

Microsphere Fabrication

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Objective

The overall objective is to develop a profitable business by fabricating custom microspheres (MS) for drug delivery. The business will service Purdue University research laboratories.

Literature

- MS can encapsulate drugs for continuous release
- Poly(lactic-co-glycolic acid) (PLGA) is a popular biodegradable polymer for MS
- MS can be made by oil-in-water OR water-in-oil-in-water emulsions

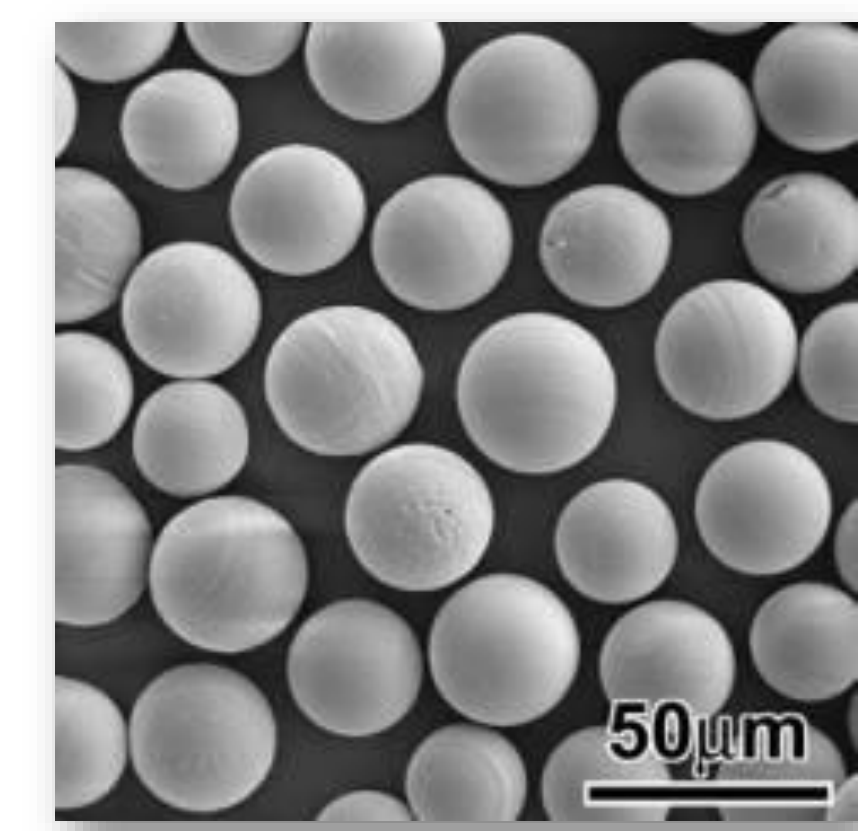
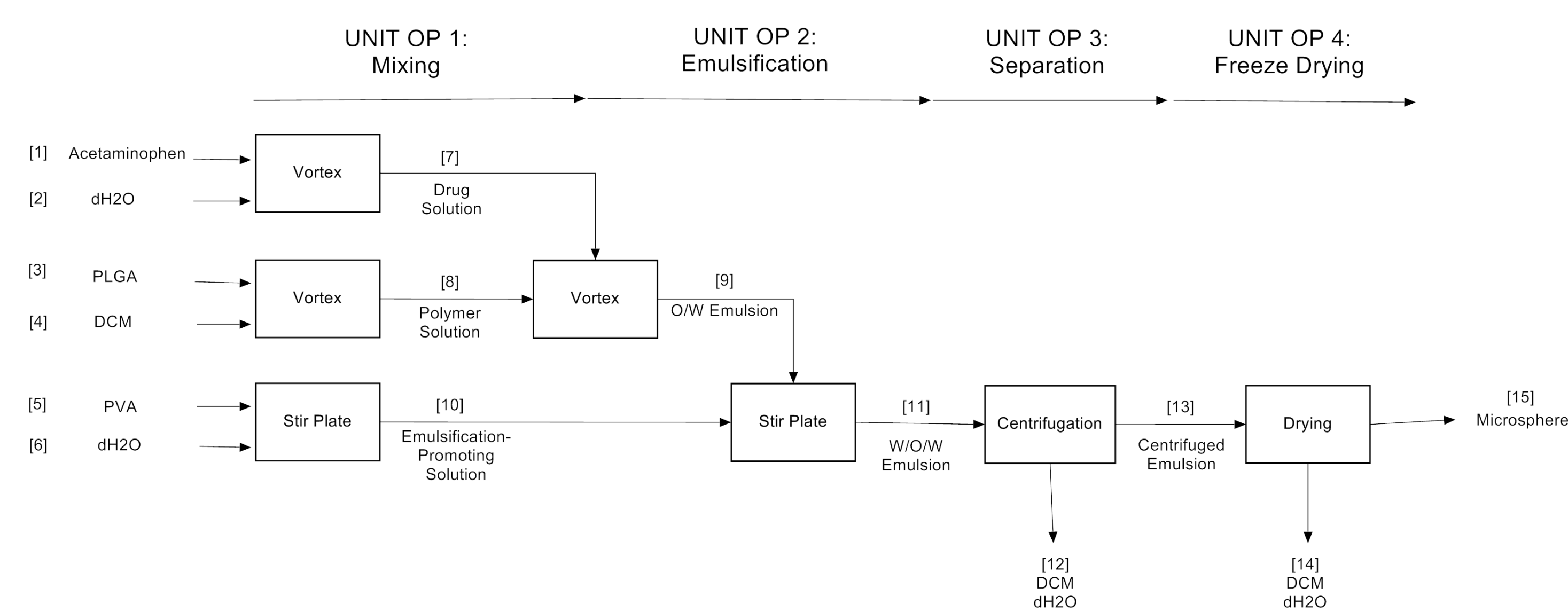
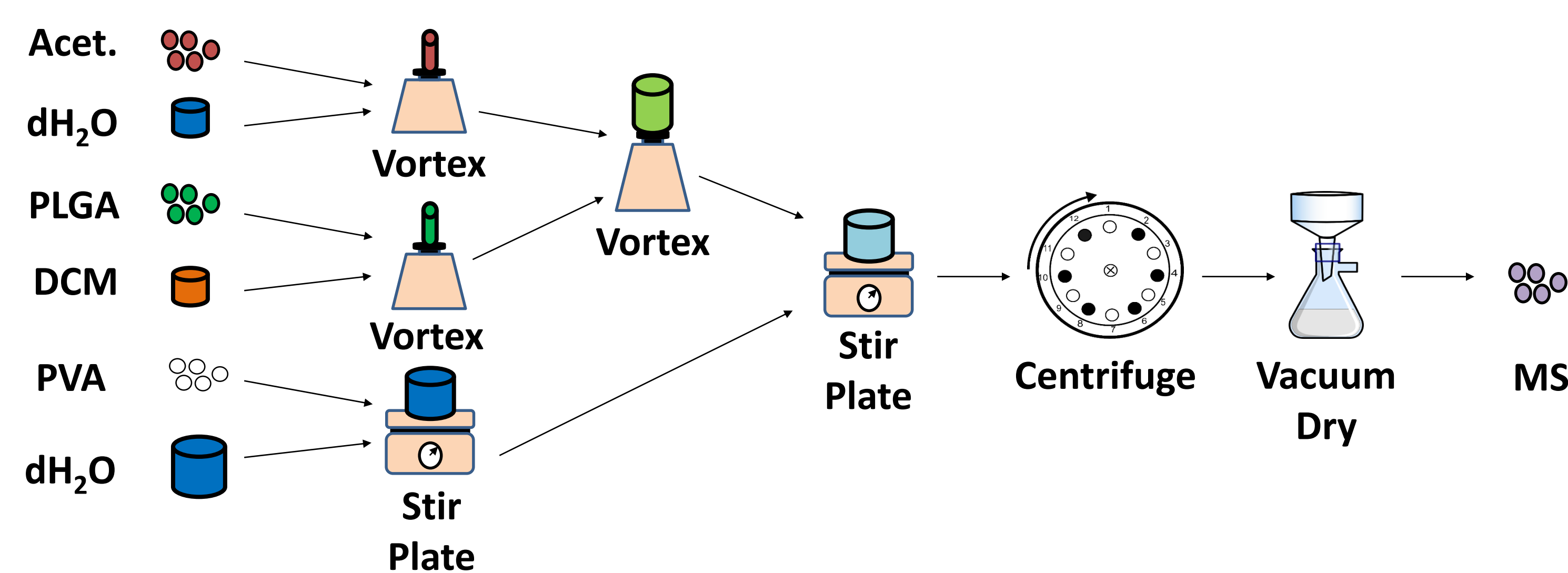


