



Application Case History

# Smart Freeze-Dryer™ Technology Delivers Robust ROI to R&D Labs

## INTRODUCTION

*Scientists in the R&D divisions of a large pharmaceutical company and a blue-chip biotech firm spent several months using SMART Freeze-Dryer Technology for freeze-dry cycle development work. Each lab used SMART technology to develop an optimized cycle for a single formulation and then compared the SMART approach with their traditional cycle development protocol. Their work was studied to identify the gains achieved using the new technology.*

## RESULTS

Both labs reported breaking-even on their investment in the new technology in **less than three months**. The primary savings were achieved through the SMART technology’s ability to deliver optimized freeze-dry cycles after just a few experimental runs. The average reduction in experimental cycles at the labs was **78% (from 9 to 2)**.

Other specific outcomes include:

- Average cycle development time reduced by 62 days, or 78%.
- Average savings per development program of \$40,029 (consisting primarily of labor savings and active ingredient materials savings).
- Average annual savings of \$320,232 (based on an average of 8 development programs per year).

In addition, because scientists were often able to produce a cycle optimized to their specifications after a single experimental run, the SMART technology enabled them to conduct additional experiments to test for process limits while still shaving months of the development program.

It is important to note that two other important economic considerations were not quantified in this study. These are:

- The value of advancing a formulation to pilot production months faster.
- The production savings available by developing a more efficient, more robust freeze-drying cycle.

These savings would be considerable for any formulation that advances into pilot or commercial production.

## Case #1 Detail

	Traditional Approach	SMART Approach	Savings
Number of Experimental Runs Performed	10	2	8
Estimated Development Time (days)	95	19	76
Analytical (DSC) Costs	\$1,000	\$1,000	\$0
Labor Costs	\$36,060	\$2,412	\$33,648
Material Costs	\$93,750	\$75,000	\$18,750
Total Costs per Development Program	\$130,810	\$78,412	\$52,398
Development Programs per Year	8	8	--
<b>Total Annual Cycle Development Costs</b>	<b>\$1,046,480</b>	<b>\$627,296</b>	<b>\$419,184</b>

**Case #2 Detail**

	<b>Traditional Approach</b>	<b>SMART Approach</b>	<b>Savings</b>
Number of Experimental Runs Performed	8	2	6
Estimated Development Time (days)	63	16	47
Analytical (DSC) Costs	\$1,000	\$1,000	\$0
Labor Costs	\$30,480	\$2,820	\$27,660
Material Costs	\$25,000	\$25,000	\$0
Total Costs per Development Program	\$56,480	\$28,820	\$27,660
Development Programs per Year	8	8	--
<b>Total Annual Cycle Development Costs</b>	<b>\$451,840</b>	<b>\$230,560</b>	<b>\$221,280</b>

**About SMART Freeze-Dryer Technology**

SMART Freeze-Dryer Technology is a breakthrough development tool that enables skilled development scientists to accelerate and streamline the arduous task of developing freeze-drying cycles for protein-based therapeutics.

Smart Freeze-Dryer technology packages control algorithms developed by leading experts at the University of Connecticut and Purdue University into an easy-to-use cycle development tool. The user enters basic data, and SMART returns a safe, optimized drying cycle after just one or two development runs. And SMART generates process data — such as product resistance and heat flow — never before available from a freeze-drying system. SMART takes the guesswork out of freeze-dry cycle development to save precious development time, eliminate product waste, and get products to market faster. SMART also safely produces streamlined cycles that shave days off the typical freeze-drying process.

SMART is available on LyoStar® II R&D and Process Development Freeze-Dryers from FTS Systems.