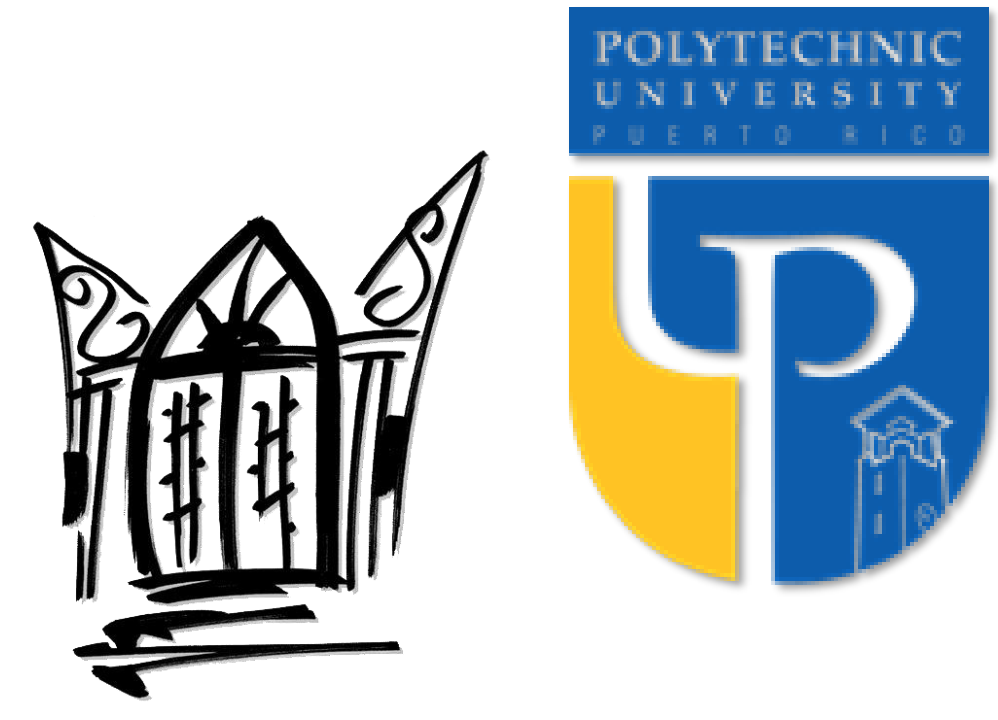




Standardization of Daily Management Systems in Medical Device Production Operations

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Abstract

This project focused on the standardization of the Tier 2 Daily Management System (DMS) within the Mechanical Heart Valve (MHV) Carbon Manufacturing Area. The project integrated KPI dashboards, visual management tools, escalation processes, and workforce readiness monitoring systems intended to support communication, operational visibility, accountability, and operational alignment across daily operations. Using the 4P Assessment Framework and DMAIC methodology, opportunities related to KPI visibility, escalation consistency, and operational monitoring were identified. Standardized Tier 2 dashboards and supporting operational tools were developed to support structured performance monitoring and cross-functional communication within the manufacturing environment.

Introduction

Medical device manufacturing environments require strong operational discipline, communication, and coordination across multiple organizational levels to ensure consistent performance and product quality. Variability in Tier 1 and Tier 2 execution may reduce KPI visibility, delay escalation of critical issues, and create inconsistencies in operational monitoring practices. This project focused on the standardization of Tier 2 Daily Management System (DMS) practices within the Mechanical Heart Valve (MHV) Carbon Manufacturing Area to support communication consistency, operational visibility, and more structured operational management activities.

Literature Review

Operational excellence frameworks emphasize the importance of standardized work, visual management, KPI visibility, and structured escalation systems to support operational consistency and continuous improvement. Standardized daily management systems improve communication flow, accountability, coordination, and operational visibility across organizational levels. Tiered escalation structures enable operational concerns, risks, and priorities identified at the frontline level to be systematically reviewed and escalated through leadership levels based on organizational impact and urgency. These structures support improved communication alignment and coordination between operators, supervisors, managers, and leadership teams.

