



Pharmaceutical Expansion: Contractor Coordination and Risk Management

Author: Kevin Santiago Mulero

Advisor: Carlos Pons, Ph.D.

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Abstract

This study evaluated the safety implications and risks associated with the expansion of a pharmaceutical granulation plant in a Good Manufacturing Practice (GMP)-regulated environment. The DMAIC and Root Cause Analysis (RCA) methodologies were used to identify recurring safety risks associated with non-compliance with PPE use, forklift operation, and work at height. The results highlight the importance of coordination with contractors, safety controls, and proactive risk management to ensure operational continuity and efficient project execution.

Introduction

Pharmaceutical facility expansions present major operational and safety challenges when construction activities occur inside active GMP-regulated manufacturing areas. This project evaluated the risks associated with contractor coordination, high-risk activities, and operational continuity during a granulation facility expansion project valued at approximately \$55 million.

Background

Pharmaceutical manufacturing requires strict compliance with Good Manufacturing Practices (GMP), contamination control, and operational reliability. Expansion projects executed within active facilities increase exposure to:

- Contractor coordination challenges
- Operational interference
- Safety risks
- Schedule delays
- Compliance concerns

Industrial engineering methodologies such as DMAIC and RCA help improve safety performance and operational efficiency for future projects.

Problem

The simultaneous participation of more than 30 contractor companies increased operational complexity and exposure to:

- PPE non-compliance
- Unsafe forklift operation
- Work-at-height hazards
- Communication failures
- JSA non-compliance

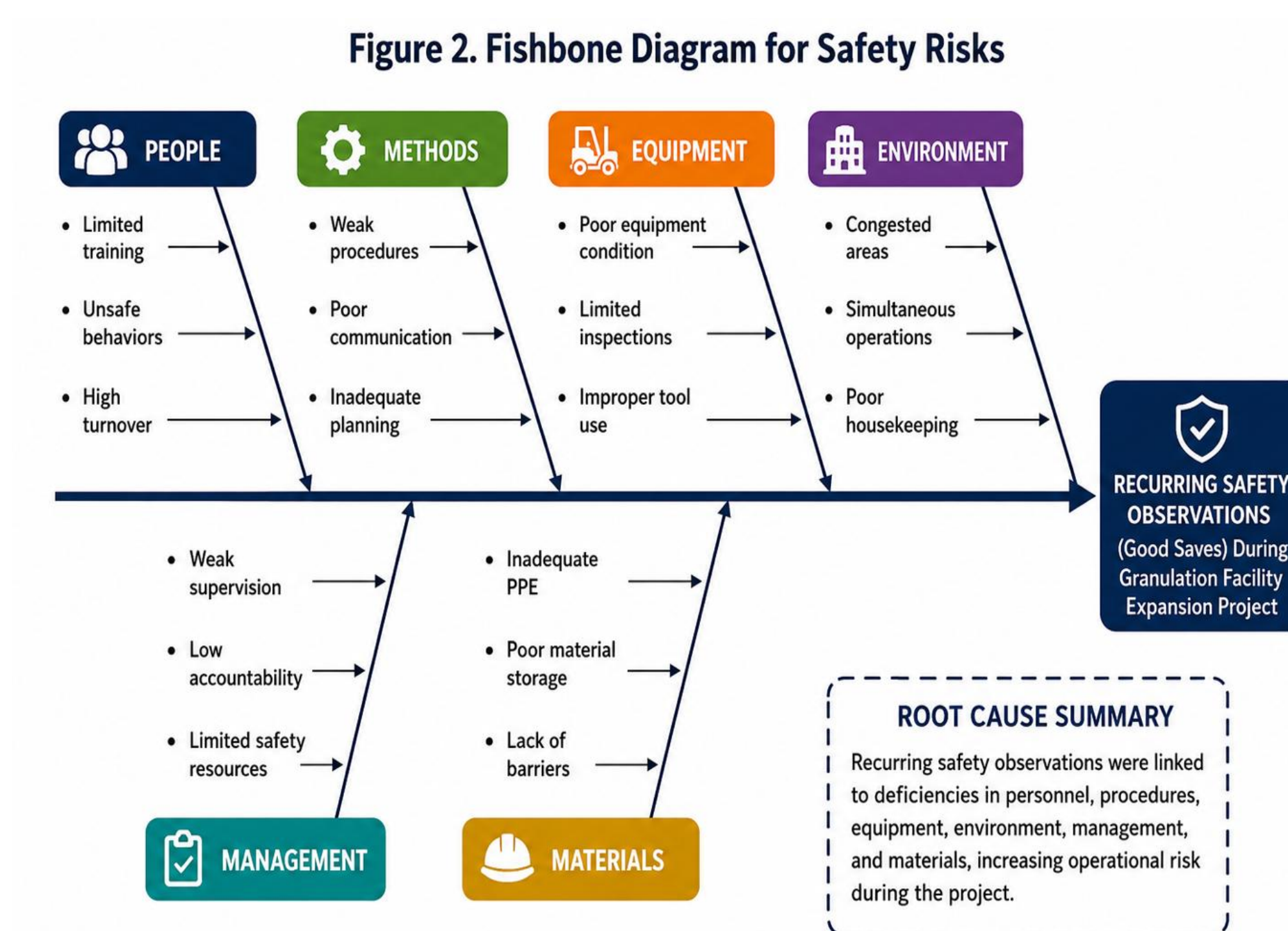
These conditions could lead to injuries, OSHA violations, production interruptions, project delays, and increased operational costs.

