Pharmaceutical Expansion: Contractor Coordination and Risk Management

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Graduate Project Expo, May 2026

Abstract *— This study analyzes the execution of a pharmaceutical granulation facility expansion project conducted within an active manufacturing environment. The project aimed to increase production capacity, optimize process flow, and improve material handling while maintaining compliance with Good Manufacturing Practices. Due to the involvement of multiple contractors and critical operational constraints, safety management and coordination were identified as key challenges. Using Define, Measure, Analyze, Improve, Control methodology and Root Cause Analysis, safety observations were evaluated to identify recurring risk patterns, high-risk activities, and root causes. Results indicated that improper use of personal protective equipment, unsafe handling of mobile equipment, and risks associated with working at heights were the most frequent and severe issues. Based on these findings, targeted improvement strategies were developed, including enhanced supervision, stricter safety controls, and improved contractor coordination. The study provides practical recommendations to strengthen safety performance and support more efficient execution of similar industrial projects.*

Keywords *— Contractor Coordination, DMAIC, Pharmaceutical Manufacturing, Root Cause Analysis.*

INTRODUCTION

Pharmaceutical manufacturing facilities operate under highly regulated environments where production continuity, product quality, personnel safety, and regulatory compliance are critical organizational priorities. As market demand for solid dosage pharmaceutical products continues to increase, many companies are required to expand existing manufacturing areas while maintaining ongoing operations and compliance with Good Manufacturing Practices (GMP). Unlike conventional construction projects, pharmaceutical facility expansions in active manufacturing environments pose significant operational and safety challenges due to the coexistence of production activities, contractors, engineering teams, and high-risk construction tasks.

This study analyzes a pharmaceutical granulation facility expansion project executed within an active manufacturing plant dedicated to solid dosage production. The project, with an estimated investment of approximately $55 million, aimed to increase granulation capacity, optimize material flow, improve storage areas for intermediate containers, and support future operational growth. Because manufacturing operations remained active throughout project execution, construction activities required strict coordination to avoid production interruptions, contamination risks, and operational disruptions that could compromise GMP compliance and product quality.

The complexity of the project increased significantly due to the simultaneous participation of more than 30 contractor companies involved in demolition activities, temporary area construction, utility installation, equipment installation, and commissioning operations. Additionally, several high-risk activities, such as work at heights, forklift operation, material handling, and simultaneous operations, had to be executed within restricted operational areas. These conditions increased exposure to unsafe behaviors, communication failures, procedural deviations, and operational conflicts between contractors and plant personnel.

In industrial construction environments, ineffective safety management could lead to serious operational and economic consequences, including injuries, work stoppages, OSHA violations, equipment damage, productivity losses, schedule delays, and increased project costs. In pharmaceutical manufacturing facilities, these impacts may become even more critical due to the strict regulatory requirements associated with GMP compliance and production continuity. As a result, safety performance becomes not only a regulatory and ethical responsibility but also a critical factor influencing operational reliability, project efficiency, and cost control.

To address these challenges, this study applies the DMAIC [1] (Define, Measure, Analyze, Improve, Control) methodology and Root Cause Analysis (RCA) [2] to evaluate safety observations collected during the execution of the expansion project. Safety trends, severity levels, and recurring unsafe conditions were analyzed to identify the primary factors affecting contractor coordination, operational efficiency, and project execution performance.

The purpose of this study is to evaluate the relationship between safety management, contractor performance, operational continuity, and project efficiency within an active pharmaceutical manufacturing environment. The findings aim to provide practical recommendations that support risk reduction, improved safety performance, reduced operational and economic impacts, and more efficient execution of future pharmaceutical expansion projects.

LITERATURE REVIEW

Pharmaceutical granulation is a critical manufacturing process used to improve powder flowability, compressibility, and content uniformity in solid dosage forms, contributing to product quality and process reliability. Because pharmaceutical operations are highly regulated, manufacturing activities must comply with Good Manufacturing Practices (GMP), which establish strict requirements related to contamination control, validation, documentation, and operational consistency. These requirements significantly increase the complexity of executing expansion projects within active manufacturing environments.

