The site at San Polo Torrile (Parma, Italy) of GlaxoSmithKline (GSK) avails itself of the largest sterile work area of Europe, in which is housed a lyophilization production line dedicated to the production of new pharmaceuticals for the global market. In collaboration with the Siemens Packaging Competence Center, the multinational pharmaceutical technicians have upgraded the filling machine of the plant using the SIMOTION platform, thereby improving the reliability and performance.

The greatest care in production

Producing for the global market demands a level of attention to detail that must be second to none. The site at San Polo Torrile (Parma, Italy) is one of 10 plants worldwide that the multinational pharmaceutical company GSK has grouped into the New Product and Global Supply organization, namely the network of installations which has been entrusted with the production of new products destined for all world markets.

Hence it is necessary to comply with all international regulations, starting with the strict U.S. FDA (Food and Drug Administration) for the production of pharmaceutical compounds. To obtain and maintain the international certifications, the surveillance and inspection activity is tightened and the internal technical structure of GSK has as its own primary objective the continuous monitoring of process quality with a view to its continuous improvement.

Changing to improve

With this background, the technical site of San Polo Torrile initiated in the course of 2007 a project to improve the lyophilization process focused on the revamping of the filling machine, a cardinal element of the entire line and the only machine of its kind in the company. As Dominic Valente, head of the factory automation GSK San Polo Torrile, relates, “The lyophilization line is composed of several processes in a cascade, it begins with the washing and the sterilization of the vials to then pass on to the filling stage with the active ingredient, prepared in the meantime in an aqueous solution, to then finish in one of five sterilizers that bring the product within a lapse of 24/36 hours to its final condition and to its ultimate sealing, which is subsequently followed by the packaging. The entire process, from the sterilization of the empty vials to the passage to the lyophilizer, always takes place in a sterile atmosphere, in a system that works continuously and with only two periods of planned downtime throughout the year; for about two weeks in December and three weeks in August. Since the year 2000, the filling phase of the vials is managed automatically by a machine that can handle about a dozen
different formats with a filling capacity several hundreds of vials per minute. For us, obviously, the running condition of this machine is very critical, since any unscheduled stop has significant negative consequences upon the production. We realized over time that the reliability of the machine, as regards to its drive system and movement controls, did not meet up to our expectations. However, what was more problematic was that the manufacturer declared some of the key components of the system to have become obsolete, particularly some motor and axis control system parts. Therefore, we decided to investigate alternative solutions that, on the one hand, protected us in the future from any unexpected failures and the risk of not finding adequate spare parts, while contemporarily allowing us to further improve the machine performance in terms of filling accuracy.

From the consulting to the assistance

The GSK headquarters San Polo Torrile has a qualified group of automation technicians who, given the difficulty of a solution proposed by the original manufacturer of the machine, decided to do their own research in finding the best solution available for a “revamping” of the filler machine. Valente continues, “We certainly did not want to be brave and we could not afford to risk making a mistake in our approach to a machine as important as the filler machine. We therefore decided to utilize the facilities of the Siemens Packaging Competence Center, our preferred partner for automation systems, in order to jointly analyze the structure of the motion controls of the filling machine and to evaluate alternative solutions based on modern components, leaving the problems of obsolescence
behind.” Isaac Contaldo, collaborator of the Siemens Packaging Competence Center, adds, “Together with the GSK technicians, we thoroughly studied the critical points of the movement control and the alternatives that were available. It was certainly not a matter of just replacing a motor or a drive with its equivalent, which weren’t available anyway, but to renovate the architecture of the motion controls, taking advantage of the mutual application knowledge and, above all, bearing in mind that, during the implementation phase of the project, there would only be a few days during the scheduled downtime in which to work, with no allowances for any mistakes.”

The feasibility study for the renovation of the machine led to dividing up the action into two phases: the first phase to be implemented during the company’s Christmas break of 2007 with the replacement of the five motors and drives that manage the movement of the machine, the second phase to be implemented in the summer break of 2008 with the replacement of the original controller unit of the cam logic, using an alternative solution based on the SIMOTION platform.
Mission accomplished: 
reliability and performance improved

The renovation work on the machine was carried out during the planned, scheduled maintenance periods. Immediately afterward, all the extensive testing procedures necessary for the recertification of the process were carried out according to the pharmaceutical industry standards. Valente comments, "The work of installing the modifications that took place successfully as planned was only the tip from the iceberg of the work still to be done, since any change in our industry strictly requires an exhaustive recertification and this was one of the critical points of the project in view of the plant's limited time available to carry out the task.

The careful preliminary activities of planning and design in collaboration with Siemens has enabled us to meet deadlines and has been a source of pride for the whole team. Furthermore, not only was the result obtained of now having a running machine built with standard components with no future problems of part availability, but we now have a machine that provides the best operating results.

In fact, the new intelligent control structure of the movements allows for a controlled shutdown and restart of the production line without generating waste and the precision of the filling phase is even better than it was before. In the end, our courageous choice was most definitely rewarded: the mission was accomplished and we thank all the technicians of the Packaging Competence Center for the results we obtained together.”