

Cognitive Factor Leading to Human Error: A Major Contributing Factor for Quality Deviation in The Pharma Industry

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ABSTRACT

One of the top research-based sectors in the world, the pharmaceutical business constantly develops novel medications that improve and save lives. Pharmaceutical companies are used by both people and medical professionals to treat ailments, therefore it's essential to supply high-quality medicines following guidelines for good manufacturing procedures ensure the product's efficacy, safety, and quality. Human cognitive errors are one of the primary causes of quality disparities. There are a number of ways to recognize and minimize human mistake. The definition and types of human error, cognitive psychology and human performance, cognitive factors that lead to human error, the impact of cognitive errors on quality deviations, root cause analysis of human errors, various tools for identification and assessment, methods to reduce cognitive errors, and the role of organizational culture are all covered in this. This overview describes typical mistakes, their impact on healthcare, and preventative measures to reduce them.

Keywords: Human error, cognitive error, cognitive factors, Root cause analysis, Cognitive psychology, Quality deviations, Good Manufacturing Practices.

I. INTRODUCTION



Figure 1: Essentials of Quality System

1.2 Importance of Quality in Drug Safety and Efficacy

A FDA-ICH (International Conference on Harmonization) document defines drug quality as

1.1 Overview of Pharmaceutical Quality Systems

The Expert Working Group (Quality) of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use and the USFDA developed the internationally harmonized guidance ICH Q10, which describes a model for a pharmaceutical quality system that encourages the use of science- and risk-based approaches and can be implemented throughout the various stages of a product lifecycle. This guidance is currently being adopted by the regulatory bodies of the European Union, Japan, and the United States.[1] The most crucial component of the management function is the quality management system, which aids in the implementation and determination of the general procedure and the course that businesses will take in order to enhance the product's quality. It puts "quality policy" into practice. In pharmaceutical companies and organizations, quality management is crucial because the products and drugs that are manufactured have a big impact on customers' bodily systems. It is essential to maintain the items' efficacy, safety, quality, purity, and identification. Every process must function properly in order to meet standard regulatory compliance, which is ensured by a well-run quality management system. Organisations can regulate quality criteria with the aid of a quality management system.[2]

“the suitability of either a drug substance or drug product for its intended use.” This phrase encompasses qualities like identity, strength, and purity. One of the key actors in the drug safety

debate, the Food and Drug Administration (FDA), defines its own role in terms of drug therapy safety as follows: "FDA requires that drugs be proven safe and effective. FDA must determine that the drug produces the benefits it is supposed to without causing side effects that would outweigh those benefits." [3] Drug Safety Communications (DSCs) avoid or lessen medication-related damage and enable consumers and medical professionals make better decisions. Visitors spent an average of 36 seconds on each of the four DSCs released in FY24. [4]The cGMP requirements were put into place by regulatory bodies all around the world to guarantee the identity, strength, purity, and quality of pharmaceutical products. To ensure the safety and effectiveness of the pharmaceutical product, staff members should be properly trained and qualified.[5]

1.3 Definition of Human Error and Cognitive Error

An inadvertent departure from safe procedure is called an error.[6]An error is defined as either using the incorrect plan to accomplish a goal (i.e., error of planning) or failing to carry out a planned action as intended (i.e., error of execution).[7] A medical error is defined as an inadvertent act that results from carelessness and has detrimental effects during medical treatments. In essence, it is a choice or conduct that deviates from the Health Care System's ideals.[8]The phrase "human error" originated from brainstorming sessions that followed human-caused mishaps.[9]Any notable departure from a previously set, necessary, or anticipated standard of performance is referred to as human error.[10]Cognitive errors are faults in thinking or thought processes that result in inaccurate diagnoses, treatments, or both.[11]It was first hypothesized in Cognitive Behaviour Therapy(CBT) that people with emotional disorders would have automatic thoughts that were characterized by logical fallacies. [12]

1.4 Scope and Objectives

One of the main causes of quality discrepancies is human cognitive mistakes. These variations in quality lead to product recalls and

regulatory product bans, which damage the company's brand and may result in lower sales and profits. There are several methods for identifying and reducing human error. The causes of cognitive mistakes, their effects on the pharmaceutical business, how to identify the cognitive errors that lead to deviations from current good manufacturing procedures (cGMPs), and difficulties in mitigating cognitive errors are all covered in this study.The study's scope includes manual processes, visual inspection, documentation, and other operational phases of pharmaceutical manufacture. Errors are classified as slips, lapses, and mistakes.[5]From diagnosis through therapy, follow-up, and even patient communication, mistakes can happen at any stage of the care process. In addition to having an effect on patient health outcomes, these errors also erode public confidence in healthcare systems, which results in a pressing need to prioritize prevention. According to earlier studies, 10% of patients have at least one adverse event.[8]

II. Human Error in the Pharmaceutical Industry

2.1 Definition and Classification of Human Error

The Latin word "errorem" which means "a wandering, straying, a going astray; meandering; doubt, uncertainty" as well as "a figurative going astray, mistake," is where the name "error" originates (Read et al., 2021). More recently, a number of definitions of human error have been recorded in literary works.[13]Human mistake is defined as an inappropriate or undesirable human choice or action that lowers or has the potential to lower system performance, safety, or effectiveness (McCormick et al., 1987).According to Erik (2005), it is described as a recognizable human behavior that is later recognized as the origin of an undesirable idea. Human error is defined as the traits of humans that include inadvertent departures from what is correct, right, or true. It is used to explain the outcome or consequence of human action, the contributing factor of an accident, deliberate deviations, and the actual action taken by a human being (Hansen, 2006).[9]

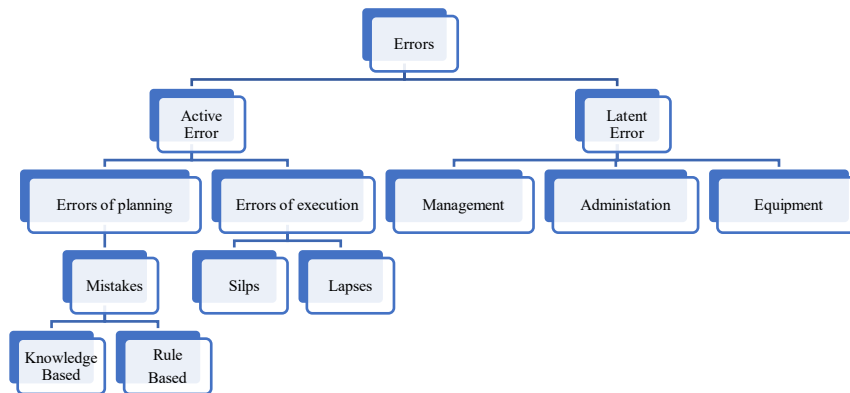


Figure 2: Classification of Human Errors

2.2 Human Error Types (Slip, Lapse, Mistake, Violation)

2.2.1 Errors in planning (missing an essential task while planning)[6]

When someone knows what they want to do but the activity does not go as planned, this is known as a slip or lapse. While lapses are internal events linked to memory failures, slips are related to observable activities and are linked to attentional failures. Slips and lapses happen when performing a typical task that is mostly automatic, usually in a familiar environment. They are virtually always linked to some kind of distraction, whether it comes from the person's surroundings or their own mental obsession.[14]

2.2.2 Errors in Execution[6]

Errors of action, or slips and lapses, occur when you plan to accomplish something but it doesn't work out. When mistakes are made, the actions may proceed exactly as planned, but the plan itself strays from a suitable route to the desired outcome. In this case, the mental processes involved in organizing, creating goals, making decisions, and solving problems are at a higher level of failure [4]. It is incorrect for a doctor to treat a patient with chest pain as though they have a myocardial infarction when, in reality, they have a perforated stomach ulcer. The strategy was flawed, but the goal is evident and the behaviour reflects it. Rule-based errors happen when someone is already familiar with a technique or rule that they have learned through training or experience. Applying the incorrect rule, such as treating someone for influenza when you should treat them for meningococcal sepsis, can result in rule-based errors. Alternatively, the error could result from flaws in the method itself (such as inadequate clinical recommendations).[14] Knowledge-based errors happen when an issue needs to be solved quickly in

novel circumstances. For example, a surgeon may have to guess at the source of the bleeding and make an understandable error in their assessment in the face of significant stress and uncertainty; a doctor may simply be unfamiliar with the clinical presentation of a particular disease; or there may be multiple diagnostic possibilities and no clear way to choose between them.[14]

