

Julphar, United Arab Emirates

Quality of Life, Quality of Product

Thanks to a fully automated production unit for insulin, Julphar (Gulf Pharmaceutical Industries) in the United Arab Emirates makes a contribution to providing affordable high-quality medicine to patients and improving the quality of life for diabetes patients in the Middle East.

Diabetes in the Middle East is rising rapidly. Illness and healthcare are causing a financial strain on regional governments and many families. Offering high-quality, affordable treatment to a growing number of patients would help ease the burden. With this in mind, Julphar, a pharmaceutical manufacturer in United Arab Emirates, worked with Siemens to automate its biotechnology process in its new insulin production plant, Julphar XI. Established in 1980, Julphar is the first pharmaceutical manufacturer in the Arab Gulf States and a leading pharmaceutical producer in the region. Julphar has 11 state-of-the-art production facilities in UAE, which adhere to the highest standards of manufacturing. Its commitment to high standards has led it to procure ISO 9001 and ISO 14001 certifications. Its products are marketed on five continents and in 2011 crossed over AED 1 billion in sales.

A new facility for fighting diabetes

Julphar's insulin production plant (Julphar XI) is its latest facility under construction and is expected to widen its product offerings and bolster its market presence, especially in diabetic care. Since diabetes afflicts sizable sections of the Middle East population, Julphar's foray into bulk insulin production could not have been more timely. Julphar's first insulin production began eight years ago when

insulin crystals were imported from European sources for the local production of Jusline. Julphar invested \$136.1 million in its new plant in Ras Al Khaimah.

» Julphar recognized a gap in the market for locally produced insulin crystals. This production will allow us to respond to an increasing market demand, making insulin more affordable and accessible. «

Dr. Ayman Sahli, CEO Julphar

Julphar XI is one of the most modern biotechnological plants producing recombinant human insulin crystals and is built in accordance with EMEA (European Medicines Agency) regulations. Improvements on the process are now ongoing to achieve the yield. The fermentation facilities are designed to produce 450 batches of 10,000 l fermentation broth per year, yielding 1,500 kg of insulin crystals, which will enable Julphar to produce more than 40 million vials of insulin. The plant has six operational suites. In the media preparation area, bulk media is formulated before inoculation and seed vessels are filled to

- ▶ begin fermentation. In the buffers preparation area, the bulk buffers are formulated before filling storage vessels for chromatography purification. A buffer hold stores formulated buffers in vessels for further use. The fermentation suite consists of four seed fermenters and four 5,000 l production fermenters, which produce 10,000 l of bacterial broth per batch. In the recovery area, the E. coli is removed and the pre-proinsulin is harvested and treated with buffers to assist it in attaining its tertiary structure. In the purification suite, peptides are removed and the pre-proinsulin is cleaved using CPB to modify its primary structure and then separated by chromatography and finally crystallized.

A trusted partner

Julphar was happy with previous Siemens solutions, such as in its Julphar VI plant for liquid and semi-solid pharmaceuticals. This plant is fully automated with Simatic components and has minimal human intervention in all stages of production. Siemens' first-class biopharmaceuticals knowledge and experience, and its innovative automation products and solutions, were the main reasons that Julphar chose Siemens to help build its new plant, the Julphar XI. In early 2009, Julphar and Siemens discussed cooperation for Julphar XI. Construction continued in

"This is the start of a long-term relationship, initially focused on successfully completing what Julphar considers to be one of their most strategic projects during recent years," said Dr. Ayman Sahli, CEO of Julphar.

Full automation for bulk production

Siemens delivered a comprehensive process control solution based on Simatic PCS 7, including batch and route control. The solution includes the automation of insulin crystal production and the affiliated tank farm, the integration of the fermentation process, and the communication to third-party packages.

The system comprises 11 Simatic S7-417s for the different suites within production, connecting remote stations with 6,000 I/Os to operate sensors and valves. Over 7,000 m of data cable were laid to connect the PLCs, PCs, and cabinets with industrial Ethernet and Profibus. Operating and monitoring can be done from the process control room and in the field with remote HMI panels. Every operation is logged safely and all executed batches are archived in a central server.

