JL Solutions

Optimizing Manufacturing

Enhancing Efficiency and Reducing Scrap

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Executive Summary: Key Insights and Objectives

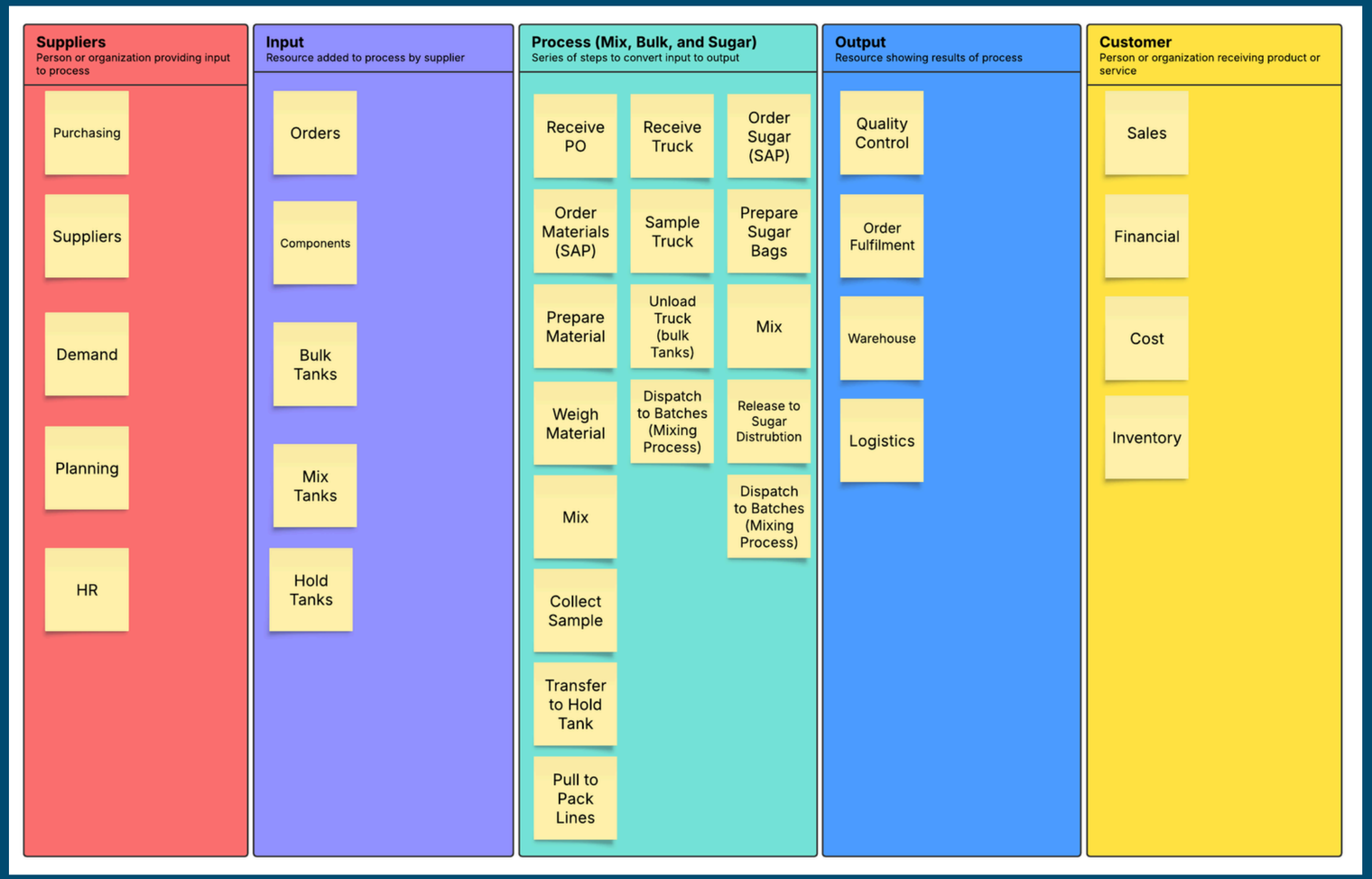
ENHANCING EFFICIENCY IN PHARMACEUTICAL MANUFACTURING

THIS PRESENTATION OUTLINES A STRATEGIC APPROACH TO REDUCE SCRAP AND IMPROVE YIELD IN PHARMACEUTICAL MANUFACTURING THROUGH DMAIC, FOCUSING ON OPERATIONAL EFFICIENCY AND REGULATORY COMPLIANCE.

Project Overview

This project aims to **reduce scrap from 8% to 3%** and improve yield from 92% to 97%, enhancing overall efficiency in liquid pharmaceutical manufacturing processes.

SIPOC Diagram Overview



SUPPLIERS AND INPUTS

Key suppliers provide essential raw materials and active pharmaceutical ingredients (APIs), ensuring consistent quality. Inputs include specifications, equipment, and personnel needed to support the manufacturing process.

PROCESSES AND OUTPUTS

The process encompasses all steps from formulation to packaging, aiming for optimal efficiency. Outputs consist of high-quality pharmaceutical products that meet regulatory standards and customer expectations.

Voice of Customer Insights

QUALITY ASSURANCE

Customers expect consistent product quality, requiring rigorous adherence to **cGMP standards** and validated processes to ensure safety and efficacy throughout the manufacturing lifecycle.

