

Ferring Pharmaceuticals St. Prex, Switzerland

Siemens provides safe, secure and compliant environmental conditions.

Ferring Pharmaceuticals is a research-driven biopharmaceutical company devoted to identifying, developing and marketing innovative products in the fields of fertility, obstetrics, urology, gastroenterology, endocrinology and osteoarthritis.

In July 2006, Ferring inaugurated a brand-new production facility and headquarters in St. Prex, Switzerland. Siemens played a pivotal role in ensuring completion of the plant within the space of just 12 months.

The project faced several exacting challenges. Compliance with US Food and Drug Administration (FDA) and European regulations was crucial. We also had to integrate the entire technical installation with standard, proven communication platforms to optimize operation and maintenance, and to protect the investment for the future.

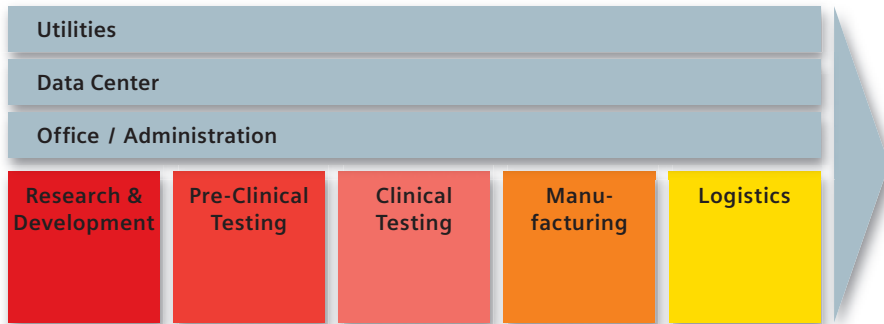

Ferring's partner of choice for the entire building technology infrastructure was Siemens. This was mainly because the company possesses a unique combination of detailed know-how and experience of the needs specific to the pharmaceutical industry. On the basis of a broad and comprehensive portfolio of solutions, Siemens was able to realize an individual solution designed to satisfy pharmaceutical needs.



Ferring's specific needs

Every step of the life sciences value chain places specific demands on the building infrastructure. Raw materials in the warehouse need to be protected. Production has to be carried out under cleanroom

conditions. And quality assurance must guarantee 100% drug purity.

François Hosotte
Site Director

"The authorities have become keenly aware of the environmental impact on drugs. For them, the environment has become as critical an issue as equipment."

Warehousing

Enormous open spaces are required to accommodate various types of raw materials, packaging and finished products, and room temperature could negatively affect drug quality. It is absolutely vital that room temperature remains constant at all levels and at all times, and that we keep records to document this for many years.

At Ferring, room temperature is measured at various levels and used directly to control the environmental conditions. The data obtained are stored in the dedicated environment monitoring system, InfoCenter.

Quality control

Before raw materials can be released for production, Ferring's quality control takes samples for analysis in the laboratory. While this operation is taking place, Siemens controls the laminar air-flow required to prevent contamination of the materials and protect the staff.

Coldroom

Strictly controlled temperature and humidity conditions are essential to ensure the stability and integrity of our finished products. Supervision of the coldroom is linked directly to our building management and environment monitoring system, which enables us to provide documented evidence that we comply with all regulations on environmental conditions.

Production facility

Ferring produces Minirin and Pentasa in Switzerland. These are manufactured on two production lines in cleanroom environments. Almost 20 separate air-handling units were needed to provide the specific environmental conditions.

The proximity of two production lines for two different products in St. Prex created a potential contamination risk. The access control system from Siemens ensures that no one can move from one production line to the other without first undergoing

a specific cleaning procedure. For this reason, the access control system had to be validated.

Offices

Ferring also made it clear that they expected safe, secure office premises with a high degree of comfort and convenience. In a solution that set a new benchmark in building automation, all services are integrated in a single system for which each office has individual control.

Atrium

The spacious, light-flooded atrium offers a warm and inviting atmosphere for visitors and employees alike. It is vital that people feel comfortable in a space this size, but achieving the necessary sense of well-being is not easy. Siemens' dedicated atrium HVAC applications not only guarantee optimum temperature and humidity levels but also maximum energy efficiency.



Warehouse



Quality control



Coldroom



Production facility



Atrium

Siemens tailor-made solution for Ferring

No other industry is subject to greater regulation than pharmaceuticals. The main focus of the regulatory bodies is on drug quality, the aim being to protect public health. A special quality assurance program known as validation is prescribed by law, and any system which may affect drug quality has to be validated. Apart from this, global pharmaceutical inspectors nowadays expect companies to adopt a risk-based approach, meaning they should be aware of potential problems and the measures they can take to ensure they do not arise.

Before designing Ferring's building infrastructure, Siemens carried out a comprehensive risk and impact analysis of all the technical systems involved. Its findings were based on the input of Ferring's experts from engineering, manufacturing and quality control combined with the experience of Siemens' own specialists gleaned from more than 1000 pharmaceutical projects worldwide.

