REVIEW ARTICLE

Cognitive Factors Leading to Human Error: A Major Contributing Factor for Quality Deviations in Pharmaceutical Industry

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ABSTRACT

The pharmaceutical sector is one of the top research-based sectors in the world which continuously produces new medications that improve and save human lives. Patients, as well as healthcare professionals depend on pharmaceutical companies for the treatment of ailments, so it is very important to develop a good quality product following Good manufacturing practices guidelines that ensure the quality, safety, and efficacy of the product. Human cognitive errors are a major cause of quality deviations. These quality deviations result in product recalls, a ban on products by regulators where the company's reputation will be tarnished which can result in loss of sales and revenue. Human errors can be identified and mitigated by various techniques. In this paper, we discuss the factors contributing to cognitive errors, the impact of cognitive errors on the pharmaceutical industry, the identification of the cognitive errors causing current good manufacturing practices (cGMP) deviations, and challenges in the mitigation of cognitive errors. A survey questionnaire and the form human error assessment and reduction technique (HEART) tool were also developed and discussed in the manuscript.

Keywords: Good manufacturing practices, Quality deviations, Cognitive errors, Cognitive factors, HEART form.

INTRODUCTION

Quality has evolved into an essential concern in the pharmaceutical industry. The main factor determining a pharmaceutical product's safety and clinical effectiveness in the human body is its quality. Food and Drug Administration's (FDA) main goal in the 21st century is to promote high-quality products by assisting the pharmaceutical business with competent, active, and high-quality manufacturing technologies.[1] Quality standards play an important role in meeting the goals of the company. High quality is an essential requirement and not an added value. Quality control and quality assurance systems make up the primary quality systems. Quality control is concerned with meeting the quality requirements whereas quality assurance is focused on giving assurance that the quality requirements are met. There are numerous techniques available in the area of quality assurance to reduce and foresee errors in any industry. Lean Six Sigma, quality management systems, and benchmarking are some of the most widely used techniques currently. There is an abundance of solid evidence to show how these techniques have aided the healthcare sector in identifying errors, waste, root causes, and ideal solutions by utilizing a variety of management tools.[2,3]

Regulatory authorities worldwide implemented the current good manufacturing practices (cGMP) regulations to ensure the identity, quality, purity and strength of drug products. Adhering to cGMP prevents contamination, mix-ups, failures, deviations and errors that help in achieving a quality standard product.[4-6] All pharmaceutical firms should follow cGMP to comply with regulatory requirements. Facilities should be in good condition. Equipment should be maintained and calibrated in a timely manner. Employees should be well qualified and trained to assure the efficacy and safety of the pharmaceutical product.[6] Any divergence from the written processes or approved instructions is referred to as non-conformance. Any type of incorrect entry, entry error, or missed entry where supporting documentation is not available may result in a deviation.[7] The incidence of deviations is a serious issue, which may lead to a market complaint or inventory loss as a recall. Deviation can occur due to failure of utility, breakdown of equipment, or due to human error.[8]
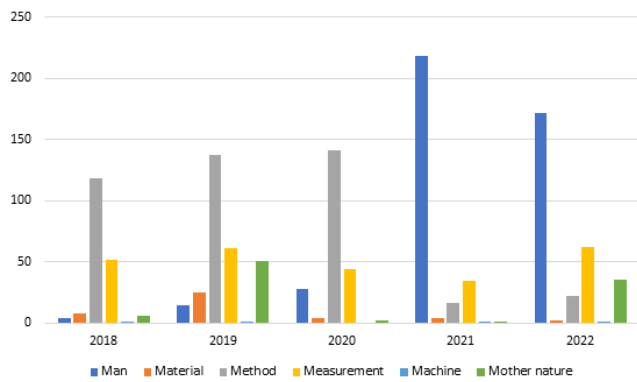
Figure 1: Comparison of errors resulted in FDA recalls from 2018 to 2022
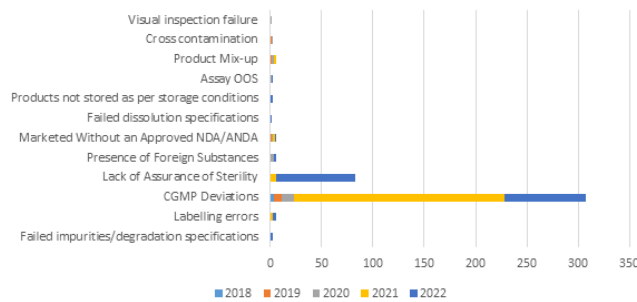
Figure 2: FDA recalls statistics based on types of human errors from 2018 to 2022