2.2.3 Violations

Since we don't wish to create mistakes, errors are by definition unintentional. On the other hand, violations are intentional departures from safe operating methods, standards, norms, or practices. This is not to mean that people want a negative outcome, such when someone purposefully damages a piece of equipment; instead, they typically believe that the procedural breach won't matter this time or will actually aid in finishing the task. Errors and violations are different in a number of significant ways. Errors are mostly produced by human limitations in thinking and memory, while violations are more closely linked to attitudes, motivation, and the workplace. Understanding the social context of infractions and, if necessary, taking steps to prevent them are critical. In reality, neither the individual in question nor an observer can always tell the difference between slips, mistakes, and violations. the connection between the simply reported seen behaviour and the frequently difficult-to-identify psychological cause. [14]

2.3 Prevalence of Human Error in Pharma Deviations

Their investigation indicates that over 25% of all quality problems, including deviations, laboratory errors, complaints, and inspection concerns, are caused by human error. According to the records that are currently available, human error is responsible for 90% of recalls, including labelling

and packaging. Additionally, it makes the assumption that any defects in quality that lack scientific backing are the result of human error. According to reports, human error accounts for 80% of industrial mishaps, 70–80% of aircraft accidents, and 85–90% of deviations in the pharmaceutical business.[5] According to an IDC poll, one of the biggest threats to the pharmaceutical industry's performance is human mistake, which results in an annual loss of £23.9 million in the UK owing to a misunderstanding of the job position (Clarke, 2009). Misunderstandings can cause organizations to stray from established procedures (Gauvin et al., 2018). In the pharmaceutical sector, deviations have always been expensive since they have a significant negative influence on supply chain productivity. In the pharmaceutical and biotech industries, the average variation typically costs between \$25,000 and \$55,000. If product loss is involved, even the highest deviation can cost up to \$1,000,000 per deviation (Benson, 2021). At one of the COVID-19 vaccine manufacturing facilities, human error turned out to be a multimillion-dollar blunder (Lowe, 2022). After the federal government forced Emergent BioSolutions to abandon a \$628 million contract after the business mishandled COVID-19 vaccine doses and lost \$180 million as a result, the company's stock fell by more than 37% (Jr, 2021). Up to 15 million Johnson and Johnson doses were ruined by human error, which is attributed to untrained lab personnel (Spencer, 2021).[8]

2.4 Regulatory Perspective (cGMP, FDA Expectations)

When accidents, subpar work, and other unforeseen outcomes are attributed to human error, it essentially suggests that human error is the only cause of these problems. This viewpoint holds that tighter rules, increased supervision, regular training, and rigorous procedures can reduce human error. In actuality, human error is not a straightforward generic category of behavior but rather a result or symptom of a deeper, more complicated issue. When human mistake is used as a root cause, it is assumed that

humans may be isolated from other seemingly innocuous aspects of the workplace, such as the organizational, technological, managerial, systemic, cognitive/psychological, and physical aspects.[13] The cGMP requirements were put into place by regulatory bodies all around the world to guarantee the identity, strength, purity, and quality of pharmaceutical products. By avoiding contamination, mix-ups, failures, deviations, and errors, adhering to cGMP contributes to the production of a high-quality standard product. The FDA saw a sharp rise in pharmaceutical sector recalls as a result of human error. Label mix-ups, cross-contamination, visual inspection failure, products not stored according to labelled storage conditions, and other manufacturing process flaws that compromise product efficacy and safety are common human errors.[5]

III. Cognitive Psychology and Human Performance

3.1 Basics of Cognitive Psychology

Cognitive psychology focuses on how people think and learn by examining how our brains work. It is a branch of psychology that seeks to comprehend how people learn, perceive, process, and retain information. Cognitive psychologists study the thought processes that lead to: Cognitive psychologists study the thought processes that lead to: Emotion, Creativity, Cognition, and Problem-solving abilities.[15] The significance of knowing, comprehending, reasoning, remembering, and perception is particularly addressed by cognitive psychology.[16]

3.2 Information Processing Model

Learning was primarily seen as a response to outside stimuli prior to the advent of cognitivism, as behaviorist theories stressed. According to information processing theory, memory and knowledge production are not distinct and mutually exclusive ideas, but rather collaborate. A person gains knowledge when they accumulate more memories. [17]

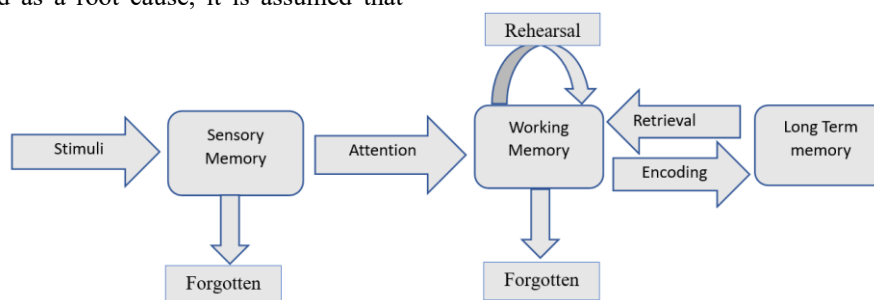


Figure 3: Information Processing Model

Sensory Memory

Take a time to consider each of your five senses separately. Our sensory memory is useful since our minds have a lot of information to process. It takes between 0.5 to 3 seconds to filter and process the information around you, identifying what is important and what is forgotten. A stimulus enters your short-term memory if you pay attention to it. A stimulus is forgotten if it is not addressed.[17]

Working Memory/Short-Term Memory

New information and long-term information come together in the short-term memory. New information can be practiced, encoded, and integrated into long-term storage for about 20 to 30 seconds, or it can be lost owing to interference or decay. The type of information, how it is delivered, and the person's storage capacity may all have an impact on the two items. Recall is frequently marginally higher for information we hear (acoustic encoding) than for information we see (visual encoding), and it is somewhat better for random numbers than random letters.[17]

Extended Memory

The Atkinson Shiffrin Model ends with long-term memory. Long-term storage has an infinite capacity and encompasses all memory, regardless of when the data was stored—two minutes ago or seventy-five years ago. Retrieval and encoding are the procedures that move information from long-term storage to short-term memory. knowledge will be easier to remember later on if it is recalled and linked to other pieces of knowledge more regularly.[17]

3.3 Attention, Perception, and Memory

The idea that memory, attention, and perception all cooperate to help us make sense of our surroundings and retain significant events lies at the heart of this interaction.[18]

Attention

Although attention can take many different forms, it is typically used to choose a subset of data to be processed further by another component of the information processing system. Perceptual processing may necessitate selection from a subset of the sensory input or sense data; this can be referred to as "attention for perception," such as gazing at something to determine its identity. As an alternative, choosing a response method can be necessary; this is known as "attention for action.[19]

Perception

The process of interpreting sensory input from our

surroundings and transforming unprocessed information from our eyes, hearing, and other senses into meaningful experiences is known as perception. Since perception supplies the data that our brain utilizes to create memories and make decisions, it is the initial stage of cognition. For example, when we see an object, like a book, our senses pick up visual, tactile, and occasionally aural cues that the brain interprets to recognize and classify the object.[18] Physical energy from the outside environment is transduced by the sense organs, encoded, and sent to the brain via sensory neurons so that the perceptual system may understand it.[19]

Memory

The next important function that interacts with perception and attention is memory, which is the capacity to store and recall information. Information is encoded into memory once attention has been drawn to pertinent sensory input. The degree of our attention plays a major role in this encoding process; if we are not paying attention to anything, it is much less likely to be encoded into long-term memory. [18]

3.4 Cognitive Load and Decision-Making

Studies looking at cognitive load have developed as a critical component of comprehending cognitive processes in more complicated decision-making settings, in tandem with the investigation of biases in decision-making. Cognitive load theory was first presented by John Sweller in his groundbreaking work in 1988. It explains how much working memory is needed to complete a particular job. Cognitive load theory, initially proposed by John Sweller (1988), is centered around the idea that the capacity of one's working memory is limited, and these limitations impact cognitive processing. Three categories of cognitive load are identified by the theory: extraneous, which is based on how the information is given; intrinsic, which is related to the complexity of the information itself; and germane, which is the mental resources needed for long-term information retention. Cognitive load can have an impact on how people absorb information and make decisions in the context of economic decision-making. Because there are fewer cognitive resources available to make methodical decisions under high cognitive load, people are more inclined to rely on heuristic processing.[20]

3.5 Human Limitations in Complex Systems

While completely new design considerations are not always urgently needed, there is a rising emphasis

on modifying current ones to account for the complexity of contemporary systems.

