

GLOBAL MANUFACTURING CAPACITY FORECAST

Determining worldwide manufacturing capacity requirements and the likely demand for outsourced manufacturing of therapeutic proteins

SITUATION

- A joint venture between a US vaccine company and an Asian contract manufacturing company was established to construct a cell culture manufacturing facility in Asia.
- The plant would be focused on the production of therapeutic proteins based on mammalian cell culture processes, with the primary focus on monoclonal antibodies and vaccines. The US company's vaccine that was in late stage development was one obvious early user of some of the manufacturing capacity, pending its approval by the FDA, but both companies sought to identify a broader base of business across worldwide protein and vaccine developers.
- The joint venture needed an understanding of drugs in development likely to use mammalian cell culture manufacturing processes that may need manufacturing capacity, as well as the expected demand and the timing associated with commercialization of each of these therapeutics.

CRITICAL QUESTIONS TO ADDRESS

- What drugs are currently in development in the US, Europe and Japan that may require the type of manufacturing capacity and capabilities the JV can provide?
- What is the timing and probability of success of this pipeline and how does that impact the likely total need for protein manufacturing in the next 10 years?
- What capacity exists currently and is scheduled to be added, and by how much will demand exceed this capacity plan in the next 10 years?
- Who are the most likely customers for this outsourced manufacturing capacity and what is the likely timing of their demand?

HEALTH ADVANCES APPROACH

- Conducted a worldwide inventory of products in development that would require mammalian cell production capacity and projected WW market size over the next 10 years. This involved a detailed review of all available drug pipeline information from secondary sources.
- As a subset of this global demand, Health Advances projected the demand for total outsourced manufacturing capacity 5-10 years out, given a broad survey of drugs in development. This was determined through review of secondary information from the target companies as well as discussions with senior executives at the target companies to assess their likely interest in using contract manufacturing resources to meet their production needs.
- The forecast was developed by assessing the market size for each specific drug and then applying industry probabilities to account for likelihood of success at each stage of clinical development.

RESULTS

- A detailed forecast model was developed by product and by year.
- Information on the most valued services that a contract manufacturer should provide, as well as the most likely timing for outsourced manufacturing was also provided (e.g. outsourced manufacturing needs during clinical trial development as well as commercial stage).
- In addition, a list of likely customers was developed, along with profiles describing each company's drugs in development and the details of the demand forecast for each company's targeted drugs for outsourcing manufacturing.

Potential Sources for JV Plant Utilization

