

# SCIENTIFIC EXPERTISE DELIVERS SAVINGS TO YOUR BOTTOM LINE.

**BUSINESS CHALLENGES.**

Expedited transfer to a new production site was needed for a commercially launched lyophilized drug. Time lines were critical, as production could not continue at the original manufacturing location, and inventory levels were running low. There was no other source of supply for this molecule, which is indicated for emergency treatment and stocked by both hospitals and national defense inventories. Adding to the challenge was the fact that the existing manufacturing process resulted in significant product losses, averaging 10% per batch due to cake meltdown.

**BAXTER SOLUTIONS.**

Baxter’s team in Bloomington, Indiana, designed the following solutions:

- Optimization of the original lyophilization cycle
- Accelerated transfer of the product to the new manufacturing location

**CYCLE OPTIMIZATION.**

A product development study conducted by Baxter’s Lyophilization Center of Excellence (BLCE) in Bloomington, Indiana, determined that the original lyophilization cycle was an excessively long and nonscientifically based cycle considering the physical attributes of the active pharmaceutical ingredient (API). A key component of the study was BLCE’s capabilities to characterize the eutectic temperature and collapse temperature properties of the product. Techniques used to improve lyophilization cycle performance:

- **Analyses** by differential scanning calorimetry (DSC) and freeze-dry microscopy establish maximum product temperature during the primary cycle at full-scale freeze-dry manufacturing.
- **Primary and secondary drying pilot studies** to determine the optimum freezing protocol and primary drying time and shelf temperature required for safe, time-efficient drying.
- **Full-shelf freeze-drying pilot study** to verify that the lyophilization cycle was robust, replicable with a full shelf of product, and able to meet requirements for residual moisture, potency/purity, crystal form, and dissolution time.
- **Heating/cooling rate studies** to determine slower heating and cooling rates similar to rates attainable in production-scale equipment.

**PROJECT OUTCOMES**

Total cost savings: **\$4.7 M**

Lyophilization cycle time reduction: **42%**

Yield improvement: **9%** per batch

Manufacturing:  
FDA approved in less than **10 months**

The new lyophilization cycle reduced total lyophilization cycle time by 42% and delivered a manufacturing method that produced a higher-quality product in less time while improving yield per batch.

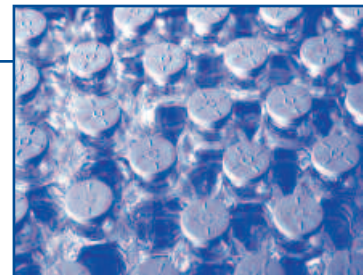
# BAXTER CONTRACT SERVICES CASE STUDY

## Time-to-market manufacturing solutions.

As the team responsible for meeting the project's time-critical milestones, the primary goal was to expedite transfer and deliver the product as rapidly and economically as possible. Partnership between the project management and manufacturing teams resulted in achievement of all manufacturing and regulatory milestones, including:

- Manufactured first process validation batch 7 weeks after completion of product development study
- FDA approval of manufacturing site in less than 10 months

Implementation of the new cycle within the manufacturing plant also resulted in immediate yield improvements, beginning with the first process validation batch and continuing through commercialization. The cycle has continued to deliver high manufacturing yields and minimized product defects from cake meltback.



## Manufacturing and operational improvements drove financial savings in excess of \$4.7 million.

### BOTTOM-LINE RESULTS.

Financial savings in excess of \$4.7 million were derived from the manufacturing and operational improvements:

- New lyophilization cycles drove immediate and sustainable yield improvements in excess of 9% per batch, increasing achievement of finished goods inventory while simultaneously providing savings in API.
- Reduction in cycle time of 42% saved a full manufacturing day per batch.
- Reliable execution in production delivered more than 60 batches with defect rates of less than 1%.
- Operational savings from reduced inventory carrying costs and improvements in the supply chain.
- Maximized revenue derived by meeting contractual commitments to customers and improving balance sheet and cash flow.

Find out how we can accelerate your product's path to success.  
Call 1-800-4-BAXTER today or visit [www.baxterbiopharmasolutions.com](http://www.baxterbiopharmasolutions.com)

BioPharma Solutions

Connect to the resources you need.

**Baxter**