People are the most crucial aspect in ensuring the quality of goods and services, as advocated by many quality experts. Managing human factors has a big impact on how well a company performs.[9] Human reliability is a crucial factor in boosting quality in the manufacturing sector because production quality is now essential for an organization's potential to compete.[10] Therefore, in this context, human errors are linked to large financial losses. It is believed that identifying and maybe quantifying the mistakes in production settings could result in higher-quality performance.[11] Human error is frequently mentioned as the root cause of quality defect complications, which has led to batch recalls, as per Irish Medicines Boards. According to their analysis, human error is responsible for almost 25% of all quality faults, including deviations, laboratory errors, complaints, and inspection concerns. As per the available reports, 90% of recalls involving labeling and packaging are attributable to human error. It also assumes that any quality flaws without scientific support are attributable to human error.[12] Reports show that 85 to 90% of deviations in the pharmaceutical industry, 80% of industrial accidents, and 70 to 80% of aircraft accidents are caused by human error.[13–15]

From 2018 to 2022, the FDA witnessed a tremendous increase in recalls within the pharmaceutical industry due to human errors. Figure 1 shows that the highest number of recalls are due to human errors (Man) as compared to the other errors. These errors were predominantly associated with deviations

from cGMP, underscoring the critical importance of adherence to these quality control guidelines (Figure 2). Common human errors include label mix-ups, cross-contamination, visual inspection failure, products not stored as per labelled storage conditions, and other lapses in manufacturing processes that compromises product safety and efficacy.[16]

Cognitive ability alludes to the ability of the human brain to process, store and extract information, including processes such as memory, attention, and the ability of reasoning.[17] It is an important psychological component for humans to complete a task. It is currently one of the most studied and most stable predictors of organizational performance.[13] The impact of cognitive errors represents the consequences or effects that are experienced when human error-related deviations occurring during manufacturing are not properly managed, reduced, or even eliminated.[18] Some of the possible human errors that can lead to quality deviations in the pharmaceutical industry are given in Table 1.

Cognitive errors can occur in all kinds of occupations. In the pharmaceutical industry, these errors can have serious consequences since pharmaceutical products are directly dealing with humans. It delays the schedule of production and can even harm the patients. Regulatory agencies will impose a fine or put some pressure, which will ultimately lead to the loss of a company.[19] During the COVID-19 pandemic, when there was an emergency of vaccines to treat the patients, a human error occurred at the manufacturing plant of Emergent BioSolutions, leading to the loss of multimillion-dollar. Emergent BioSolutions had a $628 million deal with the US government to manufacture the vaccines. Unfortunately, cross-contamination occurred at the company's Baltimore plant and 45 million doses had to be destroyed. The US government canceled the contract and the company had to forego $180 million and ultimately, the share dropped down to 37%.[20] Human error can occur due to a lack of staff, pressure, distractions and personal issues.[14,21] Some of the ways to reduce human errors are through training, proper

Table 1: Examples of human error in the pharmaceutical industry

Area	Possibility of human error
Production	Less quantity charging, wrong material charging, non-verification of the cleanliness of charging vessel/equipment before start-up of operation, sifting sequence change, wrong setting of units in compression machine, wrong calculation, logbook entries missed.
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.
Quality control (QC)	Sampling errors, dilution errors, labeling errors, and handling errors.
Quality assurance (QA)	Document review misses, missing signatures in documents.