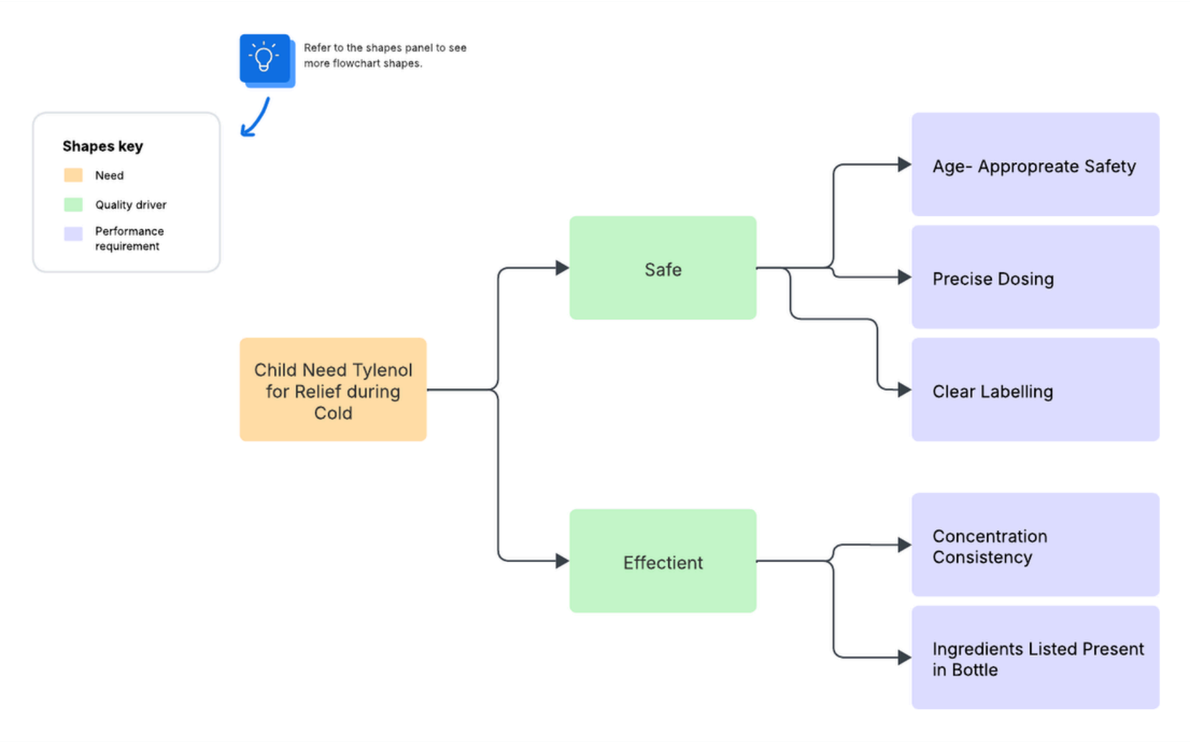
TIMELY DELIVERY

Meeting delivery schedules is crucial; customers demand reliable timelines, necessitating efficient scheduling and **inventory management** to avoid delays and ensure product availability.

COST EFFICIENCY

Competitive pricing is essential; customers seek value, which drives the need for **process optimization** to reduce waste and enhance overall operational efficiency while maintaining quality standards.

CTQ Tree Overview



DEFINING QUALITY

The CTQ Tree identifies essential quality characteristics that align with customer requirements, focusing on parameters like yield, scrap rates, and compliance with cGMP standards in production processes.

LINKING TO OBJECTIVES

Each CTQ characteristic is linked to project objectives, enabling targeted improvements in areas such as yield enhancement and scrap reduction, ultimately driving higher operational excellence and customer satisfaction.

Current State

The Current State Process Map outlines the existing workflow within the pharmaceutical manufacturing operation, highlighting key steps and associated inefficiencies.

- **Equipment Downtime:** 18 hours/month
- **Changeovers:** 12 hours
- **Operator Errors:** 8 hours
- **Deviations:** 22 human, 15 mechanical, 10 automation
- **Waiting on Packaging:** 20 hours

Takeaways:

- Packaging delays and equipment downtime account for over 65% of operational losses
- Significant opportunity for Lean improvements through SMED, preventive maintenance, standardized work, and automation

Swimlane Map

Swimlane Layout

Engineering	Supply Chain	Production	QA	Maintenance
Validate Equipment	Receive Raw Materials	Verify Batch Record	Review Material COAs	PM Schedule
	↓			
	Material Staging	Dispense Ingredients	Line Clearance Approval	
		↓		
		Prepare Mixing Vessel		Equipment Ready
		↓		
Monitor Process Parameters		Mix Batch	In-Process Testing	Respond to Equipment Failure
		↓	Sample Collection	
		Hold for QA Release	Test Results	
		↓	Approve Batch	
	Packaging Components Available	Filling Operation	Line Inspection	
	↓	↓		
	Packaging	Labeling & Cartoning	Final Batch Review	
	↓	Finished Goods	Batch Release	
	Warehouse Storage			

The Swimlane Process Map outlines key roles and handoffs in our pharmaceutical manufacturing process. It highlights responsibilities across Engineering, QA, Production, Maintenance, and Supply Chain. This visualization aids in identifying areas for improvement and **streamlining collaboration** among cross-functional teams.