Unlike conventional construction projects, pharmaceutical facility expansions performed within operational plants involve elevated operational and safety risks due to the simultaneous execution of manufacturing and construction activities. The interaction between contractors, engineering teams, operations personnel, quality departments, and Environmental Health and Safety (EHS) personnel requires effective coordination and continuous communication to maintain operational continuity and regulatory compliance. Inadequate coordination may result in production interruptions, schedule delays, productivity losses, increased project costs, and higher exposure to workplace incidents.

Safety management is a critical component of industrial construction projects, particularly in pharmaceutical environments where operational reliability and compliance must be maintained. Research identifies improper use of personal protective equipment (PPE), unsafe work at heights, poor housekeeping, and inadequate control of mobile equipment as common causes of workplace incidents. These risks become more severe when multiple contractors operate simultaneously within restricted operational areas.

From an industrial engineering perspective, safety performance directly impacts project efficiency, operational continuity, and financial performance. Safety incidents may generate direct costs such as equipment damage, OSHA penalties [3], and corrective actions, as well as indirect costs including work stoppages, schedule delays, productivity losses, retraining activities, and operational downtime.

To support continuous improvement and risk reduction, methodologies such as DMAIC (Define, Measure, Analyze, Improve, Control) and Root Cause Analysis (RCA) are widely used in industrial environments. DMAIC provides a structured framework for identifying problems, analyzing causes, implementing corrective actions, and sustaining improvements, while RCA tools such as the Fishbone Diagram help identify contributing factors related to personnel, methods, equipment, environment, and management systems.

Overall, the successful execution of pharmaceutical expansion projects depends on the integration of GMP compliance, contractor coordination, operational planning, and proactive safety management practices. This study applies DMAIC, Root Cause Analysis, and safety trend evaluation to identify recurring risks and propose improvement strategies focused on safety performance, operational efficiency, and reduction of operational and economic impacts.

PROBLEM STATEMENT

The pharmaceutical manufacturing industry continues to experience increasing market demand for solid dosage products, requiring companies to expand production capacity while maintaining operational continuity and regulatory compliance. In response to these operational demands, the company initiated a pharmaceutical granulation facility expansion project with an estimated investment of approximately $55 million. The project was developed to improve process flow, increase granulation capacity, optimize material handling operations, and expand storage areas for intermediate containers used in the manufacturing process.

Although the expansion was necessary to support future production requirements, the execution of the project within an active GMP-regulated manufacturing facility introduced significant operational, safety, and management challenges. Unlike conventional construction projects, activities had to be performed while pharmaceutical manufacturing operations remained active, requiring strict coordination between construction personnel, production teams, engineering departments, quality systems, and environmental health and safety (EHS) personnel.

The magnitude and complexity of the project substantially increased exposure to operational and safety risks. More than 30 contractor companies participated throughout different phases of the project, including demolition, structural expansion, utility installation, equipment installation, and commissioning activities. The simultaneous execution of multiple disciplines within restricted operational areas increased the probability of unsafe conditions, communication failures, procedural deviations, and coordination deficiencies.

Additionally, the project required multiple shutdown windows to execute critical activities, making schedule compliance and operational continuity highly dependent on effective planning and risk control. Any incident, unsafe condition, or project interruption had the potential to delay critical activities, impact production schedules, increase labor costs, and generate significant financial losses. In pharmaceutical environments, these impacts may also compromise GMP compliance, operational reliability, and product quality requirements.

During project execution, a considerable number of safety observations (Good Saves) were documented, revealing recurring issues associated with improper use of personal protective equipment (PPE), unsafe operation of mobile equipment such as forklifts, work at heights, housekeeping deficiencies, and inconsistent compliance with Job Safety Analyses (JSAs). These recurring observations indicated weaknesses in safety management systems, contractor supervision, communication practices, and enforcement of safety procedures.

Failure to properly control these risks may result in serious injuries, OSHA citations, legal liabilities, operational disruptions, productivity losses, equipment damage, schedule delays, and increased project costs. Furthermore, in highly regulated pharmaceutical environments, safety incidents may also affect operational compliance and create additional regulatory concerns.

Therefore, there is a critical need to systematically evaluate the recurring safety observations, identify the root causes contributing to unsafe conditions, and determine improvement opportunities that strengthen contractor coordination, safety performance, operational efficiency, and project execution. This study addresses these challenges through the application of industrial engineering methodologies, including DMAIC and Root Cause Analysis (RCA), to support data-driven decision-making and continuous improvement within pharmaceutical expansion projects.

