

Etablissement Français du Sang, Auvergne-Loire, France

Installing a sophisticated monitoring solution for critical data



Founded in 2000, the French blood agency Etablissement Français du Sang (EFS) ensures a reliable blood and plasma supply in France. The EFS is a public institution under the supervision of the French health ministry. Prof. Olivier Garraud is the director of the region Auvergne-Loire.

■ Safety comes first

EFS assumed responsibility for assuring correct storage, reliable quality controls, and national blood and plasma availability. Even though in France systems that have a direct impact on the quality of blood or plasma products are not legally required to be validated, Philippe Ligot, engineer at EFS Auvergne-Loire, believes that validation is of great importance: to assure the highest level of security in blood processing and thus safe blood products for patients. One solution was to consider blood products as drugs and apply the same norms and standards as used in the pharmaceutical industry. That is why EFS Auvergne-Loire opted for a sophisticated monitoring system from Siemens to monitor, record, archive, analyze, and safeguard all parameters that affect the storage of

labile blood products at their sites. The first system was installed in Saint-Etienne. Today, a total of seven EFS Auvergne-Loire sites are connected to the same network.

■ Sophisticated technology from Siemens

EFS complies with the European directive 2004/23/EG that sets the standards for quality and safety regarding the donation, procurement, testing, processing, preservation, storage, and distribution of human tissues and cells. The new monitoring system also ensures compliance with current and future regulatory requirements – like the Good Automated Manufacturing Practice (GAMP) recommendations and the FDA 21 CFR Part 11 regarding electronic records and signatures.



The customized sensor measures and monitors the temperature within refrigerators.



Dr. Patricia Chavarin,
Directeur
Adjoint,
EFS Auvergne-
Loire

“We wanted all relevant data like temperature, humidity, pressure, and technical alarms in laboratories, cold rooms, refrigerators, platelet storage units, and other areas to be monitored and controlled – and the data reliably archived.”

Optimal environmental conditions for highly sensitive products

EFS values the in-depth expertise that Siemens has in the highly regulated life science industry – and that is why EFS Auvergne-Loire decided to install the DESIGO™ INSIGHT building automation and control system for pharma to monitor the systems that can impact the quality of blood and plasma products.

■ Consulting and risk assessment

At the beginning of the planning phase, EFS and Siemens had to find a balance between the customer's requirements and the technical possibilities. A risk assessment helped to identify the critical processes – and to decide which processes and building areas had to be validated. The customized solution for EFS includes two building automation systems: one for processes and building areas that need validation and the other for non-critical areas.

■ DESIGO – a comprehensive solution

EFS Auvergne-Loire chose to implement the building automation and control system DESIGO INSIGHT for pharma. Each of the six sites in the Auvergne-Loire region is equipped with a workstation that can access all DESIGO INSIGHT and InfoCenter functionalities installed on the servers in a “remote office”. DESIGO INSIGHT continuously monitors and records parameters like room conditions, user access, alarms, warnings, and system functions. DESIGO also archives the collected data in real time, in compliance with 21 CFR Part 11. The long-term archival reporting functions are supplied to the InfoCenter Suite.

■ Highest data security

The data is clearly accessible at any time on the screen. Data access is securely protected, as access is limited to authorized personnel. A number of user groups with associated security levels can be defined. Additionally, each change made can be tracked via the integrated audit trail.

■ Documented proof of environmental conditions

The InfoCenter Suite manages the effective, documented tracking of critical parameters, demonstrating that conditions meet the required specifications at all times. It also stores information securely for decades. InfoCenter was developed for and in cooperation with the pharmaceutical industry, and therefore complies with the security requirements of 21 CFR Part 11 regarding user control, audit trails, safeguards, protection, and archiving of critical data.

■ Complying with regulations

To customize DESIGO to meet the validation requirements of EFS Auvergne-Loire, a document system was created according to GAMP recommendations – including risk analysis, impact analysis, URS, functional specifications, test procedures, a quality plan, and a tracking matrix. Siemens performed the system verification according to classic IQ and OQ testing approved by EFS Auvergne-Loire and wrote the procedures needed for users of the system. To meet the requirements of the GxP environment, various components were specifically developed and successfully audited.





