Process Optimization by the Application of Lean Manufacturing Principles

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Abstract

Commercial demand at a pharmaceutical facility in Juncos has been constantly increasing since 2016. Focused on process improvement strategies, our formulation capabilities were increased to support Drug Product requirements. These efforts resulted in a more agile and efficient manufacturing process by reducing 31% in lot lead time, 36% in batch record review process and absorbed an increase in lots by 9% (equivalent to 588 hours), thus increasing capacity from 2 to 4.07 lots per day without increasing headcount.

Introduction

Nowadays, the pharmaceutical industry is in constant search for process improvements by avoiding the wastes of production outages, ineffective product transitions, and poor product quality. Process improvement efforts are started for many reasons. Traditionally, the primary goal has been to improve efficiency. Improved efficiency, or productivity, allows an organization to produce the same products with reduced effort. The pharmaceutical industry needs to be able to reduce the cycle times by improving the process and eliminating associated wastes. An ideal lean production, a plant can make any product at any time in any quantity [1]. Process improvement efforts; typically require new processes and procedures development, revision or optimization, training, and deployment activities.

Methodology

A six-step process incorporating the key principles behind the highly successfully six-sigma DMAIC methodology and those of lean manufacturing will be used as guideline to optimize the manufacturing process [2].

Define

Project Charter

Project Title:	Formulation Process Optimization	**Project Leader:**	Noel Torres
Start Date:	Q1 2018 **End Date:** Q2 2019	**Project Sponsor:**	Irene Villafañe

Problem Statement	Baseline	Goal
DP facility transitioned to a commercial facility in 2015. New Products Introduction (NPI) has required an extensive amount of work to support the Amgen DP commercial strategy. The time invested during document creation/revision does not allow to be efficient and agile, limiting the resources to execute additional tasks and impacting significantly the project timelines.	Formulation Lead Time = **10 hrs** NPI Readiness = **30 days**	Formulation Lead Time ≤ **8 hrs** NPI Readiness ≤ **15 days**

Objectives

- **Objective #1:** Enable faster NPI at DP facility- Formulation through expedited document strategy.
- **Objective #2:** Reduce Formulation process lead time by ~20%.

Project Team

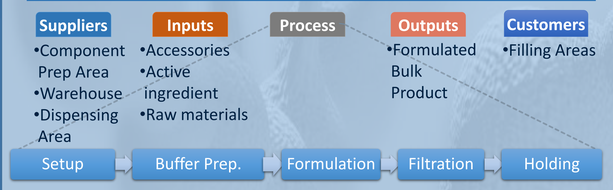
Manufacturing Specialists
Manufacturing Associates
Engineering Team
Information System Unit
Quality Assurance Unit

Project Expected Benefits & Industry Impact

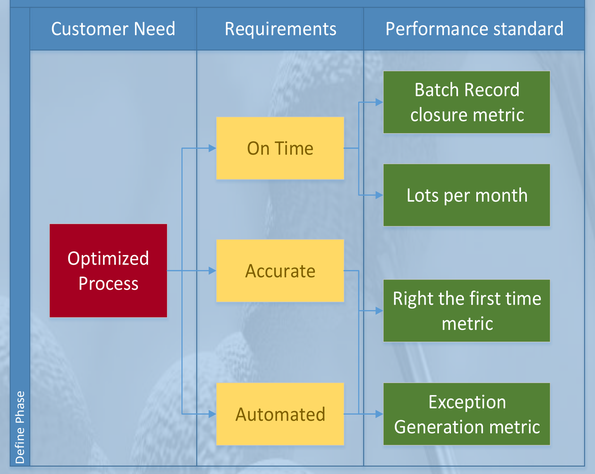
- Reduced NPI cycle time
- Improved Formulation processes lead times/Resource availability.