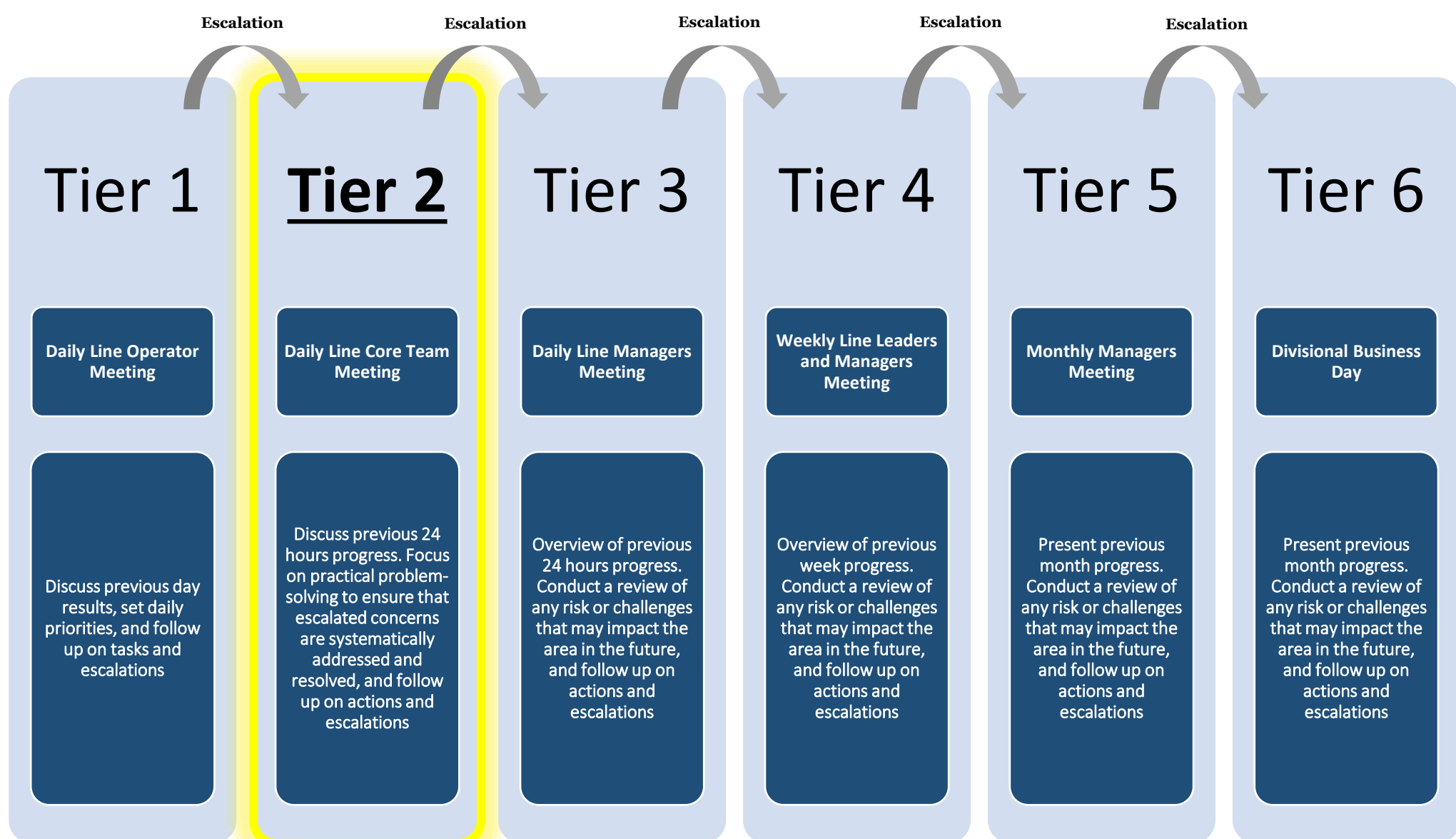
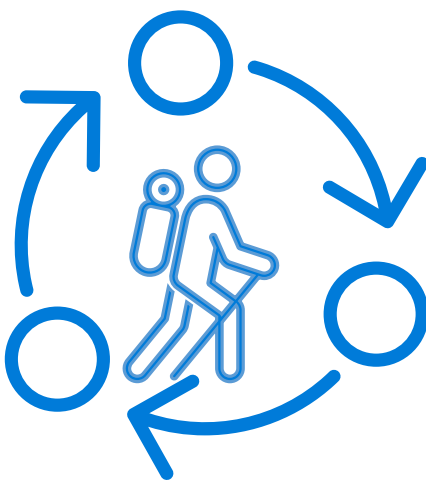