Customized sensor



Philippe Ligot,
Chef de Service
Biomédical,
EFS Auvergne-
Loire

“DESIGO is a great solution. We can monitor all environmental parameters from our workstation. It ensures real-time transmission of values and allows an immediate response when limits are reached.”

■ Developing a customized sensor

EFS Auvergne-Loire even developed a special sensor to monitor the temperature within refrigerators. The sensor is placed in a sheath and filled with glycerol. The sensor can tell if the temperature is stable or not and if a deviation occurs, it immediately triggers an alarm. Besides delivering reliable measurement results, the sensor also increases transparency and minimizes faults. Thanks to a clearly assigned number, every refrigerator can be separately monitored at the push of a button. Siemens smoothly implemented this third-party product into DESIGO. The sensor is calibrated once a year.

■ Special alarm handling

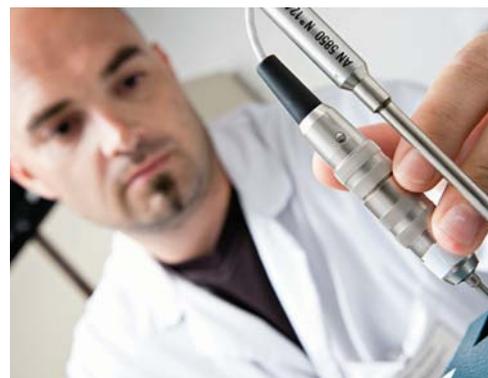
What makes the monitoring solution in Saint-Etienne so special is its alarm management. With the push of a button, all EFS sites in the Auvergne-Loire region can be monitored – and the data is stored in one system. If a refrigerator is open for too long or if there is a power outage, an alarm will be immediately triggered at a predefined site and a predefined emergency scenario will be executed.

The behavior in case of an incident is thus clearly established and the employees responsible for safety can see immediately what to do. And the safety precautions are available at one click. This minimizes the risk that employees make the wrong decision in a stressful emergency situation.

■ Double monitoring of cold rooms

At the EFS sites in Auvergne-Loire, both employee safety as well as product quality are of the highest importance. This is why for monitoring the cold rooms, DESIGO provides two designated alarms: one for the monitoring of temperature and one for the surveillance of personal safety.

DESIGO ensures the best storage conditions for blood products by keeping the set temperature of -30 °C in the cold rooms for plasma ($\pm 2\text{ °C}$ for RBC concentrated) stable at all times. If the temperature deviates from the set value, an alarm is triggered. The temperature of -30 °C , however, can become dangerous for people after a given period of time. This is why DESIGO also monitors if there is still an employee present in the cold room when a door closes. To increase safety and security even further, EFS installed 2 sensors in every cold room.





Philippe Ligot,
Chef de Service
Biomédical,
EFS Auvergne-
Loire

"We are happy that we chose Siemens as a partner. They have a deep understanding of our requirements and always came up with the right answers to all our questions. We received the ideal solution to meet our special needs."

A fruitful partnership

EFS Auvergne-Loire is highly satisfied with the monitoring solution it received from Siemens. During the project, EFS benefited from the experience and expertise Siemens has in the life science industry.

■ A win-win situation

EFS Auvergne-Loire especially values Siemens' expertise and knowledge. Siemens itself could grow and further develop its expertise in the life science industry by adapting a solution specifically for blood donation centers.

■ A highly satisfied customer

The new monitoring solution responds perfectly to EFS's requirements due to its extreme reliability, cost efficiency, and high flexibility. DESIGO is easy to use thanks to its intuitive user interface. Complex processes can be visualized quickly and easily. And in case of an alarm, problems are pinpointed and necessary actions clearly visible, increasing safety and

security for both employees and assets. The installation has passed all regulatory inspections, including those focused on audit system validation.

■ An outlook

Continuous improvement and information sharing is an essential part of the EFS Auvergne-Loire culture. Even if blood is not considered as a drug in France, the implementation of guidelines and standards from industrial production and especially pharmaceutical companies remains important. That's the reason why Philippe Ligot has decided, with the support of his management, to meet all necessary requirements.

Highlights

- Compliance with 21 CFR Part 11
- Validation and documentation according to GAMP V-model
- Completely controlled environment – 24/7, 365 days a year
- Fast response if limits are reached
- Reliable and automatic data archiving
- Critical data is stored for decades; simple data recovery process

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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