not need to enter the clean area.

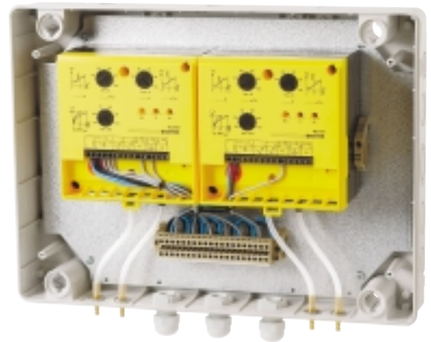
Each section of the laboratory is equipped with separate air handling units backed up by UPS systems, thus preventing shutdowns caused by failures in the main power supply system. To meet hygiene standards the air is filtered before entering the different clean rooms. Sauter Lab Systems control all room pressure levels and airflows. This increases personal safety and lessens the risk of product contamination.

In the autumn of 1998 Sauter Automation AB was awarded the contract for the laboratory control systems both of the Rudbeck and GIN Laboratories. GIN Laboratories had some special requirements. These included individual room pressure control, GMP-approved instrumentation and technical documentation

with comprehensive quality control. The documentation Sauter supplied formed the basis on which the Swedish Medical Products Agency (MPA) approved GIN Laboratories for the production of biological pharmaceuticals.

All individual room-pressure control systems feature Sauter´s industrial air-volume controllers. A separate safety system was integrated to ensure correct pressure levels under all conditions and a safe shutdown of the management system in cases of major failure.

Each room has been equipped with a display showing actual room pressure and an alarm beacon.



GMP-approved instrumentation continuously monitors and logs room temperatures, pressure levels and alarm conditions. This system is made up of Sauter automation stations.

A central PC displays actual room conditions and alarms. All historical data is saved and can be printed out.

Finally, all instruments, air and electric power supply systems are equipped with backup systems guaranteeing safe and continuous operating for one hour in case of compressor breakdown or power failures.

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