Figure 1
Tier Meetings Structure

Methodology

The project followed a structured engineering management methodology integrating the 4P Assessment Framework with the DMAIC (Define, Measure, Analyze, Improve, Control) approach to evaluate and standardize Tier 2 daily management practices within the Mechanical Heart Valve (MHV) Carbon Manufacturing Area. The methodology emphasized operational alignment, communication consistency, KPI visibility, and structured escalation management across production, quality, engineering, maintenance, and planning functions. Stakeholder assessments, operational observations, and review of existing Tier meeting practices were used to identify opportunities for improving operational monitoring and accountability. The project resulted in the development of standardized dashboards, visual management tools, workforce readiness systems, and escalation structures intended to support more consistent daily management execution and long-term operational sustainability.



Define

Identified variability in Tier execution, communication practices, escalation processes, and KPI visibility through stakeholder discussions, operational observations, and assessment of existing Tier meeting structures.

Measure

Defined Tier 1 and Tier 2 KPIs, evaluated operational visibility gaps, and assessed existing performance monitoring practices, escalation tracking methods, and operational review activities.

Analyze

Evaluated root causes of operational variability, inconsistent Tier execution, communication gaps, and lack of standardized escalation and accountability structures across organizational levels.

Improve

Developed standardized Tier 2 KPI dashboards, visual management templates, escalation tracking systems, workforce readiness tools, and operational monitoring structures intended to support more consistent daily management practices.

Control

Established sustainability mechanisms including KPI review structures, escalation pathways, standard work expectations, action follow-up practices, and visual management tools intended to support long-term operational monitoring and continuous improvement activities.

Results

The project resulted in the development of a standardized Tier 2 Daily Management System framework for the MHV Carbon Manufacturing Area. The framework incorporated standardized KPI dashboards, visual management tools, escalation pathways, accountability structures, and operational monitoring templates intended to support communication consistency and operational visibility across production, quality, engineering, maintenance, and planning functions.

