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Assessment of Efficacy of Human and Organizational Performance Methodology at a Large Biopharma Company

Christopher J Mastrangelo

A Thesis in the Field of Biotechnology Management

for the Degree of Master of Liberal Arts in Extension Studies

Harvard University

May 2026

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Abstract

This study examines how the implementation of Human and Organizational Performance (HOP) principles contributes to an organization's evolution into a learning organization. HOP, a philosophy centered on system-based thinking, risk management, and collaborative learning, provides a framework that shifts organizations away from blaming culture and toward continuous improvement. To evaluate the relationship between HOP adoption and learning-organization behaviors, multi-year trends in deviations, root-cause classifications, corrective and preventive actions (CAPAs), and Human Performance Assessment (HPA) maturity were analyzed.

The results demonstrate a strong alignment between HOP implementation milestones and improved operational and learning outcomes. Deviation initiation rates declined steadily over several years, while root-cause analysis shifted from Human Factors to Method-based causes, indicating increased system-based thinking. The rise in system-focused CAPAs, particularly Change Controls, further reflects a move toward strengthening work design and organizational reliability. Periods of reduced HOP oversight—most notably following the dissolution of the HOP team in mid-2024—corresponded with declines in training maturity, leadership engagement, and system-level corrective actions, reinforcing the importance of sustained governance.

Overall, the findings support the hypothesis that implementing HOP principles enhances learning-organization capabilities by improving psychological safety, problem solving, and error reduction. Re-establishing strong HOP governance and leadership accountability offers a clear path to stabilizing performance, reducing deviation frequency, and embedding durable organizational learning.

Frontispiece



Five Core Principles of Human Operational Performance (HOP)

(Conklin, 2019).

Author's Biographical Sketch

Chris Mastrangelo graduated from Boston College School of Arts and Sciences in 2001 and started a career in biopharma in 2007, beginning as a Manufacturing Technician in cell culture operations. Over the next several years, he became a Qualified Trainer across all cell culture processes and expanded his responsibilities to include writing deviations, CAPAs, and document revisions in support of Manufacturing. In 2011, Chris transitioned to the newly formed Investigations group, where he focused exclusively on deviation and CAPA management, strengthening his expertise in quality systems and root-cause analysis.

In 2022, Chris joined the Quality Assurance Technical team, where he now reviews and approves quality systems and documentation to ensure products are safe, effective, and compliant. His work is grounded in a strong sense of responsibility to patients and shareholders, and he is motivated each day by the knowledge that quality decisions directly impact patient safety and product reliability.

Chris is committed to acting with integrity and embraces new innovative tools and technologies to streamline deviation closure and support timely lot release. He is also proactive in identifying and escalating potential compliance or product quality concerns to ensure the organization maintains the highest standards of operational excellence.

Chris encourages others to make bold moves in their roles by speaking up when they identify potential issues. As he emphasizes, subject-matter experts are uniquely positioned to recognize risks, and raising concerns is essential to maintaining product

quality and patient safety. “Our patients depend on it,” he often reminds colleagues—a principle that guides his work every day.

Dedication

To my nephew Mason, who is like a son to me and whose buoyant spirit kept me grounded and focused when I needed it most. Watching him grow and learn, while becoming a skilled athlete, a dedicated teammate, and a child whose world is expanding through learning a second language, has been truly inspiring and one of my greatest joys. His steady encouragement reflects the remarkable young man he is.

Acknowledgments

This work is dedicated to my colleagues, Luisa Antonopoulos, Kristen Pham and Adam Borey whose collaboration and support were invaluable throughout this project. I also extend my sincere appreciation to subject-matter experts Clifford Berry and Amy Wilson, whose depth of knowledge and thoughtful guidance significantly enriched the quality and rigor of this research. Lastly, I'd like to thank Steven Denkin for providing insight and encouragement throughout the entire process.

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Table of Contents

Frontispiece iv

Author's Biographical Sketch v

Dedication vii

Acknowledgments viii

List of Tables xv

List of Figures xvi

Chapter I. Introduction 1

HOP Principles 2

Error is Normal 3

Systems drive behaviors 3

Integrated Risk Management 4

Sharp End/Blunt End Model 4

Work as Imagined / Work as Done 5

Risk Management and HOP 8

Prepare For Risk 9

Risk Ready Review 9

Pre Job Brief 9

Manage Risk 10

Touch Say Do Error-Reduction Practices 11

Learn from Risk 11
Investigations and HOP 12
Implementation of HOP Methodology 13
Definition of Terms 16
Chapter II Materials/Methods 19
QMS Data Analysis 19
Human Performance Assessment 19
Methods Summary 22
Research Question 23
Hypothesis 23
Chapter III Results 24
Quality Management System Data 24
Deviation Analysis 29
Deviation Initiation Rate 29
Root Cause Categories 30
CAPA Analysis 32
Human Performance Assessment Format 34
HPA Execution 36
Training Dimension 36
Leadership and Engagement 37
Managing Work Risk-Design 38
Managing Work Risk- Execution 38
Investigations and Learning 39

Proactive Learning 40
Monitoring Performance 40
Summary 41
Overall Element Summary 43
Chapter IV Discussion 45
Appendix 1 AAR Guide 47
Appendix 2 Causal Analysis Methods 48
Appendix 3 Human Performance Assessment Blue-Sky Descriptions and Readiness Warning Flags for each Dimension/Element 49
1. Leadership & Engagement 49
1.1 Documented HOP Guidance 49
1.2 Integration & Distinctions with Quality, Continuous Improvement, and Safety 49
1.3 Site HOP Lead / Champion Sufficient Expertise, Capability, and Resources 50
1.4 Leaders Go to Where Work is Performed to Learn About Success, Failure, and Risk 50
1.5 Just Culture 50
1.6 Strategic Deployment / Change Management 51
2. Training 51
2.1 HOP Training Strategy 51
2.2 HOP Fundamentals Training 52
2.3 HOP Role-Specific Training 53

3. Managing Work Risk - Design 53
3.1 Work Documentation Considers End User Needs and Risk Management.....53
3.2 Safety & Reliability in Engineering Design 54
3.3 Effectiveness in Response to Enterprise Business Systems Requests .54
3.4 Effectiveness in Response to Computerized Laboratory Systems Requests 55
3.5 Change Control Considers Risk.....55
3.6 Tech Transfer Considers Risk.....56
3.7 Organizational Management of Risk 56
4. Managing Work Risk – Execution.....57
4.1 Work Preparation Includes Risk Management 57
4.2 Worker Non-Technical Risk Management Practices Used to Create Safety & Reliability 57
4.3 Effective Use of Documentation to Manage Risk 58
4.4 Questioning Attitude & Stopping Work Is Institutionally Ratified and Rewarded 58
4.5 Handover and Shift-to-Shift Communications Enhance Risk Management.....59
4.6 GMP / Quality Culture.....59
4.7 Management of On-Site Contractors to Improve Reliability.....59
5. Investigations & Learning.....60
5.1 Investigation Methods.....60

5.2 Worker Involvement & Understanding Work As Done 61
5.3 Investigation Learning 61
5.4 Organizational Response to Undesirable Outcomes.....62
6. Proactive Learning.....62
6.1 Post-Activity Learning.....62
6.2 Work Observation.....62
6.3 Open Reporting.....63
6.4 Learning Culture 64
7. Monitoring Performance.....64
7.1 Deviation Management System Enables Performance Analysis.....64
7.2 Metrics Provide an Accurate Picture of Capacity to Manage Risk and Performance 65
Appendix 4 Deviation Frequency 2020 -2025.....66
Appendix 5 Event and Causal factor Chart Template 67
Appendix 6. HPA Scoring Results 2020-2024 68
Appendix 7 HPA Results by Dimension 2020-2024 69
Appendix 8 Readiness Warning Flags per HPA Dimension 2020-2024.....70
Appendix 9 Total Readiness Warning Flags per Year 2020-2024 71
Appendix 10 Deviation Root Cause Category Distribution March 2021 – July 2025 72
Appendix 11 Deviation Root Cause Category Percentage March 2021 – July 2025 73
Appendix 12 CAPA Category Distribution March 2021 – July 2025.....74
Appendix 13 CAPA Category Percentage March 2021 – July 2025.....75
Appendix 14 Overall HPA Results by Dimension 76

References.....77

List of Tables

Table 1. HOP Principles 2

Table 2. Risk Management Elements/Definitions 4

Table 3. Risk Ready Review Questions/Benefits 9

Table 4. HPA Dimensions/Elements 21

Table 5. Deviation Root Cause Category Percentage by year 31

Table 6. CAPA type percentage by year 34

Table 7. 2024 HPA Groups/Elements 35

List of Figures

Figure 1. The Sharp-End/Blunt-End model of Performance 5

Figure 2. Work As Imagined Versus Work As Done 7

Figure 3. Risk Important/Risk Critical Steps 8

Figure 4. Pre-Job Brief/Risk-Ready Review 10

Figure 5. HPA Maturity Scoring 22

Figure 6. Event and Causal Factor Chart Template 27

Figure 7. Monthly Deviation Initiation Rate from January 2020 to July 2025 30

Figure 8. Root Cause Category Frequency of Deviations initiated from 2021 to 2025 ...31

Figure 9. CAPA Type by Year 33

Figure 10. 2024 Overall HPA Results by Dimension 43

Figure 11. Human Performance Assessment Scores by Dimension 2020-2024 44

Chapter I.

Introduction

Human and Organizational Performance (HOP) is a philosophy of how humans and organizations interact to accomplish work, which when adopted creates a cultural change that enables improved overall performance for an organization. HOP integration supports better system design, allowing organizations to improve outcomes over time. HOP is based upon an understanding of how people work together with processes, facilities and each other as part of a system. This improves how organizations manage risk, enabling them to better protect people and products by establishing necessary capacities and controls. HOP creates more operational success through improving our understanding and management of risk in our work. HOP is a way of thinking. It's a philosophy that helps improve the workplace collaboratively (Edwards, 2020).

Human and organizational performance is an operational management focus that creates more success under both expected and unexpected conditions through better system design, enhanced work execution, and improved learning. This results in improved reliability with operational resilience, creating more success. This is achieved by anticipating the potential for harm to people and products, monitoring controls and margins necessary for safety, responding to off-normal conditions to recover gracefully and learning the right lessons from success and failure.

Human and Organizational Performance is not only a philosophy of risk management and system design; it is also a framework that shapes how organizations learn. The emphasis on moving away from a blaming culture, strengthening system-based

thinking, and improving the quality of learning from events aligns closely with the core attributes of a learning organization. Because HOP encourages reflection, inquiry, and continuous improvement, its implementation provides a meaningful way to examine an organization's development of the cultural and operational capacities associated with organizational learning. This connection forms the basis of the present study, which evaluates whether the adoption of HOP principles and practices contributes to measurable progress toward becoming a learning organization.

HOP Principles

The foundational principles of Human & Organizational Performance are vital to its success (See Table 1).

Table 1. HOP Principles

Principle	Description	How to help manage risk and create success?
People Want to Do a Good Job	People want to do good job; we are fallible and even experts make mistakes!	Assume people have good intentions.
Error is Normal	Error is normal and not intentional. People make between 1 and 15 mistakes every hour. Errors even occur as part of success.	Think about and discuss the steps that must go right and how risk will be managed before work begins.
Systems Drive Behaviors	Errors are outcomes of the work environment and system design. Even in a well-designed system, success is never 100%.	Look for system weaknesses that create risk and tell your supervisor/manager.
Systems are Complex and Imperfect	Fallible people created our systems. Our systems are made up of many dynamic, interconnected parts, operating in volatile and uncertain conditions.	Expect that our systems will sometimes fail. Anticipate and manage potential risk to protect our people and product.

Principle	Description	How to help manage risk and create success?
Safety is the Presence of Controls	The absence of undesired outcomes does not mean a system is safe.	Ensure all controls necessary to protect assets from harm are in place before work begins.
How we Respond Matters	How leaders and peers react when failure occurs tells people what will happen next. When people feel psychologically safe, they will be candid about risks and work context, and then leaders can learn how to improve systems.	Show people you care by demonstrating empathy and being helpful.
Learning is Vital	We can either blame or learn, but we cannot do both. Learning is vital and is essential to improving performance.	Ask HOW rather than WHY to learn about work context. Focus corrective actions on the system.

Adapted from "Do Quality Differently" (Berry and Wilson, 2023)

Error is Normal

Error is normal because people are fallible, and our workplace is a complex system. Human error is a symptom of systems shortcomings, not a cause of failure. Using systems thinking is a way of seeing and talking about reality that helps us to better understand and influence our workplace system.

Systems drive behaviors

Failures arise from multiple factors, each necessary but only jointly sufficient to create an adverse event. Many contributors are system factors that have been present (latent) in the organization for some time prior to the specific sequence of events,

influencing local factors. Some contributors are local factors, which are experienced in the workplace by people in real-time (active adaptations) during the sequence of events.

Integrated Risk Management

Integrated risk management is an approach used to protect our assets from risks and hazards.

Table 2. Risk Management Elements/Definitions

Parts of Risk Management	Definition
Asset	Anything of value – person, product, equipment, etc.
Hazard	Anything that could cause harm to an asset
Risk	The likelihood of an asset being harmed by a hazard.

Sharp End/Blunt End Model

The Sharp-End/Blunt-End Model of Performance (Figure 1) depicts the relationship between System/Organizational Factors (blunt end), Workplace Local factors, Behaviors (sharp end), and Asset Outcomes.

System/organizational factors at the blunt end occur far from where the work is done and can be thought of as how managers and designers imagine the work is performed (refer to black line Figure 2). Workplace local factors are present where the work is done which could impact behaviors and outcomes. Behaviors occur at the sharp end where the work is done (refer to blue line in Figure 2). The asset being protected is at the bottom of the model (refer to Figure 1).