61%

Current OEE Performance

Our current Overall Equipment Effectiveness (OEE) stands at **61%**, significantly below the target of 80%. This indicates substantial room for improvement in equipment utilization and efficiency.

Combine KPI cards with a simple OEE breakdown:

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------------------------------------------------------------

            Overall Equipment Effectiveness

                    61%

Target = 80%

------------------------------------------------------------

Availability          78%

Performance           83%

Quality               94%

------------------------------------------------------------

Key Loss Drivers

🔴 Equipment Downtime        18 hrs/month

🔴 Packaging Delays          20 hrs/month

🔴 Changeovers               12 hrs/month

🔴 Operator Errors            8 hrs/month

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Pareto Analysis of Variation Sources

KEY ISSUES IDENTIFIED

The Pareto chart highlights the **major contributors** to scrap and yield loss, allowing the team to focus efforts on the most impactful areas for improvement.

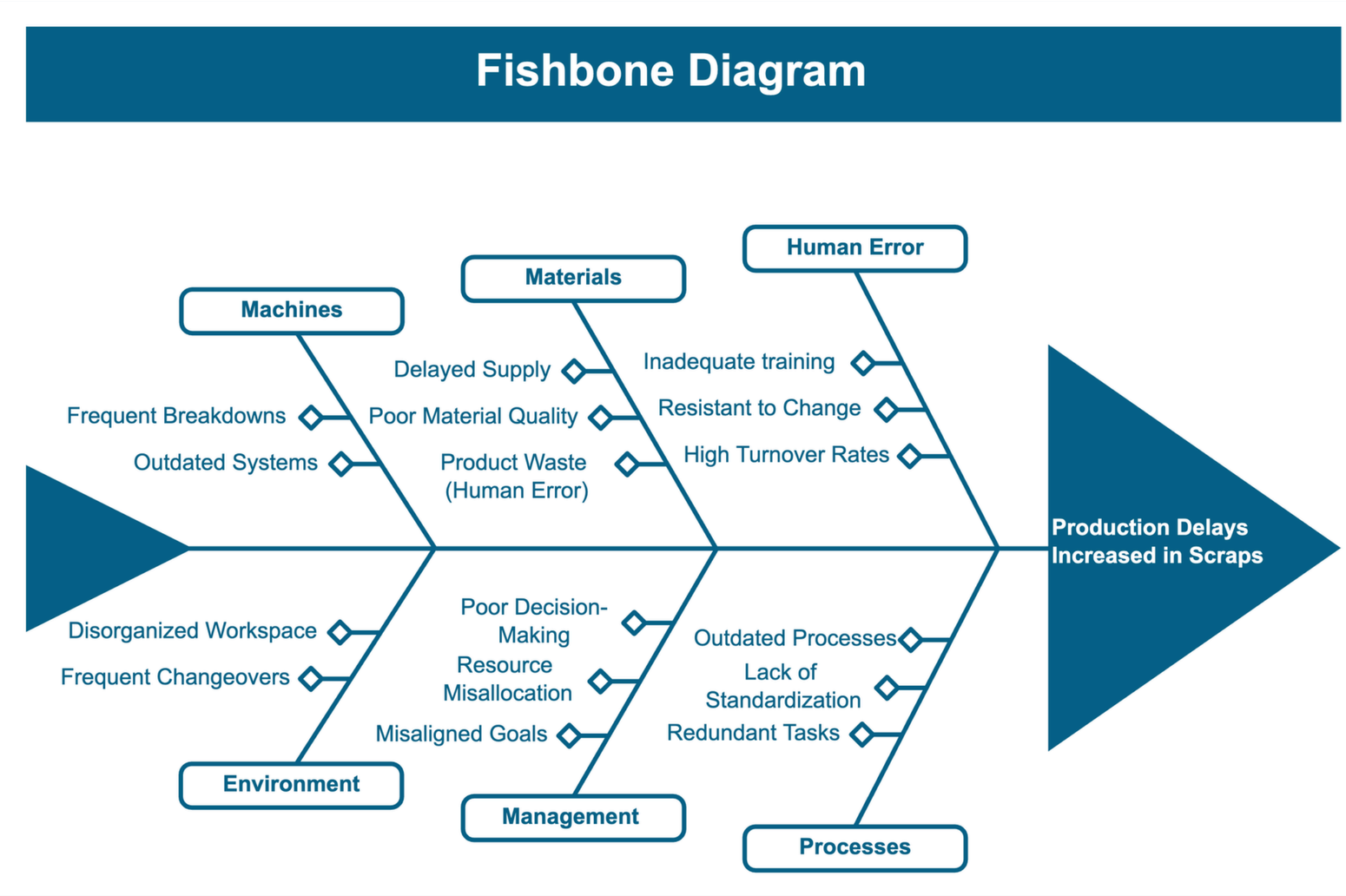
FOCUS AREAS

By concentrating on a few critical causes, such as **downtime** and changeover delays, we can effectively reduce scrap rates and improve overall yield in production.

DATA-DRIVEN DECISIONS

Utilizing the Pareto principle enables data-driven decision-making, ensuring that resources target the **most significant problems**, ultimately leading to enhanced operational efficiency and reduced costs.