Methodology

To evaluate the operational and safety challenges identified during project execution, the DMAIC methodology and Root Cause Analysis (RCA) were applied to analyze recurring safety observations, identify risk patterns and develop improvement strategies focused on contractor coordination and operational reliability.

Project Phase	Main Risks Identified	Severity Level	Operational Impact
Phase 1	PPE non-compliance, housekeeping, and uncontrolled access	Medium	Site preparation delays and unsafe work conditions
Phase 2	Work at heights, ladder misuse, harness deficiencies	High	Increased fall exposure and injury risk
Phase 3	Forklift operation, material handling, JSA non-compliance	High	Equipment interaction hazards and operational disruptions
Phases 4 & 5	GMP integration risks, personnel segregation	High	Operational interference and compliance concerns

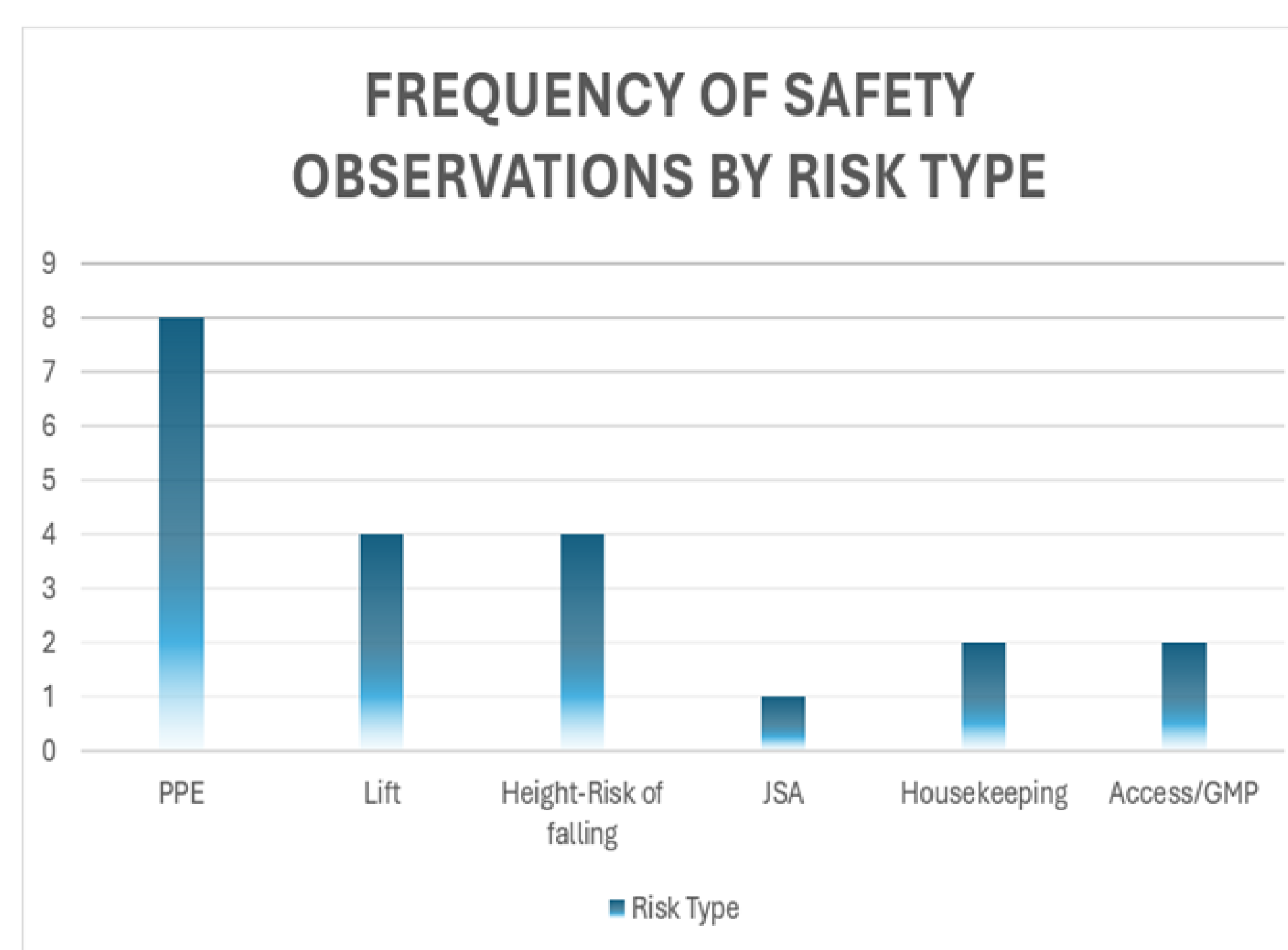
Risk severity increased as the project advanced into more complex operational phases. Early stages were mainly associated with PPE and housekeeping issues, while later phases involved higher-risk activities such as work at heights, forklift operation, and GMP integration.