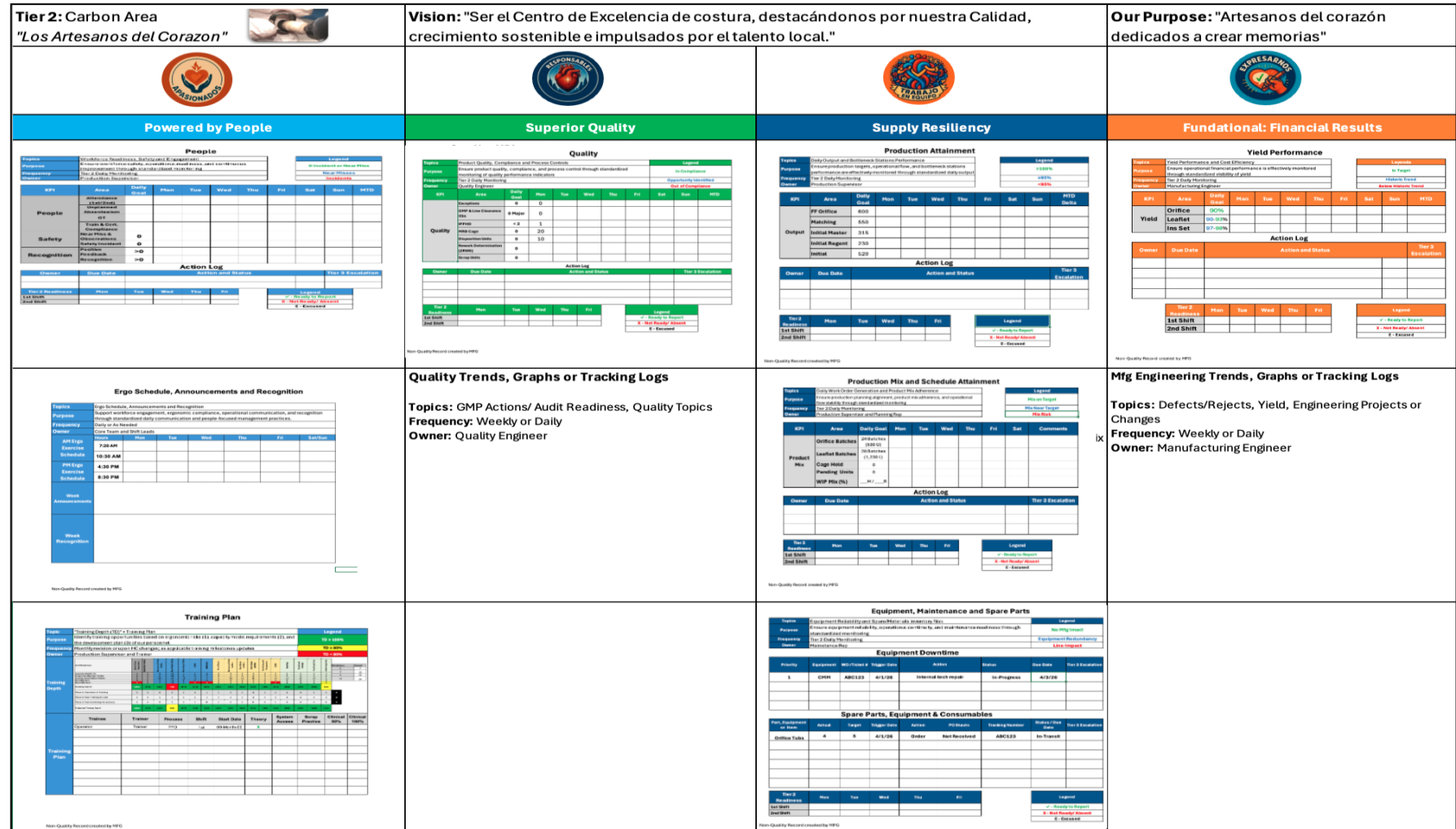


Figure 2
Tier 2 DMS Format

Operational Pillars:

Powered by People

Focused on workforce readiness, training depth, personnel allocation, and ergonomic scheduling practices.

