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Pharmaplan Case Study Green Cross Vaccine Corp.

(Member of the Berna Biotech Group)

Pic. 1

Pic. 2

Pic. 3

Pic. 4

Pic. 1: The modules with all the building services, process equipment and fittings pre-installed. Showing a HVAC unit.
Pic. 2: Start of the installation from the modules on the foundation, which was installed in parallel to the fabrication of the modules - first day of rigging up.
Pic. 3: 10 days after the installation started, all 30 modules set in position by crane and the final connection of the services could start.
Pic. 4: Outside elevation of the vaccine plant 4 weeks after installation start: A uniform outside facade was given and the interior work is going full steam ahead.

Green Cross Project Scope:

- New facility for producing vaccines
- 12,000 sq. ft. facility
- 3-story building consisting of 30 individual modules
- 6 months from date of first module until completion of IQ and OQ and handing over to the customer

Pharmaplan Modular Solution:

- Optimized overall delivery time of plant through use of modular construction

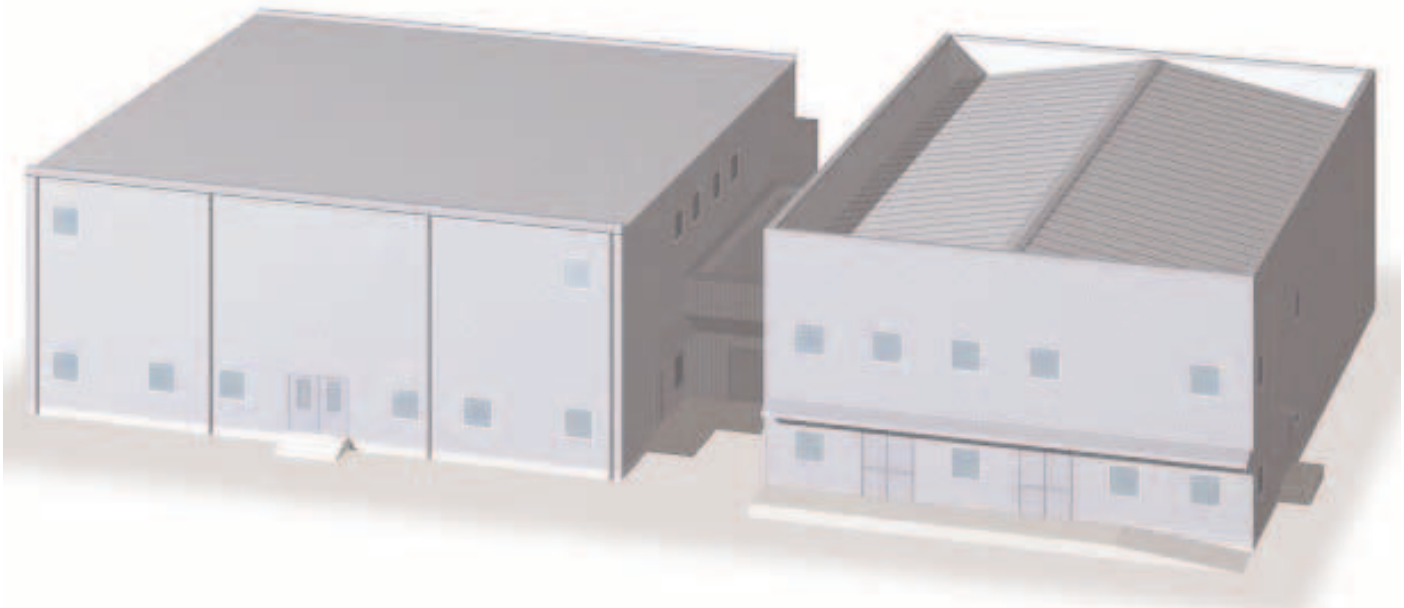
Pharmaplan's modularly constructed facilities provide customers with short delivery times, fixed project pricing while guaranteeing FDA and cGMP compliance.

With "time being money," it is an incentive to find the fastest, most efficient way to build pharmaceutical and biotech facilities. The key to faster site construction, which facilitates faster product to market, is using off-site modular construction.

Pharmaplan's recent modular project for Green Cross of South Korea involved a turnkey plant to fill hepatitis vaccines and showcased the advantages of using modular construction. Pharmaplan realized a 40 % shorter project implementation phase, which allowed Green Cross to begin producing product only six months after the first module was delivered on-site. This time saving advantage and the possibility to relocate the complete modular facility at a future date were decisive reasons why Green Cross chose the modular solution. It is important to note there were no compromises made regarding the quality, life span or architectural design of the modular facility in comparison to one designed and built by conventional means.