The RCA showed that recurring unsafe conditions were caused by interconnected factors such as contractor variability, complex work conditions, communication deficiencies, and inconsistent safety enforcement. These findings supported the development of improvement strategies focused on contractor coordination, operational reliability, and risk reduction.

Results and Discussion

The analysis identified recurring high-risk activities associated with PPE non-compliance, forklift operation, and work-at-height tasks. Results demonstrated that increased project complexity and simultaneous contractor activities significantly impacted safety performance, operational continuity, and project efficiency.



The graph shows that improper use of PPE accounts for the most observations, followed by risks associated with forklift operation and working at heights/falls.

Risk Category	Potential Operational Impact	Potential Economic Impact
PPE non-compliance	Work stoppages	Increased supervision and delays
Forklift Incidents	Material/equipment damage	Repair and replacement costs
Work at Heights	Serious injury risk	OSHA penalties and schedule delays
GMP Area Violations	Production interference	Downtime and compliance costs

The table showed that recurring unsafe conditions could generate significant operational and economic impacts, including work stoppages, equipment damage, schedule delays, productivity losses, and compliance-related costs.

Conclusions

This study evaluated a pharmaceutical granulation facility expansion in an active GMP environment, identifying key safety and operational challenges using DMAIC and Root Cause Analysis. Main risks included improper PPE use, unsafe forklift operations, work at heights, and weak procedural compliance, driven by factors such as contractor variability, communication gaps, limited training, and supervision deficiencies.

The results showed that safety performance directly affects cost, schedule, and operational continuity, with potential regulatory and productivity impacts. Improvement strategies were proposed to strengthen safety controls, contractor coordination, and compliance. Overall, the study highlights that industrial engineering tools can improve safety and efficiency in complex pharmaceutical expansion projects.

Future Work

Implement digital safety tracking systems.

- Expand KPI monitoring for contractor performance.
- Integrate predictive safety analytics.
- Periodic safety audits to verify compliance with safety controls and procedures.
- Develop standardized GMP construction safety frameworks.
- A shared file where each project engineer or EHS shares their observations, performing a high-risk analysis and what action was taken, used as a record.
- Continuous educational talks focused on high-risk activities and operational safety.

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