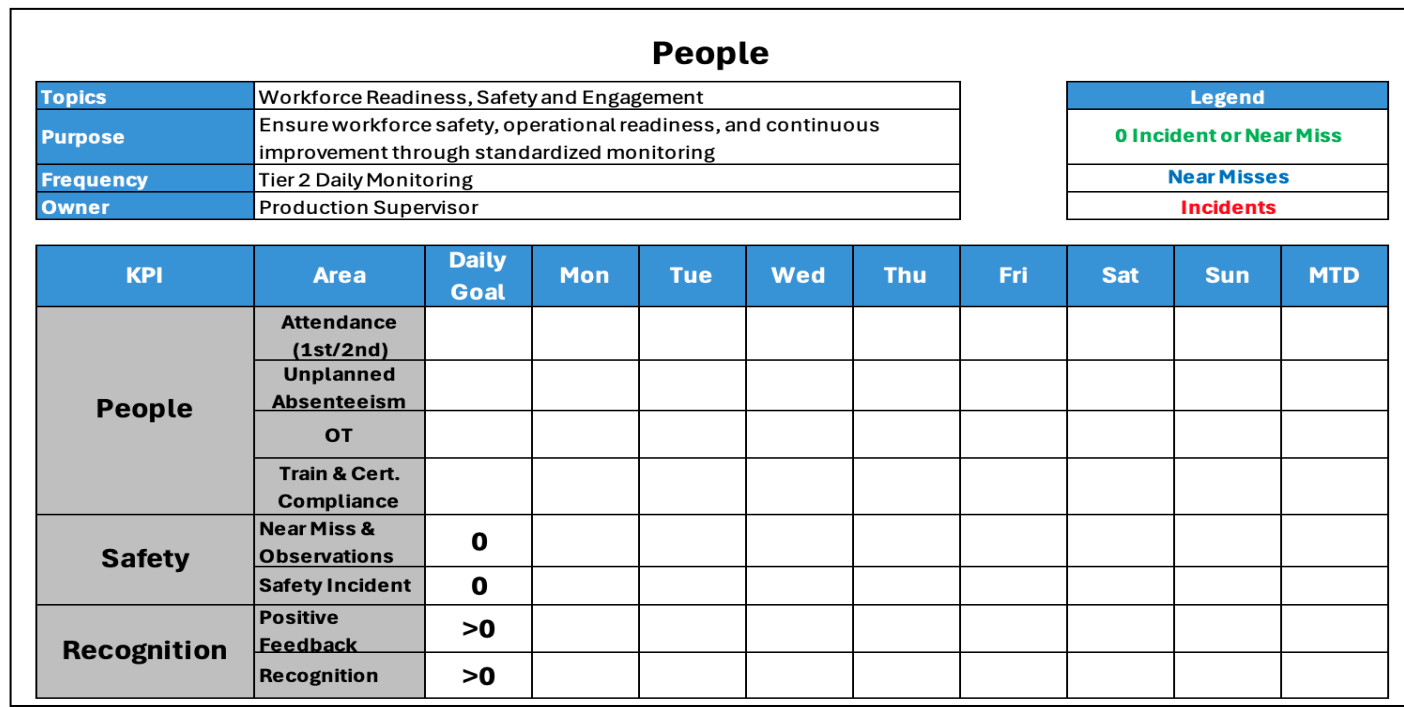


Figure 3
People KPIs Dashboard

Superior Quality

Integrated audit readiness, quality event monitoring, scrap visibility, and compliance observations.