supervision, good communication, and following a quality risk management approach.[12]

Investigating a deviation due to human cognition and identifying it as a root cause can be costly, but it is well worth it if it can stop similar deviations and failures from happening again in the future. This is because persistent issues can affect a company's reputation in its market, especially if they cause harm to customers. It will help companies to protect their reputations and also it will help in avoiding the hefty penalties from regulatory organizations. The current study discusses the factors contributing to cognitive errors, the impact of cognitive errors on the pharmaceutical industry, the identification of the cognitive errors causing cGMP deviations using the human error assessment and reduction technique (HEART) tool, mitigation and challenges in mitigation of the cognitive errors.

Factors Contributing to Cognitive Errors

Several causal factors[14] include pressure, fatigue, a lack of staff for the job, personal issues, distractions while working, equipment design and fabrication, working environment, communication, knowledge, the complexity of the job, work organization, documentation, and work planning are considered as probable cause for errors.[22,23] Some of the factors related to the pharmaceutical industry are discussed.

One of the primary factors that can lead to cognitive errors and subsequent cGMP deviation is a lack of attention to detail.[24] Pharmaceutical manufacturing processes involve numerous steps, and each step is critical to ensure that the final product meets the required standards. However, a failure to pay attention to the details can result in mistakes, such as using incorrect raw materials or not adhering to the correct manufacturing procedures. This can lead to cGMP deviations, as the final product may not meet the required quality standards. To mitigate this type of error, it is important for industries to implement robust quality control measures that focus on attention to detail and adherence to standard operating procedures.[25]

Another factor that can contribute to cognitive errors and cGMP deviations is complacency. This occurs when individuals become overconfident in their abilities and assume that they know the correct procedures and protocols. This can lead to errors when they fail to follow established guidelines or become careless in their work.[26] For example, a worker may become complacent in their cleaning processes, leading to contamination of the final product. To avoid this, companies must ensure that their employees receive regular training and education on cGMP guidelines and best practices. This will help to keep employees engaged and ensure that they are continually striving to improve their processes.

Memory errors can also contribute to cognitive errors and cGMP deviations. Memory errors occur when individuals rely on their memory rather than checking reference materials or documentation. In the pharmaceutical industry, this can be particularly problematic when it comes to drug interactions and dosages. For example, a worker may forget to check the compatibility of two drugs, leading to adverse reactions in patients. To mitigate this type of error, companies should ensure that employees have access to up-to-date reference materials and checklists. Additionally, implementing double-check procedures can help to catch potential errors before they become cGMP deviations.

As we know all the activities in the pharma industry is time bound to improve productivity. A shorter timeline to complete the activities can build up stress and anxiety that lowers individual performance. There is a possibility of skipping the steps from the previously approved procedures or written instructions. These omission errors can lead to cGMP deviations, which leads to compromise in product quality and safety.

A language barrier is also a one of the factors contributing to cGMP deviations in the pharmaceutical industry. It can occur when individuals involved in pharmaceutical manufacturing, such as workers, supervisors, or quality control personnel, do not have a common language to communicate effectively. This can lead to misunderstandings and mistakes that can result in human error deviations. For example, a worker may misunderstand a supervisor's instructions and not follow the correct procedures, leading to a deviation from the required standard. Another way that language barriers can contribute to human error deviations is through documentation errors. If personnel do not have a good understanding of the language used in documents, they may misinterpret critical information or instructions. This can lead to mistakes such as incorrect labelling, incorrect dosage instructions, or using incorrect raw materials. These mistakes can result in deviations from the required standards and can put patient safety at risk. Additionally, a language barrier can hinder effective communication during audits and inspections. If regulatory inspectors do not speak the same language as the personnel, they may not be able to communicate effectively or understand the procedures being followed. This can lead to misunderstandings and misinterpretations that can result in regulatory non-compliance and deviations from the required standards.[27]

In conclusion, cognitive errors are a common occurrence in the pharmaceutical industry and can lead to cGMP deviations. Attentional biases, complacency, and memory errors are just a few of the factors that can contribute to these errors. To prevent cGMP deviations, companies must prioritize attention to detail, provide regular training and education, and implement robust quality control measures. By doing so, they can ensure that their products meet the highest standards of quality and safety and maintain the trust of their customers and regulatory agencies.