The past 20 years has seen continual development and improvement in modular construction technology. Steel frame modules are prefabricated and equipped with building and process technology at an off-site factory under a controlled environment. The modules are disassembled and transported to the building site where they are placed into position and reconnected to each other. The same crew that disassembles them in Germany reassembles them on-site to avoid any confusion or delays. Using this building method the 3-story, 12,000 sq. ft. vaccine plant was designed and built using 30 uniquely prefabricated modules. Without any limitations to the site construction, it was possible to install up to 60 foot long modules. The end result was a 3-story building that was assembled on-site in only 10 days. These modules were manufactured in Germany with all the building services, engineering, process fixtures and fittings preinstalled. Once completed and tested they were shipped to Korea. The transport within Korea turned out to be a logistical challenge with fully equipped modules having a weight up to 60 tons and widths of 18 feet. Some of the transport vehicles that were used were nearly 100 feet long and because of the weight required some of the bridges to be reinforced.

Prior to shipment from Germany, the first installation qualification checks were performed on the climate control units, sterilizers, solution preparation tanks, compressors, control panels and the complicated water preparation units. Since 90 % of the facility and its processes were prefabricated, it allowed us to



completely assemble the initial plant in less than 3 weeks. The modular constructed facility enabled the local Korean companies to concurrently prepare the foundation work while the modules were being constructed. Local regulations required the foundation and modules to meet stringent seismic codes. Even with these complex requirements, the foundation costs for our modular facility were significantly less than that of a conventional design.

Once the modules had been set in position on the foundation by cranes, the modules were connected and the interior finish completed. The building was given a uniform outside façade matching the architect's design. All electrical media, wiring and cables were connected via previously installed flange connectors and conduit. Eight additional weeks of installation work was all that was required prior to beginning the process start-up and validation phase.

Some of the process equipment had longer lead times than that of the modules. In this situation, we designed a special delivery and inspection opening in the modules that would allow for these late deliveries on-site. These hidden openings in the outside walls increased the flexibility of the building and simplify any future replacements or additions in regards to large process equipment.

Pharmaplan was successful in turning over the completed, fully functioning vaccine plant, along with the IQ and OQ after only 6 months from the date they delivered the first module.

Pharmaplan's Module Philosophy

To continue to find the fastest way possible to design, build, deliver and turn over a completely functioning, validated facility. This is accomplished with the assistance of modern management methods and computer aided design in combination with modular construction. The basic philosophy is that instead of the floor plan being divided into individual rooms, we design and integrate process areas into modular units. These individual modules can easily accommodate a space of 140 sq. ft. with weights of 60 tons. The fabrication quality of the modules is very good and is built around our know-how of pharmaceutical production processes. We aim to build, install and test as close to 100% of the process technology as possible while the modules are in Germany. By accomplishing this, the time for the start-up phase and validation on-site will be considerably reduced.

Advantages

Construction via modules is increasingly being used to meet the stringent demands of short time, as well as the high quality requirements of the pharmaceutical industry. The most important criteria in modular construction is to:

- Shorten the Time-To-Market
- Provide Faster Return On Investment
- Stay within a Fixed Budget
- Conform to FDA and cGMP Requirements

The time advantage, parallel production, efficient production processes, standardization and assembly of sensitive production units under controlled conditions are the main strengths when compared to conventional building methods. Pharmaplan capitalizes on these advantages using a process orientated design team to help reduce this time-to-market phase. A faster return on investment is realized by shortening the time from the initial design to when the plant is ready for production. The qualification and factory acceptance test-runs for the production equipment can be carried out in Germany prior to shipping the modules. This also allows more time to resolve any problems that may

have been discovered during the test-runs, thus ensuring that the site start-up will start on time and be trouble-free.

In addition to the benefit of a short time schedule, the pharmaceutical industry likes the flexibility provided by modular construction. A small pilot plant can be easily modified to accommodate an additional production line with the simple addition of modules. Modular construction also allows the customer to react quicker to changes in the market that might have been unforeseen. For instance, a complete modular facility can be sold or relocated for as little as 10–30 % of the cost of a new facility.

It is an enormous financial undertaking to launch a new product which is in clinical phase III for most companies. High investment in engineering, process equipment and the building itself are required. The building alone generally contributes to one-third of the project's total cost. Using modular construction, it is possible to better manage the high investment phases through reduced planning and building time. The implementation phase takes place much later in the project without pushing back the date for production startup. This step-by-step investment method can have a positive effect on the company's balance sheet and their cash flow.

Module Construction is becoming more popular

Module construction is no longer looked at as a compromise or interim solution to traditional construction. Today's standards of modules are of high quality, long lasting and architecturally pleasing designs. Modular buildings are no longer seen as simple containers or as temporary facilities. The economic benefit is clearly realized with the project implementation phase being shortened by 30–40 %. It is possible to use modular buildings in all climate regions of the world and they can be designed to meet all international building regulations.

In conclusion, modular construction will never replace conventional construction methods; however, evaluating the benefit of the shortened construction phase, the avoidance of site noise and construction, minimizing existing production interruptions and the possibility of a faster return on investment, it is being recognized as a strong alternative. This recognized trend can be seen by the increasing number of modular constructed products that are being built throughout all industries throughout the world.

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