OBJECTIVE

The objective of this study is to analyze the safety observations recorded during the pharmaceutical granulation facility expansion project to identify recurring risk patterns, evaluate the effectiveness of existing safety controls, and determine the root causes contributing to unsafe conditions within an active GMP-regulated manufacturing environment.

Additionally, this study aims to apply industrial engineering methodologies, including DMAIC and Root Cause Analysis (RCA), to improve contractor coordination, strengthen safety management practices, reduce operational risks, and support more efficient project execution. The study also evaluates how safety performance impacts operational continuity, project costs, schedule compliance, and overall project efficiency during the execution of high-risk industrial activities.

METHODOLOGY

To address the identified operational and safety challenges, the DMAIC (Define, Measure, Analyze, Improve, Control) methodology was utilized as the primary industrial engineering framework for this study. DMAIC provided a structured and data-driven approach to evaluate safety performance, identify recurring risk patterns, determine root causes, and propose sustainable corrective actions within the pharmaceutical expansion project.

Define - During this phase, the project scope, operational challenges, and safety concerns associated with the granulation facility expansion were identified. Particular attention was given to the complexity of executing construction activities within an active GMP-regulated manufacturing environment, the involvement of multiple contractors, and the impact of safety risks on operational continuity, project cost, and schedule performance.

Measure - Relevant project data and safety observations (Good Saves) were collected throughout all project phases. The collected information included frequency of observations, risk categories, severity levels, work conditions, contractor activities, and compliance with safety procedures such as Job Safety Analyses (JSAs). This phase allowed the quantification of recurring unsafe conditions and the identification of high-risk operational areas.

Analyze - The collected data was analyzed using risk trend evaluation, severity analysis, and Root Cause Analysis (RCA) techniques to identify recurring patterns and contributing factors associated with unsafe conditions. Additionally, a Fishbone Diagram (Ishikawa Diagram) was utilized as part of the RCA process to categorize potential causes related to personnel, methods, equipment, environment, management, and materials.

Improve - Based on the analysis results, improvement strategies were developed to strengthen safety management, reduce operational risks, improve contractor coordination, and optimize project execution. Proposed improvements focused on PPE compliance, forklift safety, fall prevention, communication practices, supervision effectiveness, and reinforcement of safety procedures.

Control - Control mechanisms were established to ensure the sustainability of the proposed improvements. These included safety audits, KPI monitoring, standardized procedures, ongoing contractor training, toolbox meetings, and continuous field supervision. These controls were intended to support long-term operational reliability, safety performance, and compliance within future pharmaceutical expansion projects.

Risk Trends

During this phase, safety observations (Good Saves) collected throughout the project were analyzed to identify recurring risk patterns, evaluate severity levels, and determine the operational impact of unsafe conditions across different project phases (see Table 1).

Table 1
Risk Trend Analysis Across Project Phases

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

The analysis demonstrated that risk severity increased as the project progressed into more complex operational phases. Early project stages were primarily associated with PPE compliance and housekeeping deficiencies, while later phases presented higher-risk activities such as work at heights, forklift operation, and integration within active GMP-regulated areas. Phases 2 and 4 & 5 showed the highest concentration of severe observations due to elevated operational complexity and simultaneous contractor activities.

Severity Evaluation

The severity evaluation indicated that a significant portion of the observations corresponded to medium- and high-severity risks, particularly those associated with work at heights, forklift operation, and simultaneous operations between contractors and plant personnel.

These findings demonstrate that inadequate control of high-risk activities may significantly impact personnel safety, operational continuity, project schedules, and overall project costs. Additionally, in pharmaceutical manufacturing environments, uncontrolled safety risks may increase the potential for OSHA violations, operational disruptions, and regulatory compliance concerns.

The analysis reinforced the importance of implementing proactive safety management practices, continuous monitoring, and stricter enforcement of operational controls during all project phases.

Root Cause Analysis

To better understand the contributing factors associated with recurring safety observations, a Root Cause Analysis (RCA) was conducted using a Fishbone Diagram (Ishikawa Diagram) (see Figure 1) [4]. This approach allowed the identification of systemic deficiencies affecting safety performance and contractor coordination throughout the project.