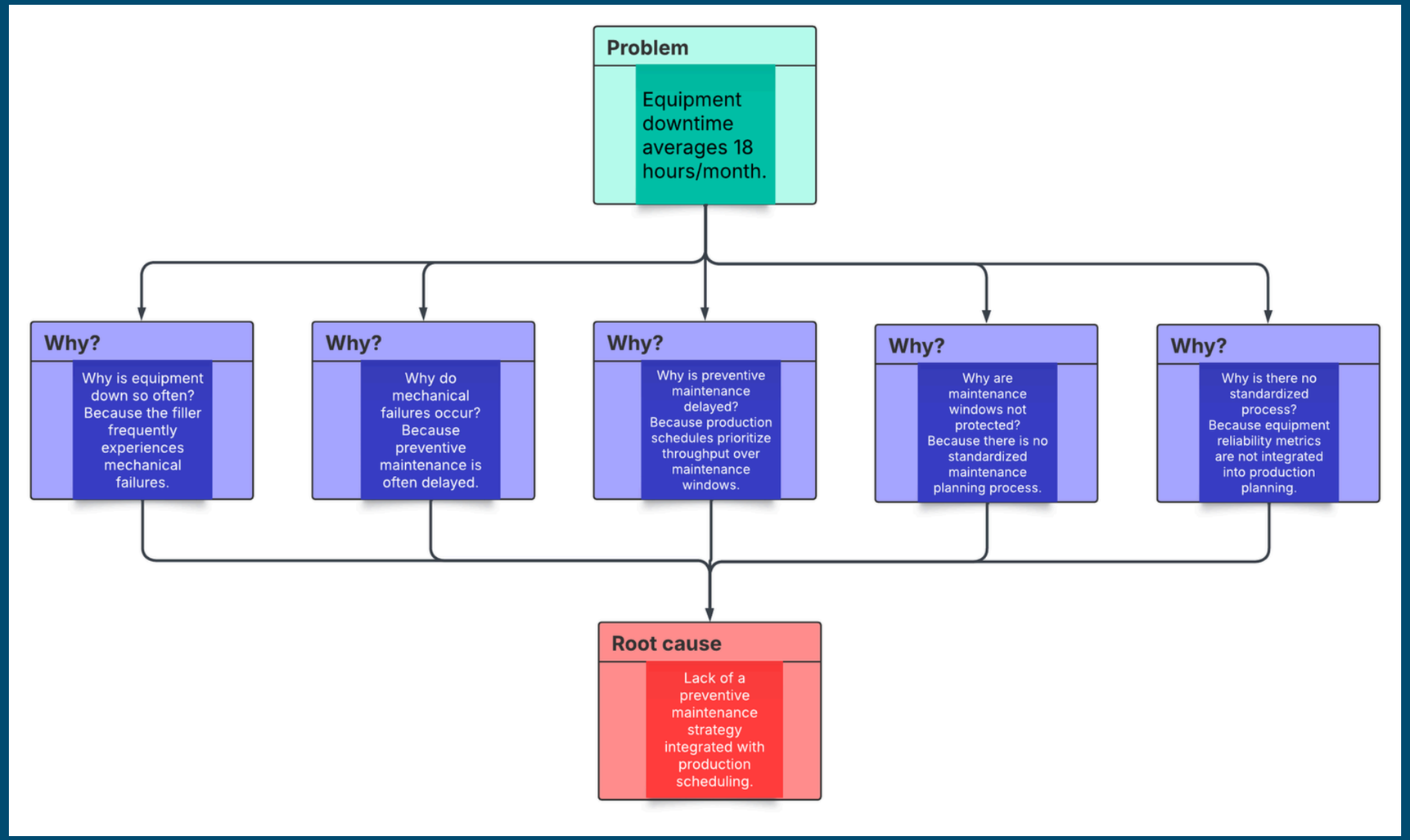
Fishbone Diagram



The Fishbone Diagram helps identify root causes of issues impacting our manufacturing process. Key categories include:

- **Machines:** Equipment Failure, Maintenance Delays
- **Human Error:** SOP Adherence, Training Gaps, Turnovers
- **Materials:** API Shortages, Quality Issues, Product Waste
- **Environment:** Equipment Setup, Changeovers, Workspace Ergonomics

5 Whys Analysis: Uncovering Root Causes



PROBLEM STATEMENT:
OEE is only 61% due to excessive equipment downtime and prolonged changeovers.

EQUIPMENT FAILURES

Frequent equipment failures lead to significant downtime. By asking "why" multiple times, we identify underlying issues such as inadequate maintenance schedules, operator training gaps, and equipment age. Addressing these can reduce failures and enhance productivity.

Executive Takeaway

Recommended Action: Implement predictive/preventive maintenance scheduling, integrate maintenance into production planning, and monitor downtime KPIs weekly.