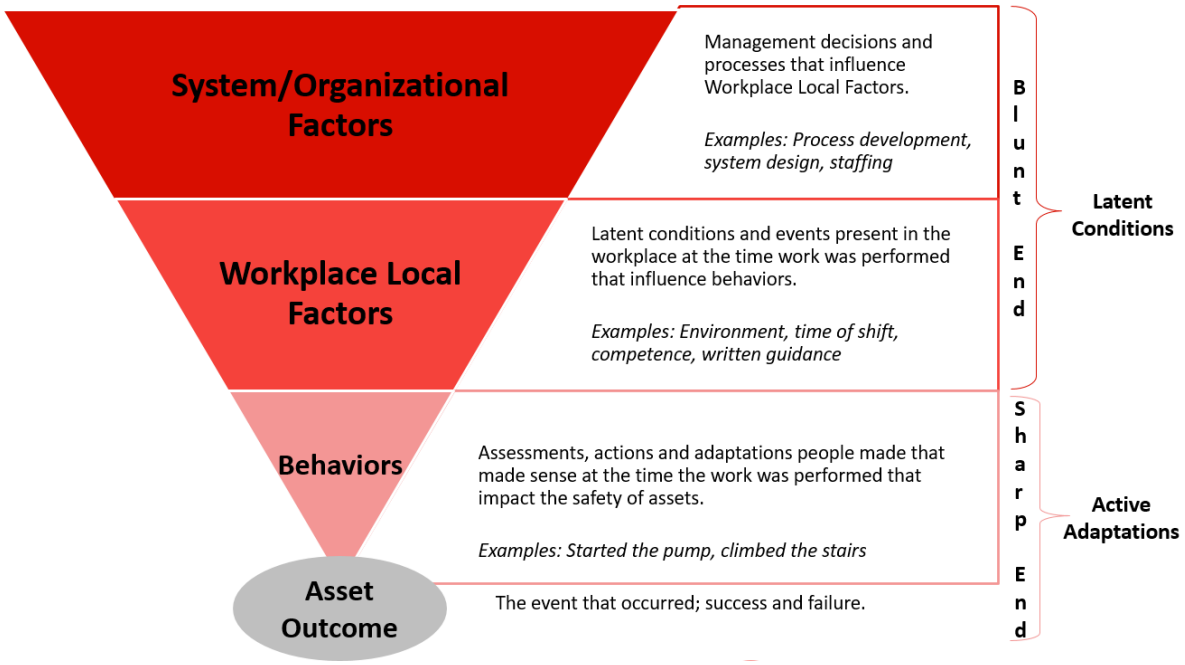


Figure 1. The Sharp-End/Blunt-End model of Performance

Diagram adapted from "Do Quality Differently" (Berry, Wilson 2023)

Work as Imagined / Work as Done

Systems are inherently complex and imperfect, which makes it essential to understand work as it is truly performed—not just how it is prescribed or imagined. "Work as imagined" often reflects assumptions embedded in processes and SOPs created in a different time, place, and context from those who now carry out the work. In contrast, "work as done" captures the real conditions, adaptations, and trade-offs that shape everyday performance. By emphasizing the importance of learning from actual work, HOP principles create the conditions for deeper organizational insight, reflection, and continuous improvement. This shift from relying on assumptions to engaging with real operational experience is a foundational mechanism through which HOP supports an organization's evolution into a learning organization.

In Figure 2 below, the black line represents work as imagined. It is how people who do not perform the work believe how it takes place. It is what designers, managers, regulators and authorities believe happens or should happen.

The blue line represents work as done. It's how good work actually happens influenced by multiple factors. The workers are the masters of the blue line, often creating success through work adaptations that cannot be imagined by people who do not perform the work. Adaptations are why the blue line varies as compared to the work as imagined.

The red line depicts risk and like the blue line, this line can also vary over time. The region between the blue line and the red line is where we ensure controls exist that help guard against the blue line touching the red line, where failure may occur. If work as done and risk intersect, this may result in undesired outcomes which are failures in our capacity and controls. Understanding the difference between work as imagined and work as done is Operation Learning. We can adjust work as imagined to better match and support work as done. The better we understand the work as done, the better our processes can be at avoiding risk. When we cannot get the two closer together, we need stronger controls where risk exists.

Work as...	Is…	Example
Imagined	is how people who do not perform the work believe it takes place.	Black line
Done	is how the work really happens; influenced by Workplace Local Factors and System / Organizational Factors.	Blue line
Risk	undesired outcomes are failure in capacities and/or controls.	Red Line

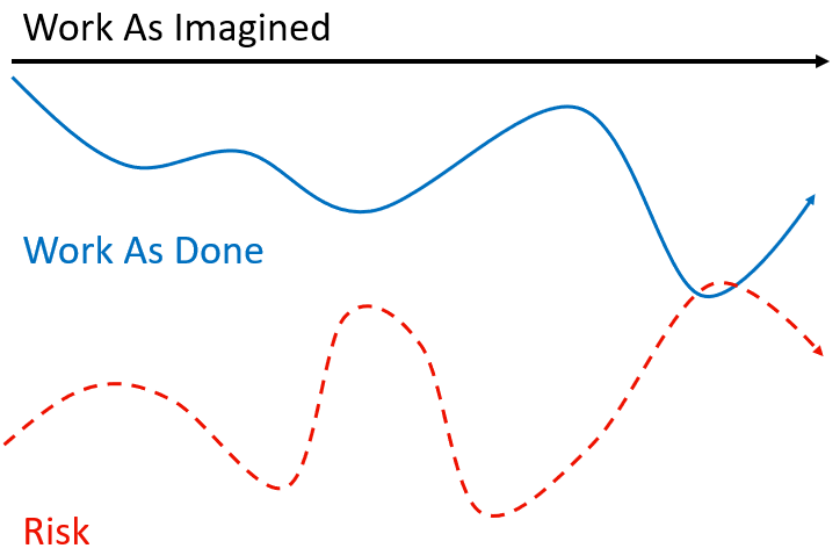


Figure 2. Work As Imagined Versus Work As Done

adapted from Pre-Accident Investigations: An Introduction to Organizational Safety Conklin, T. (2012)

HOP is based on safety science, resilience engineering, psychology, and human factors. Safety science is the field of study that investigates the science and technology of human safety. It seeks to understand risks to humans and provide guidance in mitigating them. Resilience engineering is the capability of systems and organizations to anticipate

and adapt to potential surprises and failures. Psychology explores how we behave in different work environments. Human factors is about designing work that fits the capabilities of people. When HOP is integrated within operations, better system design, enhanced work execution, and improved learning will occur. This will lead to improved reliability and operational resilience.

Risk Management and HOP

Risk-based thinking, another important concept in HOP, is the consideration of how assets may be harmed by hazards during work, and how that risk will be managed to create safety. In risk-based approach to human performance, we classify actions as Risk Important Steps—those that precede and influence a critical action—and Risk Critical Steps, which, if executed incorrectly, can cause immediate, irreversible, and intolerable harm. Refer to Figure 3 for example.

Risk Important Step	Risk Critical Step
A human action that precedes a risk critical step, that will not trigger immediate, irreversible, and intolerable harm to an asset if done improperly, while instead leading to harm if performed improperly only when the risk critical step is performed.	Any human action that triggers immediate, irreversible, intolerable harm to an asset if that action or a preceding action is performed improperly.
 Skydiver preparing for jump.	 Skydiver jumping from airplane.

Figure 3. Risk Important/Risk Critical Steps

Prepare For Risk

Biopharma systems are complex and imperfect. Simple practices are used to help anticipate risk by discussing potential hazards just prior to starting a task, creating positive control when risk is present, and learning from both success and occasional failures. To better manage potential hazards, teams typically use two preparation practices before beginning work: pre-job briefs and risk-ready reviews.

Risk Ready Review

A risk-ready review (RRR) is a self-dialogue performed by a single person, or a conversation between multiple people to improve the likelihood of success where there is a potential risk to people or products. Risk ready review is performed immediately before a work task begins. Risk ready reviews consider four key questions:

Table 3. Risk Ready Review Questions/Benefits

Question	Benefit
What are the factors that create a risk of failure?	Worker considers error traps in the standard operating procedure (SOP) or off-normal conditions.
What is the worst possible failure that could happen?	Worker assesses risk of an injury to themselves or a co-worker, or a batch loss
How will steps that must go right be performed and monitored?	Worker assesses all the critical steps before starting the process
What is the status of controls that protect people and products?	Worker assesses all the controls that will protect them and the product

Pre Job Brief

A pre-job brief is structured guide followed by the people who will perform a task to improve the likelihood of success by enhancing the management of risks, improving work execution, and preparing for contingencies where work may need to be stopped.

Ideally, the Pre-Job Brief takes place in the location where the task will occur and is performed immediately before the task is to begin.

Comparison of risk preparation practices helps workers determine best practice to use based on the risk level of the task.

Pre-Job Brief	Risk-Ready Review
• A bit more formal • A structured guide • Used by a team of two or more • Assesses Risk Critical Steps	• A bit more informal • Four simple questions • Could be used by a lone worker • Assesses potential risk to people / product

Figure 4. Pre-Job Brief/Risk-Ready Review

Manage Risk

When we engage in high-risk or high-consequence work, maintaining positive control becomes essential. Any environment where complex tasks are performed contains potential error traps, which are conditions that can lead to unintended outcomes and harm if not managed carefully.

One of the most effective ways to strengthen reliability is by building mindfulness into everyday actions. Mindfulness, at its core, is simply moment-to-moment awareness—pausing long enough to ensure that the level of attention matches the importance of the task.

Many industries have developed structured practices to support this kind of awareness. In some sectors, it is known as Self-Checking or STAR (Stop, Think, Act, Review). In others, such as the Japanese railway system, it takes the form of shisakanko, or “pointing and calling,” a technique that reinforces focus through deliberate verbal and physical cues.

Research from Japan's Railway Technical Research Institute found that people performing a simple task made an average of 2.38 errors per 100 actions. When using pointing and calling, errors dropped to just 0.38 per 100 actions—an improvement of roughly 85%. This demonstrates how simple, intentional practices can dramatically reduce human error (Iwasaki and Fujinami, 2012).

Touch Say Do Error-Reduction Practices

"Touch say do" error reduction practice was adapted at the organization in scope of this study and was based in part on "pointing and calling" methodology.

TOUCH: place your hand on the object that will be operated

SAY: state aloud the action to be performed and the name of the object

DO: perform the action

Learn from Risk

An organization needs to learn from both success and occasional failure, because each provides valuable insight into how work is actually performed. A Post-Job Review is a simple, brief conversation among the people who completed the task, focused on capturing meaningful feedback—what went well, what didn't, and what could be improved. By taking a few minutes to reflect while the work is still fresh, teams can identify practical lessons learned and opportunities to strengthen processes, tools, and behaviors. When done consistently, Post-Job Reviews help an organization build a culture of continuous learning, where both positive outcomes and missteps contribute to safer, more reliable performance.

Investigations and HOP

For quality system and safety incident investigations, industries have historically designated human error as a root cause. However, using human error is not optimal as it can curtail an investigation, which will in effect limit potential learning that should occur during the investigation/CAPA process. Simply put, when human error is determined to be the root cause, the inquiry stops and opportunities for learning and improvement are denied.

If an organization is to improve in response to adverse events, it is imperative that learning occurs during the investigation process. For this to occur, an investigation needs to be a fact-finding exercise. However, organizations that feature a blaming culture incorporate investigation processes that incorporate fault finding, which interferes with fact finding that is vital to learning. The use of Human Error as a cause is indicative of a work culture that seeks to blame, rather than to understand, which is problematic if an organization seeks continuous improvement.

An additional issue with traditional investigation practices is the tendency to use linear analysis to identify a singular root cause. However, when investigating complex systems that feature the interaction of many moving parts, finding a single root cause is not just overly simplistic, but also unrealistic. With HOP, an investigation will take a holistic view of all the systems in place that allowed the problem to occur. Using this approach, multiple system factors are usually identified that come together to create the opportunity for failure.

Also, traditional investigations are often executed far from where events occur, using information provided by management or other personnel on the periphery of the actual event. This is problematic as the investigator will only get a representation of the

event and interaction of systems in place from those who may not be involved with doing the actual work. Conversely, to get a more accurate depiction of the event, HOP methodology directs investigators to go where the work is done to learn from those who do the actual work. This is called an operational learning gemba.

Before the advent of HOP methodology, when operations involving humans went awry, investigators used terms such as fault, blame, carelessness, inattentiveness, and negligence. Characterization of human performance using these terms placed blame on front line workers, without inquiry into the systems and environment in which the work is done, which ultimately prevented any potential learning that could have been provided by the adverse event. When this happens, an organization is deprived of an invaluable opportunity to learn, improve and grow.

Implementation of HOP Methodology

Several years ago, at a large global biopharmaceutical company that employs over 50,000 employees, it was discovered that a piece of critical equipment was validated without sample valves that are critical to product sampling, which is required for product testing and release. The equipment validation process involves multiple functional groups and subject matter experts who endeavor to do excellent work and yet the error still occurred.

During investigation of the event, it became obvious that the complex and imperfect systems in place that usually allow for success, had failed in this instance. In the past, the event may have simply been attributed to human error. However, for this event, multiple contributing system failures were identified, and it became apparent the workplace operational guidance needed modification. As such, the company intended to

use this event as a catalyst to develop more effective organizational learning to reduce the risk of failure and increase the rate of success. Therefore, in 2020, to enhance organizational learning and improvement, the company implemented Human and Organizational Performance (HOP) methodology. The goal of this directive was to increase the understanding of how people interact with processes, systems, and other people, to manage risk and to better protect people and products from harm.

The primary objective of HOP is to increase the likelihood of successful outcomes such as meeting product quality standards, on-time product release and the maintenance of workplace safety, while reducing the frequency and severity of undesired outcomes such as safety incidents, product discards, and process related deviations (Edwards, 2020).

HOP changes the way safety incidents and process deviations are investigated and categorized, and how corresponding root causes and contributing causal factors are addressed. Human error is no longer the first choice in the determination of root cause of adverse events. When embarking on the HOP journey, greater focus is placed on the context in which people work, namely organizational systems, processes, and procedures, with a goal of continuous learning and improvement. One of the hallmarks of HOP methodology is that errors are viewed as learning opportunities. Frontline workers are a rich source of knowledge that when tapped effectively, can provide immense benefit to an organization. HOP methodology does not seek to blame, but rather to understand.

"Psychological safety is a belief that one will not be punished or humiliated for speaking up with ideas, questions, concerns, or mistakes. It gives us a shared sense of candor, about making it possible for productive disagreement and free exchange of ideas." (Edmondson, 2018).

Post incident operator interviews executed in an environment of psychological safety can encourage free flow of information that is invaluable to organizational growth. HOP principles can be used wherever humans work within systems. As such, the implications for its use are virtually limitless. As HOP can be broadly applied across industries with complex systems, understanding how these principles influence organizational learning becomes important for determining whether they can reliably support long-term cultural and operational improvement.

Definition of Terms

Behavior: The mental and physical efforts to perform a function; consisting of observable (movement or speech) and hidden (perceiving, thinking, assessing, analyzing, deciding) tasks or activities by an individual.

CC (Change Control): A process used to ensure that changes to a product or system are introduced in a controlled and coordinated manner

Corrective and Preventative Action (CAPA): Improvements to an organization's processes to eliminate causes of non-conformities or other undesirable situations

Culture: A pattern of shared basic assumptions that the group learned as it solved its problems of external adaptation and internal integration, that has worked well enough to be considered valid and, therefore, to be taught to new members as the correct way to perceive, think, and feel in relation to those problems.

Deviation: The action of departing from an established course or accepted standard.

Error Trap: An unfavorable condition in the workplace that increases the likelihood of error.

Error: An unexpected departure from an expected outcome. A simplistic term used to describe the outcome of a complex problem in hindsight, that indicates the speaker may not yet understand how a system works.

Gemba: Japanese term meaning “the actual place.” In the context of HOP it refers to going to where the work is done to learn from those who do the work by being curious and asking effective questions.

Effective inquiry uses three types of questions:

1) An open-ended question may focus on what, how, why, or if.

2) A closed-ended question can be answered with a simple word or a short phrase.

3) Questions that start with the word, why are considered why questions. This is a type of open-ended question.

Hazard: A source of energy, mass, or information that could cause harm to an asset.

Human and Organizational Performance (HOP): A philosophy of how humans and organizations interact to accomplish work

Human Performance Assessment (HPA): A methodology used to assess an organization's maturity in implementing Human Operational Performance philosophy.

Operational Learning: the process of continuous improvement that helps organizations become more successful

Performance: The degree to which you get what you expect from a person, machine, process, or system.