For complex systems, different design approaches are employed. The waterfall approach, spiral model, codesign method, hierarchical designs, and concurrent engineering are all covered.

- ✓ Complex systems are inherently dangerous
- ✓ There is a strong and effective defense against failure for complex systems
- ✓ Multiple failures are necessary for a catastrophe single failures are insufficient
- ✓ Various combinations of latent failures are present in complex systems
- ✓ Degraded mode is used by complex systems
- ✓ A disaster is always imminent
- ✓ It is essentially incorrect to attribute an accident to a "root cause" after it has occurred
- ✓ Post-accident assessments of performance are influenced by hindsight
- ✓ Two roles are played by human operators: They create and protect themselves from failure
- ✓ Every action taken by a practitioner carries some risk
- ✓ Human practitioners are the adaptable part of complicated systems
- ✓ The way humans interact with complex systems is constantly changing[21]

IV. Cognitive Factors Leading to Human Error

4.1 Attention Failures and Distractions

The premise that people frequently fail to process what they do not pay attention to, even if it is directly in front of them, is supported by a wealth of empirical evidence. Neural computations inside the system for managing attention in the brain are necessary since just reacting to the presence of an object will be delayed until the observer can move their attention to that object. The attended object is more firmly reflected in the neural code that a person uses to represent their environment when two objects vie for attention. Most notably, a problem known as inattentive blindness occurs when people frequently fail to notice and report something they are not paying attention to. [22-23]

4.2 Memory Limitations and Forgetfulness

Human memory can be thought of as having two sides: cognitive ability advantages (e.g., remembering people's names or previous encounters) and cognitive ability disabilities (e.g., memory loss or not recalling something when you want to). People forget things sometimes, so it

would be fair to say that they can 'forget' their past experiences entirely. In practiced memory research, researchers have referred to this as 'forgetting' (or memory loss) and identified subcategories within this category (e.g., tip-of-the-tongue sensation; amnesia). Some of the different reasons for 'forgetting' have also been identified (wrongly encoded information, interference from similar memories, or emotional state at time of retrieval). As a result, both amnesia and forgetting highlight that getting from one human cognitive functioning process (e.g., memory) through example after example, provide great evidence for advantages and disadvantages of cognitive function. Overall, overall human memory functions are not always very reliable and may not be very useful for providing benefit to people. However, it is important for humans to be able to retain memory, learn new knowledge, and enhance their skills through memory.[24]

4.3 Misinterpretation and Perceptual Errors

The complex process by which people interpret sensory data and create their conception of the environment is known as perception. The brain actively organizes and interprets inputs from our eyes, hearing, nose, tongue, and skin as part of this system. Although generally trustworthy, this process of interpretation is not perfect and can occasionally result in what are called perceptual errors. These misunderstandings are a normal part of human thought processes. Disparities between an individual's perception and what actually occurs in reality are known as perception mistakes. These are not just "mistakes" in judgment; rather, they are the results of the brain's ongoing efforts to effectively absorb enormous volumes of sensory information. In order to swiftly make sense of complex information, the brain uses a variety of shortcuts and interpretative frameworks, which may cause a divergence from reality. [25]

4.4 Decision-Making Errors

Amos Tversky and Daniel Kahnemann studied human decision-making for decades. They discovered that overconfidence bias, hindsight bias, anchoring bias, framing bias, and escalation of commitment all had an impact on people. Our capacity to make wise decisions is improved when we are aware of some of the decision-making hazards. We are happier when we make strategic choices, which leads to better interpersonal skills. When people overestimate their capacity to forecast future events, it is known as overconfidence

bias. A lot of people show signs of being overconfident. The reverse of overconfidence prejudice is hindsight bias, which happens when one looks back in time and mistakes become apparent after they have already happened. [26]

4.5 Fatigue, Stress, and Mental Overload

Workplace fatigue can affect productivity and flow regardless of the industry, but in workplaces where there is already a high degree of risk, workplace fatigue can cause difficulties for employees. Employees who are fatigued due to long hours of work may show similar signs to someone who is drunk or under the influence of another depressant, especially if they are working with heavy machinery or very fragile materials. The majority of people can function at a level comparable to having a blood alcohol content of 0.08, which is the legal threshold for intoxication, after just 21 hours without sleep.[27] According to Lazarus and associates, stress is “a specific relationship between the person and the environment that is appraised by the person as taxing or exceeding their resources and endangering their well-being.” The quantity of mental resources needed by a person to finish a task at a specific moment is referred to as their mental burden. According to Sweller's Cognitive Load Theory, this complex metric consists of three main parts: germinal load, intrinsic burden, and cognitive load. Mental workload is an important metric in the industrial setting for determining how much mental effort employees must put out, especially when there is a lot of human-machine contact.[28]

4.6 Over-Reliance on Experience and Automation

Automation is the autonomous execution of a task by a system or technology that was previously completed by a human. A new type of automation that we refer to as Intelligent Automation (the application of AI in ways that can learn, adapt, and improve over time to automate jobs that were originally conducted by a human) has been made possible by advances in AI and related sub-fields. According to Frey and Osborne (2017), algorithms that would enable the automation of cognitive processes are being developed. Additionally, they claim that the potential for automating manual jobs has increased due to the use of AI in mobile robotics. Knowledge and service labor frequently involve manual and cognitive duties (Davenport and Kirby, 2016a). According to Hislop et al. (2018), knowledge work is characterized as intellectual, creative, and non-routine work that involves the

generation and use of knowledge. Work in a variety of professional fields, including information and communication, consulting, pharmacology, and education, is referred to as knowledge work (Kuusisto and Meyer, 2003). The process of using one's resources (such as knowledge) for the benefit of another person or oneself is known as service labor (Barrett et al., 2015).[29]

V. Performance Influencing Factors (PIFs)

Any circumstance that affects performance is referred to as a performance influencing factor (PIF). These may be personal, professional, or organizational in nature.

PIFs may increase the likelihood of human error, which may result in mistakes and incidents. Both the processing of information and the decision-making process are impacted by these elements. You can enhance performance and boost safety by reducing or managing these PIFs.[30]

- Individual Factors (Skills, Experience, Health)
- Task Factors (Complexity, Time Pressure)
- Environmental Factors (Lighting, Noise, Ergonomics)
- Organizational Factors (Culture, Leadership, Training)

VI. Impact of Cognitive Errors on Quality Deviations

6.1 Types of Deviations (Manufacturing, Packaging, Documentation)

Any modification from authorized processes during manufacturing, testing, or material handling activities, as well as any discrepancy between expected and actual outcomes, are referred to as deviations. When products don't live up to the necessary quality standards, it can also be detected through client complaints. All deviations must be accurately documented and thoroughly investigated in accordance with regulatory rules in order to guarantee adherence to Good Manufacturing Practices (GMP) and promote ongoing improvement. Effective identification, control, correction, and documentation of deviations are made possible by the application of quality risk management.

Generally, there are two types of deviations: planned and unplanned.

Planned Deviations: Any deliberate, brief departure from a normal method chosen to prevent unfavorable circumstances without compromising the technique's or product's quality or safety. For instance, a batch was carried out with less input

when raw materials were unavailable.

