

CASE STUDY

UK TECHNOLOGY OPENS WORLD MARKETS TO ROMANIAN PHARMACEUTICALS

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Romanian pharmaceutical manufacturer Terapia has been carrying out a major modernisation of the tablet production facility at its Cluj Napoca site. Specialist contractor Envair UK has installed air-conditioned clean rooms to enable compliance with European Standards. The critical task of controlling and monitoring environmental conditions is performed by a Trend system supplied and engineered by Cheshire based Detail Design Engineering (DDE) Ltd. One of the system's more demanding functions is to provide automatic control of doors and air 'showers'.

The tablet production unit at Cluj Napoca makes a wide range of medicines for human use and has a capacity of 150 million tablets per month. It accounts for around 60% of the site's output and is central to Terapia's plans for increasing export sales – hence the need for it to conform to Good Manufacturing Practice (GMP) regulations as laid down by the European Commission.

Modernisation of the tablet production building began in 1996. Since then, the number of controlled clean room areas has steadily expanded, as has the Trend system. The latter now comprises over 20 network-linked IQ controllers and a '945' graphical user interface. By the end of this year it will be controlling and monitoring twelve large air handling units (30kW to 60kW fans), three chilled water systems and five air showers.

Because ambient temperatures in this part of the world can vary from -20°C to 40°C, the air handling plant is considerably larger than would be normal in the UK. Standby electric heaters have been fitted to back up the steam batteries in very cold weather. Enthalpy control is applied to some of the air handlers to maximise energy efficiency.

As well as controlling and monitoring temperature and humidity, the system also measures and logs pressure levels (to ensure a sterile environment the clean rooms must be positively pressurised). Through the 945 supervisor, it is able to provide a continuous record of environmental conditions, which the company can show to inspectors and customers as proof of compliance with the required standards. The site's engineers use the 945 for adjusting control settings and –

by studying trend graphs – for plant condition monitoring. A modem link allows interrogation of the system from DDE's offices in the UK.

Materials are brought into the clean room areas via cubicles containing air showers, the activation and stopping of which are automatically controlled by the system, as is the opening and closing of the motorised doors. Entry from the 'dirty' side is prevented when a door to the clean room is open, and vice-versa. The control strategies devised by DDE and implemented by the IQ controllers have had to involve some complex combinational logic, particularly as one of the shower cubicles has a total of four doors (two from the dirty side and two from the clean).

Terapia could have chosen to use PLCs (programmable logic controllers)



to operate the air showers and doors, but they opted for the Trend system because of the ease of monitoring made possible by the 945 operator interface, as well as for cost reasons. Through the 945's colour schematic displays, staff can monitor material movements and instantly check the status of any air shower or door. They can also adjust variables such as door opening speeds and times and duration of air shower operation.

Terapia is now considering actually interfacing the Trend system with the tablet production lines, since this would enable them to display production data at the 945.

The system's electrical installation, including wiring connection work, is now carried out entirely by Terapia's own engineers. Though originally unfamiliar with modern building controls, they quickly gained the necessary expertise. Two of the company's staff are to visit DDE's UK offices to receive training in system maintenance.

DDE has recently won an order to supply Trend controls to another Rumanian pharmaceutical plant, in Baia Mare. Once again, they are for clean rooms being fitted by Envair. DDE has considerable experience of providing clean room controls to pharmaceutical sites in the UK.

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