Psychological Safety: A shared belief held by members of a team that one will not be punished or humiliated for speaking up with ideas, questions, concerns, or to report / explain mistakes, and thus are safe for interpersonal risk taking that enhances learning and leads to team efficacy.

Quality Management System (QMS) application used in issuing and monitoring the completion of activities related to Deviations, CAPAs, and Change Controls.

Questioning Attitude: Challenging unknown and expected conditions, challenging assumptions, offering opposing views, and stopping work and escalating problems as necessary.

Recurring Deviation: Repetition of a similar root cause for a similar deviation that has been investigated and CAPA implemented.

Repeating Deviation: Repetition of a similar deviation with similar conditions.

Right First Time: A fundamental quality principle focused on completing processes correctly on the initial attempt, eliminating the need for inspections, rework, or corrections.

Risk Ready Review: A self-dialogue used by a single person, or a conversion between multiple people to improve the likelihood of success where there is a potential risk to the people or product. It is performed before a work activity begins in the location where the work takes place.

Risk-Based Thinking: The consideration of how assets may be harmed by hazards during work, and how that risk will be managed to create safety.

Root Cause Analysis: Approaches, tools, and techniques used to uncover causes of problems

Root Cause: The fundamental reason for the occurrence of a problem

System / Organizational Factors: Management decisions and processes that influence workplace local factors.

Systems Thinking: A discipline for seeing the whole picture; a framework for seeing interrelationships rather than things; for seeing patterns of change rather than static snapshots.

Work Culture: The cumulative effect that leadership practices, employee behavior, workplace amenities, and organizational policies create on a worker/internal stakeholder

Workplace Local Factors: Conditions and events present in the workplace at the time work was performed that may have influenced behaviors.

Chapter II

Materials/Methods

Quality risk management (QRM) is a process that biopharma organizations use to identify, assess, control, communicate, and review risks that could impact product quality, ensuring patient safety, regulatory compliance, and operational efficiency by proactively managing potential failures and leveraging opportunities across a product's lifecycle (SafetyCulture, n.d).

QMS Data Analysis

To determine if the HOP directive was effective in helping the organization become a learning organization, quality management system (QMS) data was analyzed. There was a specific focus placed upon Deviations, Corrective and Preventative Actions (CAPA), and Change Controls quality subsystems. These Quality Systems were assessed to determine whether HOP principles were truly shaping outcomes.

Data at the outset (January 2020) throughout implementation, (2021-2023), and during/after (2023-2025) HOP dissolution was considered. Low/Medium/High Risk deviations and CAPA/Change Controls were considered in the analysis. Deviation initiation rate, type, severity, and root cause were assessed. CAPA / CC type were evaluated.

Human Performance Assessment

A Human Performance Assessment (HPA) was performed on a yearly basis from 2020 to 2023 after commencement of HOP implementation to assess the organization’s

maturity in implementing HOP philosophy. Although the HOP group was scaled down starting in October 2022, when the HOP director left the organization in scope and was formally discontinued in July 2024, the data supports that many of its principles have endured. To assess the degree at which HOP philosophy was maintained, a final HPA was performed for 2024 in support of this thesis. This was done specifically as a development opportunity to gather thesis data to determine HOP influence during and after HOP group dissolution. The Assessment was performed using the Human Performance Assessment Tool created by the BioPhorum Operations Group (BPOG, 2022). The tool is used to gauge HOP maturity level. When an organization reaches the highest level of maturity it is deemed "Blue-Sky." Readiness Warning Flags are indicators that an organization is not ready to adopt and/or sustain HOP principles and philosophy. It identifies potential weaknesses in performance. An example of a warning flag might be that human error continues to be used as a root cause in deviation investigations

The HPA was designed with seven dimensions, and each dimension has multiple elements that were considered during execution of the HPA. Refer to Appendix 3 for Blue-Sky Criteria and Readiness Warning Flags for each HPA Element.

Table 4. HPA Dimensions/Elements

Dimensions	Elements
Leadership & Engagement	1.1 Documented HOP Guidance 1.2 Integration & Distinctions with Quality, Continuous Improvement, and Safety 1.3 Site HOP Lead/ Champion Sufficient Expertise, Capability, and Resources 1.4 Leaders Go to Where Work is Performed to Learn About Success, Failure, and Risk 1.5 Just Culture 1.6 Strategic Deployment/ Change Management
Training	2.1 HOP Training Strategy 2.2 HOP Fundamentals Training 2.3 HOP Role-Specific Training
Managing Work Risk - Design	3.1 Work Documentation Considers End User Needs and Risk Management 3.2 Safety & Reliability in Engineering Design 3.3 Effectiveness in Response to Engineering Process and Automation Requests 3.4 Change Control & Tech Transfer Considers Risk 3.5 Change Control Considers Risk 3.6 Tech Transfer Considers Risk 3.7 Organizational Management of Risk
Managing Work Risk - Execution	4.1 Work Preparation Includes Risk Management 4.2 Worker Non-Technical Risk Management Practices Used to Create Safety & Reliability 4.3 Effective Use of Documentation to Manage Risk 4.4 Questioning Attitude & Stopping Work Is Institutionally Ratified and Rewarded 4.5 Handover and Shift-to-Shift Communications Enhance Risk Management 4.6 GMP/ Quality Culture 4.7 Management of On-Site Contractors to Improve Reliability
Investigations & Learning	5.1 Investigation Methods 5.2 Worker Involvement & Understanding Work-As-Done 5.3 Investigation Learning 5.4 Organizational Response to Undesirable Outcomes
Proactive Learning	6.1 Post-Activity Learning 6.2 Work Observation 6.3 Open Reporting 6.4 Learning Culture
Monitoring Performance	7.1 Deviation Management System Enables Performance Analysis 7.2 Metrics Provide an Accurate Picture of Capacity to Manage Risk and Performance

INNOCENCE: 1 – 2	AWARENESS: 3 – 4	UNDERSTANDING: 5 – 6	COMPETENCE: 7 – 8	EXCELLENCE: 9 – 10
We have not yet begun to move toward the biopharm blue-sky, but may have begun considering benefit	We are starting to move toward the biopharm blue-sky, but currently in small pockets of implementation	We are moving towards biopharm blue-sky in many areas, but not in all areas, and with uneven results	We are moving toward the biopharm blue-sky in all areas, but with uneven results in some	We have achieved the biopharm blue-sky in all areas and with very good results in all

Figure 5. HPA Maturity Scoring

The scoring of the assessment uses a numerical scoring system. Each element within the dimension is scored using a one (1) to ten (10) point scale.

Methods Summary

Statistical analysis of quality systems and yearly Human Performance Assessments was employed to determine if HOP objectives are being achieved. Impact on work culture was assessed. Cross functional groups, front line workers, management and site leadership were part of the Human Performance Assessments and polled on several categories to gauge shift in work culture since HOP implementation and subsequent to dissolution of the HOP group. System improvements were assessed to determine impact on Human Performance. All results were assessed to determine if the ultimate objective of becoming a learning organization is being achieved.

Research Question

Does the implementation of Human & Organizational Performance (HOP) principles contribute to an organization's evolution into a learning organization?

Hypothesis

"Organizations that implement HOP principles demonstrate measurable increases in learning-organization behaviors, such as psychological safety, problem solving, and error reduction."

Chapter III

Results

Quality Systems Data and Human Performance Assessment analysis were assessed to determine if HOP affected a transformation into a learning organization. The results of this analysis are detailed below.

Quality Management System Data

Quality management system (QMS) data queries were executed to quantify the monthly deviation initiation rate from January 2020 to July 2025. This timeframe was selected because implementation of HOP methodology began in January 2020 and continued formally until July 2024 when the HOP organization was formally dissolved. QMS analysis continued until July 2025 to establish long term effects of the HOP directive on the deviation initiation rate. This latter period is important to determine whether the tenants of HOP principles continued after HOP dissolution and if the organization continued to benefit in terms of initiation rate. The analysis below contextualizes month-to-month deviation trends against key concurrent HOP initiatives, training deployments, and operational conditions (including COVID-19 impacts), providing a basis to interpret whether deviation initiation rates declined over time as would be expected if HOP principles were embedded and effective. If the HOP directive had a positive effect on deviation frequency, it would be expected that the rate would decrease from January 2020 to July 2025.

Below is a list of events/conditions that occurred during the timeframe in scope and analysis of potential impact on overall deviation initiation rate. See Figure 1 for plot of Monthly Deviation Initiation Rate from January 2020 to July 2025.

- January 2020 –. Right First Time (RFT) disruption - A global initiative (RFT) had previously been launched to encourage workers to perform tasks right the first time, which could have potentially disrupted the work that the HOP team was doing because RFT was generally interpreted to mean that processes must always be executed correctly the first time. This runs counter to HOP philosophy, which maintains that people who work within complex systems sometimes make mistakes. After RFT disruption and the onset of HOP implementation, it was observed that the deviation initiation rate began to decrease after January 2020.
- April 2020 – The idea that 'Human Error' was not a true root cause was first disseminated to Manufacturing Personnel and Manufacturing Compliance Investigators. This encouraged deeper examination of events to identify workplace local factors and system/organization factors that may contribute to cause. This in turn would lead to more effective corrective actions, which would theoretically decrease repeat events. It was observed that the deviation initiation rate continued to decrease, although the onset of the COVID 19 pandemic would serve to temper these effects, by creating acute staffing shortages over the next few months which corresponded with an uptick in overall deviation rate.
- May 2020 - Risk Ready Review was made a standard practice to help anticipate risks before they become a problem in real-time. Risk Ready Review consists of review of standard operating procedures (SOP) and master batch records (MBR) and assessment of work area and equipment prior to execution of work to identify

potential issues or error traps. It was observed that the deviation initiation rate continued to decrease after Risk Ready Review was established.

- May 2020 – HOP staffing increased to 3 full time employees. This resulted in greater on the floor presence during operations and more support for the MFG Compliance Team during event investigation and root cause analysis.
- July 2020 – Pre Job Briefs made standard practice prior to execution of work.
- Nov 2020 - HOP Fundamentals Trainings were launched
- Dec 2020 – Touch-Say-Do methodology implemented with MFG Operations groups
- January 2021 – HOP Overview eLearning implemented and assigned to multiple functional groups including MFG Compliance Investigations and MFG Compliance CAPA/CC teams.
- January 2021 –Operational Learning (OL) Gemba / Humble Inquiry was implemented for use during investigations to enhance psychological safety during on the floor walkthroughs and operator interviews. Operational Learning is accomplished by observing work as done. Gemba is a Japanese word meaning "the actual place." In this case, it means the place where the work happens. During Gemba, investigators and/or leaders go to where the work is done to learn from the people who do the work. Humble Inquiry is building relationships by asking questions verses telling. The belief is that asking questions will lead to trust which, in turn, leads to better communication and collaboration.
- Gemba data is reported by users and managed using a centralized cloud-based enterprise application.

- February 2021 – Event and Causal Factor (E&CF) Charting implemented for Quality System Investigations. This non-linear Root Cause Analysis tool is useful to identify system factors and local conditions that contributed to cause events that were previously assessed as Human Error events. See below and Appendix 5 for E&CF template

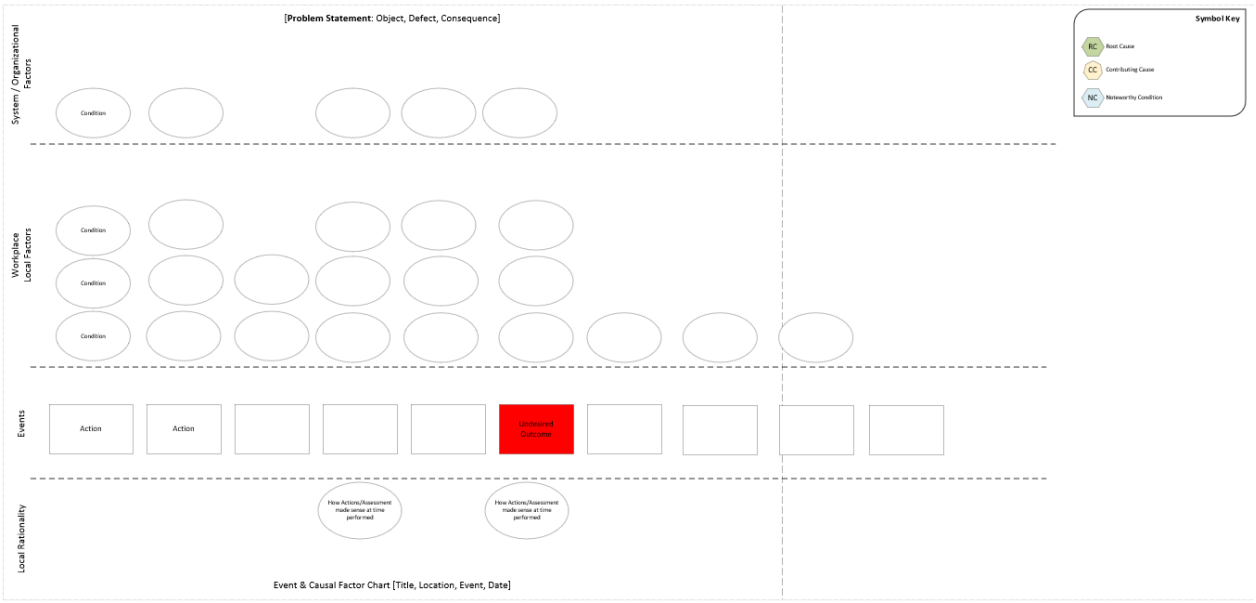


Figure 6. Event and Causal Factor Chart Template

- May 2021- HOP Fundamentals Training expanded to include risk-based thinking, Risk Ready Review, Pre-Job Brief, and Post-Job Review, which is a simple and brief discussion among workers to collect meaningful feedback, both good and bad, and lessons learned. The information collected is used to make work process improvements.
- June 2021 – After Action Review (AAR) Formalized - AAR is a guided analysis of an organization's performance to be conducted during and at the conclusion of an event

for future improvement. The purpose of an After-Action Review (AAR) is to understand how things go right as well as explain how things occasionally go wrong in our work, in order for the team and the organization to learn. The goal is to improve systems to make it easier to get it right, and harder to get it wrong. AAR data is reported by users and managed using a centralized cloud-based enterprise application. See Appendix 1 for AAR Guide

- September 2021 - HOP Peer2Peer implemented – Peer2Peer is a recognition program that acknowledges Manufacturing personnel for use of HOP risk-management practices on the manufacturing floor, and for providing positive reinforcement to teammates. Weekly/Monthly winners are randomly selected and are awarded points on the company recognition/reward system. Valid submission must be for someone using a HOP tool e.g. Touch-Say-Do, Risk Ready Review, Pre-Job Brief, or After-Action Review. This will empower Manufacturing to champion HOP risk management practices while building trust and teamwork.
- April 2022 - Post-Job Review Formalized – Post Job Review is a simple and brief discussion among workers to collect meaningful feedback, both positive and constructive, and lessons learned for use in making work process improvements. They are intended to be performed after unit operations that have a Pre-Job Brief. Post Job Review data is reported by users and managed using a centralized cloud-based enterprise application.
- October 2022 - HOP Director leaves company which resulted in additional turnover within the HOP organization. Vacated HOP roles were not backfilled. Priorities shifted and HOP goals were reprioritized based on less headcount e.g. Peer2Peer program discontinued.