Figure 1: Scanning Electron Micrograph (SEM) of PLGA microspheres.

Process Flow Diagram



Experimental Procedure



Results

- MS formed a yellow-green film, rather than a powder as expected
- Vacuum drying was insufficient

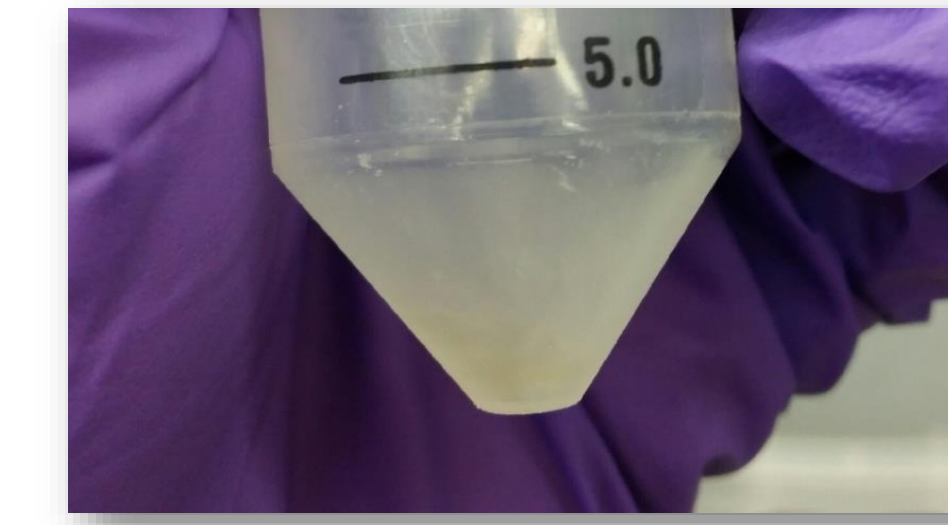


Figure 2: PLGA microspheres from lab experiments.

Optimization

Mixing & Emulsification

- Optimized with respect to impeller speed
- Trade-off between power consumption and mixing time
- Identical models used for both unit operations

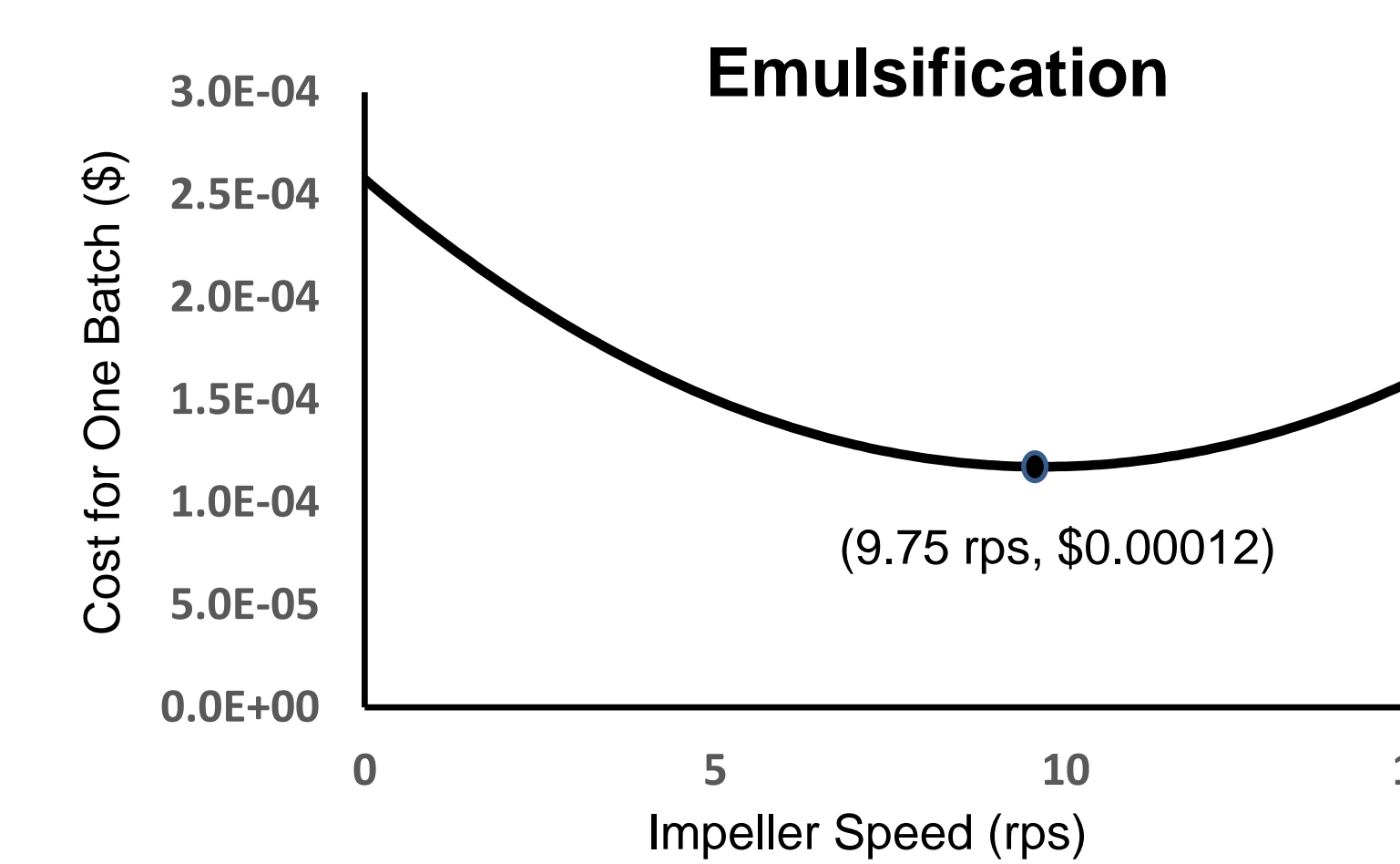


Figure 3: Emulsification batch operating cost as a function of impeller speed. The optimization point for this unit operation is a speed of 9.75 rpm for a batch cost of \$0.00012.

