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Implementation of Lean Six Sigma in Pharmaceutical Manufacturing

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Abstract: *Pharmaceutical manufacturing is one of the most critical and highly regulated industries worldwide. The complexity of production processes, coupled with stringent regulatory requirements, necessitates a focus on quality, efficiency, and cost optimization. Lean Six Sigma (LSS) combines Lean principles for eliminating waste and Six Sigma methodologies for reducing variability, ensuring both quality and efficiency.*

This document explores the comprehensive application of LSS across pharmaceutical processes, including API synthesis, granulation, tablet production, capsule filling, coating, and packaging. The implementation is illustrated through case studies, step-by- step methodology, tables, charts, value stream maps, SIPOC diagrams, FMEA analyses, 5S/Kaizen practices, ROI calculations, and regulatory compliance frameworks.

This document is designed to serve as a full reference for pharma professionals looking to implement LSS in manufacturing, ensuring measurable improvements in defect reduction, cycle time, yield, and cost savings..

Keywords: Lean Six Sigma, Pharmaceutical Manufacturing, DMAIC, Process Optimization, Quality Improvement, FMEA, 5S, SIPOC, Value Stream Mapping

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