Impact of Cognitive Errors on the Pharmaceutical Industry

Cognitive errors can have a significant impact on the pharmaceutical industry. The consequences of these errors can range from minor deviations from the required standards to serious safety incidents, product recalls, regulatory action, and damage to a company's reputation.[19] If a pharmaceutical

product is found to have been manufactured incorrectly due to cognitive errors, it may need to be recalled. Product recalls can have an impact on economic loss, the reputation of a company, corporate science and the supply chain.[28] Cognitive errors can result in mistakes such as incorrect labeling, dosage instructions, or incorrect raw materials. These mistakes can put patient safety at risk[29], which is the most significant impact of cognitive errors on the pharmaceutical industry. A drug label helps in the identification of medicine, it is required in the marketing of drug products and helps in pharmacoeconomic studies.[30] Proper labeling includes information about the ingredients with their quantity, dosage form, manufacturing date, expiry date and direction of use.[28] Since the patients rely on directions of labeling before the use of the product, any error in labeling can affect the health of the patient.[28,29] In November 2020, Aurobindo Pharma USA recalled 7,440 bottles of Ibuprofen oral suspension due to an error in labeling. Dr Reddy recalled 2,770 bags of levetiracetam sodium chloride injection due to a labeling error.[31] The drug development process takes at least 10 to 15 years and requires millions of dollars.[32] If any product is recalled, it affects the market share and results in an economic loss for a company.[28] A product recall will also affect the reputation and brand integrity of a company.[33] This can create bad image and loss of trust among patients and physicians.[34] The supply chain helps consumers in the accessibility of drug products and plays an immense role in implementing product recalls from the market. They can help in again gaining the trust in the brand, managing the capital loses and reforming the image of a brand.[28]

In a nutshell, product recalls can be costly for pharmaceutical companies and can damage their reputation in the market. Pharmaceutical companies that have been involved in safety incidents or product recalls due to cognitive errors may suffer reputational damage. This can lead to a loss of trust among patients, healthcare providers, and regulators, which can ultimately impact the company's bottom line. Regulatory agencies such as the FDA closely monitor the pharmaceutical industry to ensure that companies are adhering to the required standards. If cognitive errors lead to cGMP deviations, regulatory action may be taken, such as warning letters, fines, or even product bans. If a product is recalled due to cognitive errors, it can result in a loss of revenue for the pharmaceutical company. Additionally, if the company's reputation is damaged, it can result in a loss of sales and market share.

Identification of the Cognitive Factors Leading to cGMP Deviation using the HEART Tool

HEART is a tool used to identify potential sources of human error in complex systems. The HEART tool can be used in the pharmaceutical industry to identify cognitive factors that may lead to human error deviations.[35]

The HEART tool categorizes cognitive factors into four main categories: task factors, personnel factors, environmental factors, and organizational factors. Task factors include the complexity of the task, the level of automation, and the degree of supervision required. In the pharmaceutical industry, tasks such as manufacturing, packaging, and labeling require high levels of attention to detail and can be complex. If the task is too complex, it may be difficult for the individual to focus on all the necessary details, increasing the risk of human error deviations.[36] Personnel factors include the individual's level of experience, training, and workload. In the pharmaceutical industry, individuals who are new to a particular task or have not received adequate training may be more prone to making mistakes. High workloads can also lead to fatigue, reducing cognitive abilities and increasing the likelihood of human error deviations. Environmental factors include the physical environment and external distractions. The pharmaceutical industry often involves working in a cleanroom environment, which can be challenging due to the need to wear personal protective equipment (PPE) and maintain a high level of cleanliness. External distractions, such as noise or interruptions, can also increase the risk of human error deviations. Organizational factors include the organizational culture, communication channels, and the management system. In the pharmaceutical industry, a culture of safety and open communication can help reduce the risk of human error deviations. Additionally, a management system that emphasizes quality control and continuous improvement can help identify and address potential sources of human error deviations.[37]

A sample HEART form is represented in Table 2.