Solvent Removal

- Both the filtration and drying stages contribute to solvent removal
- Optimized around the percent of solvent removed in each phase

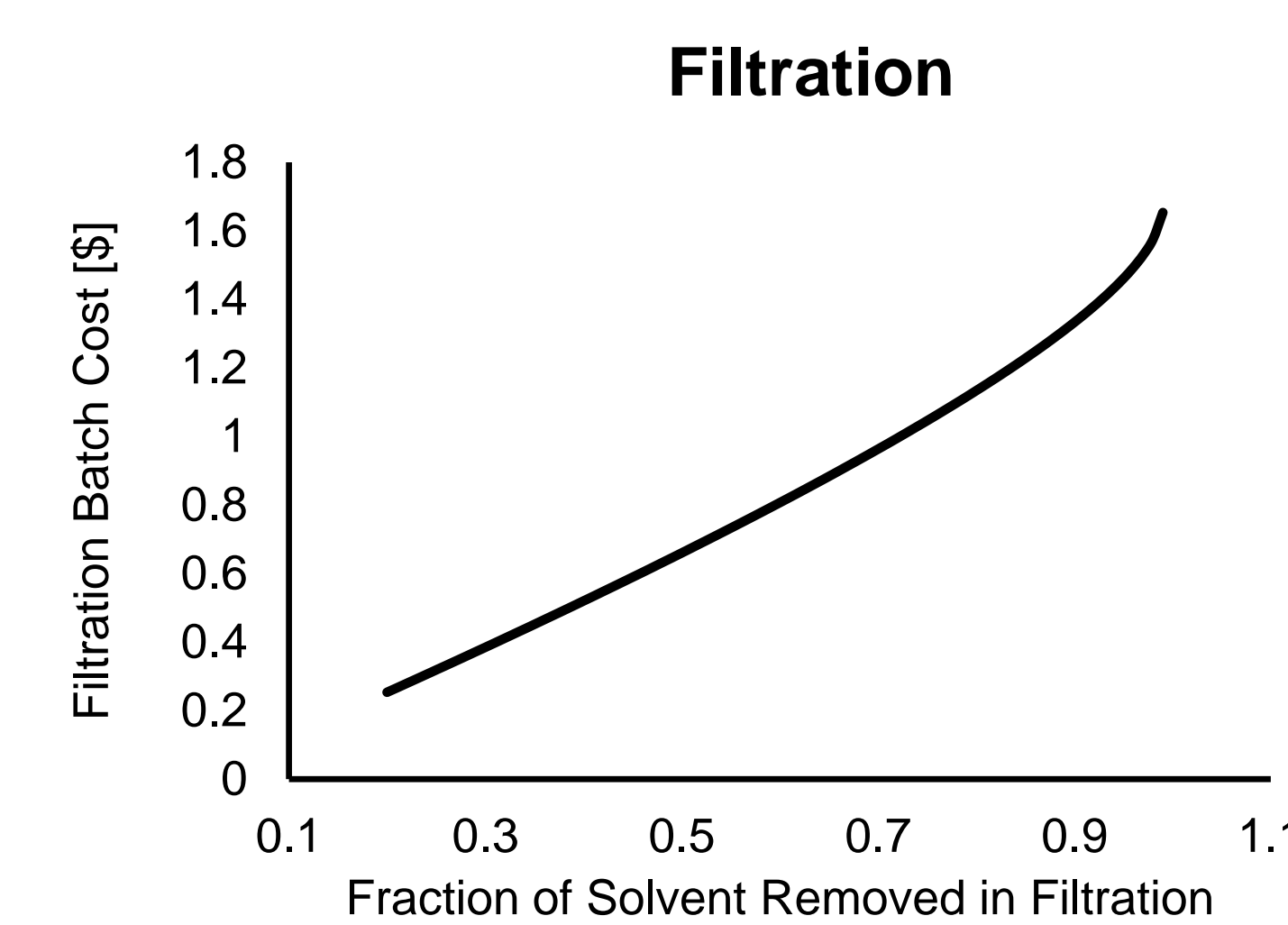


Figure 4: Total cost of filtration stage as a function of solvent fraction removed during filtration. The relationship is mostly linear with a sharp upwards tick in the upper range.