FMEA with RPN

Process Step/Input What is the process step, change or feature under investigation?	Potential Failure Mode In what ways could the step, change or feature go wrong?	Potential Failure Effects What is the impact on the customer if this failure is not prevented or corrected?	SEVERITY (1 - 10)	Potential Causes What causes the step, change or feature to go wrong? (how could it occur?)	OCCURRENCE (1 - 10)	Current Controls What controls exist that either prevent or detect the failure?	DETECTION (1 - 10)	RPN	PRIORITY	Action Recommended What are the recommended actions for reducing the occurrence of the cause or improving detection?	Resp. Who is responsible for making sure the actions are completed?	Actions Taken What actions were completed (and when) with respect to the RPN?	SEVERITY (1 - 10)	OCCURRENCE (1 - 10)	DETECTION (1 - 10)	RPN
Material Mixing	**Inconsistent Material Mixture - Inaccurate mixture of products may result in texture inconsistencies and useful ingredients resting at the bottom.**	Batch Rejection.	10	Machine calibration error or uneven starch distribution.	3	Regular machine calibration; Quality checks for mix consistency.	3	90		Implement automated material distribution systems to ensure consistent mixing. - Introduce periodic third-party audits to verify machine calibration accuracy.	John Doe	Implemented automated material distribution systems; Introduced third-party audits for machine calibration.	5	1	2	10
Cleaning	**Contamination - Foreign particles or contaminants are mixed with the batch.**	Bottles with impurities, affecting appearance and safety.	10	Dirty equipment or compromised raw materials.	2	Regular equipment cleaning; Batch testing of raw materials.	2	40		Introduce more stringent equipment cleaning schedules. - Enhance raw material screening processes and work with suppliers to ensure cleaner raw materials.	Jane Smith	Introduced stringent equipment cleaning schedules; Enhanced raw material screening processes.	6	2	1	12
Filling	**Equipment breakdown**	Production downtime	9	Outdated equipment or lack of PM.	5	Regular scheduled PM's	4	180		Prioritize PM's over prodution to prevent longer downtimes and interruptions in flow which leads to waste if batches are already waiting in tanks.	John Smith	Conducted PM's in a timely manner	6	4	3	72
Packaging	**Label mismatch**	Recall risk	10	Operator error when assembling the label machine	2	SOPs and Training	3	60		Properly train operators on task ensure they are paying attention to detail and verifying labels	Jane Doe	Updated SOP's, enforced proper training protcols in a timely manner, enforce dual label verification protocols.	10	2	1	20
Changeovers	**Extended setup**	Low OEE	7	Inexperenced staff, mechanical issues, and calibration issues.	6	SOPs and Traini	5	210		SMED Implementation	John Jane	Implemented SMED, Staged material and tools.	7	4	3	84

Executive Risk Matrix

Highest Risks

- 🔴 **Changeovers 210**
- 🔴 **Equipment Downtime 180**
- 🟡 **Material Mixing 90**
- 🟢 **Packaging 60**
- 🟢 **Cleaning 40**

Color Coding:

RPN < 75 🟢 Low Risk

75–150 🟡 Moderate Risk

>150 🔴 High Priority

FAILURE MODES

Identifying potential failure modes is crucial to mitigate risks. Each mode is assessed based on its impact on quality and safety, ensuring proactive measures are implemented.

RISK PRIORITY NUMBER

The Risk Priority Number (RPN) quantifies the severity, occurrence, and detection of failures. Prioritizing actions based on RPN helps focus resources on the most critical areas needing improvement.

Control Charts

Control charts serve as essential tools in monitoring process stability and performance over time. They help identify variations and trends, enabling proactive management. Key components include:

- Upper and lower control limits
- Centerline
- Data points
- Trends and patterns analysis

Chart Takeaways:

Before Improvement (Batches 1–6)

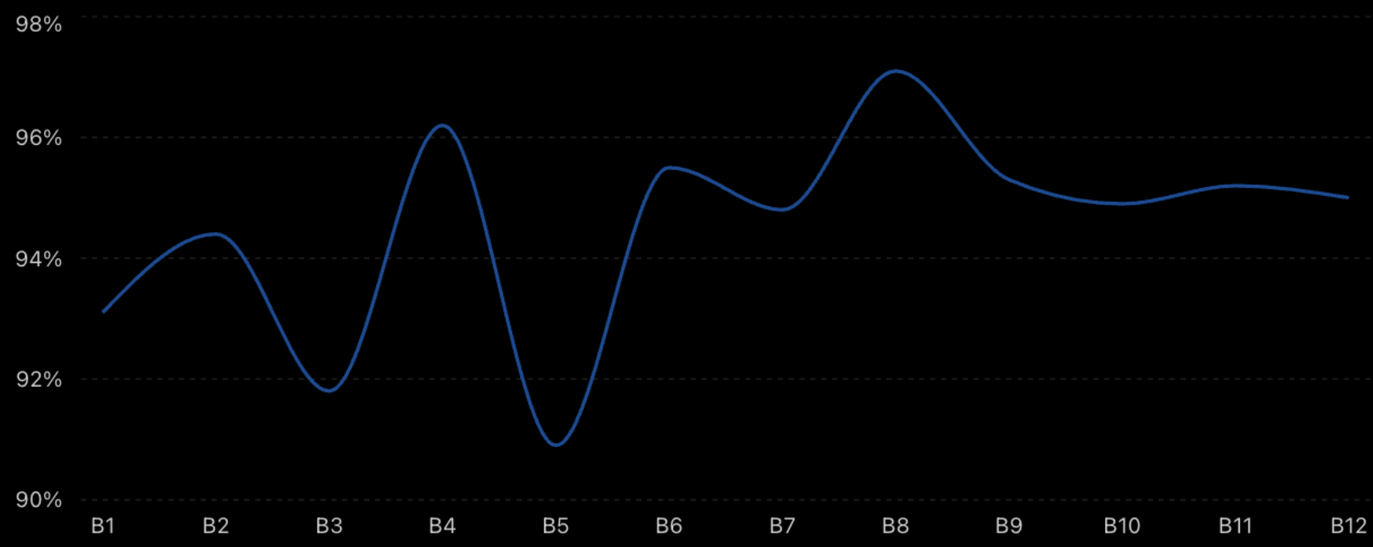
- Wide variation in batch yield
- One batch falls below the Lower Control Limit (LCL)
- Special-cause variation from equipment downtime and operator inconsistency
- Frequent process adjustments

After Improvement (Batches 7–12)

- Stable process centered around the target
- No points outside control limits
- Reduced variability
- Predictable, repeatable performance

Batch Yield Control Chart

Simulated batch yield showing process stability before and after Lean Six Sigma improvements.



