



How to Invest \$5 Million and Receive \$100 Million

CASE STUDY – CLVE1

Services:

Strategic Planning, Management, Implementation and Project Assurance.

Client:

Public pharmaceutical firm

Requirement:

Provide client with a firm that could manufacture cGMP Active Ingredient for pre-clinical evaluation that would scale into larger production quantities and assure successful delivery of the ingredient.

Situation:

Client required a minimum of 1.5 kg of active ingredients, manufactured under cGMP conditions and needed to present a plan for larger quantity production to its potential licensing partners.

Scope:

Staffing: 16 person weeks.

Deliverable: Assure delivery of 1.5 kg of cGMP material and provide a scalable larger quantity production plan with appropriate cGMP documentation.

Discovery:

The consulting and contracted laboratory team identified workable options that included manufacturing a larger quantity of the penultimate intermediate. While this was not in the budget it would ensure delivery of the next 100+ kilos of cGMP material by an approved and scalable process.

An integral part of the contract was to assure the execution and delivery of the

materials in a step-wise fashion; planning and production were timed and overlapped to ensure the highest quality at the lowest cost with the highest throughput. A major discovery was related to the ultimate value of the newly developed technology. This allowed the Client to proceed with licensing and receive nearly \$100 million in payments from licensing partners.

Semaphore advised the client to invest \$5 million to produce the larger quantities of material, ensuring that the Client could maintain control of the active ingredient manufacturing and nearly all the clinical development planning. In addition to the new strategy, internal processes for transfer of the technology to a large pharmaceutical partner were also adopted. This tactic provided two rapid production routes to market rather than only one.

Outcomes:

1. The decision was made to proceed with the \$5 million investment to initiate the contract. The material was delivered on time and to specification.
2. A new process was patented, extending the life of the existing patent while providing an alternative route for manufacturing of the active ingredient.
3. The client received initial payment of \$35 million from a Japanese partner, followed by a \$65 million payment from a large pharma partner.
4. The client was able to get the drug approved using a majority of the process developed by Semaphore and the identified chemistry team.



5. The lead product was released to the market in record time. It is in wide

distribution generating nearly \$500 million in sales worldwide.