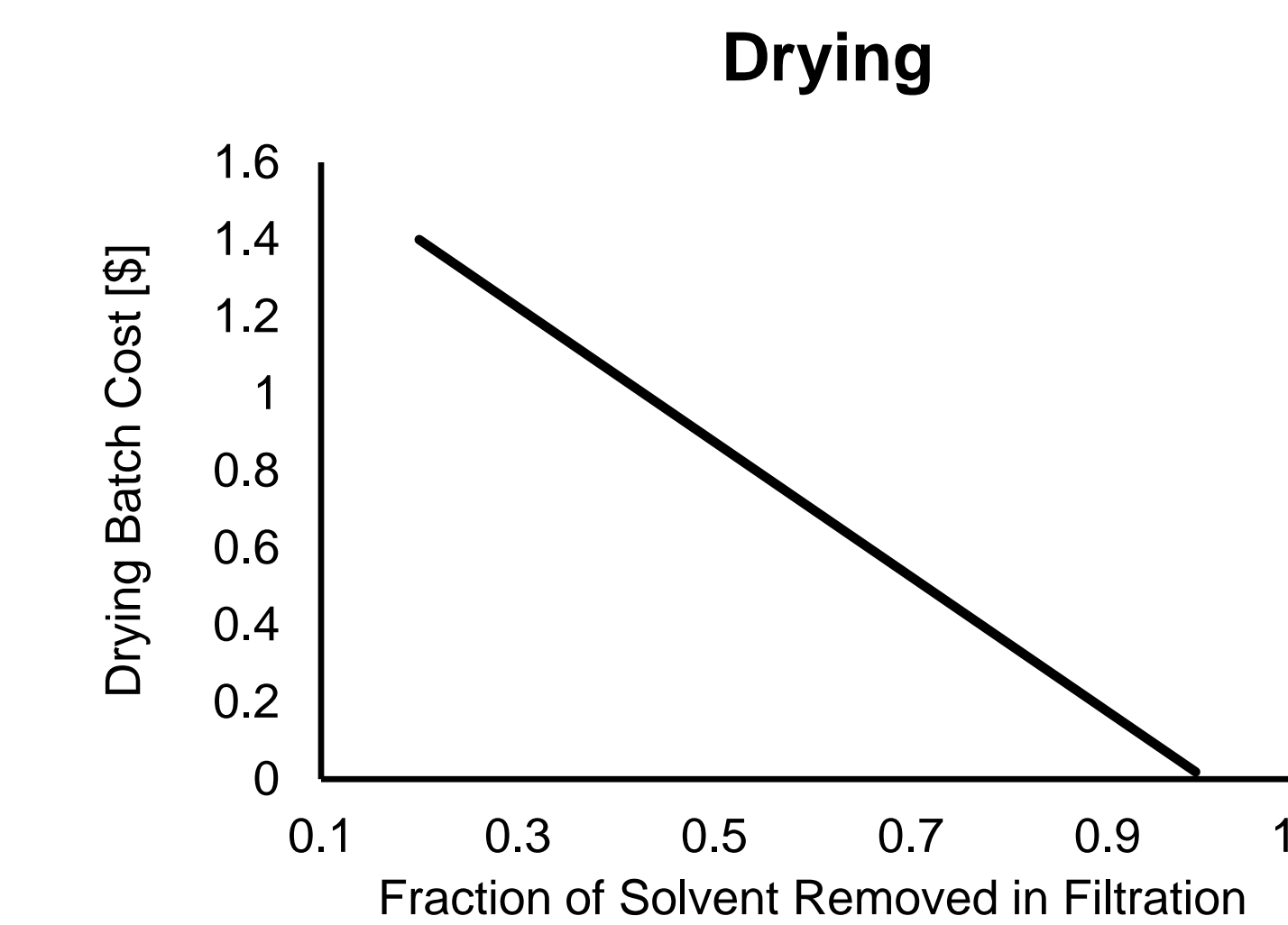


Figure 5: Total cost of drying stage as a function of solvent fraction removed during filtration. The relationship is strictly linear and proportional to amount of solvent remaining after the filtration stage.