Whenever deviation occurs during any cGMP activities, it has to be stopped immediately and the issue has to be escalated to the supervisor. The supervisor has to take immediate action and raise the deviation. Once the deviation has been initiated, the deviation number is assigned. The lead investigator reviews the area where the deviation is seen for the evidence and an interview is taken with the personnel involved in the activities by addressing the issue. The lead investigator, with the help of a cross-functional team, will develop an investigation plan based on the criticality level of the deviation, which the QA will approve. Root cause analysis is performed to identify the probable causes contributing to the deviations. Different statistical quality control (SQC) tools like fishbone diagrams, 5Why's, brainstorming, and fault tree analysis were used as primary tools for the identification of human error.[38]

Questions in the HEART should be open-ended to encourage people to provide a full, meaningful answer in their own words coming from their knowledge and feelings about the situation. These questions can vary from industry to industry. Based on the questions in the HEART form, an interview with the employee is conducted shortly after the incident occurs. Otherwise, important information may be forgotten, or it may become too biased. Create an open-minded atmosphere for the interview and try to avoid quick judgments. During the interview, all the information given has to be documented, even if it does not seem important for later analysis. This is to make sure not to miss any key information. A root cause analysis has to be performed to ensure that the error is because of human involvement. The conclusion from the interview responses was discussed with

Table 2: HEART form format

HEART FORM – Cognitive assessment		
Date PR created		Date of interview
PR number		Responsible Department
Short Description		Operator
Problem Type L1/L2		Interviewer Name
Task performed		

Interview Questions	Response	Conclusion
What happened? Who observed the event? When and where did the event occur? What did you do immediately after observing the event? How did you perform this task? Are the Instructions in the procedures clear and with sufficient details? Were there any unusual occurrences (e.g. alarms, noises, etc) at the time this occurred?		If personnel is thought to be a possible root cause, continue with the cognitive load assessment tools.

Categories	#	Key Information	Response	Conclusion (✓)	Verified (Yes/No/ NA)	Comments
Time of occurrence	1	Shift issue occurred?		Day Afternoon Night		
	2	Issue occurred during regular hours or overtime?		Overtime Regular		
Individual performance						
Time management	1	Enough time to perform the task?		Sufficient Not Sufficient		
	2	Performing other tasks at the same time (multitasking)?		Single task Multitasking		
Decision making	1	Conscious of action performed?		Unintended action Aware of action		
	2	Aware of the Consequences?		Unknown Known NA		
Personnel state	1	Atypical personnel state factors?		Stressed Fatigued Feeling unwell None		
Task processing	1	Procedure clear, complete instructions?		Adequate Confusing Incomplete NA		
	1	Performance influenced by work environment factors? (Light/Noise level/Air quality/Workplace layout)		Poor lighting High noise level Air quality Normal conditions		
Work environment	2	Any interruption /distraction while performing the task (attention diverted)?		High Moderate Insignificant		
Communication	1	Did supervisor/team lead provide clear instructions?		Clear Misunderstood NA		
	2	Issue happened on Task/Shift/Break turnover?		Shift turnover Break turnover Task turnover		

| Training | 1 | Level of Training / Experience of Personnel? | 0-2yrs
2-5yrs
5+ yrs |
| | 2 | Frequency of Task Performance. Last performed date. | Infrequent
Recently done
First time |