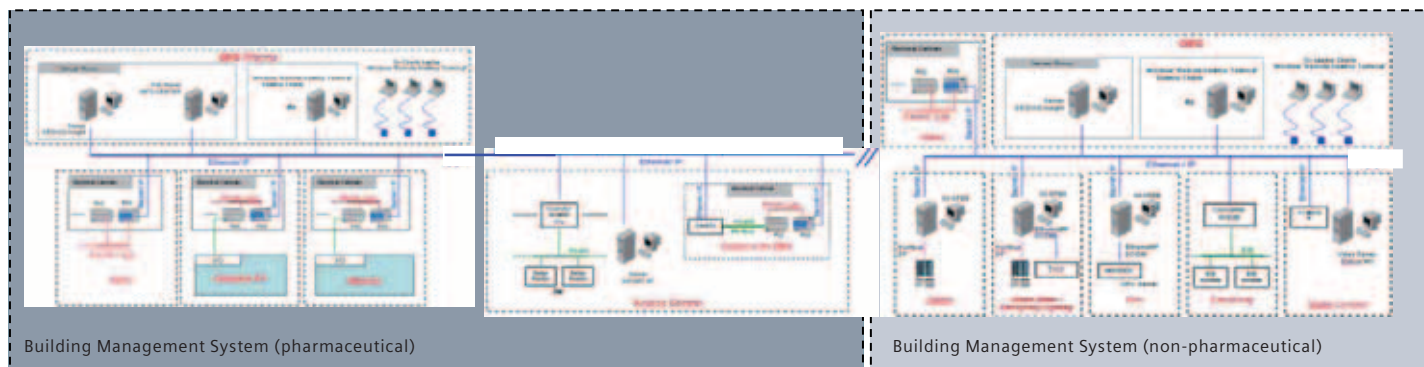
As part of the assessment, the building infrastructure systems were subdivided into those that would have a direct impact on drug quality and those that would have little or none at all. This distinction was to prove crucial, because it highlighted the reasons why certain systems require validation and others do not. In the end, only 10% of the installations in St. Prex had to be validated.



Ignacio Rodicio
Head Engineering and Maintenance

"Our main criterion when selecting a supplier was the measure of support the company could supply and its familiarity with compliance needs and the pharmaceutical industry. Siemens was able to deliver on all counts."

Two Building Management Systems for required compliance



The building management system is part of Ferring's standard IT-infrastructure and divided into two separate systems: one for the validated environment and a second one for all non-process-critical applications.

This approach reduces the effort necessary to validate installations and makes operations more flexible. Validated installations require a detailed change management procedure and approval before any change to the system is permitted. By clear distinguishing between the two management systems, Ferring needs to document only the validate BMS and can focus on increasing uptime for the non-pharmaceutical system. The pharmaceuticals industry requires

dedicated measures to protect sensitive data, prevent falsification and trace all modifications in a secure audit-trail. The dedicated functionality delivered by the installed building management system and the environment monitoring systems provide users with an efficient, convenient means of complying with the regulations in question (21 CFR Part 11 and Annex 11). All data relevant to the quality of the building environment are stored on a separate server with the InfoCenter environment monitoring solution. This information may be trend information from the different areas (temperature, humidity, differential pressure) or various types of alarms, but also system activities that have been

performed automatically or manually during the operation. Apart from archiving the information securely for an indefinite period of item, InfoCenter automatically provides a comprehensive report with all building-related information required by quality control to decide the final release of the drug product. The building management system can be operated using terminal server application from any point in the building, with the additional advantage that local clients do not require any application-specific installations or software. In the event of a fire, the Siemens gas extinguishing system would be activated immediately, resulting in minimum damage to personnel or equipment.

Total Building Solutions (TBS)

All technical installations in the building's infrastructure are integrated in two separate building management systems: one for validated applications, the other for non-validated applications. The Ethernet-based integration backbone was realized with BACnet while the 160 room controllers are linked via Konnex (EIB) and LONnetworks.

The main advantage of integration via worldwide standard protocols for the building infrastructure is that these communication protocols fit their specific applications precisely and that the investment is protected for the future. Connecting two separate systems during a project may not seem like much of a challenge; however, guaranteeing this interconnection in the future, when the various users update their systems at different times, poses much more of a problem.

Thanks to the Total Building Solutions approach, Ferring has a single common interface, which provides all the information required relating to the building infrastructure. Alarms for all subsystems are linked to the general alarm system, guaranteeing that staff are informed swiftly and efficiently of any irregularities. Moreover, operations are simplified by the fact that the various applications all have the same look and feel. Remote desktop functionality permits access from any Ethernet port in the building and increases operational flexibility.

As a result of all these measures, Ferring is able to run this new state-of-the-art facility and its complex technical infrastructure efficiently, with the help of a small engineering and maintenance team.

Facts and figures

- Two building management systems (about 6100 data points)
 - DESIGO pharmaceuticals solution (DIPS)
 - Windows remote desktop terminal with four clients
 - one validated monitoring system (InfoCenter)
- 160 room controllers RC
- One validated access control system (SIPOPT)
 - 17 access controllers
 - 35 badge readers
- Video surveillance system
- Fire detection with 1400 detectors
- Gas detection
- Automatic extinguishing system with water sprinklers (stocking)
- Automatic extinguishing system with natural gas (computer rooms)
- Integration in DESIGO INSIGHT:
 - steam
 - waste water
 - fire detection and fire extinguishing
 - electricity
 - compressed air
 - access control
- A&D Process automation (SIMATIC S7 solution)



Lars Peter Brunse
Vice President of technical operations

"In order to produce in such a facility, we are using state-of-the-art technology and the Siemens products are certainly state-of-the-art. We have a variability of Siemens products and we are taking the benefits to work with a very professional partner. Should we want to construct something new soon, who knows when that will be, than it would be very natural for us to copy and paste the good solutions we have found here for the St. Prex facility."

The information in this document contains general descriptions of technical options available, which do not always have to be present in individual cases. The required features should therefore be specified in each individual case at the time of closing the contract.

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