

THE PHARMADULE MODULAR CONCEPT FOR PHARMACEUTICAL AND BIOTECH PRODUCTION FACILITIES

What the innovation is.

A new approach to delivering manufacturing plants; such as, pharmaceutical and biotech facilities has been developed and perfected. Instead of the lengthy and unpredictable conventional construction approach, this new approach utilizes a modular construction technique at an off-site location. The individual modules are constructed under controlled conditions with highly predictable outcomes of quality, cost, and schedule. The modules are assembled at the initial construction site; process and utility equipment is installed and thoroughly function tested for both processes and services, then the modular plant is disassembled and transported to the client's site. There the modules are reassembled and subjected to final validation of all processes and systems before handing over to the client. The modules are of rugged steel construction with concrete floors and can weigh 30-plus tons. The interior room finishes are equivalent to the best conventional construction and employ sanitary design features for floor, wall and ceiling surfaces. Utilities and services are of proven design and easily validated. The modular concept has been able to accommodate any client's requirements with respect to processes, services and environment.

Why it's innovative.

The modular approach is fundamentally different from conventional. Unlike conventional, the modular technique assures the client a guaranteed fixed price and schedule at the preliminary design stage. The completion schedule is normally 12-18 months, in contrast with 24-36 months for conventional and at a cost that is comparable, or even less, than conventional. The modular approach requires fewer client resources, since they are dealing with a single vendor in a true turnkey approach to project delivery. But probably the most innovative characteristic of modular construction is the fact that the entire facility is readily moveable to another site at a fraction of new construction cost. The modular approach gives predictability of quality, schedule, and cost and provides a guarantee of no surprises for the client's project business case. Another unique feature of the modular approach is the fact that the facility is inspected by the Swedish Medical Products Agency (equivalent to FDA, Food and Drug Administration) for compliance with international cGMP (current Good Manufacturing Practices) standards. A certificate of compliance is issued prior to shipment to the final site, contingent upon acceptable final validation results.

What it has changed.

The modular technique has changed the project delivery focus when compared with conventional. The modular constructor assumes a greater and more responsible role in the delivery process; from initial design, procurement, validation, and training through start-up. It replaced the unpredictability of weather, trades, and local equipment and materials, with virtual total predictability of these elements by using indoor construction and known trades, equipment, and materials. The modular technique is really an assembly line approach to delivering high technology manufacturing projects.

- The fast delivery time shortens Time to Market for new and existing pharmaceuticals.
- The short project time, compared to conventional, allows companies to defer decision to start a project to a later stage when the viability of the client's product/project is better known.
- The controlled and repeatable conditions under which the modular plants are constructed enables true standardization, and identical plants can easily be constructed for placement on different sites around the world allowing enhanced product portability.

Where and when it originates and it's use.

A Project Director of a Swedish pharmaceutical company conceived the modular approach in 1986, in Sweden based on experiences from conventional projects and the problems with delays and cost overruns. The first projects were in Sweden and then expanded to several projects in Eastern Europe and a large volume parenteral plant in Canada. Eli Lilly and Co./USA have contracted four projects; one in Egypt, two in China, and currently a large parenteral freeze dry facility in Indianapolis. Cook Imaging, Inc./USA has contracted two parenteral facilities in the USA. In total, thirty-five (35) projects have been completed around the world, including a large biotech facility in China and among the clients are companies like Eli Lilly, Pharmacia Corp., AstraZeneca, Bristol-Myers Squibb, Baxter, and Nycomed Amersham. A total of three facilities have been relocated. There is growing interest in the USA, Latin America, and Western Europe to embrace the modular technology, due to its obvious advantages over conventional construction.

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After completed scope definition and contract signing the Detailed Design takes off in parallel with construction.



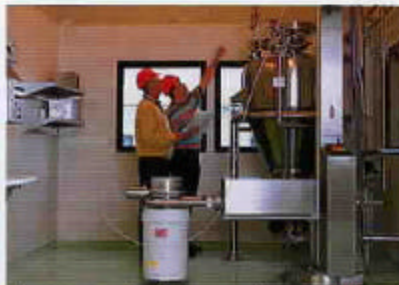
The construction of modules takes place indoors under controlled conditions.



Entire plants can be assembled indoors for maximal control. Example: A 50,000 sqf facility for Eli Lilly & Co.



The plant is assembled in Sweden and pipework and equipment installation are carried out.



Process and utility equipment is installed in Sweden. A pre-IQ and test-run is performed to secure the quality.



The Client's staff can be brought to Sweden for hands-on training on their actual plant.



After the final tests in Sweden the plant is broken down to modules and shipped to the final site by boat and truck.



The modular plant sits on a simple foundation that has been prepared in advance by the Client.



The modules are lifted in place with all equipment pre-installed. Each module weighs 15-35 tons.



Modules are set with a pace of 4- 6 per day. In a few days to a week or two the entire building is installed at the final site.



The final result can not be distinguished from a conventionally built plant.



After final finishing and OQ the plant is handed over to the Client for subsequent PQ and start of production.