Center Line (CL): 95% | UCL: 98% | LCL: 92%

Executive KPI Box

Metric	Before	After
Average Batch Yield	93.2%	95.4%
OEE	61%	80%
Downtime	18 hrs/month	7 hrs/month
Deviations	47	18
Scrap	6.5%	2.1%

Cp/Cpk Capability Analysis

Process Capability Analysis (Cp/Cpk)

Objective: Evaluate whether the liquid manufacturing process consistently meets batch yield specifications.

Pharmaceutical Example

Assume the product specification for **Batch Yield** is:

- **LSL (Lower Specification Limit):** 94.0%
- **Target:** 95.0%
- **USL (Upper Specification Limit):** 96.0%

Executive Dashboard

Metric	Before DMAIC	After DMAIC
Mean Yield	94.3%	95.1%
Standard Deviation	0.75	0.28
Cp	**0.44**	**1.19**
Cpk	**0.13**	**1.08**
Process Status	Not Capable	Capable

Capability Visualization

UNDERSTANDING PROCESS CAPABILITY

The Cp/Cpk analysis measures the process's ability to produce output within specified limits, ensuring that operations meet customer specifications and quality standards efficiently.

IMPORTANCE OF MONITORING

Regular monitoring of Cp/Cpk values helps identify variations, enabling proactive adjustments that enhance process stability, reduce scrap rates, and improve overall manufacturing effectiveness.

EXECUTIVE INTERPRETATION:

