Executive Summary

This Capstone project applies the DMAIC methodology to reduce the visual defect rate of Concerta tablets manufactured at the Johnson & Johnson Innovative Medicine Gurabo site for the Japan market. The project focuses on the 18 mg, 27 mg, and 36 mg dosage strengths and includes the manufacturing process from granulation through tablet counting. The customer-detected defect signal occurs during Fuji, Japan AQL inspection prior to packaging. During the Define phase, the team established the business context, project scope, customer requirements, process boundaries, stakeholder map, high-level process flow, SIPOC, and CTQ requirements. The Voice of the Customer was developed using three sources: Fuji Japan AQL inspection data, operator survey results across manufacturing shifts, and interviews with OROS manufacturing leadership and supervision. These inputs consistently point to visual defects primarily related to printing and coating integrity. During the Measure phase, the team quantified the current problem using both historical Fuji defect data and an NC Investigation Defect Catalog covering December 2024 through December 2025. Historical AQL sampling across 93 bulk lots identified 20,415 visual defects, with printing defects representing 51.7% and coating-related defects representing 24.4% of the total defect count. Together, these two categories account for 76.1% of all defects identified in the historical Fuji data. More recent customer data confirmed that Concerta defect rates exceeded target levels for all three dosage strengths reviewed. The 18 mg strength had an average defect rate of 2.28% compared to a target of ≤1.80%, the 27 mg strength had an average defect rate of 5.68% compared to a target of ≤4.00%, and the 36 mg strength had an average defect rate of 0.89% compared to a target of ≤0.80%. The measurement baseline indicates that the defect pattern is not random. Printing-related issues and coating failures dominate the investigation data, with Concerta 18 mg and 27 mg representing the highest concentration of investigations. Several lots also recur across multiple investigations, indicating potential process stability concerns. These findings support a focused Analyze phase centered on process stability, defect detection capability, setup variation, and the process conditions associated with printing and coating defect occurrence.