

MERCK Process Scale up and Technical Transfer for an Existing Life Saving Product

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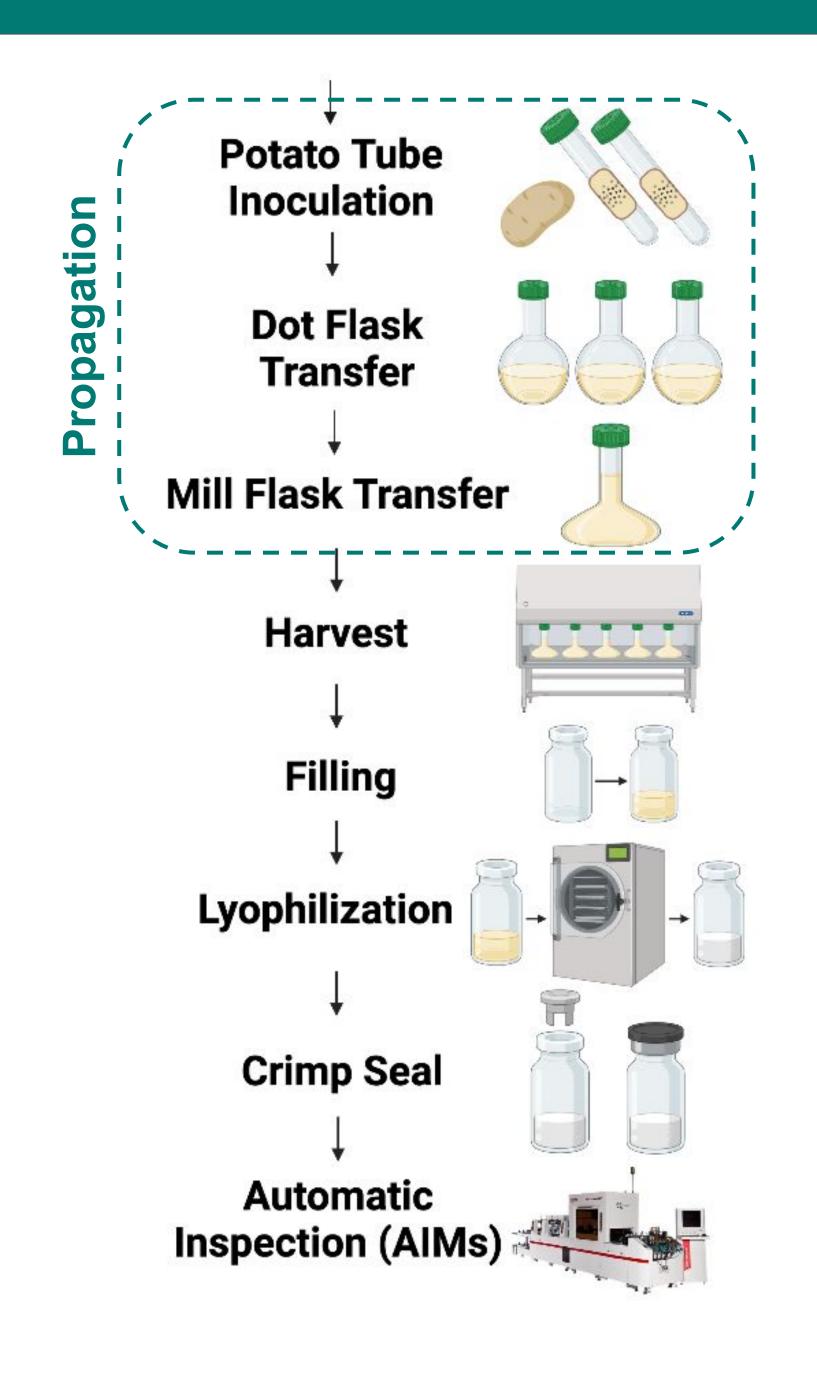


