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## API Drying and Packaging Technology Upgrades

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Certain classes of active pharmaceutical ingredients (APIs) require higher levels of containment during handling. This project explores upgrades and new technology to improve currently used systems. The upgrades will include containment during drying and packaging while maintaining required ergonomic, industrial health, and GMP requirements. Design of this system and a full economic analysis have been performed for these upgrades.

This project details the profits and costs that are associated with the conversion of the API drying process from a batch process to a semi continuous process using an agitated thin film evaporator. The implementation of the new equipment is expected to improve the containment of high potency API products with OEB 4 and OEB 5 ratings. The implementation of the evaporator would allow for the API drying process to be fully contained, limiting the amount of operator exposure. Using the current system, operators must manually discharge the product after each batch of drying, which puts the operators at increased risk for product inhalation. The agitated thin film evaporator is self-discharging, which reduces the amount of product contact operators experience during processing. The agitated thin film evaporator operates on the principle that a thick, washed slurry is fed to the equipment and is dried in a rotational drum using steam while an agitator continuously agitates the product for homogeneity. In conclusion, the team determined that it would cost the company approximately 19 cents to dry one gram of product A to meet an assumed minimal acceptable rate of return (MARR) set at 25% for the project.

With a projected payback period of 3.74 years, and a return on investment (ROI) of 24.437%, given a MARR of 25%, the team concluded that the estimated fixed capital investment for the implementation of the agitated thin film evaporator would be approximately \$16,200,000. This cost includes parts, shipping, installation, labor, and the acquisition of any additional piping or utilities. The calculated internal rate of return (IRR) for the project is 25%, indicating that establishing a MARR below 25% for the project would not be profitable. Based on these findings, the design team recommends that the agitated thin film evaporator is implemented to increase operator safety and maximize process efficiency by reducing drying time.