

Industry Sector Building Technologies Division

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Siemens Desigo monitors blood for French transfusion service

Siemens Building Technologies Division has supplied its Desigo Insight Pharma solution to a regional department of L'Etablissement Francais du Sang (EFS), the French Blood Establishment. Desigo Insight is a building automation system from Siemens that continuously monitors environmental parameters - such as room conditions, user access, alarms, warnings and system functions - and archives the collected data in real time, in compliance with 21 CFR Part II.

In 2000, EFS assumed responsibility for high-quality blood products in France. The organization must assure perfect storage, reliable quality controls, and that enough blood and plasma supplies are available country-wide. In France, validation of the systems that can have a direct impact on the quality of blood or plasma products must be performed. Nevertheless, standards to validate the systems are not clearly established. One solution was to consider blood products as drugs since in the pharmaceutical industry rules and standards are well established and at a high safety level. That is why the EFS Auvergne-Loire decided to install a sophisticated monitoring system from Siemens that monitors, records, archives, analyzes, and safeguards all parameters that affect the storage of the labile blood products at the EFS sites. The first installations from Siemens were undertaken in Saint-Etienne-Bellevue, Robespierre, and Saint-Priest-en-Jarez. Since the end of June 2010, three other sites from EFS Auvergne-Loire have been under the control of Siemens monitoring.

Each of the six sites in the Auvergne-Loire region is continuously monitored and long-term archival reporting functions are supplied to InfoCenter Suite, the software package from Siemens that converts building systems data into powerful information, automating the process of archiving, collecting, analyzing, managing and reporting facility information.

InfoCenter Suite manages the effective, documented tracking of critical parameters, demonstrating that conditions meet the required specifications at all times. It was developed 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. The EFS sites are all equipped with a workstation that can access all Desigo Insight and InfoCenter

functionalities installed on the servers in a 'remote office'.

The EFS is the sole organisation in France with authority for the collection and distribution of high-quality blood products. It is a public institution under the supervision of Le Ministère Français de la Santé and provides blood and plasma throughout the whole of France. It must ensure that correct storage conditions and reliable quality controls are in place throughout its sites and that supplies are always sufficiently available countrywide. EFS Auvergne-Loire chose to install the Siemens' system to protect the labile blood products that it supplies - not only to all the local hospitals but also research organisations (such as pharmaceutical companies using blood products to produce medications).

Philippe Ligot, biomedical engineer from the EFS Auvergne-Loire, believes that validation is of highest importance because the conditions of storage of blood products are one step in the high safety and quality blood chain that EFS has to provide to the patients who need transfusions. EFS needs to provide not only for blood quality, but also to ensure its partners have the highest level of security in its processes for preparation, storage and distribution.

The customized solution for EFS Auvergne-Loire includes two building automation systems: one for processes and building areas that need validation and another for non-critical areas. Mr Ligot commented: "L'Etablissement Français du Sang has blood banks all over the region to provide RBC and Platelets concentrates, and plasma to hospitals and healthcare establishments. After the decision to proceed was eventually taken, we looked for the best system that we could find to provide continuous monitoring. The implementation process of Desigo made us review and improve our whole process, particularly in risk analysis and risk management."

Siemens' experts met with Mr Ligot and his colleagues to find a balance between the EFS'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. To customize Desigo to meet the validation requirements of EFS Auvergne-Loire, a document system was created according to GAMP recommendations and included risk and 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. Both sides also used their combined expertise to improve and develop the existing sensor, which is placed in a sheath that contains glycerol, specifically made for the EFS. The sensor is particularly effective and 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

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now be separately monitored at the push of a button.

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 (4±2 °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 – increasing safety and security for employees at EFS. To further enhance the security and safety processes of monitoring temperature, every sensor in the cold rooms is doubled.

“The culture of quality is a fairly recent thing in hospitals” said Mr Ligot. “Blood is a scarce and precious commodity that costs a lot of money to collect. But if you lose 10,000 bags of plasma, the loss is not about only the cost. It’s about the people who have donated it and the sick people waiting to receive it. Blood is a medicine and the transfusion service is a pharmaceutical-like process. Industry manages its processes well because it does not want to lose production. We have the same attitude in the rigor of our process, along with the added concerns of the patients. We have to save lives and to do that we need a professional system that allows us to manage conditions of storage in the best possible way. Associated with a revamping of our systems of storage, the more powerful and high level of safety afforded by the Desigo System has allowed us to obtain a high level of safety in the blood storage process. We are proud of the systems that we now operate here.”

Even though every region within the organisation is independent, Philippe Ligot has resolved to convince the other regions to implement the Desigo monitoring solution from Siemens throughout L’Etablissement Francais du Sang: “After an initial period of adjustment, we worked well with Siemens. There was a good interchange of ideas and expertise from both sides. We are the first region to implement the Desigo Pharma system throughout all our storage sites, but I believe it’s the only way forward. The most important focus is to meet the highest safety standards in the interest of the patients.”

Siemens’ Desigo stores information securely for decades. The EFS will store collected medical data for 40 years and maybe more, and in choosing Desigo Insight from Siemens, has a monitoring system that can grow to accommodate all its future requirements.

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