Unplanned Deviations: The unintentional non-conformance seen during or after the execution of an activity is known as an unplanned deviation. The following factors could lead to unplanned deviations: Equipment failure, power supply interruption, site mishaps, and utility failure, mistakes made during documenting. Based on how they affect the facility's and process's validation state, safety, and product quality.[31]

6.2 Case Examples of Human Error in Pharma

Production-less quantity charging, incorrect material charging, failing to check the cleanliness of the charging vessel or equipment before starting up, changing the sifting sequence, incorrect compression machine unit settings, incorrect calculations, and missing logbook entries. Warehouse-Material labels and certificate of analysis (COA) are not checked properly, like storage conditions, weighing mismatch, improper segregation of material, using the same scoop for active pharmaceutical ingredients (API) and excipients. Errors in sampling, dilution, labelling, and handling are all part of quality control(QC). Misses in document review and missing signatures are examples of quality assurance(QA).[5]

6.3 Product Recalls and Regulatory Actions

The pharmaceutical sector may be significantly impacted by cognitive mistakes. These mistakes can have a variety of repercussions, from little departures from the necessary standards to major safety problems, product recalls, legal action, and reputational harm to a business. A pharmaceutical product may need to be recalled if it turns out that cognitive errors contributed to improper manufacturing. Product recalls can affect the supply chain, corporate science, financial loss, and a company's reputation. [5]

6.4 Economic and Reputational Impact

Cognitive biases have a major effect on economic decisions. This happens because many times human judgement is affected by non-rational factors (non-income), and as a result people make decisions which are contrary to what would be the best economic decision. Cognitive biases can have very large effects on market outcomes, consumers' behaviour and how we make financial decisions. Overconfidence causes us to take too many risks. For example, an overconfident investor may take on too much risk for them to be able to manage;

resulting in a bubble in the stock market or personal loss due to poor financial decisions.[32]

VII. Root Cause Analysis of Human Errors

7.1 Limitations of Labelling "Human Error" as Root Cause

When something goes wrong in a life sciences or pharmaceutical context, the investigation that follows frequently comes to the same conclusion: human error. The simplest approach to end an investigation without finding a solution is to identify human error as the primary cause.[33] Despite its advantages, RCA has a number of drawbacks and restrictions that may limit its ability to effectively treat medical errors. Underreporting is a major problem; RCA frequently depends on voluntary incident reporting, which may result in inadequate data. Because of a corporate culture that discourages transparency or fear of punitive repercussions, many healthcare personnel may be reluctant to report errors. Bias in the analysis process is another possibility. Preconceived assumptions regarding the reasons behind an error may force the RCA team to overlook important details or assign blame incorrectly. Furthermore, even though root cause analysis (RCA) seeks to discover systemic problems, some investigations have a propensity to concentrate on individual errors rather of more general organizational aspects, leading to suggestions that fail to adequately address underlying causes. Additionally, doing comprehensive RCAs can be resource-intensive, requiring a large amount of time and effort from medical personnel. This can make it difficult to allocate enough resources for thorough examination in hectic clinical settings. Furthermore, businesses may find it difficult to follow through on suggested changes because of conflicting goals or a lack of accountability, making it difficult to execute recommendations from RCA results. Finally, because healthcare systems are complex, errors frequently result from a number of interconnected causes. Conventional RCA methods might find it difficult to properly capture this complexity, which could result in findings that are too simplistic.[8]

7.2 Fishbone Diagram and 5M Approach

In terms of the cutting-edge advancements in the field of quality management, Dr. Kaoru Ishikawa (1915–1989) was a Japanese professor, advisor, and motivator.[34] A cause-and-effect diagram, often known as a fishbone diagram, is a tool used in the healthcare industry to help identify the underlying cause of quality-related issues like

subpar performance or safety occurrences. With the help of this technology, the team may concentrate on the underlying cause of an issue rather than its symptoms. The team may need to adopt a different fishbone diagram process for each root cause if there are multiple. A fishbone diagram is a visual aid that shows, in a manner akin to a fish's bone, the relationship between the several factors that contribute to a specific impact or problem (i.e., causes and consequences).[35] The Fishbone Diagram, which graphically divides possible causes into discrete branches like people, procedures, equipment, and environment, is a crucial tool in this process. Teams can methodically investigate different error-causing elements with the use of this structured technique. For example, a Fishbone

Diagram can identify important contributors to medicine administration problems, such as poor staff training and communication breakdowns.[8] Five M Ishikawa diagram: Fundamental Man - is human error the cause of quality loss? Methods - What production or labor techniques were employed? Machinery - Could the error be caused by a defective machine? Materials - Could the product's substance be the source of the issue? Management - Do issues stem from inadequate planning, supervision, and work organization; inadequate leadership and motivation; a lack of control; and deficiencies in conceptual, technical, and social skills? [36]

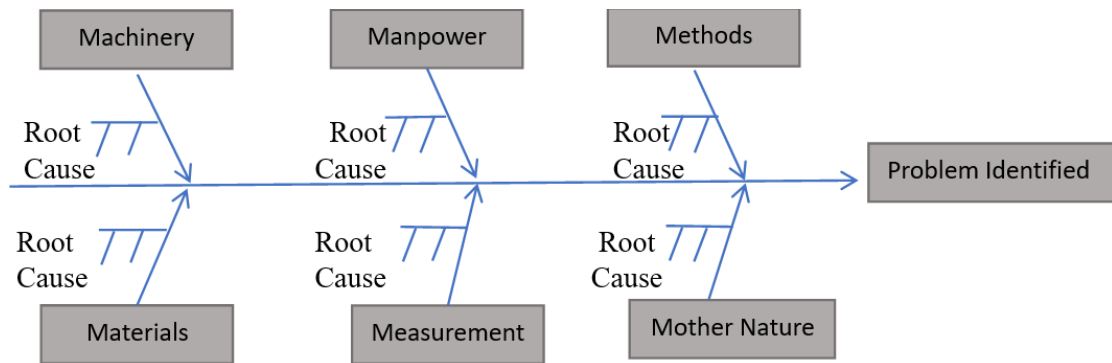


Figure 4: Ishikawa Fishbone Diagram

7.3 Swiss Cheese Model

A key paradigm for comprehending the complex nature of medical errors in healthcare settings is the Swiss Cheese Model (SCM), which was developed by James Reason. This model shows how mistakes might happen when several defenses don't stop unfavorable things from happening. Every layer stands for a risk-reduction measure, including procedures, instruction, and technology. But when these layers holes, which stand for flaws or shortcomings, line up, the chance of an error getting to the patient rises dramatically.[8]

Active Failure: Unsafe Behaviors

Latent Failure: Preconditions for Unsafe Acts

Latent Failure: Supervisory Factors (unsafe supervision)

Latent failure: organizational influences.[13]

Time restraints and stressful situations can make these cognitive difficulties worse, increasing the likelihood of mistakes. The alignment of holes in this model is also a result of training problems.

Healthcare workers' capacity to handle challenging clinical conditions declines if they are not properly

trained in procedures or equipment use. Gaps that coincide with other systemic weaknesses may result from this lack of readiness. A key factor in the SCM's efficacy is organizational culture. The barriers against medical errors are strengthened when management places a high priority on patient safety and devotes funds to system upgrades and training. This proactive strategy reduces the alignment of gaps between various layers. The SCM has been extensively used in healthcare risk management strategies. Organizations can find particular weaknesses and carry out focused responses by methodically examining situations via this lens. When there is an incident related to administering or taking a medicine incorrectly, there are investigation systems that can be used to investigate what caused this incident to occur. For example, the SCM can be used to analyze whether the cause(s) were the result of a lack of policies or procedures, ineffective communication between coworkers, or lack of appropriate education and training. Additionally, by also discussing that defenses must not be in a constant state, this will

allow for continued growth and improvement. Therefore, continual assessment and revision of training programs and policies will help to ensure

that new vulnerabilities do not exist as changes occur in healthcare.[8]

