SIEMENS
Ingenuity for life

Everything clean – and seamlessly traceable

Reference project: Production building of Develco Pharma GmbH in Schopfheim, Germany

Task: Fully comply with GMP and GAMP 5 requirements

Research, development and the manufacture of pharmaceuticals are subject to strict international regulations such as Good Manufacturing Practice (GMP) and the European Good Automated Manufacturing Practice (GAMP 5). Building technology must protect laboratories and production facilities as effectively and efficiently as possible from all influences that could compromise the quality and safety of drug production. Employees, the drugs themselves and the environment must be protected across the entire production cycle. For its new production facility in Schopfheim, Germany Develco Pharma wanted an overall concept that complies with the drug industry's strict requirements for maintaining room conditions such as pressure, temperature and humidity and monitoring them using a validated monitoring system. Building automation, intrusion detection, video surveillance, an access control system and a comprehensive fire safety solution were also needed.

Solution: Integrated laboratory solution connected to Desigo CC

Siemens offered all disciplines from a single source, including the laboratory solution, and networked everything via the Desigo CC management platform. The

Develco Pharma specializes in developing and manufacturing pharmaceutical products with known active ingredients; it also produces generics and performs additional development on drugs. The company is an internationally recognized supplier of drugs for treating severe pain (opiates) and sells its products mainly on the European and North American markets. Develco Pharma Schweiz AG was founded in Binningen in 2006; today it is headquartered in Pratteln. At the company's second location in the German town of Schopfheim near the Swiss border, a new production facility was set up to manufacture pain medications and drugs for attention-deficit hyperactivity disorder (ADHD).

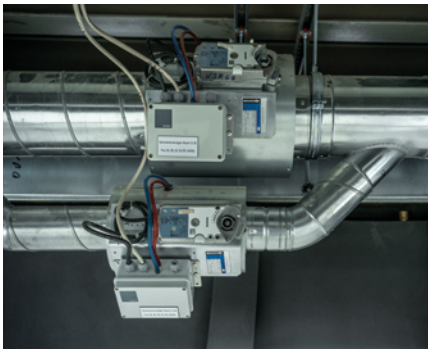
Highlights:

- Desigo CC building management platform
- Building automation with Desigo PX
- Critical Environment Technology (CET)
- Compact Monitoring Technology (CMT)

installed laboratory solution continuously monitors the fume hoods to protect precisely defined areas. Exhaust air is extracted based on demand, preventing contamination of substances as well as uncontrolled backflow of air into the room. Particle counters detect particulate matter in the air that might be hazardous to the environment or production and dynamically adjust the air exchange rate to reduce the concentration and render it harmless. Critical Environment Technology (CET) from Siemens is a range of reliable air volume controllers and additional components for safe, precise and fast measurement, regulation and monitoring of air volumes and room pressures in laboratories. CET consists of independently functioning controllers (base components) and a number of peripheral devices (add-ons) such as VAV dampers, sensors and actuators. All components are interconnected via interfaces based on open standards. CET is easy to add to building automation systems like Desigo; in this case it was connected to the Desigo CC management platform at a higher level. Compact Monitoring Technology (CMT) from Siemens ensures seamless monitoring. CMT monitors and documents all GMP-relevant pharmaceutical production parameters.

Benefits: Precisely customized – and under constant control

As an integrated building management platform, Desigo CC displays the status of the different disciplines in real time and applies intelligent algorithms to the data. This allows mutual dependencies and influences to be quickly detected and analyzed. The customer benefits because the building automation for their production facilities is integrated into the management platform and because Desigo CC has an extensive standardized library with static and dynamic icons especially for clean rooms and laboratories. If requested by the customer, Desigo CC can send error messages directly to a smartphone; an app for smartphones and tablets is available for controlling the systems. Develco Pharma now has a winning building automation concept for its laboratories that is precisely tailored to its requirements and fully complies with regulatory provisions, including those relating to the documentation of production and access.



Photographs: Siemens