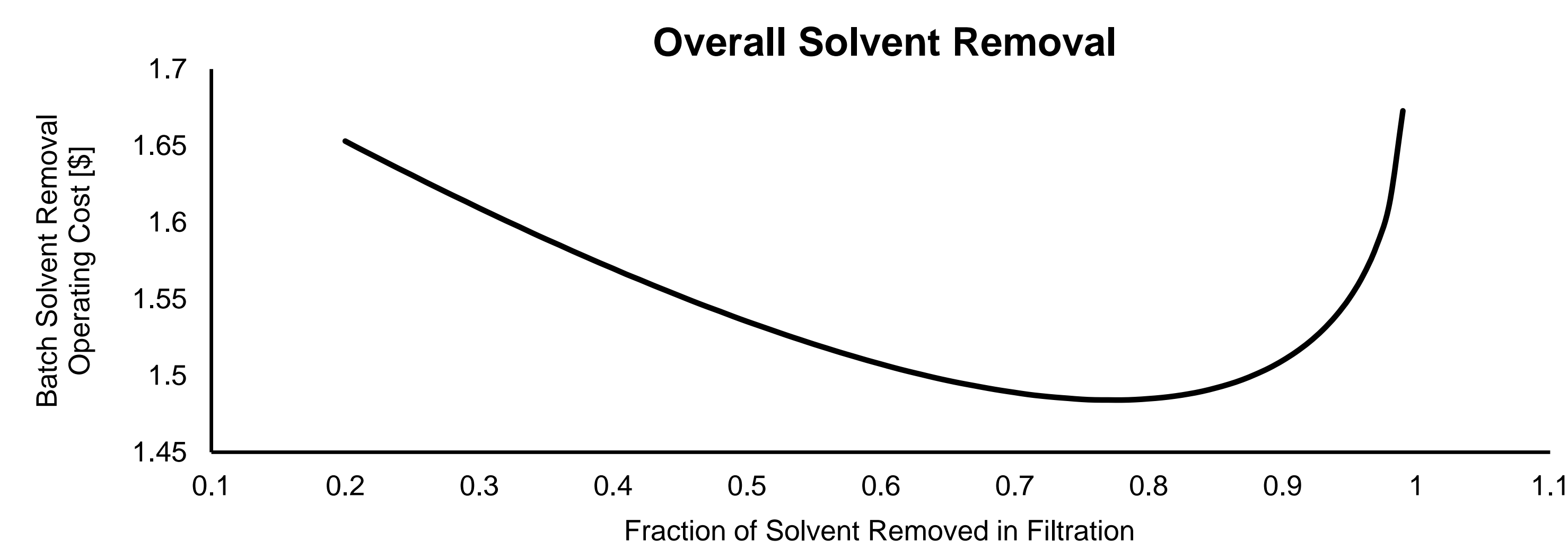
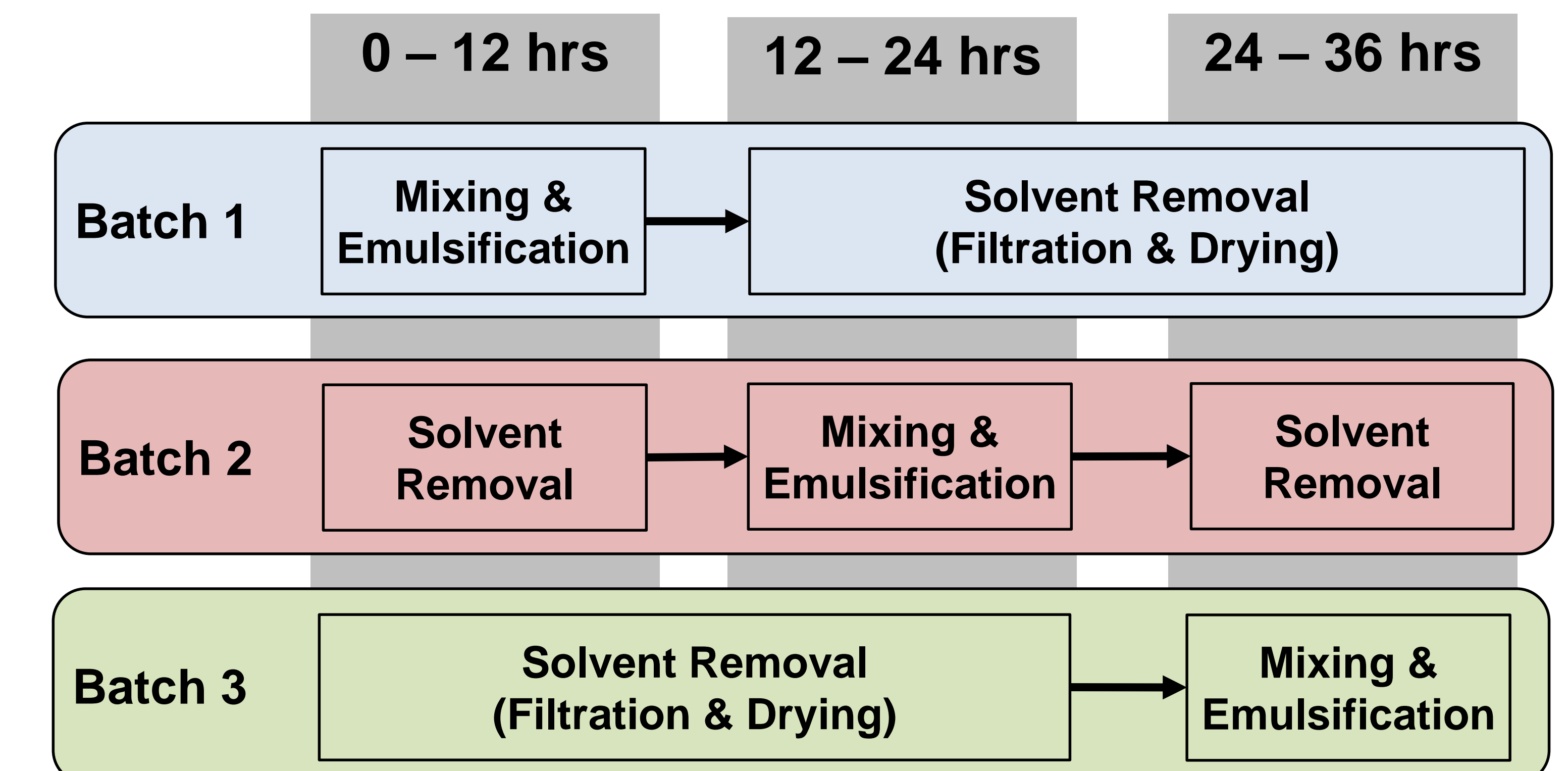