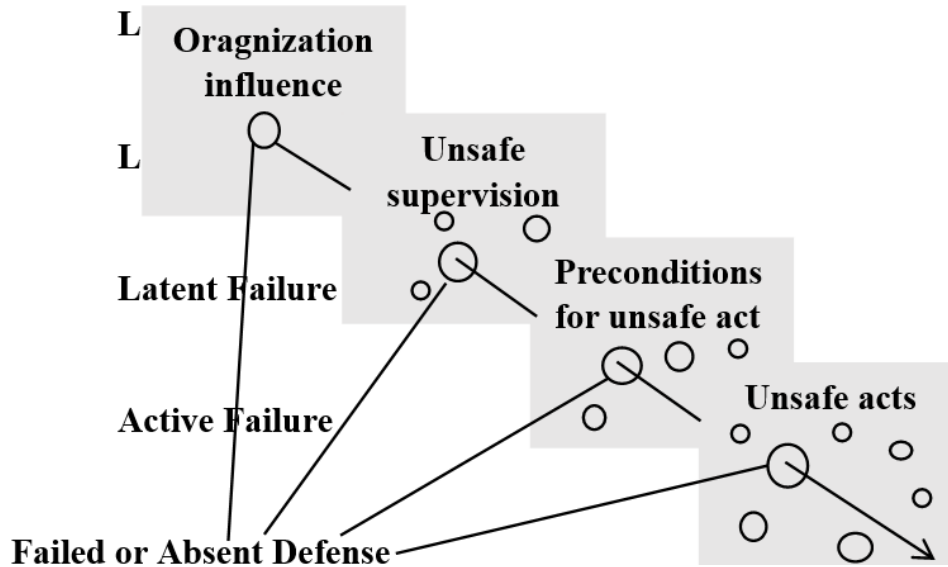


Figure 6 : The swiss cheese model

7.4 HFACS Framework (Human Factors Analysis and Classification System)

Although frequently used for incident analysis, Reason's Swiss Cheese Model (SCM) has limits in real-world situations since it is less successful at tackling complex human aspects because it does not explicitly identify the vulnerabilities within each layer. In order to address this, the Human Factors Classification and Analysis System (HFACS) was created to identify both active and underlying causes of errors, thereby bridging theory and practical application. HFACS is used in a variety of industries, including manufacturing, healthcare, and aviation. It provides an organized method for examining occurrences using specific categories associated with varying degrees of mistake, ranging from individual acts to organizational influences. It assists investigators in methodically tracing errors by classifying causes into hierarchical layers. By broadening the framework and improving its categories, a revised version called HFACS-MEs further enhances this approach for medical errors and offers a more thorough and in-depth way to comprehend and prevent errors.

1) Unsafe acts

Errors

Decision errors: Also known as "thinking" errors, these blunders happen when planned actions are executed as anticipated but the strategy turns out to

be inadequate or inappropriate for the situation. They frequently show up as improper decisions, badly carried out processes, or the abuse and misinterpretation of pertinent data.

Skill-based errors: These are behaviors that happen with little to no cognitive awareness because they have been rehearsed to the point of automaticity. Breakdowns in visual scanning patterns, inadvertent activation or deactivation of controls, forgotten tasks, and missing items from checklists are examples of such "doing" failures. These mistakes may even arise from the method or methodology used to complete a task.

Perceptual Error: When sensory input is degraded, as is frequently the case when flying at night, in bad weather, or in visually demanding locations. Aircrew may misunderstand distances, altitudes, and descent rates when given insufficient or ambiguous information. They may also react wrongly to a variety of vestibular or optical illusions.

Violations

Bending The Rules (Regular Violations): These types of violations are often referred to as habitual violations. They will generally be tolerated by either the supervisor or management, who allow variations from established rules and procedures.

Not Following The Rules (Exceptional Violations): These violations take place on a sporadic basis when an employee violates authority; but they are outside

the norm for that employee and are not condoned by management.

2) Preconditions for unsafe acts

Technological Environment: This includes various task-related items, including automation levels, display/interface features, design of equipment/control and format of checklists.

Physical Environment: This encompasses ambient conditions such as heat, vibration, light and presence of hazardous materials, as well as aspects of the operational context, including weather, altitude and terrain.

Physical and mental limitations are long-term, physical or mental impairments that could affect your performance in a negative way. Some examples of long-term physical or mental limitations include long-term problems related to mental health, weakness, poor vision/poor eyesight, and limited ability to think properly.

Personnel issues

Planning, Coordination and communication is a broad area encompassing a variety of areas of communication, collaboration, and coordination related to performing at your best.

Fitness for duty is again referring to the behaviours you will be expected to follow away from the work environment in order for you to perform your job to the best of your ability such as to follow crew rest requirements, to abstain from alcohol, etc.

3) Unsafe supervision

Insufficient Supervision: Management has insufficient resources, personnel management and operational leadership, as well as providing professional guidance and training.

Improper Job Assignments: Organizing personnel to perform certain jobs takes into consideration a variety of factors, such as employee pairing or risk management, while also providing jobs at an appropriate pace.

Taking No Action Against Known Problems: Management is aware of any deficiencies in personnel, tools, training or any other safety related items and has been given the opportunity to address those problems but has taken no action to fix them.

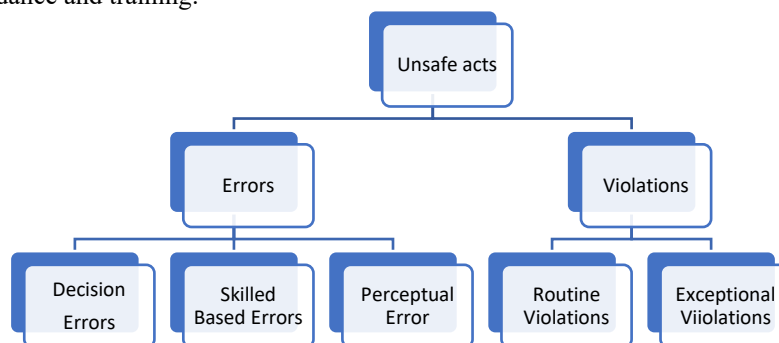
Violation of the Rules of Supervisory Management: Managers intentionally distance themselves from the established rules, regulations and/or standard operating procedures that govern their actions as leaders, resulting in a failure to enforce compliance with these standards.

4) Organizational Influences

Organizational Climate: The overall environment or culture of an organization, which includes everything from the rules and regulation regarding management and control of the organization to the organization's cultural values, such as how employees view themselves and their roles within the organization.

Operational Process: The step-by-step process that organizations follow in order to achieve their goals, including everything from operations and procedures to supervisory and management functions.

Management of Resources: The management of an organization's primary resources, including equipment, financial resources and human resources.[8]