Deviation Analysis

Deviation Initiation Rate

The overall trend for deviation initiation rate from 2020 through 2024 was downward. The trend line was calculated using an Excel linear regression of the monthly deviation generation rate that finds the best fit straight line through the entire data set. The deviation initiation rate decreased steadily except for isolated periods in March 2022 and June - August 2024 when conflicting priorities, i.e. regulatory audits, prevented supervisors and management from providing regular oversight on the manufacturing floor. For these periods, a one-off increase in initiation rate was observed. Overall trend results indicate strong correlation between HOP implementation and decrease in deviation initiation rate. See Appendix 4 and Figure 7 for plot of monthly deviation initiation rate from January 2020 to July 2025.

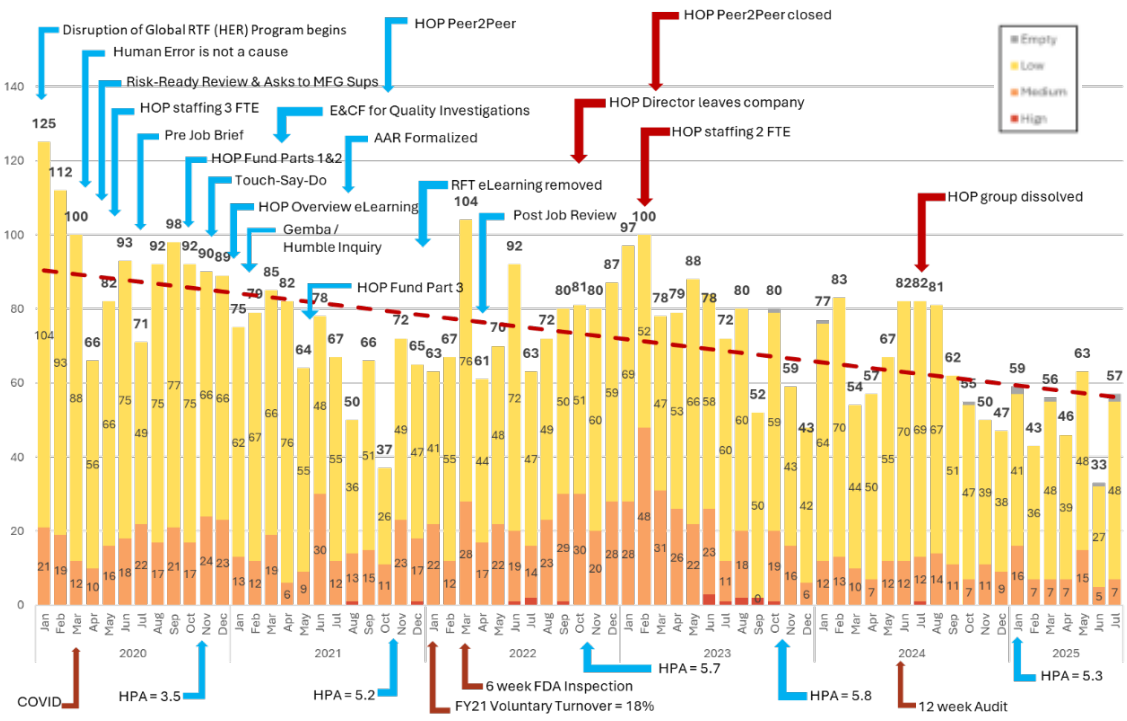


Figure 7. Monthly Deviation Initiation Rate from January 2020 to July 2025.

HOP implementation milestones are represented by blue arrows. Events with potential to increase deviation initiation rate are represented by red arrows.

Root Cause Categories

In addition to deviation initiation rate, root cause category percentage was considered. It was discovered that the percentage of Human Factors deviations decreased steadily from 2021 to 2023 and increased from 2024 to 2025, which signals a departure from blaming culture and correlates to timeline of both implementation and discontinuance of the HOP program. It was also discovered that the percentage of Method deviations increased steadily from 2021 to 2023 and decreased from 2024 to 2025, which corresponds to system-based thinking during investigations and also

correlates to implementation and discontinuance of the HOP program. See Appendix 10 and Appendix 11 and Figure 8 and Table 5 below.

Count of PR ID	Column Labels								
Row Labels	Environment	Human Factors	Machine	Material	Measurement	Method	Root Cause - Not Identified	(blank)	Grand Total
<3/28/2021									
2021	29	53	122	76	35	276	33		624
2022	65	78	145	128	62	638	63		1179
2023	47	39	147	103	50	755	42		1183
2024	95	64	122	99	39	631	26	3	1079
2025	60	55	72	62	4	314	7	87	661
Grand Total	296	289	608	468	190	2614	171	90	4726

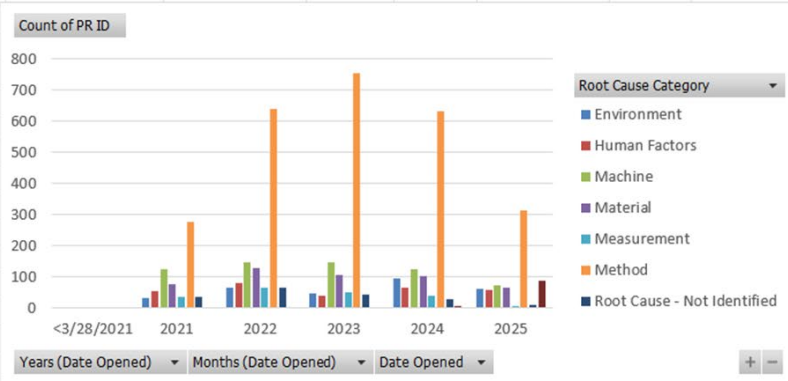


Figure 8. Root Cause Category Frequency of Deviations initiated from 2021 to 2025

2021 Data collected from March 2021 to December 2021; 2025 Data collected from January 2025 to July 2025

Table 5. Deviation Root Cause Category Percentage by year

Year	Grand Total	Environment	Human Factors	Machine	Material	Measurement	Method	Root Cause - Not Identified	Blank (Root Cause not selected)
2021*	624	4.60%	8.50%	19.60%	12.20%	5.60%	44.20%	5.30%	0.00%
2022	1179	5.50%	6.60%	12.30%	10.90%	5.30%	54.10%	5.30%	0.00%
2023	1183	4.00%	3.30%	12.40%	8.70%	4.20%	63.80%	3.60%	0.00%
2024	1079	8.80%	5.90%	11.30%	9.20%	3.60%	58.50%	2.40%	0.30%
2025**	661	9.10%	8.30%	10.90%	9.40%	0.60%	47.50%	1.10%	13.20%

**Data collected from March 2021 to December 2021 **Data collected from January 2025 to July 2025*

CAPA Analysis

CAPA data was compiled from March 2021 to July 2025. It was discovered that the percentage of Change Control CAPAs increased from 6.3% in 2021 to 16.6% in 2022, which aligns with HOP implementation and an increased focus on system factors. In 2023 the percentage of Change Control CAPAs decreased to 11.2% which correlated to the HOP Director leaving the company and a temporary increase in focus on retraining CAPAs, which spiked to 5.4% in 2023. However, the organization continued to drive down the frequency of retraining CAPAs even after the HOP Director's departure because it remained committed to improving system design, strengthening work execution, and deepening organizational learning.

In 2024 the percentage of Change Control CAPAs increased to 18.7% and the percentage of retraining CAPAs decreased to 1.3%, which indicates the organization continued to focus on system-based corrections, rather than Human Performance/Training issues. See Appendix 12 and Appendix 13 and Figure 9 and Table 6 below for CAPA data.

Count of PR ID	Column Labels						
Row Labels	Change Control	Document Revision	Gap Assessment	Other	Retraining	(blank)	Grand Total
2021	10	93	14	40	2		159
2022	40	122	18	57	4		241
2023	27	120	14	67	13		241
2024	29	84	12	28	2		155
2025	15	52	12	23	2	1	105
Grand Total	121	471	70	215	23	1	901

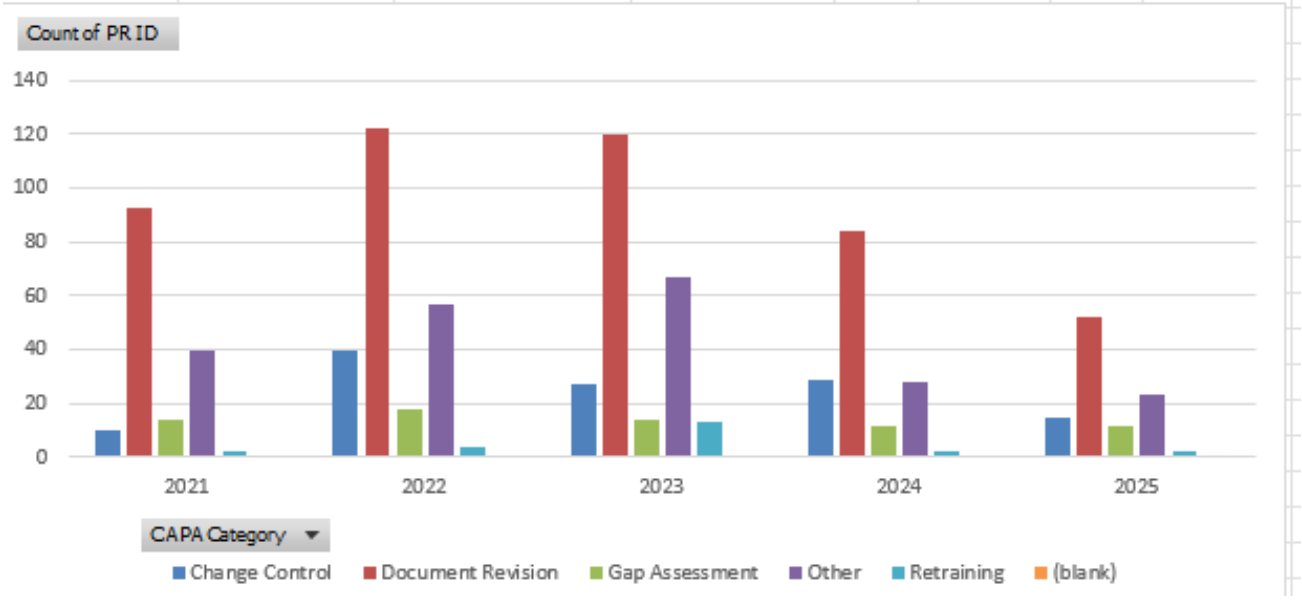


Figure 9. CAPA Type by Year

2021 Data collected from March 2021 to December 2021; 2025 Data collected from January 2025 to July 2025

Table 6. CAPA type percentage by year

Year	Change Control	Document Revision	Gap Assessment	Other	Retraining	(blank)	Total
2021	6.3%	58.5%	8.8%	25.2%	1.3%	0.0%	159
2022	16.6%	50.6%	7.5%	23.7%	1.7%	0.0%	241
2023	11.2%	49.8%	5.8%	27.8%	5.4%	0.0%	241
2024	18.7%	54.2%	7.7%	18.1%	1.3%	0.0%	155
2025	14.3%	49.5%	11.4%	21.9%	1.9%	1.0%	105

2021 Data collected from March 2021 to December 2021; 2025 Data collected from January 2025 to July 2025

Human Performance Assessment Format

To understand how deeply Human and Organizational Performance (HOP) principles were embedded over time—and whether that adoption was sustained through organizational change—a Human Performance Assessment (HPA) was used as the primary qualitative maturity measure.

The 2024 HPA was conducted over the course of four forums administered by the thesis author and co-facilitated by two former members of the HOP group.

To prepare for sufficient HPA participation the team developed and implemented a communication plan. The plan included messages from leadership about the importance of the assessment and that conversations would be kept confidential to continue to build psychological safety which is essential to HOP implementation.

The HPA forums at the organization in scope consisted of representatives from multiple cross-functional departments. The groups each covered multiple HPA dimensions and elements. The 2024 HPA consisted of 4 interdepartmental groups. Each group focused on different dimensions/elements and there was some overlap between

groups (Groups 1 and 3 included elements 6.1, 6.3, and 6.4). See Table 7 below for details.

Table 7. 2024 HPA Groups/Elements

Group	Departments	HPA Elements
1	Environmental Health and Safety (EHS) Engineering Manufacturing (MFG) Business Excellence Leaders	3.2 Safety & Reliability in Engineering Design 3.3 Effectiveness in Response to Engineering Process and Automation Requests 4.7 Management of On-Site Contractors to Improve Reliability 6.1 Post-Activity Learning 6.3 Open Reporting 6.4 Learning Culture
2	Manufacturing Compliance (MC) Quality Assurance (QA) EHS	5.1 Investigation Methods 5.2 Worker Involvement & Understanding Work-As-Done 7.1 Deviation Management System Enables Performance Analysis
3	Manufacturing (MFG) Quality Control (QC) QA Floor Support (QA-FS) Facilities/Engineering & Validation (FEV) Manufacturing Sciences (MS)	3.1 Work Documentation Considers End User Needs and Risk Management 3.4 Change Control & Tech Transfer Considers Risk 4.1 Work Preparation Includes Risk Management 4.2 Worker Non-Technical Risk Management Practices Used to Create Safety & Reliability 4.3 Effective Use of Documentation to Manage Risk 4.4 Questioning Attitude & Stopping Work Is Institutionally Ratified and Rewarded 4.5 Handover and Shift-to-Shift Communications Enhance Risk Management 4.6 GMP/ Quality Culture 5.4 Organizational Response to Undesirable Outcomes 6.1 Post-Activity Learning 6.3 Open Reporting 6.4 Learning Culture

Group	Departments	HPA Elements
4	Site Leadership Team (SLT)	1.1 Documented HOP Guidance 1.2 Integration & Distinctions with Quality, Continuous Improvement, and Safety 1.3 Site HOP Lead/ Champion Sufficient Expertise, Capability, and Resources 1.4 Leaders Go to Where Work is Performed to Learn About Success, Failure, and Risk 1.5 Just Culture 1.6 Strategic Deployment/ Change Management 3.5 Change Control Considers Risk 3.6 Tech Transfer Considers Risk 3.7 Organizational Management of Risk 5.3 Investigation Learning 6.2 Work Observation 7.2 Metrics Provide an Accurate Picture of Capacity to Manage Risk and Performance

HPA Execution

The HPA was conducted on a yearly basis between 2020 and 2024. It was observed that the organization matured between 2020 and 2023 in most dimensions. Refer to Appendix 3 for the definition of Blue-Sky and Readiness Warning Flags for each dimensional element.

Training Dimension

In 2024 a decrease was observed in some dimensions corresponding to the timeframe of the HOP team dissolution. The biggest change in 2024 was in the Training dimension, which decreased from 8.0 (2023) to 2.7 (2024). This resulted in the maturity level declining from “Competence” to “Understanding.” In addition, the Readiness Warning Flags in this dimension increased from 0 (2023) to 2 (2024). It is believed these results were obtained because the job role was eliminated for the SME responsible for

creating and administering training materials. As a result, HOP training was removed from individual training requirements of most employees.