AMGEN

SIPOC



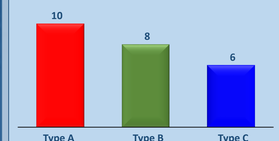
Critical to Quality Diagram



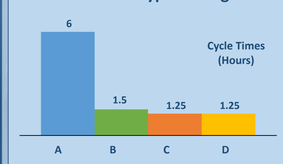
Measure

Active Process

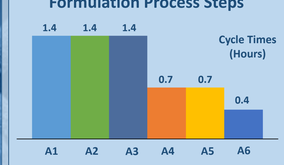
Formulation Lead Time



Formulation Type A: Stages

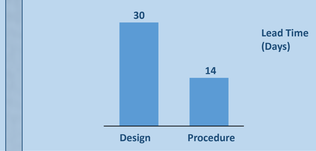


Formulation Process Steps

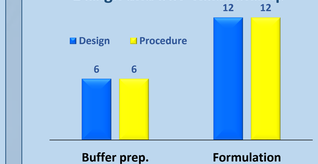


Documentation Readiness

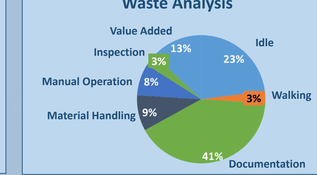
Batch Record & Procedure Lead Time



Design and SOP Relationship

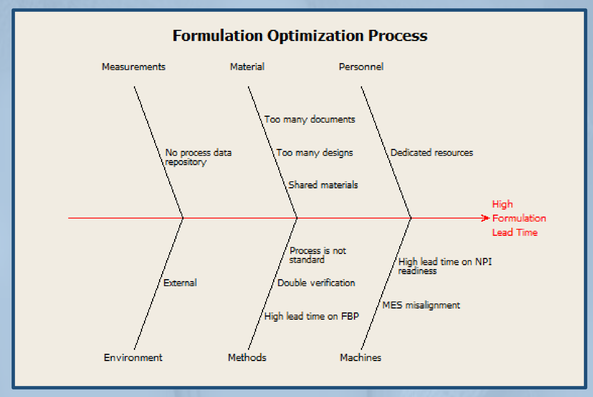


Waste Analysis

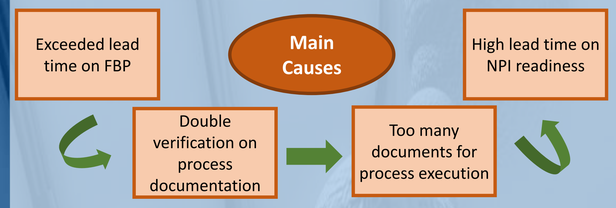


Analyze

Ishikawa Diagram



Kaizen



Improve

Prioritization process

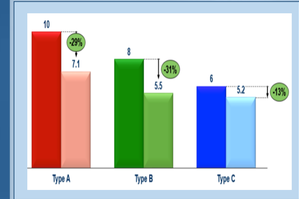
Alternatives	Time Impact	Viability	Total
Objective 1: Lead Time Reduction			
Review electronic batch record	5	5	10
Eliminate double verification from process	1	3	4
Objective 2: NPI Readiness Lead Time Reduction			
New FBP Platform Designs	5	5	10
Documents optimization	5	4	9

Control

Control phase allows monitoring all implemented changes, and completes the DMAIC methodology.

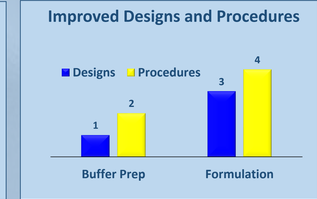
Results

Active Process

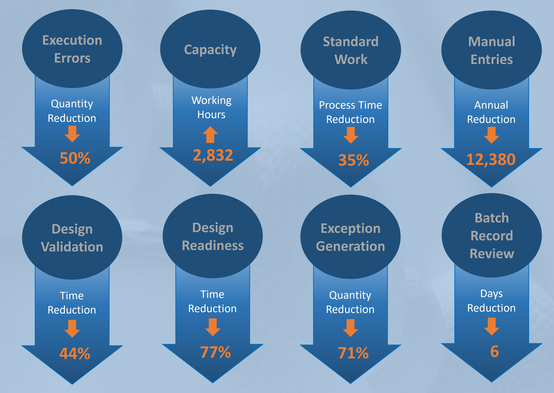


Documentation Readiness

Improved Designs and Procedures



Additional Benefits



Conclusions

In today's global business environment, the importance of first-to-market, cost-competitiveness, and quality are key factors in determining an organization's success. The current and future commercial demand can be allocated at the commercial facility because of the optimization of the formulation process documents and batch record designs. The new and optimized process will serve as a standard for future product or process introduction. When operating in a highly competitive market, it is more difficult to implement improvements because of commercial requirements. The lean methodology allowed to increase manufacturing capacities, reduce operational costs, and increased the robustness of the documentation systems without impacting the commercial production schedule.

Future Work

Operational Excellence is a never ending cycle, allowing additional improvements to be identifies as time goes by and process mature as well as it's understanding. Proposed and implemented strategy is being evaluated for the upstream functional areas.

Acknowledgements

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All data numbers on dummies to protect Amgen Confidentiality.