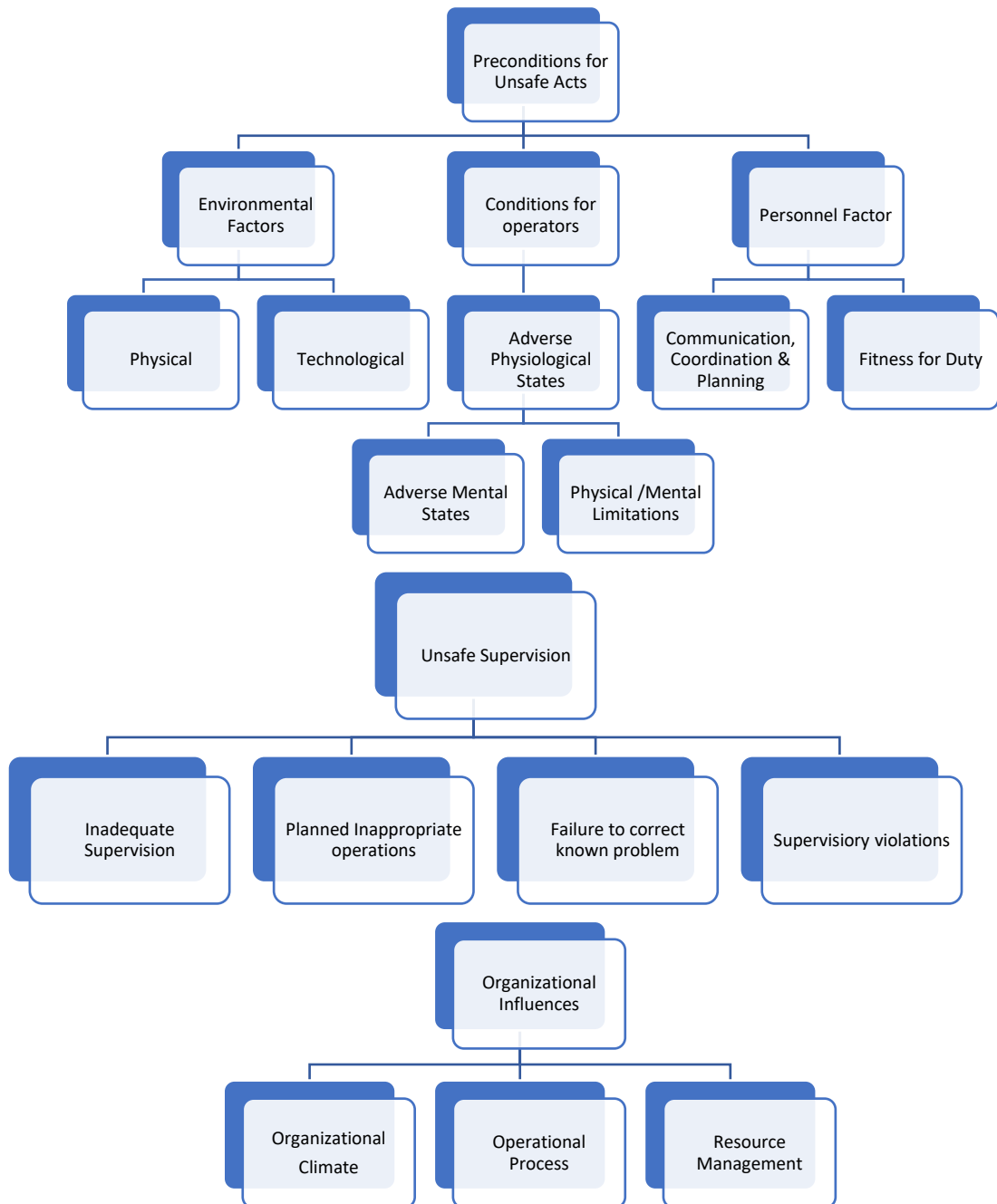


Figure 7: HFACS Framework

7.5 SRK Model (Skill–Rule–Knowledge Framework)

Jens Rasmussen of the Risø Laboratory in Denmark created one of the most well-known and significant models for identifying the kinds of errors that might arise in various operational scenarios. Throughout the latter quarter of the 20th century, Rasmussen's "skill-rule-knowledge" (SRK) paradigm made him a prominent figure in the field

of safety research, particularly in the areas of major hazard prevention, human performance, and human error analysis. A (cognitive) engineering and behavioral approach was put forth by Rasmussen's categorization system, known as the SRK model, which claimed that human performance could be categorized according to the degree of cognitive control that underpins an individual's behavior at a certain moment. Errors are therefore likely to happen

based on the various information processing demands imposed on the person or in various operating scenarios. According to Rasmussen, there are three levels of human performance: knowledge-based, rule-based, and skill-based. Each of these levels produces distinctive error forms. Skill-based Behaviour: Performance and functions are carried out as automatic or unconscious processes, which is primarily associated with regular, least difficult jobs. These mechanisms are triggered by sensory inputs and have been developed and internalized by experience. It only requires a minimal amount of conscious thought. Rule-based Behaviour is associated with unfamiliar activities and depends on an individual's experience, skills, and capacity to alter automatic behaviour when a problem or difficulty arises. People should have procedures (rules) telling them what to do, be taught to handle this situation, or have prior experience with the

problem. The resulting behaviour draws from stored knowledge of rules, i.e., if X occurs, then perform Y (an occurrence and an action), by comparing the information with well-known patterns or rules on a "if-then" basis. In rule-based performance, behavior and action are in line with defined rules that are deliberately adhered to in order to carry out particular tasks. This is because the individual functions primarily automatically, matching the situation or occurrence to a stored answer. After that, deliberate consideration can be used to confirm that the right course of action was taken. Knowledge-based performance necessitates a high level of focus and attention, because the operator must deal with unfamiliar circumstances and cannot automatically or directly apply well-known patterns or rules. It necessitates a high level of conscious thought.[13]

Skill-based	Rule-oriented	Knowledge-based
<ul style="list-style-type: none"> • Well-practiced tasks • Little cognitive effort, almost automatic tasks 	<ul style="list-style-type: none"> • There are established rules available. • More intricate than skill-based 	<ul style="list-style-type: none"> • Unfamiliar circumstances with no established routine or guidelines • Using information to solve a problem • Completely mindful activity

Figure 8 : Characteristics of SRK Model[13]

VIII. Tools for Identification and Assessment

8.1 Human Error Assessment and Reduction Technique (HEART)

In complicated systems, such as the pharmaceutical sector, HEART (Human Error Assessment and Reduction Technique) is utilized to find possible human error causes. Task, human, environmental, and organizational are the four categories into which it divides contributing factors. Human aspects include workload, training, and experience; task-related factors include complexity, automation, and the need for supervision. Performance can also be impacted by environmental factors like PPE use, cleanroom regulations, and outside distractions. Error reduction is greatly aided by organizational components such as safety culture, management procedures, and communication systems. Deviations during cGMP operations must be reported right away and thoroughly investigated. Using techniques like fault tree analysis, fishbone diagrams, and the 5 Whys method, a lead investigator creates an investigation strategy and performs root cause analysis with the assistance of a cross-functional team. In order to obtain all pertinent information

impartially, interviews are conducted quickly and meticulously recorded. In order to determine underlying causes and carry out corrective and preventive actions (CAPA), the results are examined. The efficacy of these interventions is confirmed by follow-up assessments, which also aid in preventing recurrence. Investigations must be finished on schedule, accurately recorded, and, if needed, in accordance with HR and organizational regulations.[5]

8.2 Failure Mode and Effects Analysis (FMEA)

For many years, engineers have employed the analytical technique known as FMEA to find and minimize risks. This procedure looks at a system's separate parts to ascertain the range of potential failures for each part and the impact of a specific failure on the system's overall stability. FMEA, which focuses on manufacturing processes, uses a three-variable equation with scores ranging from 1 to 10 to determine a risk priority number. This method is used by medical device makers to assess their products. Design FMEA and process FMEA are the two categories of FMEA techniques. Both

approaches are frequently used to assess system safety in a variety of industries, including computer program design, manufacturing, and aviation. Healthcare failure mode and effect analysis (HFMEA) and failure mode effects and criticality analysis (FMECA) are two examples of modified FMEA techniques. The National Center for Patient Safety (NCPS) of the US Department of Veterans Affairs created HFMEA in 2002 by fusing terminologies, concepts, and elements from root cause analysis, hazard analysis and critical control point (HACCP), and FMEA. This approach was created to help healthcare organizations assess and enhance healthcare procedures prior to actual

occurrences. Although FMEA has been widely used in the industrial sector, its deployment in the healthcare sector has been sluggish. FMEA has been used to evaluate risks and pinpoint areas where the healthcare system needs to be improved. Before putting new policies and procedures into effect, the National Patient Safety Agency of the United Kingdom advises using FMEA to evaluate them. Every year, the JCAHO has requested that its authorized institutions conduct a proactive risk assessment study, such as an FMEA. Priority actions for improvement and failure-prevention countermeasures are established with the use of the FMEA process results. [37]

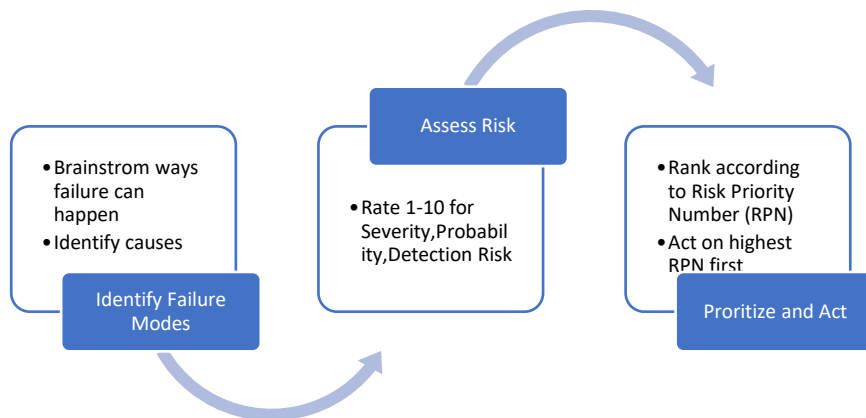


Figure 9 :FMEA Process

8.3 Root Cause Analysis (RCA) Tools

Root cause analysis (RCA) is a promising method that helps maintain a consistent lab management system. RCA helps to start remedial action by identifying the different causes of the result. RCA is a methodical technique that concentrates on identifying defects that could be fixed for improved performance and predictable results.