Before Improvement

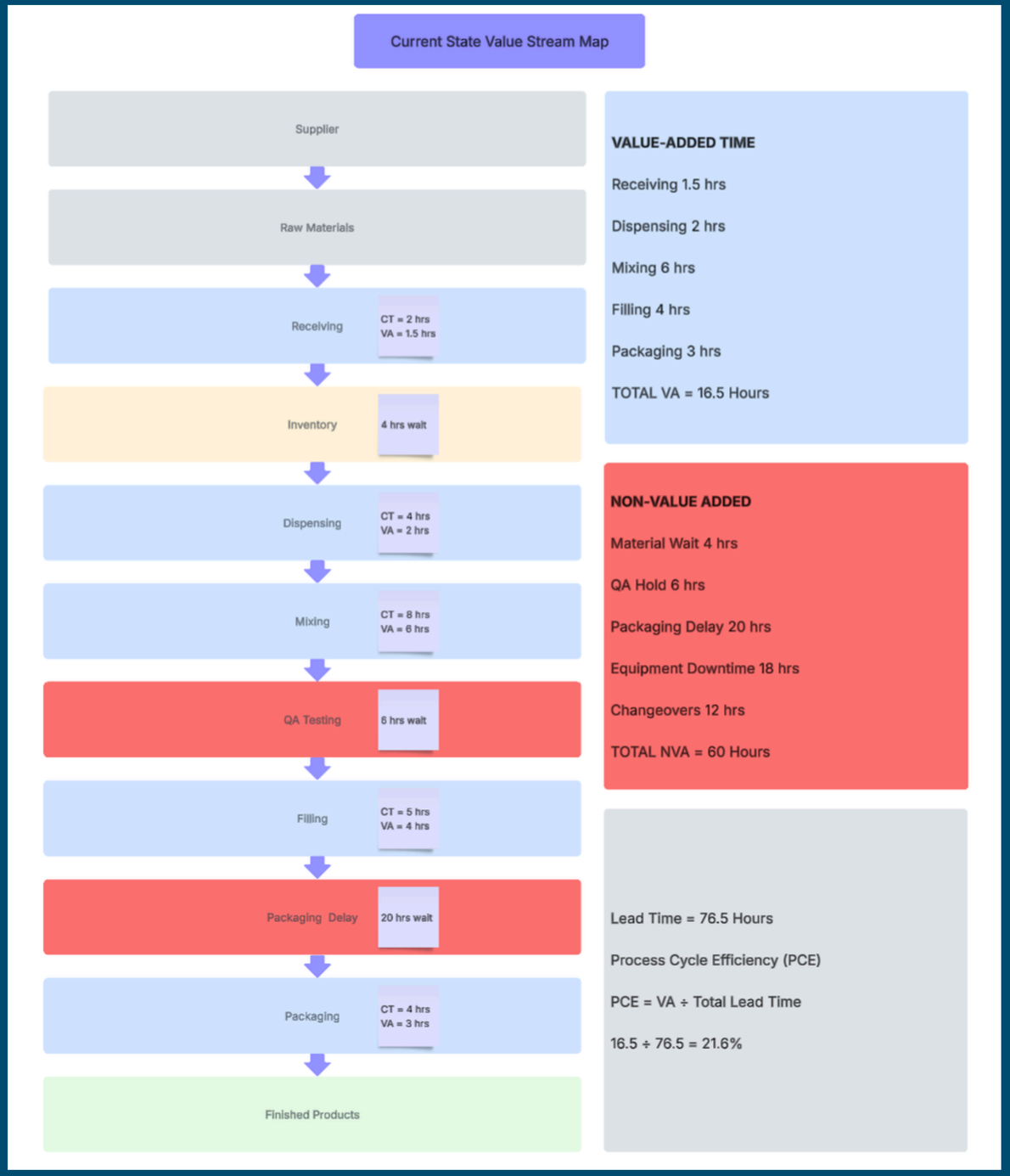
🔴 High process variation

- Frequent deviations
- Batch rework
- Higher scrap
- Low confidence in meeting specifications

After Improvement

🟢 Stable process

- Consistent batch yield
- Reduced variability
- Predictable production
- Meets customer specifications



Value Stream Map

The current state analysis reveals key areas for improvement:

- Scrap reduction from 8% to 3%
- Yield enhancement from 92% to 97%
- OEE increase from 61% to 80%
- Identified downtime due to equipment failure and changeovers
- Emphasis on cGMP, validated SOPs, and data integrity

Executive KPI Box

Current State

- Lead Time: 76.5 hrs
- Value-Added Time: 16.5 hrs
- Non-Value-Added Time: 60 hrs
- Process Cycle Efficiency: 21.6%
- OEE: 61%

Future State Value Stream Map

Metric	Before	After
Lead Time	76.5 hrs	46 hrs
Waiting Time	30 hrs	10 hrs
Downtime	18 hrs	7 hrs
Changeovers	12 hrs	5 hrs
OEE	61%	80%
PCE	21.6%	39.1%

SMED Changeover Reduction Strategies

QUICK SETUP

Implementing standardized procedures allows for **efficient transitions** between product lines, significantly reducing downtime and enhancing overall production speed and flexibility in operations.

TRAINING SESSIONS

Regular training for operators ensures they are well-versed in **best practices**, minimizing human error and fostering a culture of continuous improvement within the production environment.

EQUIPMENT OPTIMIZATION

Upgrading machinery and automating specific processes can lead to **enhanced performance**, lowering changeover times and increasing the overall efficiency of production workflows, contributing to scrap reduction.

cGMP and Change Control Workflow

REGULATORY COMPLIANCE

Adhering to **cGMP regulations** ensures that all processes meet safety, quality, and efficacy standards, protecting patient health and maintaining product integrity throughout manufacturing.

CHANGE MANAGEMENT

Implementing a structured change control process minimizes risk by thoroughly evaluating proposed changes, documenting impacts, and ensuring proper communication across all involved departments.

TRAINING AND DOCUMENTATION

Comprehensive training and clear documentation are vital in maintaining compliance, providing employees with necessary knowledge and resources to follow validated procedures and effectively manage deviations.

CAPA Process: Ensuring Compliance and Improvement

ROOT CAUSE IDENTIFICATION

A thorough investigation of non-conformances is essential to identify underlying issues, allowing for targeted corrective actions to prevent recurrence and ensure continuous improvement.

CORRECTIVE ACTIONS

Implementing effective corrective actions based on root cause analysis is crucial for addressing immediate problems, enhancing process reliability, and minimizing the risk of future deviations in production.

PREVENTIVE ACTIONS

Developing preventive actions proactively mitigates potential risks, ensuring compliance with cGMP regulations while fostering a culture of quality and accountability within cross-functional teams in the organization.

Validation IQ/OQ/PQ

EQUIPMENT QUALIFICATION

Ensuring that all equipment meets **stringent requirements** is crucial for maintaining compliance. This includes exhaustive testing during Installation Qualification (IQ) to confirm proper specifications.

PROCESS VALIDATION

Process validation verifies that manufacturing procedures consistently yield products meeting predetermined quality standards. This involves Operational Qualification (OQ) and Performance Qualification (PQ) testing throughout production.

Qualification Phase	Objective	Result
IQ	Verify installation of mixing vessel, filler, and CIP system	✅ Pass
OQ	Challenge alarms, speeds, temperatures, and operating ranges	✅ Pass
PQ	Three consecutive conforming validation batches	✅ Pass
Change Control	All documentation approved	✅ Closed
Training	Operators qualified on revised SOPs	✅ Complete

IQ/OQ/PQ Details

Installation Qualification (IQ)

Verified

- Equipment installation
- Utilities connected
- Instrument calibration
- Equipment identification
- Documentation complete

Deliverable

✓ IQ Protocol Approved

Operational Qualification (OQ)

Tested

- Mixing speed
- Temperature control
- Agitator performance
- Filling accuracy
- Alarm functionality
- CIP cycle verification

Deliverable

✓ Equipment operates within approved operating ranges

Performance Qualification (PQ)

Validated

Three consecutive commercial-scale batches demonstrated:

