Verta Life Sciences | Molecule to Market Consulting.
Supporting Life Science Companies; Develop, Manufacture, Register, Launch, and Supply their Products.

FACILITY STRATEGY CASE STUDY

Verta Life Sciences and Strategic Partners help our clients to develop long-term facility strategies that support their business strategies. Depending on the size and complexity, facilities can be costly and require long lead times to create, commission and validate. Without the necessary strategic thinking, there is no assurance that the right facilities will be available when required.

A facility strategy will provide answers to questions such as:

- What are the types and sizes of space required over time to support our business needs?
- When are the different types of spaces required?
- Where should our facilities be located?
- What are the capital and operating costs of the facilities that we require?
- Should we modify or add to our existing facilities?
- Should we rent, buy, build or consider another model?

ISSUE:

A major pharmaceutical company experiencing significant growth realized that it may outgrow their facilities.

OBJECTIVE:

Project the company's long term space and functional requirements, analyze the options to meet its facility needs and recommend the way forward.

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DELIVERABLE:

The most significant challenge usually faced in the development of space and functional requirements of multi-disciplined organizations is that long term business plans usually look out from 5 to 10 years, while the life expectancy of facilities is at least 25 to 50 years. The task is further complicated by the impact of unknown future technology changes.

Starting with the long term sales projections and working with key representatives of all departments, a software model was developed to project a range of functional and space requirements for each department and the overall organization over the next 50 years and beyond. In work sessions with executives and key representatives of each department, these requirements projections were then rationalized and refined into three scenarios namely; most optimistic, most pessimistic and most likely.

Next, the company's existing facilities were assessed to determine their ability to accommodate (with changes and additions) the most likely requirements projection as well as the marginal impact of the most optimistic and pessimistic requirements projections. A further analysis was also done to assess the impact on the business of creating the changes and additions to the facilities while continuing with normal business operations.

A financial model was developed to analyze and compare the above option of changing the company's existing facilities to that of creating all or some new facilities on a green field site. This model took into account the impact of issues such as: continuation of operations in existing facilities during changes and additions, transition to new facilities, capital costs, projected long term operational cost, etc.

The company's final decision was to develop an entire new campus for its head office, manufacturing, research and development requirements with enough land to allow for future growth. Some functions, including distribution, remained in other locations.

FACILITY CREATION

Verta Life Sciences and Strategic Partners have had leadership roles in the creation of pharmaceutical and biotech manufacturing and support facilities in North America, Asia, Europe, and Africa.

The process we follow usually involves the following major activities:

- Establish project requirements.
- Develop conceptual options to provide the facility space and functional requirements that support the process systems to be accommodated in the facilities.
- Select a preferred facility option.
- Assemble a suitably qualified design team, including process engineering, facility design, structural, mechanical and electrical engineering.
- Produce process engineering (including material flows) and facility design documentation.
- Construct facilities and process system.
- Commission facilities and process systems.
- Qualify facility and process systems.

The key ingredient to the success of any facility project is focused project management. This ensures the scope (requirements), cost and schedule for the process systems, equipment, and

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facilities are established at the start of a project and maintained throughout the life of the project.

Verta Life Sciences and Strategic Partners have managed numerous projects to successful completion, on time and on budget.

ISSUE:

A major international pharmaceutical company wanted to create a new manufacturing plant on its existing campus.

OBJECTIVE:

Create a manufacturing plant for solid dosage and liquid products that leverages technology to allow efficient production of short runs of multiple products.

DELIVERABLE:

The key criteria by which project managers measure their projects' performance are scope, schedule and cost. They have to remain in balance. Changes in any one will affect the others. On most facility projects, the process is to define the scope (functional and space requirements) of the project first, then develop an acceptable conceptual design that deliver the requirements. A budget and schedule to deliver the project are developed next. If the budget and/or schedule are unacceptable, the scope has to be adjusted until the three criteria are in balance.

Initial cost estimates and schedules were developed as soon as the project requirements (scope) were known. These estimates and schedules were based on historical information for similar manufacturing facilities.

Our view is that the form of manufacturing facilities should be driven by the functional and space requirements of the manufacturing processes and equipment. It is necessary to understand and design the manufacturing technologies first, before the facility is designed. On this project, task forces were formed to study and evaluate different technologies, including containment, material handling, etc.

Once a decision had been reached on the technologies that would be used, the process/industrial engineers were engaged to develop the concepts for the manufacturing processes and material management systems. Conceptual designs for the building and its systems followed.

More detailed estimates and schedules were produced, based on the manufacturing equipment and building conceptual designs. Once corporate approved, these estimates, schedules and concept designs became the baselines against which the project performance was measured until its completion.

Based on experience on pharmaceutical manufacturing projects, a contracting strategy was developed that allowed flexibility to make changes to the layout and equipment cost effectively. This strategy paid off when a number of changes had to be made during the life of the project.

Project controls focused on monitoring, reporting and controlling the project scope, budget and schedule. When the systematic monitoring identified deviations from the base lines, corrective actions were taken. The project was completed on schedule and on budget in about 30 months and at a final cost of $105 million (2010 dollars).

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