Five Whys

Finding the root of any problem can be aided by asking why five times. The problem of subpar H&E staining can be methodically traced down to its underlying cause using the Five Whys approach:

1. What made the staining inadequate? The staining procedure needs to be improved.
2. Why was the procedure ineffective? The stains weren't in good shape even though the technician followed the procedure.
3. What caused the stains to be in bad shape? They can have become polluted as a result of poor or insufficient cleaning.
4. Why weren't the stains changed on a regular basis? Fresh stock was not available in the lab.
5. Late ordering of reagents caused a lack of

inventory, which was identified as the reason for inadequate staining results. Implementing weekly inventories, creating cutoff values, and reporting deficiencies of lab reagents with a plan to expedite their purchase are all ways to utilize RCA in the future to avoid the same challenge. Additionally, RCA gives you evidence-based ways to take action or improve a process because trends and patterns are identified through the study of data.

Diagram of a fishbone

Fishbone analysis is a visual aid that resembles a mind map and is also known as an Ishikawa diagram or cause and effect diagram. When we incorporate team members' ideas and thoughts into our action plans, it helps identify nearly every potential cause of an issue.

The subject at hand needs to be written on the whiteboard's right side. Draw an arrow that ends at the problem in question. The six main categories that caused the problem should ideally be listed as principal branches. All potential causes should be included under each major category. As a result, the fishbone should contain a variety of potential causes for the problem. The aforementioned

process could be used to find and fix a problem's underlying cause.

Other methods

It is simpler to comprehend relationships between variables when numerical data is shown as points in a scatter chart. It is frequently used in quality analysis, decision-making, and root cause analysis to find correlations, whether positive, negative, or nonexistent. If FMEA isn't being completed, this will create documented and validated evidence as to how a process could potentially fail, the impact of one of those failures, and how to assign the risk priority of that failure based on the three scores assigned (severity, occurrence, and detection). Another method used to evaluate failures is FTA, where a structure that resembles a tree is used to deconstruct an issue into contributing causes. Evaluating failure is effective at improving system safety by identifying root causes providing probability estimates, and creating prevention or risk mitigation strategies. The Pareto analysis is based on the concept that a small number of causes often account for most of the effects/impacts. The goal of the Pareto analysis is to find the most important parts of a problem or the parts which contribute the most to the problem so that the organization can effectively manage its resources and give priority to the most important items (issues). The Pareto chart shows the major contributors to the problem. DMAIC is a structured methodology for improving processes. This process includes defining the problem, collecting and analyzing data to determine the root causes of the problem, implementing the improvement, and controlling the results to ensure that the improvement has been sustained. The DMAIC approach encourages data-driven decision making and continuous improvement.[38]

8.4 Risk-Based Approaches in Quality Management

The goal of a risk-based approach to quality management systems (QMS) is to recognize,

evaluate, and manage possible risks related to medical devices over the course of their whole life cycle. In order to guarantee patient and user safety, this involves phases including design, development, manufacture, distribution, and post-market monitoring. Manufacturers must assess the possibility and seriousness of any risks and take action to lessen or eliminate them. Stronger quality control procedures, process enhancements, and design modifications are a few examples of these actions. How these risks will be managed is outlined in a systematic risk management plan. This strategy promotes ongoing improvement and is a crucial prerequisite for regulatory compliance, including frameworks like the EU MDR. Manufacturers can sustain the efficacy, safety, and quality of medical devices throughout time by routinely evaluating and revising risk management techniques.[39]

8.5 Deviation Investigation Systems

When a deviation is noticed, the department head should discuss it with QA and make a choice based on how serious it is, such as stopping the process right away. Subsequently, document the deviation using SOP instructions, including process, person, timing, production stage, department, and category. Following the initiation of this inquiry process.

Investigative step:

1. Prompt notification to the appropriate user department upon identification of a deviation.
2. Initial analysis.
3. Examine all of the information that is now accessible.
4. Conduct suitable interviews.
5. Based on the preliminary assessment, an immediate measure or corrective action should be planned.
6. Data collecting and investigation methodology: Examining documents and records. Examine comparable incidents during the last five years. Interview with an operating person about the products history.[40]

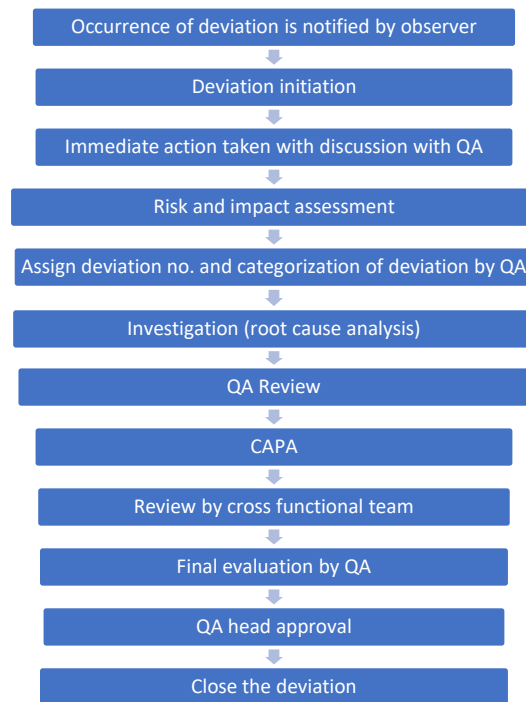


Figure 8 : Flowchart of Deviation Handling System

IX. Strategies to Minimize Cognitive Errors

A crucial tactic to lower human error is strict adherence to SOPs (Standard Operating Procedures), which guarantee jobs are carried out accurately and consistently while offering crucial operational and safety information. Through organized procedures and checklists, SOPs also assist new hires in avoiding errors and support both skill-based and decision-based jobs. Employee education is just as crucial. Frequent training on cGMPs, SOPs, and job-specific duties increases comprehension, lowers cognitive errors, and fosters communication and teamwork. Structured handoffs, briefings, and debriefings are examples of procedures that enhance coordination and reduce communication-related mistakes. The goal of human factors engineering is to create settings, tools, and systems that are less likely to make mistakes. Root cause analysis and error reporting systems aid in problem identification and recurrence prevention. Automation and technology like artificial intelligence and robotic process automation minimize errors in jobs like data entry and decision-making, enhance data processing, and lessen manual labor. By offering real-time information, alarms, and a decrease in the need for handwritten records, electronic systems such as EHRs (Electronic Health Records) and clinical decision support tools increase accuracy.[5,8]

Shigeo Shingo created Poka-Yoke, a mistake-proofing technique that uses straightforward, dependable system designs to either prevent errors or identify them early. It improves customer satisfaction, efficiency, and quality.[41] Lastly, by addressing both perceptual and skill-based errors, simulation-based training and team exercises assist professionals in honing their skills, making better decisions, and managing stressful situations.[8]

X. Role of Organizational Culture and Quality System

A just culture encourages candid communication and psychological safety, enabling staff members to voice issues, challenge procedures, and disclose mistakes without worrying about repercussions. By encouraging businesses to learn from both small and large negative events, this strategy helps them enhance processes and lower risks in the future. By emphasizing personal guilt rather than systemic flaws, a blame culture, on the other hand, discourages reporting, instills fear, and restricts innovation.[42] According to Human and Organizational Performance (HOP), work is a system made up of individuals, equipment, and procedures. It highlights that mistakes are unavoidable, assigning blame is pointless, context

shapes behavior, and learning from mistakes is crucial.[43-44] In order to make systems easier to operate correctly and more difficult to operate badly, leadership is crucial in determining how failures are handled. Workplace safety is greatly impacted by supervision and leadership. Both following the law and actively working to increase safety are examples of safety behavior.[45] Adherence to safety procedures is promoted, injuries are decreased, and a positive safety environment is fostered by effective leadership styles, particularly transformational and reward-based methods. Kaizen and the PDCA (Plan-Do-Check-Act) cycle are examples of continuous improvement techniques that emphasize incremental, continuous process improvement. These strategies assist businesses in adjusting to shifting needs and gradually raising quality. In the pharmaceutical sector, Corrective and Preventive Action (CAPA) systems are essential for locating, examining, and fixing quality problems. While preventative measures seek to stop future recurrence, corrective measures deal with current issues and their underlying causes. Regulatory compliance, ongoing development, and general product quality are all supported by a robust CAPA system.[46-48]