1. Introduction/Project Overview

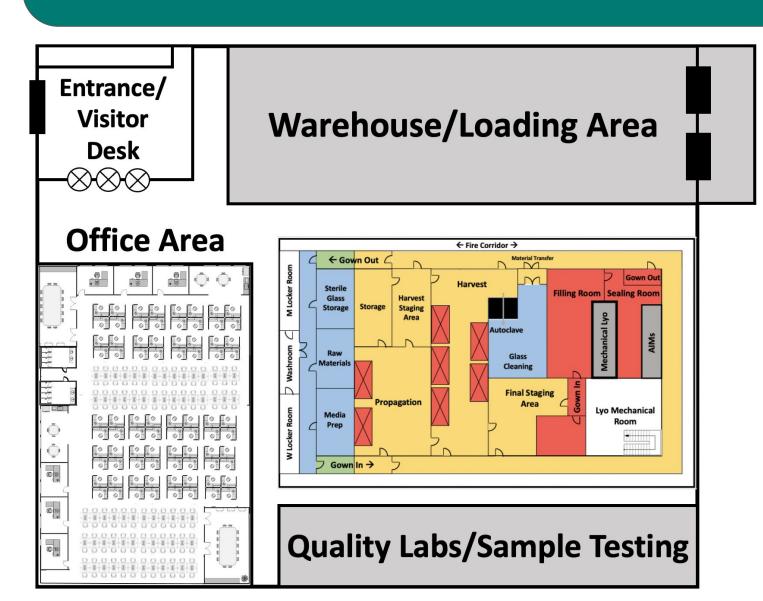
Goal: Design a new facility to accommodate a three-fold increase in capacity of an existing product. Explore equipment, safety, human resources, and facility space needed for the new process. Motivation: With Merck being the sole manufacturer of this product, increasing production capacity will help save thousands of lives.

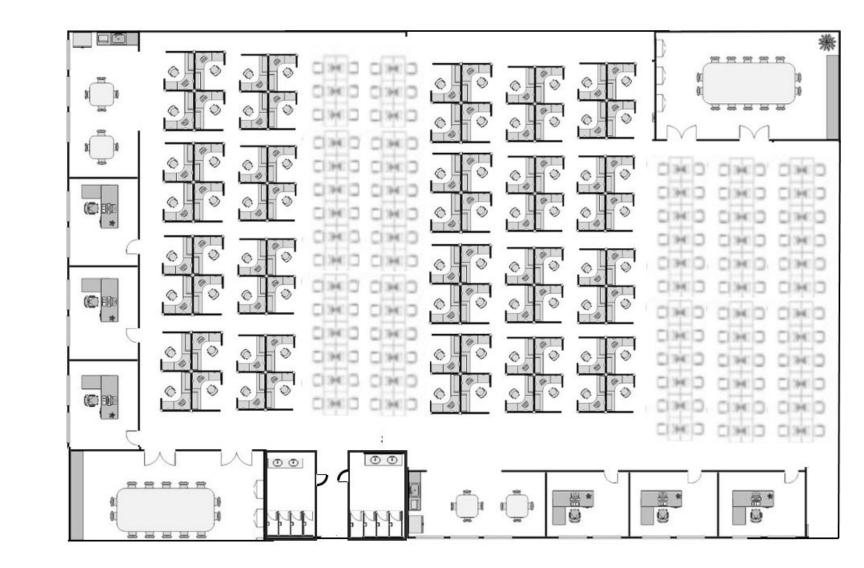
Challenges: Seamless transfer to new facility utilizing updated technology and equipment