Project management a crucial factor

Considering the high standards for the pharmaceutical industry, the need for bulk production, and the desire to reduce total costs, expert project management and engineering was a must. The Siemens project management approach PM@Siemens strictly followed the V model and complied with the latest GAMP regulations. From the start, project approaches were specified, the responsible roles defined, and expected results described. In addition, deviations in the process were anticipated and planned for. This helped minimize project risks and improved project transparency and control. Project interfaces were also standardized to ensure easy communication

between all stakeholders. A project quality plan served as a base for all referenced documents. This ensured compliance with relevant standards, so project goals could be met efficiently. Siemens developed the quality-related documents during the early phase of the project in cooperation with Julphar. Testing plans and standard operations were created and used during the entire project lifecycle. The complete set of documentation was given to Julphar for its own quality assurance and regulation acceptance.

» We have chosen Siemens as they are world leaders in automation process control systems, for both the pharmaceutical and biopharmaceutical industry. They were able to provide a good platform suitable for our manufacturing needs. «

Eng. Essam Hammad, Julphar Diabetes

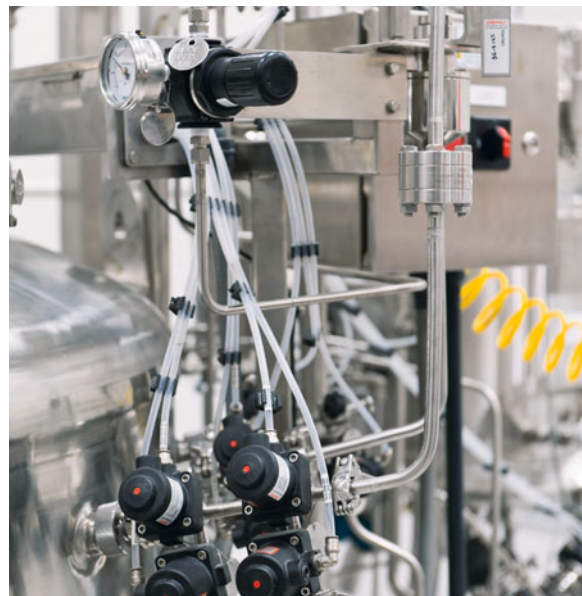
2010 and was accomplished in two phases. In phase 1, the user requirement specifications and process-related functional specifications were determined. In phase 2, the hardware and software for the control systems were designed. The control system was configured, hardware was integrated, and the system was tested. In 2011 the control system was delivered and the plant was completed. In March 2012 site acceptance was performed and operation started.



Julphar XI: the key points

The new facility will serve the growing market for insulin in the Middle East

- ▶ By choosing a fully automated bulk process, Julphar wanted to be able to provide high-quality, affordable products
- ▶ A Simatic PCS 7 system with 11 S7-417s was used to automate the plant's six production suites and 6,000 I/O points, reducing production costs
- ▶ Siemens automation, expert project management, and customizable after-service solutions ensure that the plant is on target to achieve its production goal of 40 million vials of insulin each year



all photos: Siddharth Siva

"This is the start of a long-term relationship," says Dr. Ayman Sahli, general manager of Julphar. The new plant, Julphar XI, was completed in 2011 but Siemens will provide ongoing service for the installed base over the entire lifecycle.

To create more value for customers and best fulfill requirements, Siemens combines solutions services from different organizational units. For this project, a team of several experts was formed. The core project management and engineering operations were executed in Karlsruhe and Marburg as well as on-site in Ras Al Khaimah. This project team delivered excellent performance for the customer.

Service for life

With Simatic PCS 7, Julphar is well positioned to serve the needs of the growing market for diabetes medication. The process control system makes a significant contribution to optimizing operating costs, protecting investments, and securing plant availabil-

ity. To ensure that Julphar can benefit from the full performance of the system over the entire lifecycle, Siemens will provide ongoing service for the installed base. For Julphar, this means that Siemens solutions and expert project management not only contributed to completing the project on time and meeting production goals but will also continue to improve its manufacturing process as time goes on – to make sure that the new plant will keep improving the lives of diabetes patients in the Middle East. ■

info
contact

www.siemens.com/pharma
sebastian.voss@siemens.com
guido.pareijn@siemens.com