Leadership and Engagement

The score decreased moderately for Leadership and Engagement from 6.2 (2023) to 5.0 (2024) and the organization maturity level dropped from “Competence” to “Understanding.” The Readiness Warning Flags in this dimension increased from 1 (2023) to 3 (2024). It was discovered that senior leadership annual goals do not include HOP elements (e.g. initiatives, KPIs/metrics). In addition, the HOP Sponsor was not a member of the site leadership team (SLT). It was also discovered that leaders believe workers' behavior is the key focus that requires correction for HOP to be successful, which runs counter to HOP system-based thinking. However, it was determined that there was no misconception that having a healthy Lean /Operational Excellence or Six Sigma program is the same as having a strong HOP program. In addition, it was reported that learning Gembas are still practiced regularly. A potentially confounding variable for this dimension is that only one member of SLT attended the HPA session for 2024. This could potentially introduce bias to the data, particularly as the SLT participant had a vested interest in HOP as he was present from the outset of HOP implementation. By comparison, the HPA for previous years included multiple members of SLT including the HOP Director. The lack of participation could also point to a deprioritization of the implementation of HOP directives.

Managing Work Risk-Design

The score for Managing Work Risk-Design increased slightly from 4.9 to 5.0 and the organization remained in the realm of "Understanding." The Readiness Warning Flags in this dimension decreased from 5 (2023) to 2 (2024). It was determined that end users are involved with documentation creation, revision, and/or field-testing and that process engineers and automation engineers have HOP training and guidance. However, it was also determined that reliability by design is not always achieved i.e. optimum serviceability of equipment; consideration of human factors in performing maintenance and general interaction with equipment e.g. working at heights (newer air handler needed to be relocated at a lower height to facilitate servicing). Additionally, multiple QMS roll outs have excluded potential improvements that could have been implemented based on end user feedback. In addition, corrections and improvements to the work order system are frequently delayed or rejected due to cost and/or difficulty in implementation. The responses provided indicated that although the score improved slightly, there is still room to grow in this area.

Managing Work Risk- Execution

The score for Managing Work Risk- Execution increased moderately from 6.0 to 6.7 and the organization maturity level increased from "Understanding" to "Competence." The Readiness Warning Flags in this dimension decreased from 5 (2023) to 2 (2024). It was determined that workers regularly perform and create pre-job briefs. Manufacturing (MFG) is also involved in troubleshooting activities with Engineering and Automation, and MFG shift handoffs follow a standardized process. It was also reported that contractors are always escorted by a full-time employee (FTE) while on site.

However, HPA feedback included reports that document quality and revision timelines have room for improvement and that standard operating procedures (SOP) do not always communicate well with master batch records (MBR). Additionally, it was reported that performers and verifiers sometimes swap roles during execution of work, which can lead to gaps in execution and documentation. The responses provided indicated that although the score improved moderately, there is still room to grow in this dimension.

Investigations and Learning

The score for Investigations and Learning remained unchanged at 6.3 and the organization remained in the realm of "Competence." The Readiness Warning Flags in this dimension increased from 0 (2023) to 1 (2024). Manufacturing Compliance (MC) personnel reported the use of non-linear root cause analysis (RCA) tools such as E&CF charting and Kepner Tregoe Problem Analysis for complex medium risk deviations. This indicates that investigations continue to take a systems-based approach in line with HOP philosophy. However, an uptick in the use of Human Error as a contributing causal factor, and an increased usage of a singular cause for deviations were reported, both of which indicate that HOP philosophy is losing momentum in those areas.

However, it was reported by multiple investigation groups that both Gemba and humble inquiry are still frequently used during investigations and that much learning is derived from those who are closest to the work. In addition, it was noted that workers reported not feeling blamed when involved with an undesirable outcome, which indicates that psychological safety, a prime directive of HOP culture continues to be achieved.

Responses for this dimension indicate the organization has not experienced measurable progress in this area. However, responses also indicate that an erosion in

HOP philosophy was not observed which indicates that HOP methodology and cultural impact was sustained through 2024.

Proactive Learning

The score for Proactive Learning increased substantially from 5.0 (2023) to 6.5 (2024) which resulted in the maturity level increasing from "Understanding" to "Competence." The Readiness Warning Flags in this dimension decreased from 2 (2023) to 1 (2024). It was reported that post-job reviews and AARs are being widely used to capture learning during projects and other activities where the team works together. However, it was also reported that in some instances, AARs were only used in response to adverse events. It was reported that events are reported and documented in the incident reporting system, but not always properly categorized and that follow up actions are not always approved or completed. The responses indicated that a speak up, learning culture exists where workers feel comfortable reporting events and near misses and that leaders support this behavior by validating/rewarding worker feedback. The responses provided indicate that the site has an overall culture that promotes continuous improvement, as indicated by the significant score increase.

Monitoring Performance

The score for Monitoring Performance increased from 4.0 (2023) to 5.0 (2024) and the maturity level remained at "Understanding." The Readiness Warning Flags in this dimension remained unchanged from 1 (2023) to 1 (2024). It was reported by one Manufacturing Compliance (MC) manager that "Human Error" is not frequently determined to be the primary root cause of events. However, an increase in the use of

"Human Error" as a contributing casual factor was reported which was supported by Table 5: "Deviation Root Cause Category Percentage by year" that showed an increase from 3.30% in 2023 to 5.90% in 2024. Although the 2024 HPA did not assess 2025 data, deviation trend analysis performed as part of this thesis showed the rate had increased to 8.30% from January 2025 to July 2025, which indicates a continued migration away from HOP philosophy with regards to RCA performed for deviation investigations.

A Quality Assurance Technical (QAT) Manager reported that teams are proficient in monitoring/reporting true repeat issues, but the root cause category and subcategory selection options in the current QMS can sometimes lack granularity which can prevent accurate event characterization and trending analysis. The responses provided indicated that although the score showed moderate improvement, system limitations remain that prevent the maturity level from reaching a level of "Competence."

Summary

For the 2024 HPA, scores for two dimensions decreased significantly, which correlated to the HOP group being scaled down starting in late 2022 and formally dissolved in mid-2024. However, scores for the five other dimensions either increased or remained unchanged, resulting in a 2024 overall assessment as 5-Understanding. This data indicates the integration of HOP principles has persisted considerably even after the HOP group was scaled down and dissolved. The responses provided across all departments indicate that HOP shifted from a program to a mindset.

When HOP is implemented well, it stops being a standalone initiative and becomes part of how people think, lead, and solve problems. Leaders begin asking better

questions and respond differently when things go wrong. Investigations naturally incorporate systems thinking versus focusing on trying to fix people.

Risk based practices and tools continued to be utilized by employees. For example, pre-job briefs, risk ready reviews, and event and causal factor charts for investigations. These tools continued to shape behavior long after the original HOP team was dissolved.

Leaders and key stakeholders have internalized HOP principles. The HOP group successfully influenced frontline leaders, SMEs, and cross-functional partners to carry the practices forward.

Because HOP consistently delivered measurable improvements, such as fewer repeat events, stronger investigations, better psychological safety, and more effective corrective actions, employees continued to use it.

HOP continues to be aligned with the organization's values, strategic priorities, and goals by driving patient safety, regulatory compliance, and operational efficiency by anticipating risks.

The data reflects consistent behaviors, stable performance indicators, and continued use of HOP tools and practices.

Overall Element Summary

The figure below outlines the overall score and the number of warning flags present for each element. These warning flags indicate potential weaknesses in the performance outcomes related to each dimension when present.

Dimension	Dimension Score	Warning Flags Present
Leadership & Engagement	5.0 - Understanding	3 of 6
Training	2.7 - Awareness	2 of 3
Managing Work Risk - Design	5.0 - Understanding	2 of 7
Managing Work Risk - Execution	6.7 - Competence	2 of 7
Investigations & Learning	6.3 - Competence	1 of 5
Proactive Learning	6.5 - Competence	1 of 4
Monitoring Performance	5.0 - Understanding	1 of 2

Figure 10. 2024 Overall HPA Results by Dimension

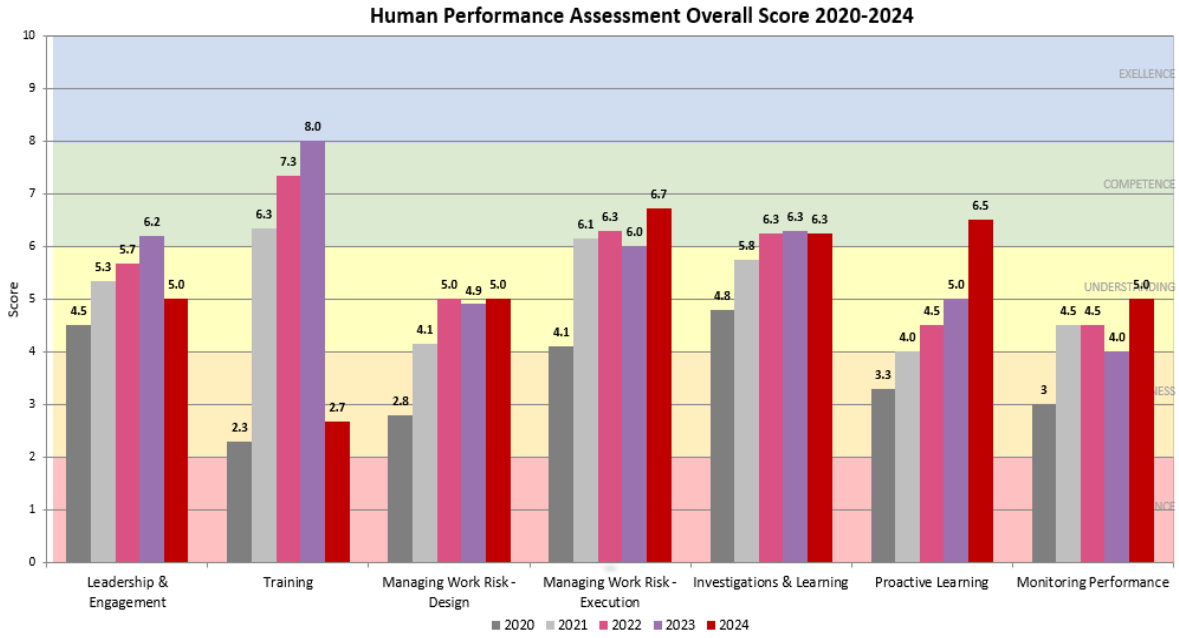


Figure 11. Human Performance Assessment Scores by Dimension 2020-2024

Chapter IV

Discussion

The data accumulated during execution of this study provides strong evidence of HOP efficacy. Taken together, the deviation, root-cause, CAPA, and HPA results validate HOP as a meaningful performance lever for the organization in scope. The sustained multi-year reduction in deviation initiation rates aligns closely with HOP implementation milestones. The shift away from the use of Human Factors as a root cause during deviation investigations coupled with the use of Method based causes demonstrates movement towards system based thinking, which is a hallmark of HOP philosophy. This also signals departure from blaming culture and movement towards becoming a learning organization.

The use of non-linear Root Cause Analysis tools e.g. Event and Causal Factor Charts and Kepner Tregoe analysis, shows that a system based approach is still being used during investigation of adverse events. The fact that on the floor Gembas and humble inquiry are still in use shows that many of the HOP tenants have taken hold, and that is because *they work*.

Increased use of system-focused CAPAs (notably Change Controls) demonstrates that the organization endeavored to strengthen reliability by improving how work is designed and executed, rather than relying on retraining. The use of cloud based systems to compile and share Post Job Review data and other operational learning, indicates movememt towards becomimg a learning organization. Indeed, it has often been said during HOP implementaion, that *none of us* are as smart as *all of us*.

Where performance softened, the pattern is consistent: periods of reduced managerial oversight on the manufacturing floor during FDA inspections and other audits, and the mid-2024 HOP team dissolution coincided with declines in Training and Leadership/Engagement maturity, a re-emergence of Human Factors root cause, and a temporary slowing of system-level corrective actions.

Importantly, many HOP-aligned behaviors persisted through 2024, indicating cultural adhesion to HOP principles, but the data also shows that continued gains depend on sustained leadership attention, visible floor presence, and a deliberate recommitment to HOP governance and capability-building.

Re-establishing HOP practices, paired with stronger leadership accountability and system-based learning offers a clear opportunity to stabilize performance, reduce deviation frequency, foster psycholicical safety, and embed durable operational excellence. The compiled data indicates that using these measures of success shows the hypothsisis is correct and implementation of HOP principles and practices enables improvement towards being a learning organization.

Appendix 1

AAR Guide

After Action Review (AAR) Guide

The purpose of an After Action Review (AAR) is to understand how things go right as well as explain how things occasionally go wrong in our work, in order for the team and the organization to learn, and then improve things that will "make it easier to get it right, and harder to get it wrong".

Conducting an AAR is as simple as facilitating a dialogue with your team by asking the questions below. Roughly 25% of the time should be devoted to the first two questions, 25% to the third question, and 50% to the fourth question.

1: What did we set out to do?

- Describe in detail the overall objective of the activity, as well as the specific measures that define success.

2: What actually happened?

- List the actual results achieved for the overall objective and the success measures.

3: How did it happen?

- Follow a path of exploration by reconstructing a timeline of events.
- Identify the desired and undesired conditions, actions, and context that influenced performance along the timeline.

4: What are we going to do next time?

- Brainstorm and agree on changes to make that will improve performance for next time.
- Document the changes, make them actionable, and assign them to owners.

After Action Review (AAR) Guide

The AAR process may be formal or informal, may involve large or small groups, and may take minutes or hours.

The following are three keys to AAR success:

1. Kickoff the meeting by explaining both the purpose and process of the AAR.
2. Set the stage for psychological safety by reminding the team of the fact that we work in a complex work environment that includes constraints, goal conflicts, trade-offs, and many interdependencies within our systems.
3. Focus on the HOW of what happened, not the WHY.

As the facilitator, ask questions that reveal:

- Context for assessments or judgments
- Rationale for choices or decisions
- Things that people know (and might assume are common knowledge)
- People's states of mind at the time
- Mental models for how things "should" work
- Factors that led people to take a specific action

Scribe exactly what the participants say, as they speak, using their own words. Be sure the participants can read what you are writing in real-time.

As the facilitator, you need to counter the most human urge to find a single explanation and single fix aimed at improvement. There will be multiple conditions that drive performance in most cases.

Appendix 2

Causal Analysis Methods

Name	**Purpose**
Event & Causal Factor Charting	Events and Causal Factor Analysis identifies the time sequence of a series of tasks and/or actions and the surrounding conditions leading to an occurrence. The results are displayed in an Events and Causal Factor chart that gives a picture of the relationships of the events and causal factors
Hazard - Barrier - Target	Barrier Analysis is a systematic process that can be used to identify physical, administrative, and procedural barriers or controls that should have prevented the occurrence.
Fault Tree	Fault Trees model the possible combinations of equipment failures, errors, and external conditions that can lead to a specific accident. A Fault Tree follows a top-down structure and represents a graphical model of the pathways within a system between basic events that can lead to a loss event (or failure) referred to as the top event
Kepner-Tregoe Problem Analysis	Kepner-Tregoe provides a systematic framework to analyze a problem based on changes and distinctions. Kepner-Tregoe is similar to change analysis.
Management Oversight Risk Tree (MORT)	MORT is used to identify inadequacies in barriers/controls, specific barriers and support functions, and management functions. It identifies specific factors relating to an occurrence and identifies the management factors that permitted these factors to exist.
Change Analysis	Change Analysis is used when the problem is obscure. It is a systematic process that is generally used for a single occurrence and focuses on elements that have changed.
Comparative Timeline	A visual method to compare Work As Imagined to Work As Done be laying the process flow for each alongside each other.