Recommendations from the interviewee

Comments

| | Name and Title | Signature and Date |

Interviewee

Interviewer

Verifier**

the cross-functional team to finalize the cognitive factor as a root cause and corrective action and preventive action (CAPA) is implemented. Consequent CAPA follow-up, including an effectiveness check, is performed to avoid the recurrence of the issue. Immediately after the confirmation of the person's involvement in the deviation, he will be restricted to perform other activities. Deviations should be closed within 30 calendar days of the occurrence of deviation and in case of deviation is not closed within span of time, then the responsible department shall fill in the justification. All the activities performed during the investigation have to be documented. Wherever applicable, the HR escalation process shall be followed as per the company policy.[39]

Mitigation of Cognitive Errors using Survey in the Pharmaceutical Industry

Conducting a survey is an effective way to take a proactive approach to reduce the risk of human error deviation due to cognition in the pharmaceutical industry. Here are some steps that can be taken:

Develop a survey questionnaire

Develop a survey questionnaire that assesses cognitive factors that may lead to human error deviations. The questionnaire should be designed to identify potential areas of improvement in the organization's processes, procedures, and training. A sample questionnaire to identify the cognitive factors causing human error deviation in the pharmaceutical industry is provided in Table 3.

Identify participants

Identify the participants who will take the survey. This can include employees who are involved in manufacturing, packaging, labeling, and quality control.

Administer the survey

Administer the survey to the identified participants. The survey can be conducted electronically or on paper. It is essential to ensure that the survey is anonymous and confidential to encourage honest and open feedback.

Analyze the results

Analyze the survey results to identify common themes and areas of improvement. Look for trends and patterns in the responses and identify the cognitive factors that have the highest impact on the likelihood of human error deviations.

Develop interventions

Develop interventions based on the survey results to reduce the risk of human error deviations. This can include developing training programs to improve personnel knowledge and skills, redesigning work processes to reduce complexity, or implementing technology to reduce the risk of human error deviations.

Implement and monitor

Implement the interventions and monitor their effectiveness in reducing the risk of human error deviations. This can include tracking the frequency and severity of human error deviations and evaluating the effectiveness of interventions in reducing these deviations.

By using a survey to identify cognitive factors that contribute to human error deviations, in the pharmaceutical industry can take a targeted and data-driven approach to improving processes and procedures. This can help reduce the risk of human error deviations and enhance patient safety.

Current Implemented Techniques to Reduce Cognitive Error

There are various techniques implemented in the pharmaceutical industry to reduce cognitive errors. Strictly following the SOP is one way to reduce the human error. SOPs are written instructions that describe how to perform a task or activity. They are designed to ensure that each step of a process is carried out consistently. Adherence to SOPs ensures that the operation is carried out in standardized procedures, reducing the likelihood of errors caused by variability in task performance.[40] SOP provides functional, environmental and safety-related information to the employees. It makes sure that the operations are completed in a timely manner. SOP serves as the best document when a new employee joins the company and help prevent errors.[41] Employees play a crucial role in an organization and employee effectiveness can be achieved by training them.[42,43] Providing regular training and education to employees on cGMPs, SOPs, and specific job-related tasks can help to reduce cognitive errors by ensuring that employees have a clear understanding of their roles and responsibilities.[25,44] A

Table 3: A sample questionnaire to identify the cognitive factors causing human error deviation in the pharmaceutical industry

1	Is your role stressful?	Yes/No
2	Are you multitasking?	Yes/No
3	Is the timeframe/deadline assigned for the activity sufficient?	Yes/No
4	Whether the training content/methods adequate?	Yes/No
5	Is the procedures/ standard operating procedures (SOPs)/ batch manufacturing record (BMR) easy to understand?	Yes/No
6	Did you ever skip the step/procedure?	Yes/No
7	Have you ever witnessed a coworker engaging in behaviour that could lead to a cGMP deviation?	Yes/No
8	Do you feel comfortable asking for help or clarification when you are unsure of how to perform a task correctly?	Yes/No
9	Do you communicate with your previous shift colleague about the ongoing activities?	Yes/No
10	Whether clear instructions were given before the start of the batch/operations/Analysis?	Yes/No
11	Do you feel recognized and appreciated for your contributions?	Yes/No
12	Do you escalate issues to your supervisor?	Yes/No
13	Have you ever had difficulty communicating with someone due to a language barrier?	Yes/No
14	What do you think is the major source of distraction while at work?	
15	Do You think [Company Name] System is robust enough to prevent the mistakes? If not, what can be done?	