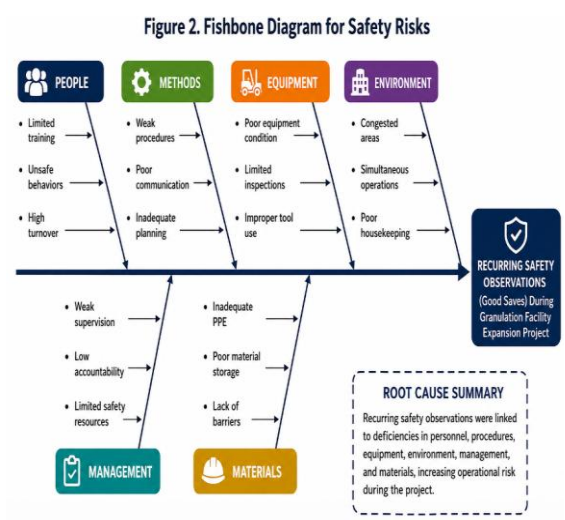

Figure 1
Fishbone Diagram

The RCA demonstrated that recurring unsafe conditions were not caused by isolated events but rather by multiple interconnected operational and organizational factors. The combination of contractor variability, complex working conditions, communication deficiencies, and inconsistent safety enforcement contributed significantly to the recurrence of safety observations.

These findings provided a strong foundation for the development of targeted improvement strategies focused on operational reliability, contractor management, and risk reduction.

Economics Impact

Although the project did not quantify the exact financial losses associated with each safety observation, the analysis demonstrated that recurring unsafe conditions could have significant operational and economic impacts throughout project execution. Safety deficiencies, such as PPE noncompliance, unsafe forklift operations, work-at-height hazards, and GMP area violations, could result in work stoppages, equipment damage, schedule delays, productivity losses, increased supervision requirements, and potential compliance-related costs. Table 2 presents a qualitative analysis of the potential operational and economic impacts associated with the primary risk categories identified during the project.

Table 2
Potential Operational and Economic Impact

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

Results

Figure 2 shows that improper use of PPE accounts for the largest number of observations, followed by risks associated with forklift operation and working at heights/falls.

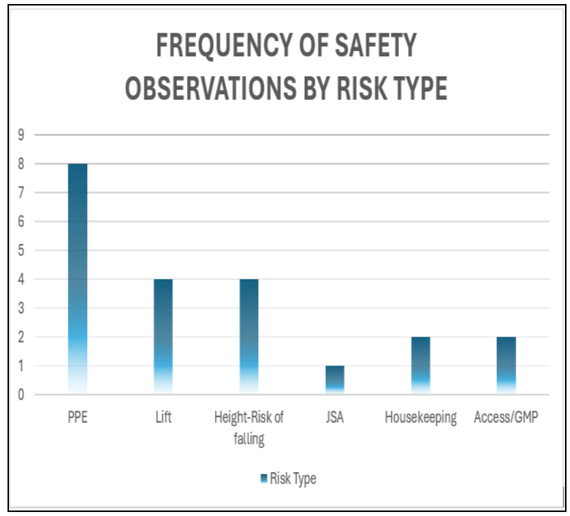

Figure 2
Frequency of Safety Observations by Risk Type

It is observed that the largest number of observations occurs in Phases 2 and 4 & 5, which coincide with higher-risk activities such as working at heights, handling equipment, and wearing PPE (see Figure 3).

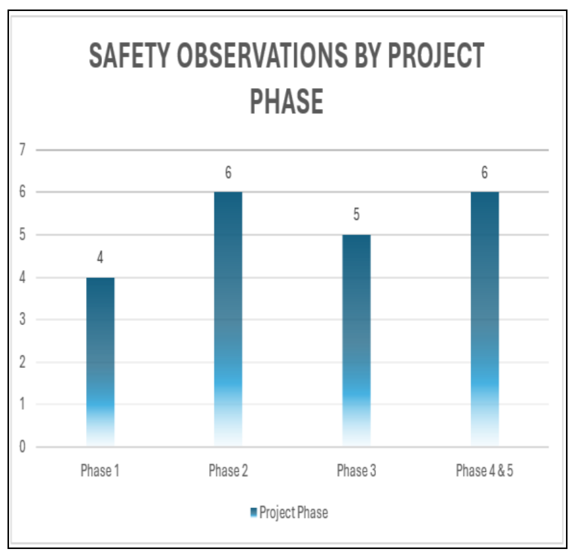

Figure 3
Safety Observations by Project Phase

Most observations correspond to medium-severity risks, underscoring the importance of effective controls during project execution (see Figure 4).