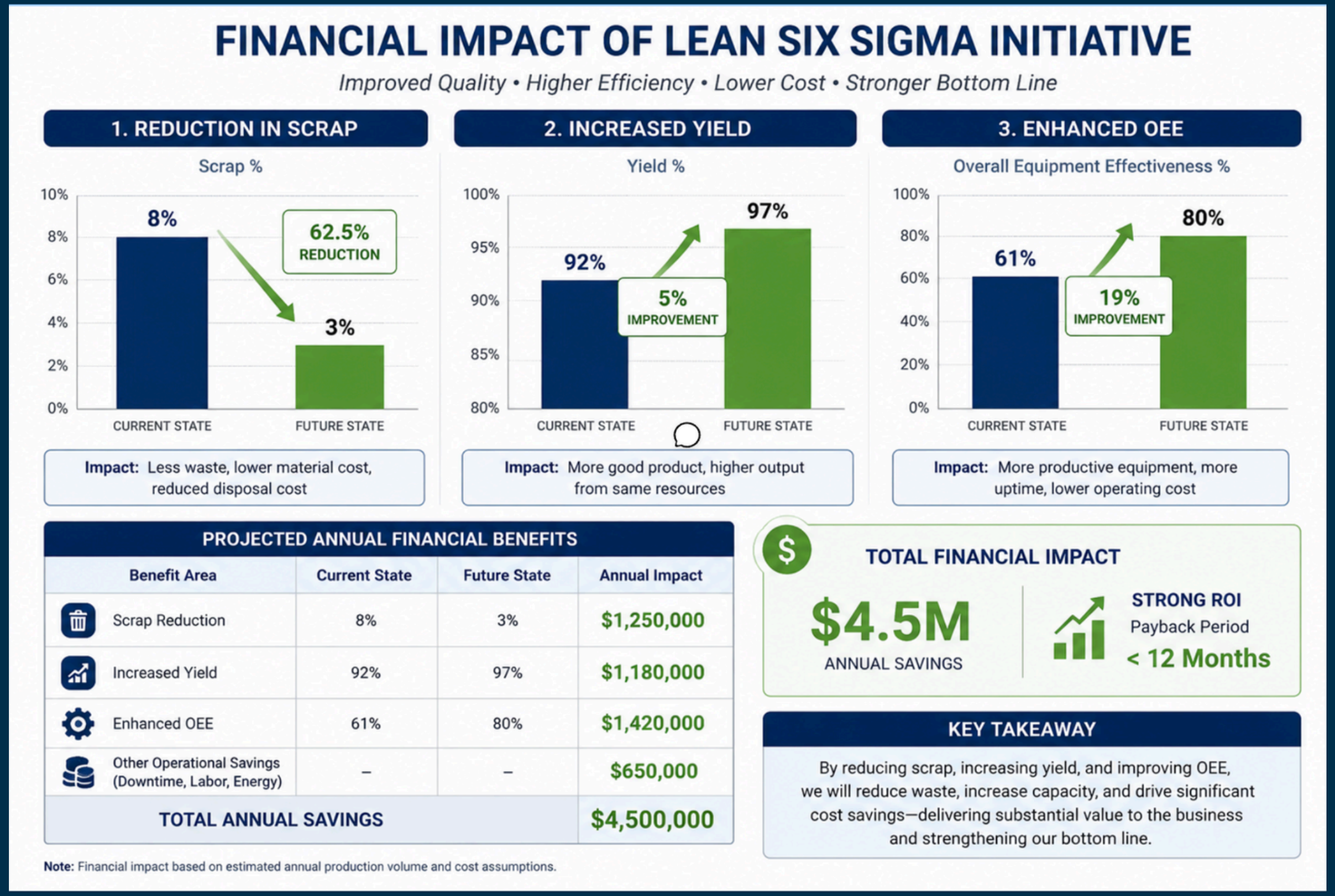
Parameter	Target	Result
Batch Yield	≥95%	95.4%
OEE	≥80%	80%
Batch Deviations	0 Critical	Achieved
Fill Weight	Within Specification	Pass

Financial Impact

The projected benefits of the initiative include:

- **Reduction in Scrap:** Decrease from 8% to 3%
- **Increased Yield:** Improvement from 92% to 97%
- **Enhanced OEE:** Increase from 61% to 80%

These improvements will lead to significant cost savings and improved operational efficiency, positively impacting the bottom line.



Implementation Timeline

PHASE 1

Initial assessments and training sessions for all team members on new SOPs and change control processes.

PHASE 2

Launching the SMED implementation to reduce changeover times while enhancing automation for increased efficiency.

PHASE 3

Conducting a comprehensive review of process performance metrics and adjusting strategies based on collected data insights.

Team Collaboration Success

"Working alongside our cross-functional teams has proven to be transformative. Together, we will have identified root causes and implemented effective solutions, resulting in a significant reduction of scrap and an increase in yield. This collaboration will truly enhanced our operational efficiency."

Cross-Functional Collaboration for Project Success

Workstream	Production	QA	Engineering	Maintenance	Supply Chain	Validation	Regulatory
Current State Assessment	●	●	●	●	●		
Process Mapping	●	●	●				
Root Cause Analysis	●	●	●	●			
FMEA	●	●	●	●		●	
SMED Implementation	●		●	●			
Preventive Maintenance			●	●			
SOP Updates	●	●				●	
IQ/OQ/PQ Validation		●	●	●		●	
Change Control	●	●	●			●	●
Operator Training	●	●				●	
Performance Monitoring	●	●	●	●			

Legend:

- ● = Primary contributor

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