Appendix 3

Human Performance Assessment Blue-Sky Descriptions and Readiness Warning Flags for each Dimension/Element

Derived from Human Performance Assessment Tool (BioPhorum, 2022)

1. Leadership & Engagement

1.1 Documented HOP Guidance

Blue-Sky Description: A document or philosophy exists which is easily accessible to all employees, that describes the purpose, principles, roles & responsibilities, and governance for Site HOP. The guidance is kept current; not stale. Site leadership annual goals include aspects of HOP that need further development and focus.

Readiness Warning Flag: SLT Annual Goals Do Not Include HOP elements (e.g. initiatives, KPIs/metrics)

1.2 Integration & Distinctions with Quality, Continuous Improvement, and Safety

Blue-Sky Description: A document or philosophy exists which is easily accessible to all employees that describes the integration of HOP with Quality, Continuous Improvement and Safety. This document highlights the commonalities and differences which may exist. Site leadership has the knowledge to communicate the distinctions and different purposes, and when doing so (via videos, townhall, written, etc.) describes the alignment between Quality, Continuous Improvement and Safety.

Readiness Warning Flag: Misconception that having a healthy Lean / OEx or Six Sigma program is the same as having a strong HOP program.

1.3 Site HOP Lead / Champion Sufficient Expertise, Capability, and Resources

Blue-Sky Description: Site has an experienced and qualified HOP champion / lead, who has the support of a strong sponsor on-site. The HOP champion / lead is either a member of the Site Leadership Team (SLT) or has an "open door" to work with the SLT, which could be supplemented with a designated team focused on HOP strategy and oversight of HOP integration with operations. The HOP champion / lead stays current with latest practices in human performance such as "new view" through interaction within biopharm and external industry benchmarking.

Readiness Warning Flag: HOP Sponsor is not the GM or not a member of SLT

1.4 Leaders Go to Where Work is Performed to Learn About Success, Failure, and Risk

Blue-Sky Description: Leaders rely on the understanding that the difference between work-as-imagined (WAI) and work-as-done (WAD) is a critical perspective to address risk in their organization, and they express reluctance to simplify explanations for unexpected significant events.

Readiness Warning Flag: Leaders Articulate That Workers' Behavior Is the Key Focus That Requires Correction for HOP to Be Successful

1.5 Just Culture

Blue-Sky Description: Leaders understand that their reaction to failure matters. When failure does occur, Leaders first show concern for the employees well-being & dignity, and

then what must be done to ensure effective organizational learning. Discipline is never used in response to errors, mistakes, and trade-offs (well-meaning violations).

Readiness Warning Flag: A Process or Culture Exists Where Workers Are Systematically Disciplined for Mistakes

1.6 Strategic Deployment / Change Management

Blue-Sky Description: The organization has the ability to drive and sustain large-scale change and to anticipate and adapt to an increasing volatile environment. Change is a disciplined cascade and the organization is evolutionary. Leadership communicates and engages with key stakeholders in order to maintain confidence and commitment. The implementation process assigns individual accountabilities and empowers supervision with flexibility to anticipate and adapt to changing conditions.

Readiness Warning Flag: HOP Improvements Consist of Copying Program Aspects of What May Have Worked At a Different Organization and Implementing with Insufficient Consideration for Sustainability, Existing Systems / Processes, or the Site Culture.

2. Training

2.1 HOP Training Strategy

Blue-Sky Description: A comprehensive HOP training strategy is in place for all employees with role specific education and capability building training. The training is timely for staff new to the company or role, effective and routinely updated based upon industry best practice and HOP new view current thinking. Training is continuous, not a

singular training session, and consists of multiple forms of training methods, in both formal and informal settings, potentially including but not limited to:

- Classroom learning
- Simulations and Experimental Learning
- Case Studies
- Video
- Community of Practice

Readiness Warning Flag: HOP training is either not in place, or is just "once-and-done".

2.2 HOP Fundamentals Training

Blue-Sky Description: Employees and contractors (staff augmentation) are provided training on HOP fundamentals. Training includes the following elements and is delivered by subject matter experts who may be members of leadership or peers. Training is in alignment with company's global strategy. Training content includes:

- Principles of HOP
- Risk and Error Traps
- Stories of Success and Failure
- The role of workplace local factors and system / organizational factors on human error and how we learn from failure and success
- HOP Tools specific to employees' work
- Alignment of HOP with Business Objectives

Readiness Warning Flag: Re-training on HOP is considered a CAPA

2.3 HOP Role-Specific Training

Blue-Sky Description: Additional HOP training is provided to employees as necessary based on their role. Such roles include supervisors & managers, investigators, and engineers. This additional HOP training may include topics such as:

- Investigations methods and causal analysis
- Accident models
- Systems theory
- Local rationality and emergence
- Schein's Culture Model
- Work As Imagined vs. Work As Done
- Work Observation practices
- Design of Work for Humans

Readiness Warning Flag: The design of HOP training delivers more training hours to workers and less training hours to managers and the SLT.

3. Managing Work Risk - Design

3.1 Work Documentation Considers End User Needs and Risk Management

Blue-Sky Description: A design standard exists and is used to revise and create new documentation that provides human factors guidance to ensure optimum usability for end users. This standard includes characterization of risk in documentation that aids the end-users risk-based thinking. Requests to change documentation are dispositioned in a timely manner that encourages workers to continue using the process.

Readiness Warning Flag: Workers (end-users) are not involved with documentation creation, revision, and/or field-testing.

3.2 Safety & Reliability in Engineering Design

Blue-Sky Description: Safety & Reliability in design guidance exists and is used by Engineering to ensure that equipment and processes are designed based on technical standards, physical capabilities and limitations of the people. Workers are involved in the design process before the installation of new equipment.

Readiness Warning Flag: Process Engineers and Automation Engineers have no training or guidance on the subject of human factors.

3.3 Effectiveness in Response to Enterprise Business Systems Requests

Blue-Sky Description: We have organizational support and resources to maintain our capability to meet acuity and volume demands to requests for enterprise business systems problem reports and change requests from end-users. The reporting and resolution process use risk ranking and feedback from end-users to help prioritization and the time from the submission of the report until a response is acceptable and transparent to end-users is minimized. Submitted reports are being investigated sufficiently and necessary changes are timely.

Readiness Warning Flags:

1) End-users do not speak in positive terms concerning the ability of the organization to eliminate work arounds and / or improve enterprise business systems.

2) Corrections and improvements to enterprise business systems are frequently delayed or rejected for administrative (high validation effort) or cost concerns.

3.4 Effectiveness in Response to Computerized Laboratory Systems Requests

Blue-Sky Description: There exists organizational support and resources to maintain the capability to meet acuity and volume demands to requests for computerized laboratory systems problem reports and change requests from end-users. The reporting and resolution process use risk ranking and feedback from end-users to help prioritization and the time from the submission of the report until a response is acceptable and transparent to end-users is minimized. Submitted reports are being investigated sufficiently and necessary changes are timely.

Readiness Warning Flag: End users do not speak in positive terms concerning the ability of the organization to eliminate work arounds and / or improve computerized laboratory systems.

3.5 Change Control Considers Risk

Blue-Sky Description: Meetings that assess changes to systems / processes consider risks and specifies appropriate mitigation actions. Cross-functional impacted stakeholders attend these meetings and the wisdom of the crowd is effective in driving discussions and thinking. Programmatic documentation defines roles and responsibilities to ensure clarity for reviews and approvals. Resources required for changes are understood and managed.

Readiness Warning Flags:

1) Key stakeholders frequently miss meetings and perform their work in relative isolation of the team.

2) Timelines for change have many extension requests permitted

3) Closed change controls are re-opened/ new change opened to address missed or incomplete tasks

3.6 Tech Transfer Considers Risk

Blue-Sky Description: Meetings that plan readiness of future work consider risks and specifies appropriate mitigation actions. Cross-functional impacted stakeholders attend these meetings and the wisdom of the crowd is effective in driving discussions and thinking. Programmatic documentation defines roles and responsibilities to ensure clarity for reviews and approvals.

Readiness Warning Flags:

1) Key stakeholders frequently miss meetings and perform their work in relative isolation of the team.

2) Team is primarily focused on project schedule / milestones, but not the quality of the output.

3.7 Organizational Management of Risk

Blue-Sky Description: Systematic risk assessments are routinely conducted throughout all unit operations using standardized risk approaches. In addition to focusing on operational risk, management also captures how operations are successful. Risk assessments (e.g. HAZOPs, FMECAs, PHA, etc.) are routinely performed on routine operational procedures in order to prioritize tasks by risk and define appropriate risk mitigation solutions.

Readiness Warning Flags:

1) High risk tasks are not identified and mitigated.

2) Management does not anticipate unplanned events, especially during planned changes and high workload periods.

3) Metrics are commonly set to "Target 0" (zero waste, zero accidents, etc.), and the focus is on the results more than the process of how to achieve the visions.

4. Managing Work Risk – Execution

4.1 Work Preparation Includes Risk Management

Blue-Sky Description: Immediately before critical unit operations and/or high-risk work, workers meet to conduct a dialogue where roles & responsibilities are made clear, risk and associated controls are identified, essential verifications are assigned, and past lessons learned are discussed (e.g., Pre-Job Briefing).

Readiness Warning Flag: No pre-job briefs are being performed, or infrequent use of pre-job briefs or Pre-Job Briefs Are Treated As a Checklist Activity By Workers With Little to No Dialogue, and Discussions Around Risk are Vague and Superficial.

4.2 Worker Non-Technical Risk Management Practices Used to Create Safety & Reliability

Blue-Sky Description: The organization recognizes the work design is imperfect and incomplete, and thus has established guidance, training, and workplace opportunities that allow time for workers at the sharp-end to manage risk and create safety using non-technical skills (a.k.a. Hu Tools). These may include Call-Outs, Self-Checking (STAR), Three-Part Communication, and Peer-Checking as part of Performed by / Verified by.

Readiness Warning Flag: The organization communicates on HOP Tools with a tone similar to "old-view human error", where workers are blamed for failures for reasons such as not using HOP Tools or using HOP Tools improperly. Leaders are more interested in knowing the "who did it" rather than "how did it happen".

4.3 Effective Use of Documentation to Manage Risk

Blue-Sky Description: Workers are guided by only one source document or Human Machine Interface (HMI) at any given time, and there is a smooth transition between guidance documents. Workers follow guidance in documentation because it is well-written, aids the process, and follows the workflow. When documentation is incorrect, workers notify supervision and a change request is submitted.

Readiness Warning Flag: Workers speak in negative terms of documentation quality or revision process timeliness & effectiveness.

4.4 Questioning Attitude & Stopping Work Is Institutionally Ratified and Rewarded

Blue-Sky Description: Leaders actively encourage dissenting opinions within teams as means to reduce the rate of failure. The organization is aligned that when confronted with confusion or uncertainty, staff members speak up and ask questions, and if the issue cannot be resolved the work is stopped and a supervisor / manager is notified to assist in resolution.

Readiness Warning Flag: High levels of workaround evident in process and seen as normal or acceptable

4.5 Handover and Shift-to-Shift Communications Enhance Risk Management

Blue-Sky Description: A formal standardized handover process is used between workers from shift to shift for ordinary work, as well as during troubleshooting activities when teams are replaced. The handover process is structured to ensure important information is passed along successfully, and the organization provides the time and resources for this activity to occur and be effective.

Readiness Warning Flag: Handovers do no follow a standard company format and electronic devices in use are a distraction.

4.6 GMP / Quality Culture

Blue-Sky Description: The organization defines the synergy between effective GMP methods and Hu Tools in managing risk. Leaders understand and manage the factors that could degrade GMP methods as an effective risk management measure, such as requiring a third person if Performer is not qualified, limiting the swapping of roles between Performer and Verifier, and not jumping ahead and back when executing batch documentation.

Readiness Warning Flag: Performers and Verifiers swap roles during the execution of work.

4.7 Management of On-Site Contractors to Improve Reliability

Blue-Sky Description: Management systems are in place to ensure contractors (project-based workers, not staff augmentation) performing work at a manufacturing site understand at a high-level Human Performance and participate in Work Preparation (Pre-Job Briefs), Proactive Learning (Post Job Reviews), and Open Reporting. The organization

manages the risk of contractors on-site by reviewing job plans, observing contractor pre-job briefs as well as work execution by Project Managers, and periodic visits to the contractor job site by Project Managers to ensure risk is managed effectively and all required resources are available.

Readiness Warning Flag: Work performed by contractors does not receive daily oversight at the work location by our company leaders.

5. Investigations & Learning

5.1 Investigation Methods

Blue-Sky Description: Investigators take a complex adaptive systems approach to causal analysis, by recognizing that social, cultural and technical contexts impose significant constraints and influences on the way systems function, and that most significant incidents arise from the interaction between the many elements. Investigators use methods such as Event & Causal Factor Charting, Fault Tree, and Kepner-Tregoe, while not using "guess & check" methods, gut instinct by area managers, or linear methods such as Fishbone and 5-Why's.

Readiness Warning Flags:

1) 5-Why's and Fishbone are the predominant methods used for analysis during investigations.

2) The organization speaks in terms of singular "root cause" and "CAPA" as opposed to multiple causal factors.

5.2 Worker Involvement & Understanding Work As Done

Blue-Sky Description: Workers involved with undesirable outcomes are involved with investigations as learning partners, where they may work with the Investigator through data collection, analysis, and CAPA development. The Investigator watches the work that is subject of investigations to understand the gap between Work As Imagined vs. Work As Done, and analyzes the entire work process as opposed to only trying to find the single-point where failure occurred.

Readiness Warning Flag: The tone of interactions with workers during investigations is that of "potential wrong-doers" as opposed to a partner in learning.

5.3 Investigation Learning

Blue-Sky Description: Leadership monitors the level at which root causes are identified and expects no person-focused root causes, and instead urges staff to have root causes at a systems level / organization factor level, but where recurrence can be tolerated causes may be at a workplace local factors level. CAPAs that improve conditions within a system are favored over quicker band-aid fixes such as adding a new review / verify step, and CAPA relative strength is discussed during investigations and monitored by the organization. The criteria by which investigations will be reviewed and approved are clear and understood by Investigators, Area Managers, and QA.

Readiness Warning Flag: Investigations teams and the organization when speaking about in-progress investigations use language similar to "finding & fixing the cause in order to release" or to meet a deadline as opposed to "truly learning" about risk across a process or system and leading to a real solution.

5.4 Organizational Response to Undesirable Outcomes

Blue-Sky Description: When undesirable outcomes occurs leaders assume positive intent of all staff involved. The questions that leaders ask when they learn of an undesirable event seek to ensure the safety and dignity of those involved, the condition of the facility, how they personally and the team can help return to service, and how they personally and the team can ensure the organization learns what must be learned to improve future performance.