XI. Regulatory Expectations and Compliance

In pharmaceutical production, cognitive errors and cGMP deviations are largely caused by a lack of attention to detail. Even minor errors, like utilizing the wrong materials or omitting steps, can have an impact on the quality of the final product. Overconfidence and complacency lead to disregard for established procedures, which raises hazards even further. Maintaining accuracy and consistency requires regular training, rigorous adherence to SOPs, and robust quality control systems. Serious mistakes like wrong formulas or dosages can arise from memory lapses, particularly when workers rely on recall rather than appropriate recordkeeping. Checklists, double-checking procedures, and current references can all help lower these risks. The need for clear communication and encouraging work environments is highlighted by the fact that workplace stress, strict deadlines, and language obstacles can also lead to errors through miscommunication, skipped tasks, or wrong paperwork. Regulators like the FDA and EMA no longer accept the simple explanation of "human error" in deviations investigations. To find deeper systemic problems, such poor process design or insufficient training, they anticipate a comprehensive root cause study. Identifying the

problem, carrying out root cause analysis, putting CAPA into practice, and assessing efficacy are all steps in an organized inquiry process. The goal is to stop recurrence by fixing flaws at the system level.

Another crucial component is data integrity, which guarantees the accuracy, completeness, and dependability of every record. Traceability, transparency, and regulatory compliance are all supported by Good Documentation Practices (GDP).[5,48-50]

XII. Case Studies and Practical Applications

12.1 Manufacturing Error Case Study

Important details regarding drugs and allergies were not adequately conveyed when a patient with a complicated medical history was moved from the intensive care unit to a normal ward. Consequently, the patient experienced a severe reaction after being administered a medication to which they were allergic. The hospital stay was prolonged and expenses rose as a result of the delay in identifying the problem. The event exposed flaws in the handoff procedure, especially the absence of organized communication techniques like SBAR. It demonstrated how inadequate communication can have a direct negative impact on patient outcomes. In order to improve communication during patient transfers, the hospital implemented a standardized handoff system (SBAR) and started offering staff training on a regular basis.[8]

12.2 Laboratory Error Case Study

Surgical mistakes, such as wrong-site procedures and retained instruments, were common at a large university medical facility. The WHO Surgical Safety Checklist, which covers crucial safety checks prior to anesthesia, prior to incision, and prior to the patient leaving the operating theater, was implemented by the department in order to address this. By standardizing safety procedures and lowering practice variation, the program increased consistency. Additionally, it promoted team members' active involvement, which improved responsibility and communication in the operating room. Over time, staff comments and ongoing monitoring helped to improve the procedure. As a result, overall collaboration and communication greatly improved, and surgical errors decreased by almost 40% in just six months.[8]

12.3 Packaging/Labelling Error Case Study

When opioids were replenished, they were ordered as a 1 ml vial containing 7.5 mg/ml of Piritramid rather than the typically ordered and used 2 ml vials

containing 15 mg/2 ml of Piritramid, still from the same manufacturer. Dipidolor™, a trade name of Piritramid from the Janssen-Cilag GmbH, Germany, was replaced with the generic brand Piritramid (Hameln Pharma, Germany). Nevertheless, these stocks were mistakenly listed in the ward's drug cupboard logbook as 2 ml vials. In certain instances, doctors wrote prescriptions that included, "administer half a vial of Piritramid." Although a Critical Incident Reporting System (CIRS) was submitted anonymously, it was not yet possible to determine how many patients had been involved or which patients had received what dosage. Some individuals have received 3.75 mg of Piritramid rather than 7.5 mg due to the assumption that they were given "half a vial" of the medication. The published recommendations concentrate on enhancing drug safety and lowering errors using a variety of strategies. To guarantee safer pharmaceutical practices, they place a strong emphasis on cooperation between medical experts, including doctors, pharmacists, and support personnel. Hospitals are urged to use ready-to-administer pharmaceuticals whenever feasible and to create non-standard medications in-house pharmacies. Look-alike, sound-alike (LASA) medications receive special attention by raising awareness, keeping lists up to date, and changing branding or labeling to lessen confusion. It is also advised that internal reporting systems provide regular updates. To reduce administration errors, barcode scanning at the point of care is advised. Previous suggestions included switching from Piritramid vials, since a significant amount was being wasted, and taking into account generic substitutes to increase cost effectiveness. The conversation emphasizes how human variables like staff weariness and cognitive biases, together with comparable packaging and labeling, are associated to a number of pharmaceutical mishaps. Language limitations and labeling errors are other contributing factors that can raise the risk of errors in therapeutic practice.[51]

12.4 Lessons Learned and Preventive Measures

The success of the project and the long-term viability of the organization depend on identifying human mistake at every stage of project construction. Any type and degree of accident raises a number of social, economic, and health concerns for the community. Because the consequences can go beyond the project's scope, preventive measures are required to prevent recurrent incidents by learning from prior experiences and lessons.

According to research, predicting and identifying possible errors, analyzing the underlying reasons, and putting appropriate control mechanisms in place are all effective ways to prevent and reduce human errors. Many efforts have recently been made to identify the reasons behind accidents in many businesses. The majority of accidents are thought to be the product of human error brought about by carelessness or inept work performance.[52]

XIII. Future Perspectives

Using technologies like artificial intelligence (AI), the Internet of Things (IoT), cloud computing, cyber-physical systems, and big data, digitalization is revolutionizing occupational safety and health (OSH). By automating dangerous jobs, improving temperature and noise monitoring, and lowering human error, these developments increase worker safety. Additionally, they provide improved safety management and free up employees to concentrate on more difficult tasks. But there are new concerns associated with digitalization, such as mental strain, exhaustion, information overload, ongoing surveillance, and demands for perpetual availability. There are also ethical issues such as algorithmic bias, job displacement, cybersecurity risks, and physical risks. To make sure that automation enhances rather than replaces human decision-making and avoids problems like diminished awareness and skill loss, it is crucial to uphold the "human in control" paradigm. In the healthcare industry, human-centered design (HCD) is being used more and more to produce solutions that prioritize user demands through iterative development and teamwork. Similar ideas underpin methods like design thinking and user-centered design, which place a strong emphasis on empathy, collaboration, and ongoing development. These techniques have been effectively used to enhance healthcare systems and patient care. Predictive analytics analyzes data and projects future results using statistical and machine learning methods. It facilitates prompt, evidence-based decision-making in the healthcare industry by assisting in the anticipation of risks such as disease trends, hospital readmissions, and adverse events. It advances proactive problem-solving by building on descriptive and diagnostic analytics. With the help of technologies like IoT, AI, big data, robotics, and cloud computing, Industry 4.0 is bringing about significant changes in manufacturing. Autonomous robotics, digital twins, augmented reality, additive manufacturing, and system integration are important pillars. These technologies are essential to the

development of effective, automated, and networked production systems in smart manufacturing. Immersion reality, 3D printing, big data analytics, and IIoT are examples of technologies that enhance design, customisation, monitoring, and decision-making. By identifying problems, controlling operations, and facilitating predictive maintenance, AI-powered solutions increase productivity and eventually result in safer, more effective, and extremely flexible industrial processes.[54-57]

XIV. Conclusion

In the pharmaceutical industry, human error is a big problem because of stringent regulations and the potential effects on product quality and business competitiveness. By conducting appropriate research, providing ongoing training, and raising awareness, batch losses and deviations brought on by human error can be reduced, strengthening the quality management system. Although mistakes are unavoidable, their probability can be decreased by staying focused, fostering a positive work atmosphere, and utilizing resources like checklists, algorithms, and effective communication techniques. In order to make improvements, effective reporting systems assist in identifying areas that are prone to errors. According to the system viewpoint, errors are not personal failures but rather the result of defective systems. Rather than placing blame on specific people, it places an emphasis on finding flaws in organizational processes and bolstering protections. By anticipating possible failures and creating robust systems that can adjust and bounce back from setbacks, high-reliability firms use this strategy. Human mistake is largely caused by cognitive variables like stress, exhaustion, distraction, and bias, especially in complex pharmaceutical processes. Reducing errors, enhancing product quality, and guaranteeing patient safety can all be achieved by addressing these through training, awareness, and improved process design.

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