

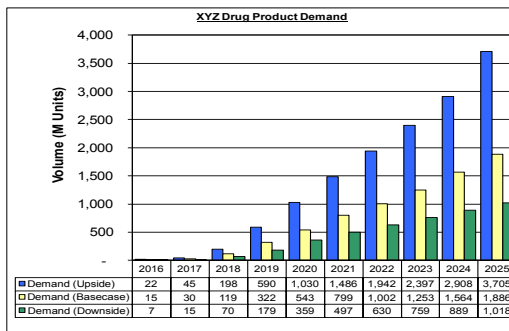
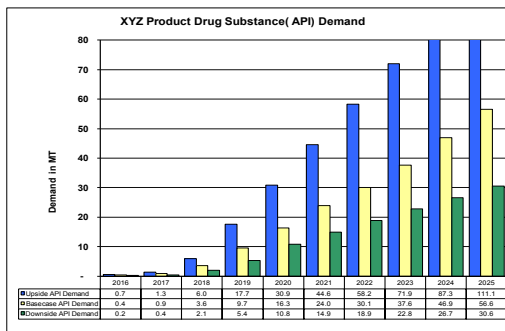
**Driving the Pharmaceutical and Biotech Industries towards Excellence in Manufacturing, Supply and Quality**

**MANUFACTURING STRATEGY**

NDA consultants have helped Pharmaceutical and Biotech companies plan the successful launch of new products and the secure supply of existing products. This is by developing and implementing robust sustainable Manufacturing Strategies that ensure sufficient capacity is in place to meet anticipated customers demand. Risks associated with complex supply chains during the life cycle of a product are actively and effectively managed.

We do this by taking a life cycle approach to manufacturing supply, allowing our clients to better understand their customer demands, and answering such questions as:

- How much should we make and when?
- Where should we make it?
- What technology is required to make it?
- Do we have sufficient capacity or do we need to invest in more?
- What is the estimated Cost of Goods?
- How can we leverage our existing supply chains to make it cheaper or do we need to look at alternative suppliers?
- How can we ensure continuity of supply?



Product Demand modeling

## MANUFACTURING STRATEGY CASE STUDY

### ISSUE:

A not for profit Product Development Partnership (PDP) with product entering Phase II/III clinical trials wanted to establish the basis for the supply of product to meet the projected demand for clinical trials and launch.

### OBJECTIVE:

Establish a manufacturing strategy to provide sufficient manufacturing capacity to meet projected demands at key stages of the product development pipeline. This needed to be scalable to allow for launch in selected markets and eventually be the basis of global supply at a very low cost of goods.

### DELIVERABLE:

Modeled the projected volume of product required to meet clinical trial needs.

Using worldwide population growth data, modeled projected demand for the product post approval based upon various launch and approval scenarios.

Established a Manufacturing Strategy that identified the annualized demand for drug substance and drug product, the increases in batch size required to satisfy demand, and the capital investments required to establish sufficient capacity to ensure security of supply during clinical trials and eventual launch.

Gained Board endorsement for the manufacturing strategy.

## Contact Us

To learn more about how Nick Davies & Associates LLC (NDA) can help you, please contact us:

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