Readiness Warning Flag: Leaders express their belief that they know what happened and how before an investigation is complete, as well as suggesting a fix to the problem.

6. Proactive Learning

6.1 Post-Activity Learning

Blue-Sky Description: Expectations are defined, a method established, and systems are in place to make learning routine at the conclusion of work activities involving critical unit operations or when teams work together on projects.

Readiness Warning Flags:

1) Post-Job Reviews aren't occurring, are ineffective, or are blame-focused.
2) Post-Job Reviews only occur when things go wrong, but not when things go well.

6.2 Work Observation

Blue-Sky Description: Leaders regularly watch normal work from the perspective of reliability risk management to learn what drives success and failure, and then through a dialogue with workers, leaders learn which workplace local factors and systems can be

improved. Observations are proactive in nature and allow leaders to view ‘work as done’ in order to understand the gap to ‘work as imagined’.

Readiness Warning Flags:

1) Leaders focus on ‘work as imagined’ in the conference room and not learning how employees navigate and interact with systems under varying conditions on the floor.
2) Outcomes of observations are punitive to employees; Employees feel they are being lectured or blamed rather than empowered to make improvements.

6.3 Open Reporting

Blue-Sky Description: A simple and user-friendly process exists and is used to identify and report reliability work risks, undesirable outcomes, and good catches beneath the threshold of a deviation / safety incident, where this proactive learning is used to improve workplace local factors and systems. Staff understand the difference between the system for open reporting and other systems such as those to report deviations, injuries, and submit work orders.

Readiness Warning Flags:

1) A culture of learned helplessness exists that discourages people from reporting issues.
2) A system is in place but does not have a mechanism to manage prioritization of efforts and close the loop on why certain ideas will not be acted upon.

6.4 Learning Culture

Blue-Sky Description: An organizational climate exists where people are prepared and voluntarily reporting work risks, good catches, undesirable outcomes below the threshold of a deviation, rework, work delays, and workplace local factors that influence risk to reliability. These reports are acted upon by the organization to mitigate risk and improve reliability. There is no concern or fear of punishment or retaliation associated with reporting an issue.

Readiness Warning Flags:

1) Leaders communicate to staff that problems below the threshold of a deviation need not be reported for reasons that may include that resources do not exist to resolve such issues.
2) The site does not have a culture that promotes proactive Continuous Improvement.

7. Monitoring Performance

7.1 Deviation Management System Enables Performance Analysis

Blue-Sky Description: The Deviation Management System includes a set of cause codes that support systems-learning from investigations. This set of cause codes allows for effective trend analysis of system issues that influence performance, and active plans are in place to mitigate top issues based on the trending data.

Readiness Warning Flag: "Human error" is frequently determined as the primary root cause in Investigations.

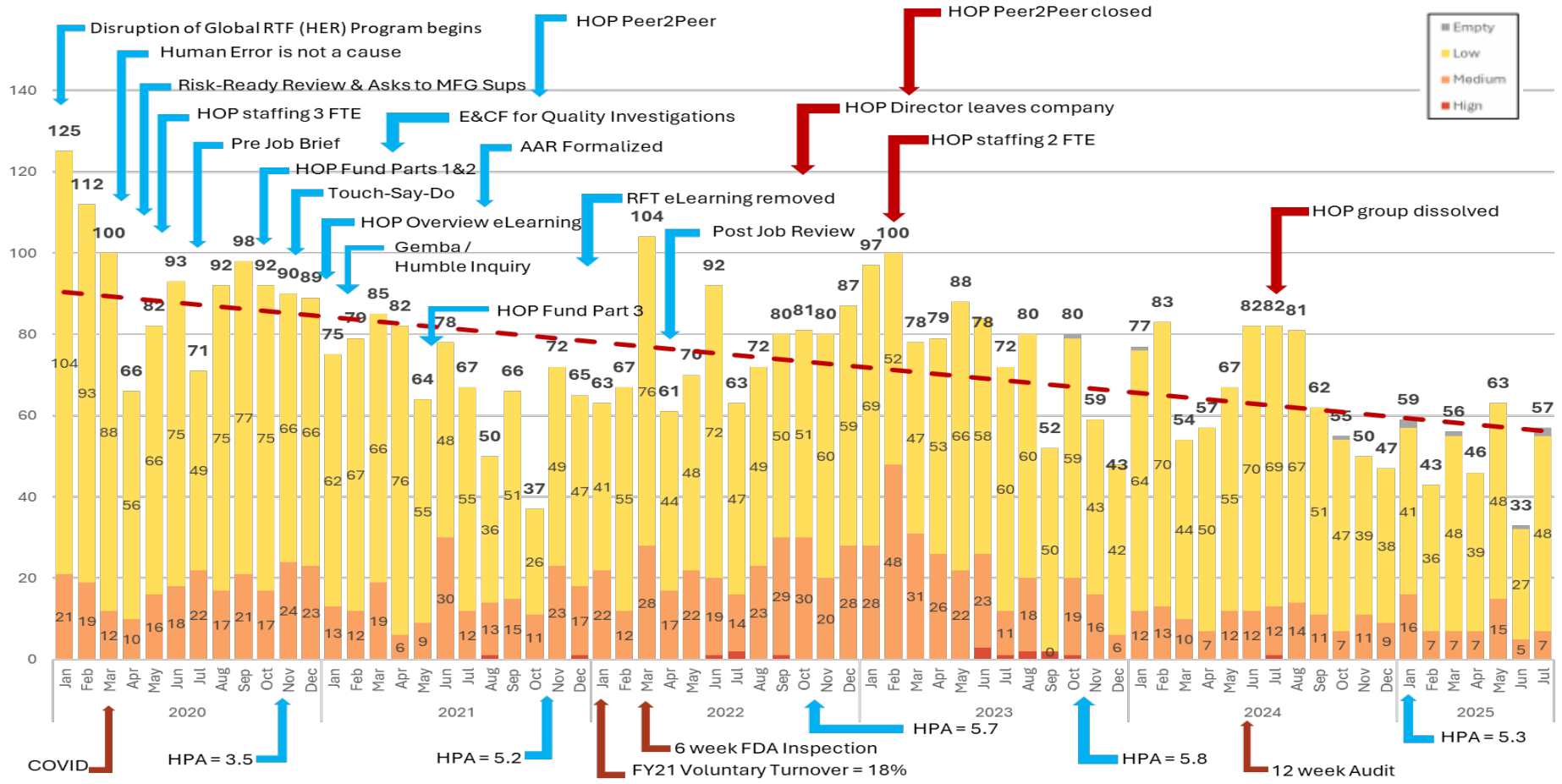
7.2 Metrics Provide an Accurate Picture of Capacity to Manage Risk and Performance

Blue-Sky Description: The organization monitors a set of meaningful leading indicators that measure capacity of processes and organizational aspects that are valid and predict future reliability performance. One source of the needed data is from Proactive Learning processes. The organization may also monitor a set of related lagging indicators.

Readiness Warning Flag: Leadership views a lack of negative events as a signal of success.

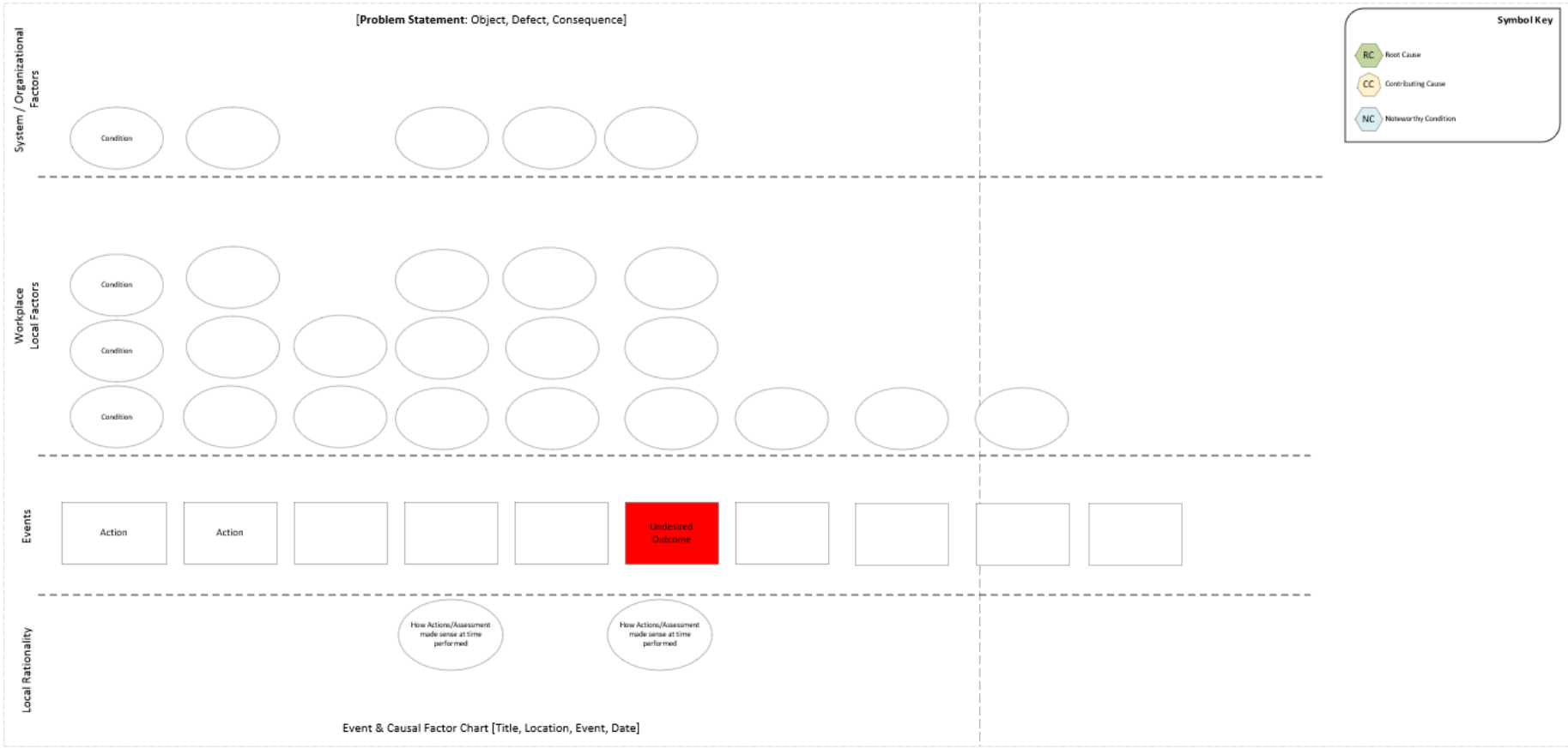
Appendix 4

Deviation Frequency 2020 -2025



Appendix 5

Event and Causal factor Chart Template



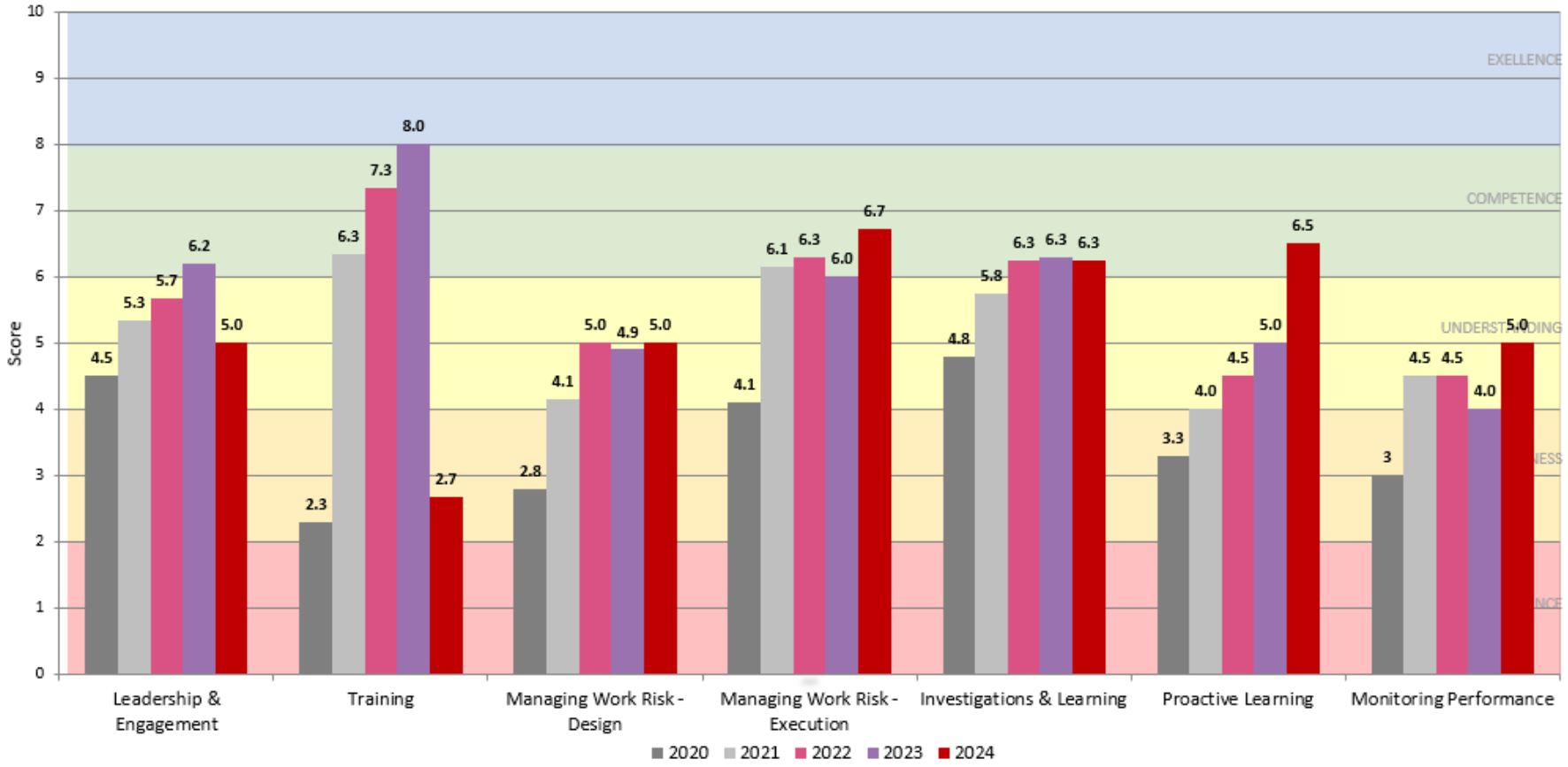
Appendix 6.