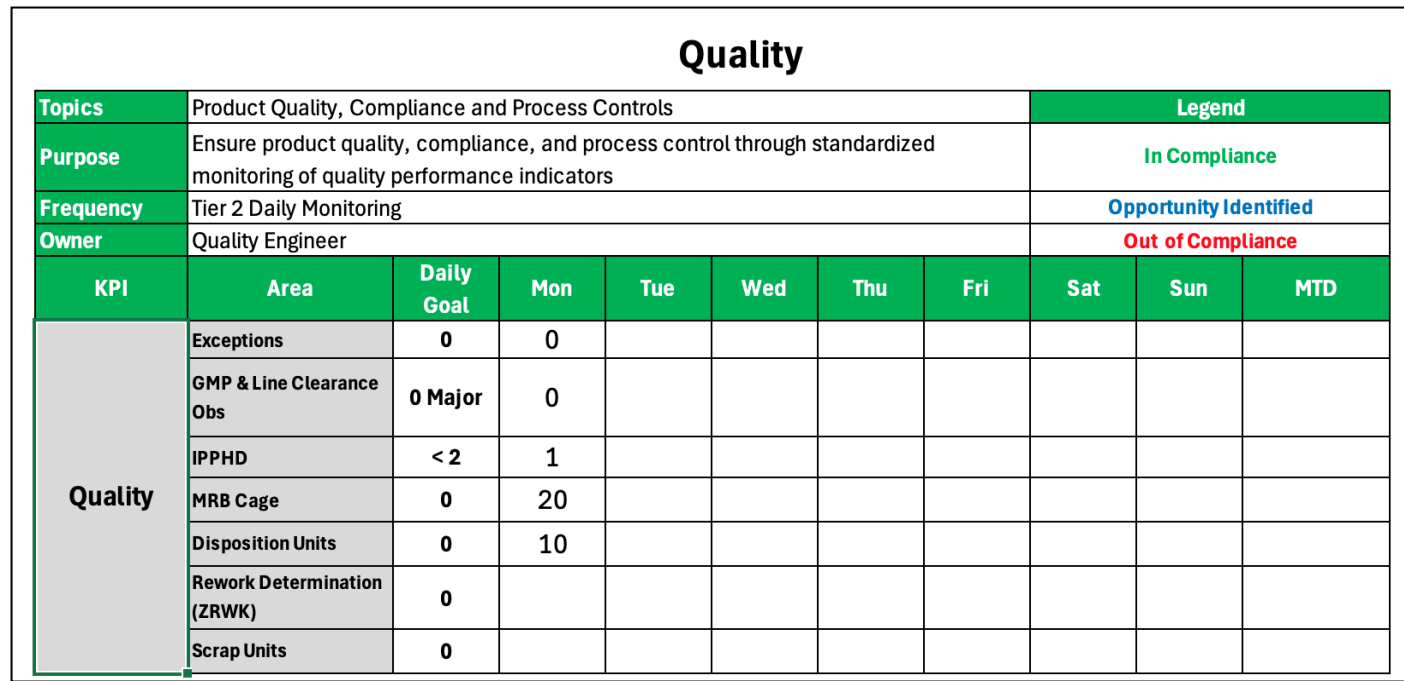


Figure 4
Quality KPIs Dashboard

Supply Resiliency

Included production attainment, schedule adherence, downtime monitoring, and inventory management metrics.

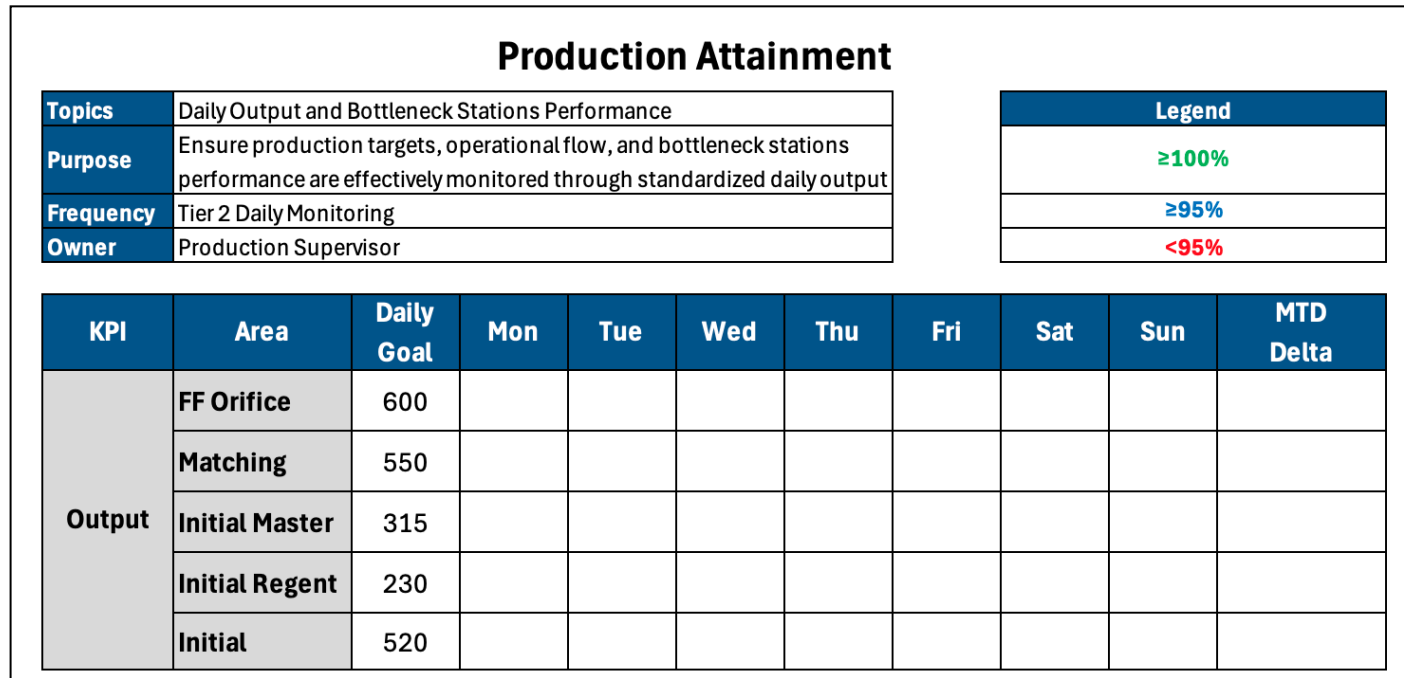


Figure 5
Supply Resiliency KPIs Dashboard

Foundational Financial Results

Focused on yield monitoring, operational efficiency visibility, and engineering-related operational metrics.