Figure 6: Total operating cost per batch of solvent removal plotted against fraction of solvent removed during filtration. The optimization point is at 78% solvent removal during filtration with an operating cost of \$1.41 / batch.

Plant Schedule

- Mixing and emulsification operate for around 12 hours
- Filtration and drying operate for around 24 hours
- 3 batches can be run simultaneously



Business Plan

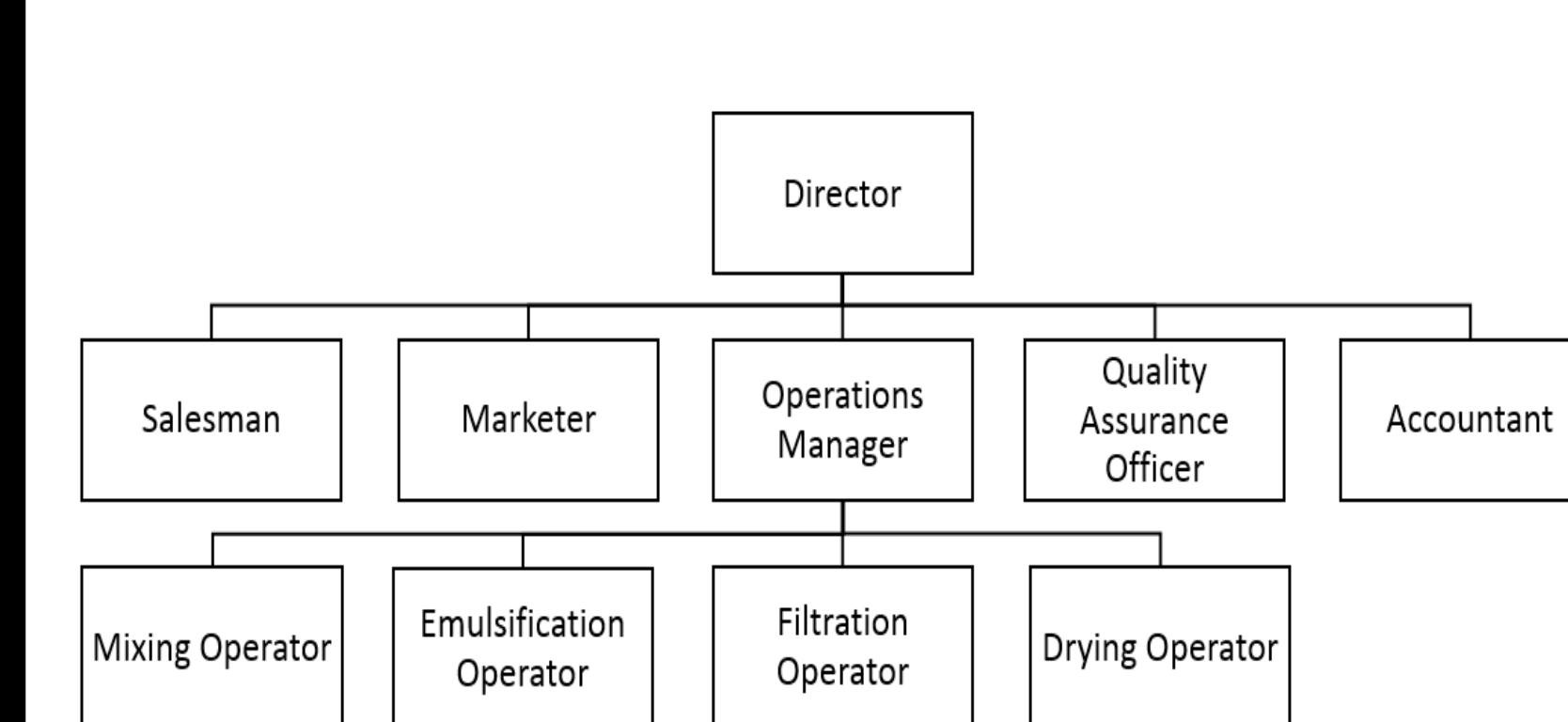


Figure 7: Employee organizational chart for plant operation.