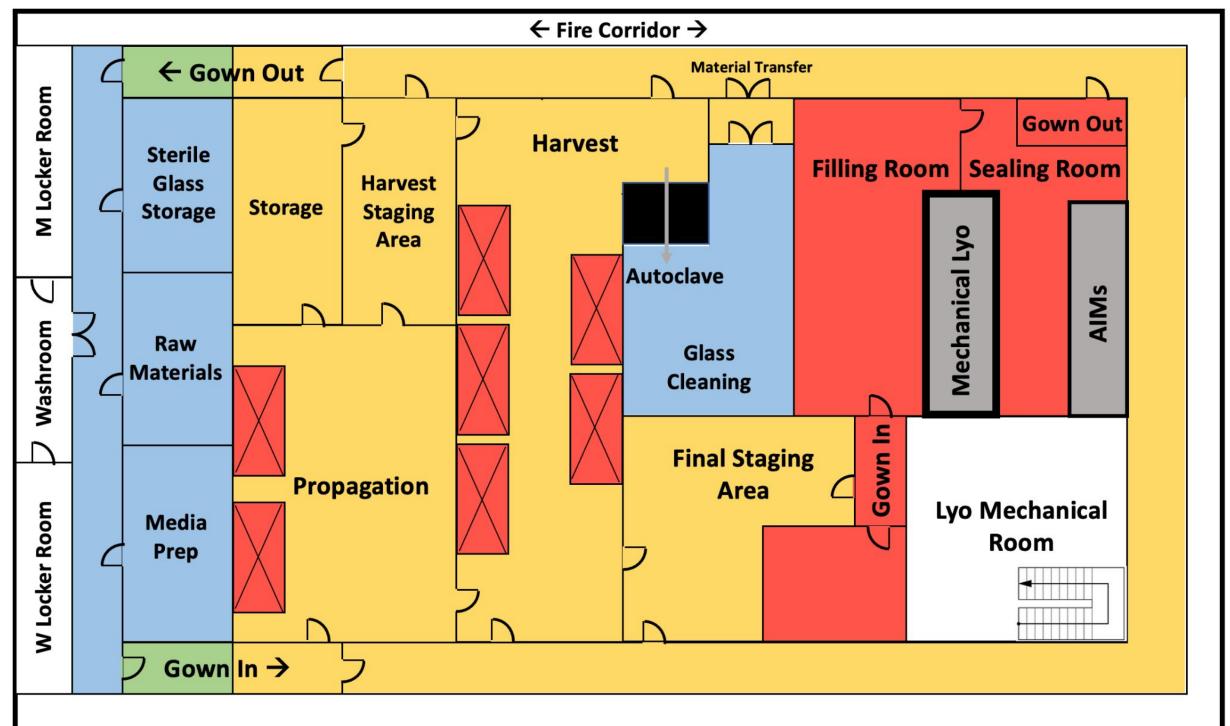
2. Process Flow Diagram

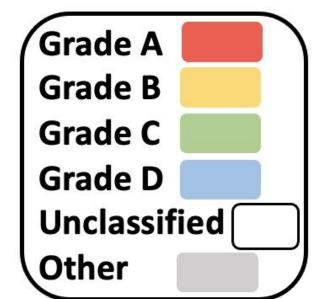


3. Facility Layout









4. Proposed Modifications for Upscale

Considered Modifications:

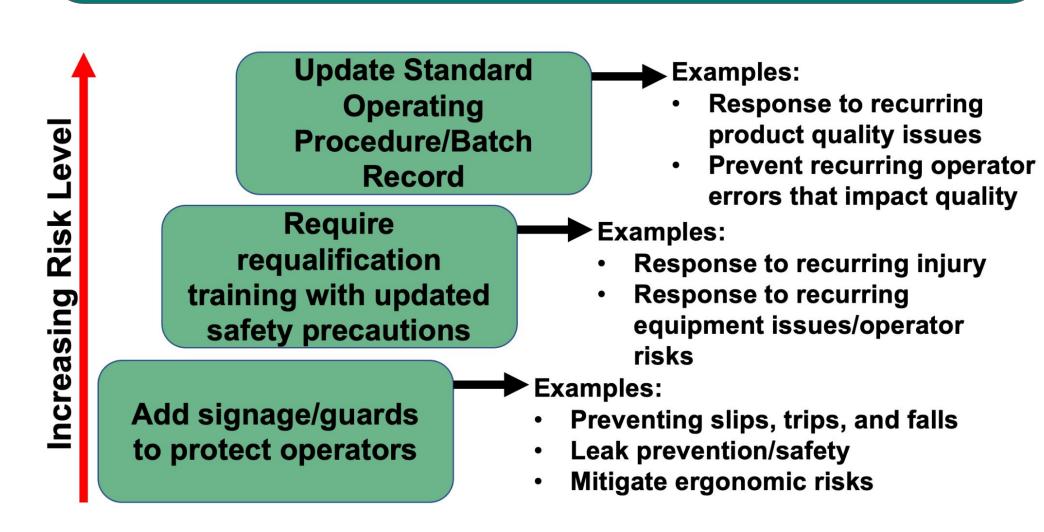
Single-Use Equipment in Culture Propagation and Harvesting

- Different sizes of Lyophilizers
 Purchasing a backup and redundancy to accommodate new production capacity
- Implement new technology to decrease inspection time

Implemented Modifications:

- Use of one lyophilizer, 3x the size of the current production lyophilizer
- lyophilizer to account for maintenance and downtime
- Utilize Automatic Inspection Machines (AIMs) to increase efficiency

5. Risk Mitigation Safety Hierarchy



6. Projected Financial Analysis

 $COM_{d} = 0.180FCI + 2.73C_{OL} + 1.23(C_{IIT} + C_{WT} + C_{RM})$

Cost Category	Cost/yr (USD)
Utility Cost	13,252,359.84
Capital Cost	20,000,000
Direct Labor Cost	1,120,000
Raw Material Cost	1,600,000
Waste Cost	3,008

Cost of Manufacturing: \$ 13,252,360/yr **Net Profit:** \$82,747,640/yr

7. Conclusion

- Scaled-up manufacturing process to meet the global demand
- Implemented new technology and equipment such as AIMs and Lyophilizers

Acknowledgments

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