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■ **CSL Bioplasma, Australia**

It's in Our Blood

Australia's national fractionator of plasma-derived therapeutics, CSL Bioplasma, has adopted Siemens' leading automation technology and benefits from a modern system platform.

CSL Limited, headquartered in Parkville, Victoria, is one of the largest manufacturers of plasma-derived therapeutics in the world. Plasma-derived therapeutics are made by separating (fractionating) the proteins in human plasma, the liquid part of blood. The plasma in Australia is donated voluntarily by Australia's nonremunerated blood donors and collected by the Australian Red Cross Blood Service. CSL Limited has a plasma fractionation facility in Australia and subsidiaries in Europe and the United States.

CSL Limited's plasma fractionation facility in Australia is operated by its Bioplasma Division (CSL Bioplasma), located in Broadmeadows, Victoria. CSL Bioplasma has selected Simatic PCS 7 as the platform for its plant monitoring and control system (PMCS) upgrade. Siemens Australia has been engaged to provide engineering services to design and implement the new control system, while replacing the existing distributed control system (DCS) progressively in a series of staged cutovers.

Chromatography – gentle means for a high yield

CSL Limited has been Australia's fractionator of plasma-derived therapeutics under various agreements with Australia's Commonwealth Government since 1954. CSL Bioplasma's unique, state-of-the-art facility in Broadmeadows – which began operations in 1994 – employs chromatography, a method of separating proteins based on their differing size and charge. Chromatography is a gentle way of fractionating proteins, allowing CSL Bioplasma to produce plasma-derived therapeutics of high purity with high recoveries, thus optimizing the yield of every protein of interest from each blood donation. CSL Bioplas-

ma's facility is one of the most sophisticated plasma fractionation plants in the world.

Besides being the chosen plasma fractionator for Australia, CSL Bioplasma has also been selected by the governments and blood services of New Zealand, Singapore, Hong Kong, Malaysia, and Taiwan. The plasma-derived therapeutics that CSL Bioplasma produces for Australia are provided free of charge by Australia's Commonwealth, state, and territory governments for use in Australian hospitals in the treatment of serious medical conditions. These include disorders of the immune system, various serious nerve and muscle diseases, bleeding disorders such as hemophilia, blood loss and blood replacement in trauma and surgery, and hemolytic disease of the newborn.

Keeping up production while becoming state of the art

Focused on maintaining a facility at the forefront of production technologies, CSL Bioplasma recently decided to upgrade its existing DCS to a new state-of-the-art system. The company conducted extensive research into the available technologies and supplier capabilities and selected Siemens as the preferred partner for this crucial project.

Although the project is particularly challenging because of the continuous nature of production at CSL Bioplasma, the selection of the Siemens platform is providing CSL Bioplasma with several benefits. CSL now can employ a modern innovative process automation system platform, and it has been able to draw on Siemens' expertise in the pharmaceutical industry, both local and international, as well as its expertise in batch processing, S88/S95 modeling, and manufacturing execution systems. Moreover, Siemens has worked ►►



CSL Limited

- ▶ CSL Bioplasma's facility in Broadmeadows began operations in 1994
- ▶ The Broadmeadows facility is one of the most sophisticated plasma fractionation plants in the world
- ▶ CSL Bioplasma uses chromatography to gently fractionate proteins for plasma-derived therapeutics of high purity and optimal yield
- ▶ CSL Bioplasma has been chosen by the governments and blood services of Australia, New Zealand, Singapore, Hong Kong, Malaysia, and Taiwan

▶▶ with CSL to provide a strategy for the smooth migration of process control and legacy systems.

Beyond the modernization of the process control system, CSL Bioplasma will achieve process optimization and production streamlining, reduction of validation costs, simplification of system maintenance, and reduction of total cost of ownership.

"One of the primary reasons CSL chose Siemens was the organization's commitment to the project at all levels. Another significant factor was the continuing development by Siemens of their local expertise in PCS 7 and in the pharmaceutical sector. This commitment has continued to be strong since the contract was signed in mid-2005," explains Geoff Armstrong, senior projects manager, CSL Bioplasma.

Teaming with Siemens for customized functionality

Throughout 2006, a project team including members from both CSL Bioplasma and Siemens specified the hardware and software design for the project. CSL Bioplasma staff provided process and production input expertise and Siemens contributed highly experienced system engineers to the project team. The

team's major objective was to achieve CSL Bioplasma's desired functionality by maximizing Siemens' software modularity and support for software reuse. The final components chosen by the project team include Simatic PCS 7, Simatic Batch, Simatic Route Control, and Simatic IT Historian.

Following the definition phase, a pilot project was undertaken. This involved implementing the new PCS 7-based system and the new software standard in a selected part of the plant. The system's original scope was extended to accommodate a new air-handling unit that was successfully commissioned in January 2007.

Geoff Armstrong sums up the results of the implementation: "The rollout of the PCS 7 system for the new air-handling unit in January 2007 and then the pilot plant in May 2007 has gone extremely well. The PCS 7 system was well received by both the Manufacturing and Engineering Services groups who operate and maintain the new systems. The introduction of new systems is always a challenge due to the involved learning curve and the acceptance of a significant change in the interface to the process."

The final phase of the upgrade project – implementation – will be rolled out over the next three years,



CSL Limited



CSL Limited

The modernization project at CSL Bioplasma is particularly challenging because of the continuous nature of production



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with a progressive changeover to the new control system. The joint CSL Bioplasma and Siemens project team is confident that the expected results will be achieved.

Passing on project benefits

The CSL Limited Biotherapies Division, located in Parkville at CSL Limited’s headquarters and specializing in vaccines and antitoxins, has also started implementing other smaller upgrade/expansion projects with PCS 7.

Both projects – at CSL Bioplasma and CSL Biotherapies – use the software standards and libraries developed for the PMCS project, thus allowing CSL Limited to benefit from system uniformity and software reuse, including increased functionality, reduced software engineering and validation costs, less maintenance, and lower training expenses.

Engineering director Mark Abdallah of CSL Bioplasma is very satisfied with the collaboration between the two companies: “The relations with Siemens have continued to develop over the last two years. When issues have arisen on projects, the established relations between CSL and Siemens have

System solution

The project consisted of migrating the existing control system with 18,000 installed I/O to a modern solution that maximizes Siemens’ software modularity and software reuse by combining the following components:

- ▶ Simatic PCS 7
- ▶ Simatic Batch
- ▶ Simatic Route Control
- ▶ Simatic IT Historian

enabled appropriate resolutions to be reached to CSL’s satisfaction. There is a monthly high-level CSL-Siemens management meeting at which progress on projects is reviewed and issues raised and discussed to ensure that roadblocks are avoided and the relationship continues on a positive footing.” ■

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