Capital Costs	
Purchased Equipment	\$31,135.90
Equipment Installation	\$12,139.10
Contingency	\$11,516.58
Rent for 1 Year of Operation	\$91,980.00
Working Capital	\$23,344.43
Total Capital Investment	\$138,980.11

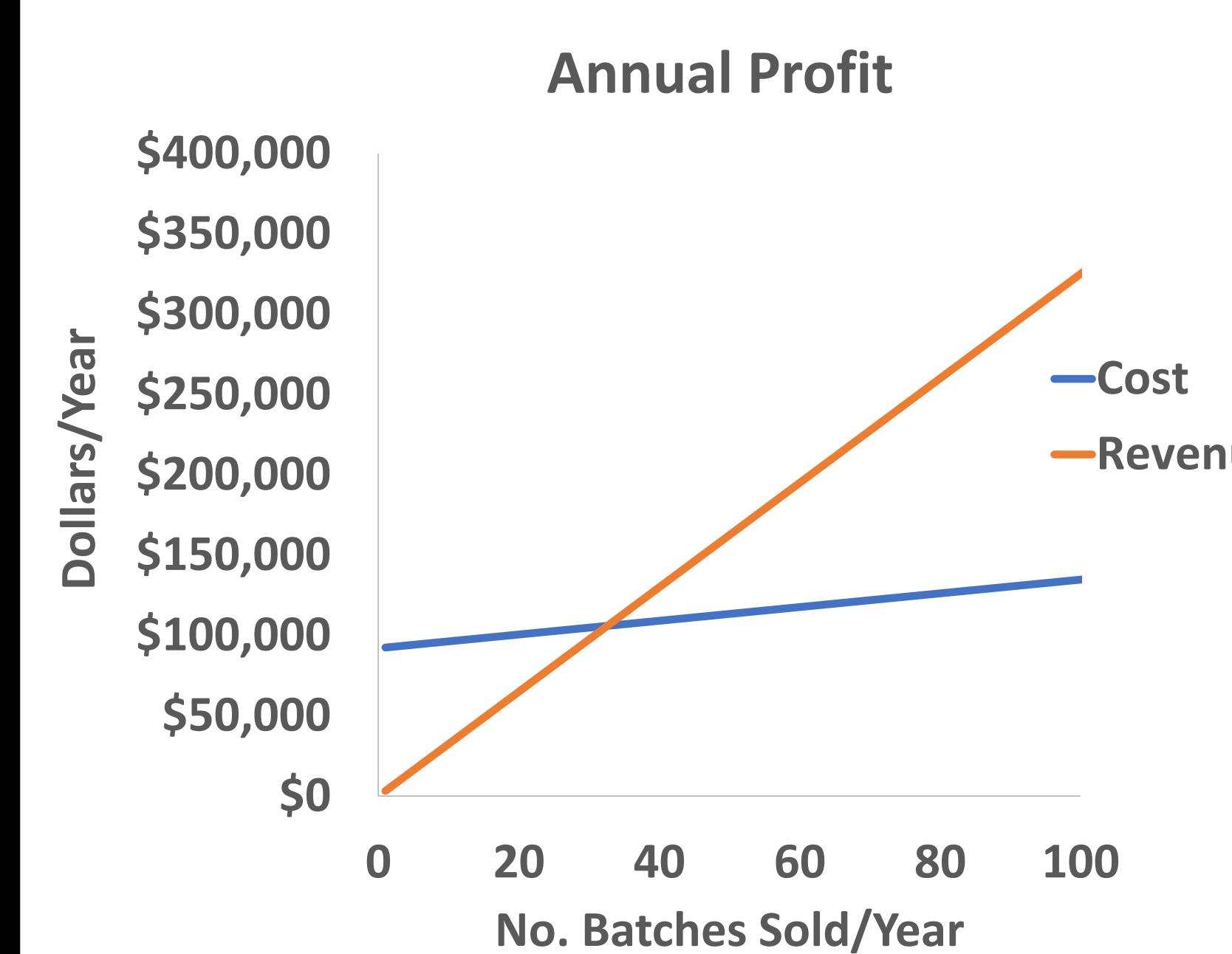


Figure 8: Total revenue and cost (\$/year) as a function of the number of microsphere batches sold annually. The price per batch was \$3,250.

Manufacturing Cost Per Batch	
PLGA	\$51.20
DCM	\$24.98
PVA	\$21.36
Methanol	\$1.59
Labor	\$144.00
Delivery	\$40.00
Utilities	\$1.68
Total Direct Costs	\$284.81
Indirect Costs	\$142.41
Total Manufacturing Cost	\$427.22