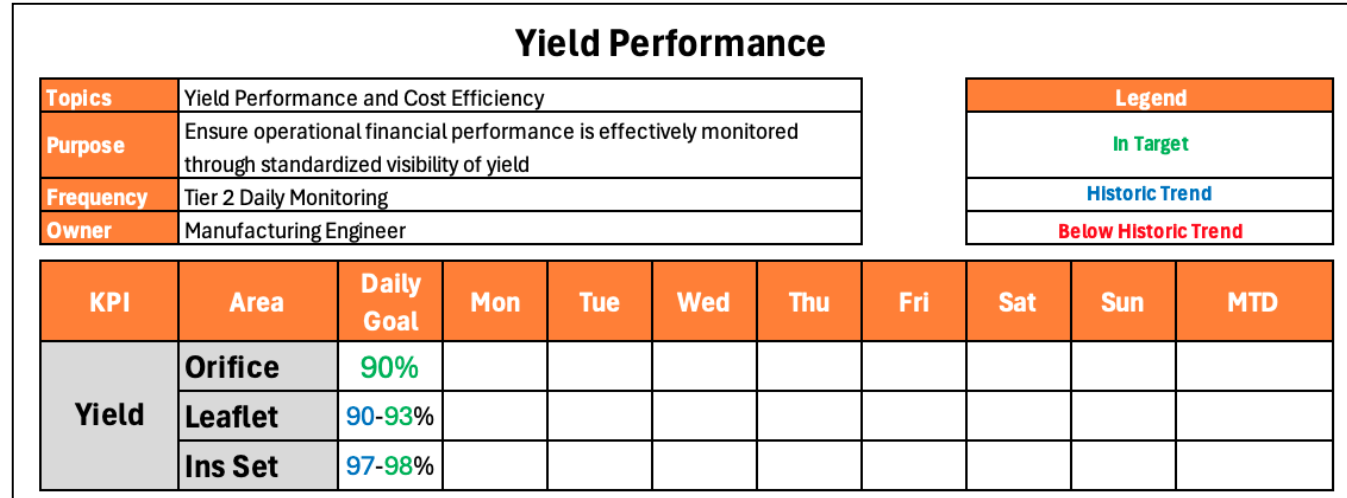


Figure 6
Financial KPIs Dashboard



Figure 7
MHV Yield performance trend from 2024 through April 2026

Early Tier 2 standardization efforts began in July 2025, with additional project implementation activities starting in March 2026. During this period, yield performance increased from 71% in April 2024 to sustained results between 91% and 94% during late 2025 and early 2026, consistently meeting or exceeding the 90% target. Additionally, 2026 yield performance remained at or above 92% through April 2026, reflecting reduced month-to-month variability compared with earlier operational periods. Although no formal quantitative analysis was conducted to establish direct causation, leadership feedback and operational trends suggested that the standardized Tier 2 structure and supporting management tools were supportive of improved operational consistency and daily review practices.

Conclusions

This project demonstrated the application of standardized daily management system principles through the development of a structured Tier 2 framework for the MHV Carbon Manufacturing Area. The project resulted in standardized dashboards, escalation pathways, accountability structures, and supporting operational tools intended to support KPI visibility, communication consistency, and operational monitoring across multiple organizational functions. Operational observations, leadership feedback, and yield performance trends observed during the project timeline suggested improved consistency in Tier 2 review practices and operational monitoring activities. Future opportunities include expansion of the standardized DMS framework into additional manufacturing areas, continued KPI trend evaluation, and future quantitative assessment of operational performance impact associated with standardized Tier management practices.

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