study was conducted on employee performance of PT Ferron Par Pharmaceuticals to determine the effect of knowledge management, training and kaizen culture. The results showed a positive and significant effect on knowledge management, training and kaizen culture.[45] Human factors engineering is the study of how people interact with systems, processes, and equipment. It involves designing processes, equipment, and work environments to reduce the likelihood of human error. This system helps improve communication, making the correct decisions, reducing distractions and ensuring the safety of the patients. Establishing a reporting system for errors and conducting root cause analysis can help to identify the underlying causes of errors and implement corrective actions to prevent them from occurring again.[9] Automation and technology can be used to reduce cognitive errors by automating repetitive tasks, minimizing the need for manual data entry, and providing real-time feedback and alerts to operators.[46] The robotic process automation helps by taking up the employee's workload on a daily basis. Pharmaceuticals generate a lot of data that is difficult to manage. This robotic process automation manages the huge data, which helps prevent human errors.[47] Checklists and job aids can help to reduce cognitive errors by providing operators with a step-by-step guide for completing a task, ensuring that critical steps are not missed.[41] Conducting risk assessments can help to identify potential hazards and develop strategies to mitigate or eliminate them, reducing the likelihood of cognitive errors.[48] Artificial intelligence can also help in reducing human errors like data entry and evaluation of adverse events.[49] Overall, a combination of these techniques can be used to reduce cognitive errors in the pharmaceutical industry, ensuring that products are manufactured to the highest possible standards.

Challenges in Mitigation of Cognitive Errors in the Pharmaceutical Industry

Despite the various techniques implemented to reduce cognitive errors in the pharmaceutical industry, there are several challenges that can make it difficult to mitigate these errors. Some employees may be resistant to changing their work processes, which can make it challenging to implement new techniques or technologies to reduce cognitive errors. Implementing new techniques or technologies can require significant resources, including time, funding, and personnel. Without adequate resources, it can be difficult to implement effective strategies to reduce cognitive errors. Human factors, such as fatigue, stress, and distractions, can contribute to cognitive errors. These factors can be difficult to control, making it challenging to mitigate cognitive errors. The pharmaceutical industry involves complex processes and procedures, which can make it difficult to identify and mitigate cognitive errors. Inadequate training or education on cGMPs, SOPs, and job-related tasks can contribute to cognitive errors. Poor communication between employees, departments, or shifts can lead to misunderstandings, errors, and cGMP deviations. Inadequate reporting of errors or cGMP deviations can make it difficult to identify cognitive errors and implement effective corrective actions. To address these challenges, it is essential to foster a culture of continuous improvement and encourage open communication and collaboration between employees, departments, and management.[50] Providing adequate resources, training, and support can also help to mitigate cognitive errors in the pharmaceutical industry. Additionally, implementing effective reporting systems and conducting regular risk assessments can help to identify potential hazards and develop strategies to mitigate them.

CONCLUSION

In conclusion, cognitive factors play a pivotal role in human error within the pharmaceutical industry, significantly contributing to quality deviations. The intricate and highly regulated nature of pharmaceutical processes demands meticulous attention to detail, making human cognition a critical element. Factors such as distraction, stress, fatigue, and cognitive biases can impair decision-making and lead to

deviations from established quality standards. Recognizing these cognitive influences is essential for the industry to enhance error prevention strategies such as the development of appropriate tools such as HEART tool, survey questionnaires, etc., to prevent errors due to human cognition and thus to improve overall product quality and, most importantly, ensure the safety of patients who rely on pharmaceutical products. Addressing these cognitive factors through training, awareness, and process optimization can help mitigate the risk of human errors in this vital sector.

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