HPA Scoring Results 2020-2024

	2020 Process Score	2021 Process Score	2022 Process Score	[illegible] Score	[illegible] Score	Process Score 22-21	[illegible] Score 22-23	Process Score 23-24	2020 Readiness Warning Flags	2021 Readiness Warning Flags	2022 Readiness Warning Flags	2023 Readiness Warning Flags	2024 Readiness Warning Flags	Change Readiness Warning Flags 21-22	Change Readiness Warning Flags 22-23	Change Readiness Warning Flags 23 - 24
Leadership & Engagement	4.5	5.3	5.7	6.2	5.0	0.3	-5.7	1.2	3	0	0	1	3	0	-1	-2
Training	2.3	6.3	7.3	8.0	2.7	1.0	-7.3	5.3	1	0	0	0	2	0	0	-2
Managing Work Risk - Design	2.8	4.1	5.0	4.9	5.0	0.9	-5.0	-0.1	2	6	3	5	2	3	-2	3
Managing Work Risk - Execution	4.1	6.1	6.3	6.0	6.7	0.1	-6.3	-0.7	6	6	3	5	2	3	-2	3
Investigations & Learning	4.8	5.8	6.3	6.3	6.3	0.5	-6.3	0.0	3	1	1	0	1	0	1	-1
Proactive Learning	3.3	4.0	4.5	5.0	6.5	0.5	-4.5	-1.5	2	2	3	2	1	-1	1	1
Monitoring Performance	3	4.5	4.5	4.0	5.0	0.0	-4.5	-1.0	1	1	1	1	1	0	0	0
									18	16	11	14	12	5	-3	2

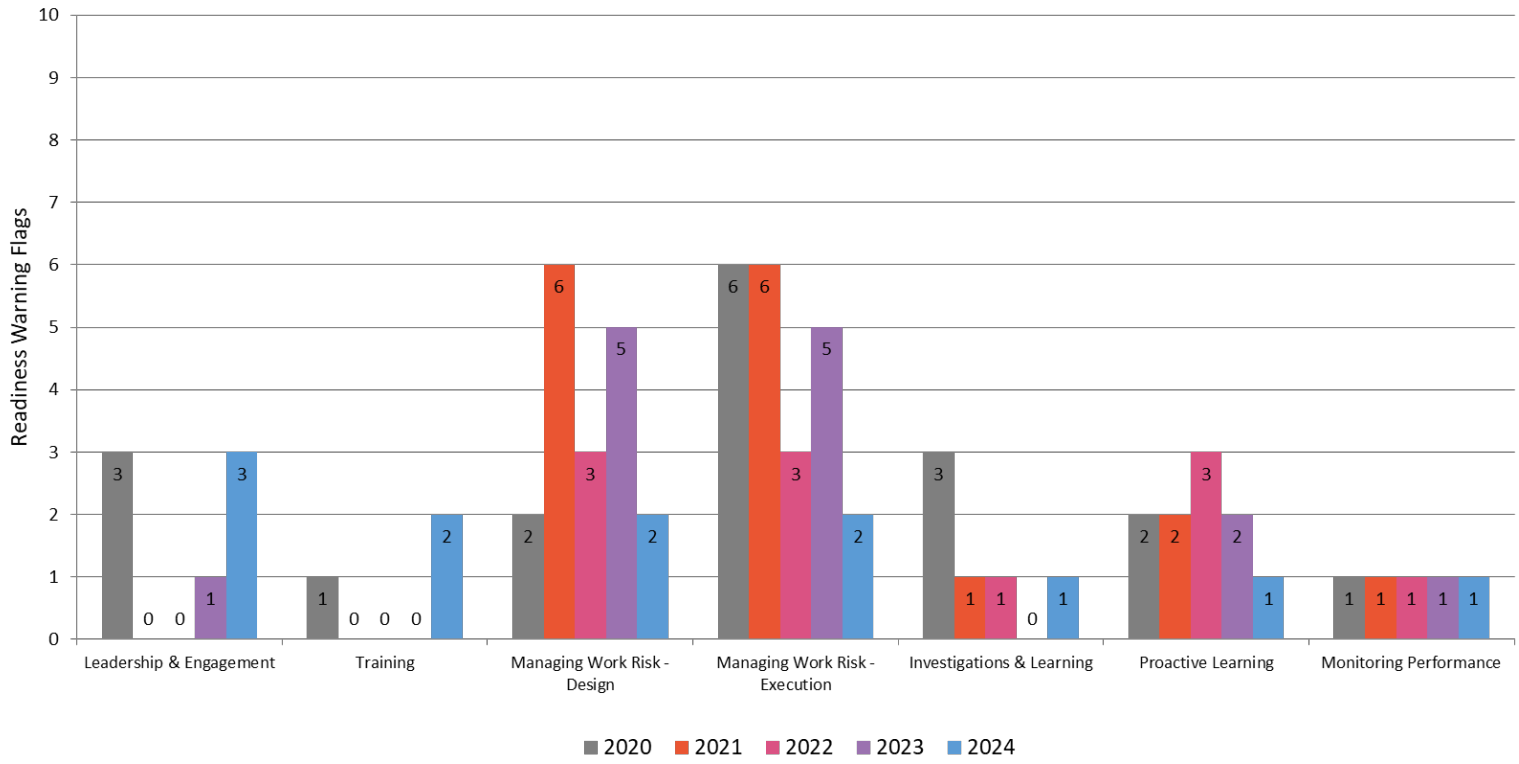
Appendix 7

HPA Results by Dimension 2020-2024



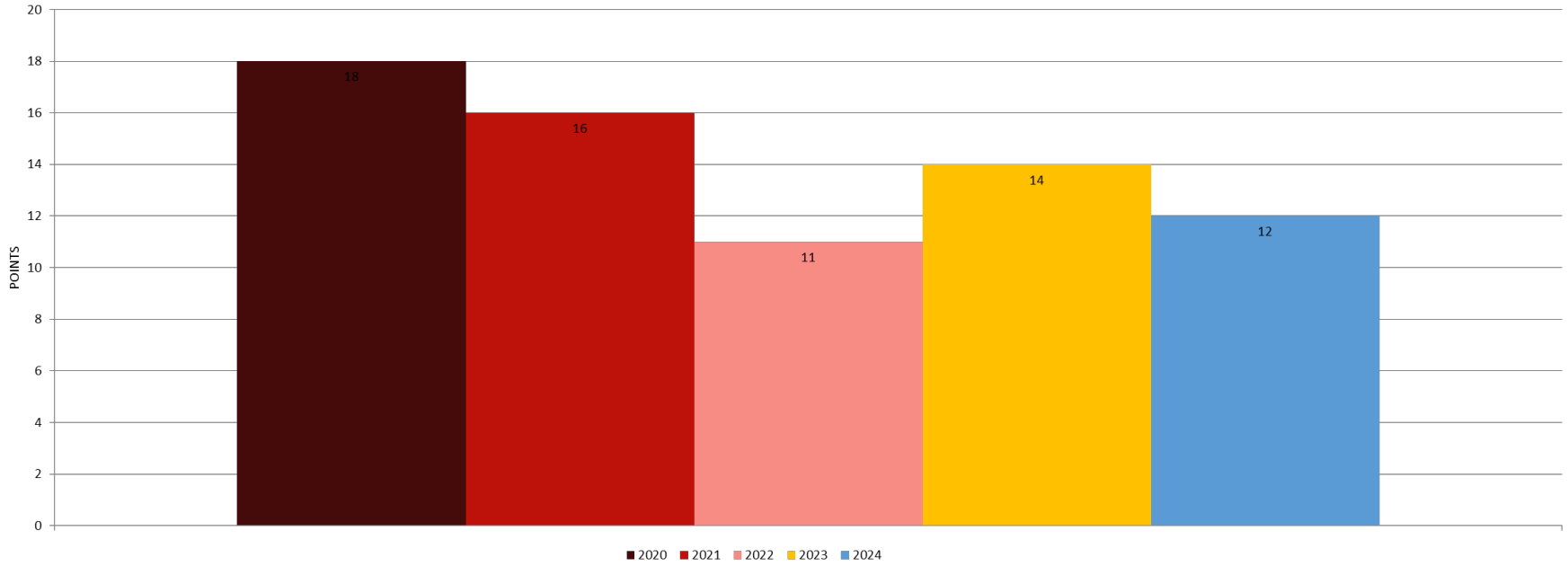
Appendix 8

Readiness Warning Flags per HPA Dimension 2020-2024



Appendix 9

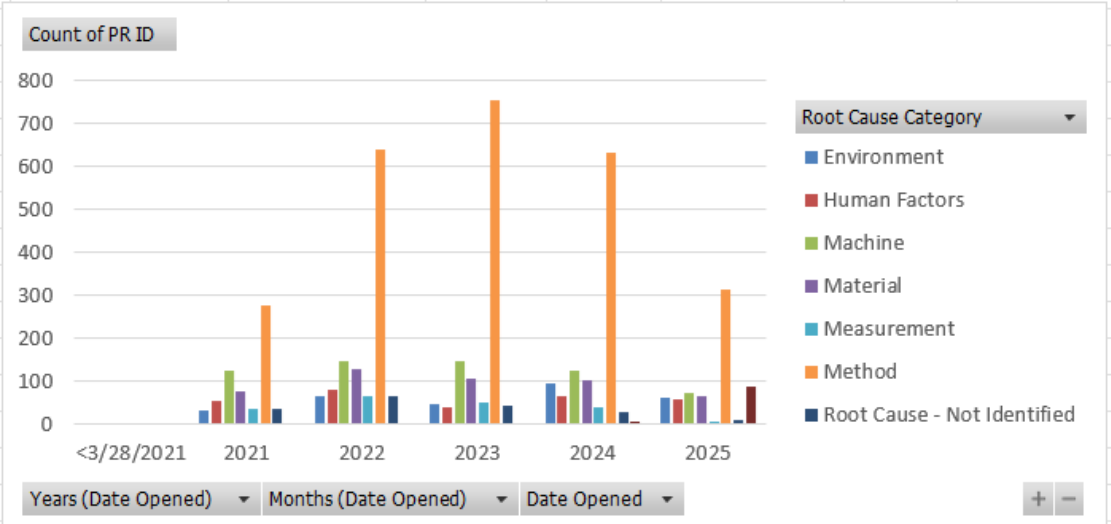
Total Readiness Warning Flags per Year 2020-2024



Appendix 10

Deviation Root Cause Category Distribution March 2021 – July 2025

Count of PR ID	Column Labels								
Row Labels	Environment	Human Factors	Machine	Material	Measurement	Method	Root Cause - Not Identified	(blank)	Grand Total
<3/28/2021									
2021	29	53	122	76	35	276	33		624
2022	65	78	145	128	62	638	63		1179
2023	47	39	147	103	50	755	42		1183
2024	95	64	122	99	39	631	26	3	1079
2025	60	55	72	62	4	314	7	87	661
Grand Total	296	289	608	468	190	2614	171	90	4726



Appendix 11

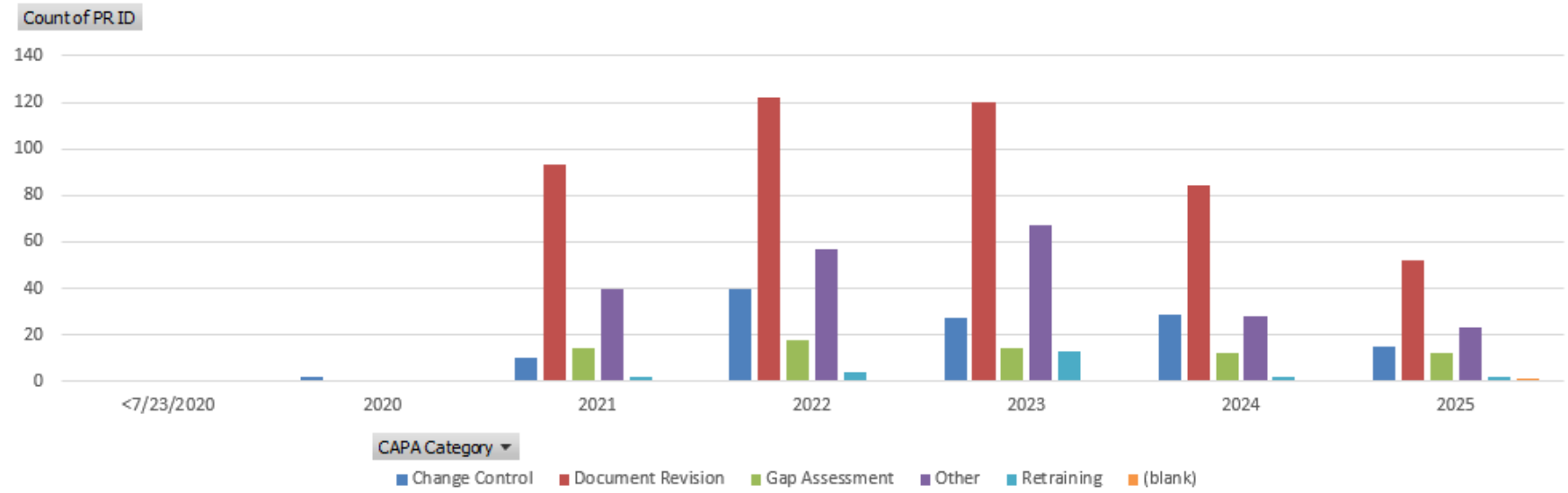
Deviation Root Cause Category Percentage March 2021 – July 2025

Year	Grand Total	Environment	Human Factors	Machine	Material	Measurement	Method	Root Cause - Not Identified	Blank (Root Cause not selected)
2021*	624	4.60%	8.50%	19.60%	12.20%	5.60%	44.20%	5.30%	0.00%
2022	1179	5.50%	6.60%	12.30%	10.90%	5.30%	54.10%	5.30%	0.00%
2023	1183	4.00%	3.30%	12.40%	8.70%	4.20%	63.80%	3.60%	0.00%
2024	1079	8.80%	5.90%	11.30%	9.20%	3.60%	58.50%	2.40%	0.30%
2025**	661	9.10%	8.30%	10.90%	9.40%	0.60%	47.50%	1.10%	13.20%

Appendix 12

CAPA Category Distribution March 2021 – July 2025

Count of PR ID	Column Labels						
Row Labels	Change Control	Document Revision	Gap Assessment	Other	Retraining	(blank)	Grand Total
⊞<7/23/2020							
⊞2020	2						2
⊞2021	10	93	14	40	2		159
⊞2022	40	122	18	57	4		241
⊞2023	27	120	14	67	13		241
⊞2024	29	84	12	28	2		155
⊞2025	15	52	12	23	2	1	105
Grand Total	123	471	70	215	23	1	903



Appendix 13

CAPA Category Percentage March 2021 – July 2025

Year	Change Control	Document Revision	Gap Assessment	Other	Retraining	(blank)	Total
2021	6.3%	58.5%	8.8%	25.2%	1.3%	0.0%	159
2022	16.6%	50.6%	7.5%	23.7%	1.7%	0.0%	241
2023	11.2%	49.8%	5.8%	27.8%	5.4%	0.0%	241
2024	18.7%	54.2%	7.7%	18.1%	1.3%	0.0%	155
2025	14.3%	49.5%	11.4%	21.9%	1.9%	1.0%	105

Appendix 14

Overall HPA Results by Dimension

Dimension	Dimension Score	Warning Flags Present
Leadership & Engagement	5.0 - Understanding	3 of 6
Training	2.7 - Awareness	2 of 3
Managing Work Risk - Design	5.0 - Understanding	2 of 7
Managing Work Risk - Execution	6.7 - Competence	2 of 7
Investigations & Learning	6.3 - Competence	1 of 5
Proactive Learning	6.5 - Competence	1 of 4
Monitoring Performance	5.0 - Understanding	1 of 2

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