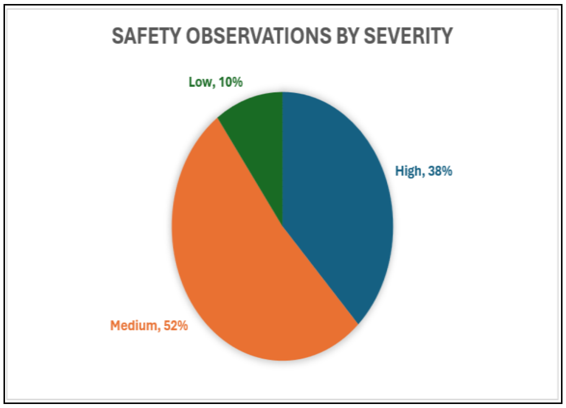

Figure 4
Safety Observations by Severity

Improvement

Based on the analysis results, several improvement initiatives were proposed to strengthen safety performance, improve contractor coordination, and reduce operational risks throughout project execution.

PPE Compliance Improvement - Because improper PPE use represented the most frequent safety observation, stricter enforcement measures were recommended, including daily field inspections, reinforced contractor accountability, ongoing training, and progressive disciplinary actions for repeated non-compliance.

Mobile Equipment Safety Control - To reduce forklift-related risks, the implementation of spotters in congested areas, speed limitations, designated travel routes, and improved visual signaling was recommended to minimize interaction hazards between personnel and equipment.

Fall Prevention Strategies - For work-at-height activities, mandatory harness inspections, reinforced fall protection training, and the implementation of collective protection systems such as guardrails and lifelines were proposed to reduce fall exposure and improve compliance.

Strengthening JSA Compliance - It was recommended that all critical activities include documented Job Safety Analysis (JSA) discussions prior to work execution. Additionally, random audits and supervisory reviews were proposed to reinforce procedural compliance and contractor accountability.

GMP Area Control - To reduce operational interference within active GMP areas, additional segregation barriers, stricter access controls, improved signage, and enhanced coordination between operations and contractors were recommended.

Communication and Contractor Coordination - Due to the large number of contractors involved in the project, daily coordination meetings (toolbox meetings) and improved communication practices were proposed to strengthen alignment between project teams, operational requirements, and safety expectations.

Control Strategies

To ensure the sustainability of the proposed improvements, several control mechanisms were established:

- Periodic safety audits to verify compliance with safety controls and procedures.
- KPI monitoring, including observation frequency, JSA compliance rates, and contractor safety performance.
- Standardization of safety procedures and best practices for future projects.
- Continuous training programs focused on high-risk activities and operational safety.
- Reinforced field supervision to ensure immediate correction of unsafe conditions and procedural deviations.

Conclusion

This study evaluated the execution of a pharmaceutical granulation facility expansion project within an active GMP-regulated manufacturing environment, highlighting the operational and safety challenges associated with contractor coordination, regulatory compliance, and high-risk construction activities.

Using DMAIC and Root Cause Analysis (RCA), the study systematically identified recurring safety trends, severity patterns, and contributing factors affecting project execution. The findings revealed that the most critical risks were associated with improper PPE use, unsafe forklift operation, work at heights, and deficiencies in procedural compliance and supervision.

The Fishbone Diagram analysis demonstrated that recurring unsafe conditions were influenced by multiple interconnected factors, including contractor variability, communication deficiencies, inadequate training, supervision gaps, and the complexity of working within active GMP operational areas.

Additionally, the study showed that safety performance directly impacts operational continuity, schedule compliance, project costs, and overall project efficiency. Safety incidents and operational disruptions within pharmaceutical environments may result in OSHA violations, productivity losses, project delays, and increased operational risk [5].

Based on these findings, targeted improvement strategies were developed to strengthen safety controls, improve contractor coordination, reinforce operational discipline, and support continuous improvement initiatives. The implementation of these measures is expected to reduce unsafe conditions, improve project execution efficiency, and enhance long-term safety performance within future pharmaceutical expansion projects.

Overall, this study demonstrates how industrial engineering methodologies and proactive safety management practices can support safer, more efficient, and more reliable execution of complex pharmaceutical facility expansion projects.

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