For more than 30 years B. Braun Medical AG, a global leader in health care technology, has produced high-quality medical equipment. Their manufacturing facility has become a recognized “Center of Excellence” for injection and infusion therapy systems. Incorporating a modern LON®-based building automation system from TAC® ensures the company complies with FDA production standards and sets the stage for future growth.

Producing technical equipment for the medical sector is a demanding challenge. To strengthen their global leadership position, B. Braun Medical AG faced the requirement to modernize and expand their existing production facilities. Primary goals were to improve overall processes, adapt the organization to the larger infrastructure, support new factory equipment, optimize facility operations, increase plant security, improve the working environment, and ensure continued compliance with FDA (Food and Drug Administration) standards.

The B. Braun Medical AG production facility includes a 43,000 square foot (4,000 square meters) clean room. This provides a controlled manufacturing environment for producing equipment and protecting it against particle or microorganism contamination from initial production through final inspection and packaging. Key attributes of the project included maintaining complete flexibility and high efficiency while maintaining very exacting production standards.
The Challenge
To realize these goals and support future growth, a building automation system provides a key component of the manufacturing and production process. Climate controls including strict temperature, humidity, air pressure and air cleanliness are critical to maintaining exacting production standards. Ensuring strict compliance with FDA standards is a necessity to support international marketing efforts.

In addition to these very strict quality standards, building integrator Hälg Building Services Group also had to meet additional requirements that included:

- Supporting existing as well as new equipment to minimize the impact on existing production
- Ensuring continued safe operation
- Maintaining maximum flexibility
- Ensuring utilization of existing equipment
- Maintaining a uniform mixture of clean room, office, and administration environments
- Meeting FDA manufacturing and production requirements
- Complying with the rules for facility development, project planning, installation and qualification based on GAMP 4 (Good Automated Manufacturing Practice) and 21 CFR Part 11

The Solution
To meet these requirements, B. Braun Medical AG installed an integrated building automation system using TAC’s LON-based technologies. A decentralized architecture and consistent device communication between all components can significantly reduce investment costs during the construction phase.

In one combined network the building automation solution integrates heating and cooling, air quality, relative humidity, lighting, sun blinds and electrical devices. Integrating these products into one flexible, user-friendly and fail-safe system allowed the Hälg Group’s building automation unit to develop a tailor-made automation concept for the complete facility. More than 2,500 data points permit operators to access and obtain information from all monitored systems. In close cooperation with B. Braun Medical AG it was possible to individually design the complete system infrastructure using state-of-the-art technologies. This design process was continuously monitored and optimized.

Clean Room
To provide an optimum environment, clean room tasks had to be identified and maintained throughout the production process. These tasks included:

- Maintaining a higher air pressure within the clean room when compared to the surrounding environment
- Adapting air exchange (turnover) intervals and air flow direction to production requirements
- Maintaining a precise temperature and humidity controlled environment
- Adhering to hygiene requirements
- Monitoring all aspects of clean room operations
- Providing a double door mechanism for staff and material entry and exit

This concept maximizes clean room flexibility so that it is possible to quickly react to new products,
production technologies, and working methods. The new clean room was conceived as one consistent area allowing for maximum autonomy in the way the production process is designed. This facilitates the subsequent integration of clean rooms requiring higher cleanliness levels. Moreover, the modular ceiling construction combined with the specific energy/media supply for production machines and atmospheric control system guarantees high flexibility and area efficiency.

Monitoring
To meet FDA clean room monitoring standards, the Hälg Group chose the TAC Vista™ system. The TAC Vista system is already successfully installed in numerous life sciences facilities. A second totally independent license supports building management systems external to the clean room. The monitoring system and parts of the building management system were qualified and validated.

Monitored data is gathered and maintained by the TAC Vista system to continuously monitor specific room conditions. This provides the ability to maintain compliance with very exacting requirements and record any deviations from specified conditions (e.g., pressure, temperature and humidity) over a period of up to six years for each monitored data point (according to 21 CFR Part 11). Deviations from preset limits are reported to the operator on a predefined interval permitting the operator to quickly respond to and correct the problem.

Monitored processes and data points that include data readings, set points, operator actions, system reports, facility parameters, or individual component conditions are stored by the system in a database. The database retains key information including date and time information, individual data point readings, user name and records changes to the system.

Recorded data is securely protected against unauthorized access and modification. Data is also periodically archived for long term storage and review. The data can be retraced whenever the need occurs.

The Bottom Line
Continual system availability combined with ease-of-operation provides for substantial operating benefits including maintaining personnel comfort, system operating efficiencies and data collection, and monitoring for assurance of regulatory compliance. Furthermore, an integrated building management, control and recording system provides precise controls for the production process. Using LON-based technology creates a world class manufacturing and production environment making it easier for B. Braun Medical AG to support future production and facility expansion. The LON-based open system framework offers superior performance at a competitive price.
On October 1st, 2009, TAC became the Buildings Business of its parent company Schneider Electric. This document reflects the visual identity of Schneider Electric, however there remains references to TAC as a corporate brand in the body copy. As each document is updated, the body copy will be changed to reflect appropriate corporate brand changes. All brand names, trademarks and registered marks are the property of their respective owners.

Schneider Electric
One High Street, North Andover, MA 01845 USA
Telephone: +1 978 975 9600 Fax: +1 978 975 9698 www.schneider-electric.com/buildings

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