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Strategies to Minimize Human Error: Applications in the Pharmaceutical Industry

Leandro Luiz Soares de Souza
Fundacao para Pesquisa e Desenvolvimento da Administracao, Contabilidade e Economia - FUNDACE, Ribeirao Preto, Brazil

Leonardo Augusto Amaral Terra
Universidade Virtual do Estado de Sao Paulo – UNIVESP, Sao Paulo, Brazil

ABSTRACT

Given the magnitude of the pharmaceutical industry, human errors in production processes have a significant impact on operations and manufacturing activities, representing one of the major challenges faced in this business sector. This research aims to identify the best practices within industry to minimize human errors. Through exploratory research with specialists working in diverse industries, including small, medium, and large-scale national and multinational companies, using a semi-structured questionnaire analyzed via a mental map, We have identified the following good practices for error reduction: Training; Error Mapping; Documentation; Process Automation; Competency Evaluation; and Open Communication Culture. These six best practices were ranked and analyzed in detail and contrast with previous research that points to exhaustion as the main cause of human error in the pharmaceutical industry.

Keywords: Human Error, Pharmaceutical Industry, Mental Map, Training, Technical Documentation, Error Mapping.

INTRODUCTION

From research and development to mass production and distribution, the pharmaceutical industry is vast and complex. Comprising multinational corporations and local companies, it plays a significant role in global health by offering a wide variety of treatments for numerous diseases. Additionally, it contributes to technological innovation, represents an important component of the global economy, and is a significant source of employment. Its impact is evident in the continuous pursuit of scientific advancements and in improving the quality of life for patients worldwide [1].

Human errors in the pharmaceutical production process can have severe consequences on the final quality of processes and products. Examples include risks to patient safety, increased costs in production and corrective actions, regulatory issues, and damage to the reputation and trust of consumers. These illustrate the challenges human errors can pose in this sector.

Given these points, the objective of this study is to identify best practices to mitigate human errors in the pharmaceutical industry. This is justified by the fact that human errors can lead to significant implications. An operational failure, such as the incorrect dosing of raw materials or

poorly executed procedures, can lead to cross-contamination, which compromises medication safety and endanger patient health [2]. Errors can also lead to consequences such as non-compliance with regulations, which may result in severe sanctions, including fines or even suspension of licenses by regulatory authorities [3]. The absence of these licenses prevents companies from operating, directly impacting production and the business itself, making the containment of human errors a crucial component for success in this sector.

LITERATURE REVIEW

Human Error in Industry: Causes and Consequences

Human error in industry is a critical issue, defined as an operational mistake by workers that leads to accidents, productivity loss, and material or environmental damage. Understanding the root causes of these errors and developing preventive measures is essential to enhance safety and efficiency in industrial environments. Factors such as fatigue, distraction, lack of training, and overconfidence are highly relevant and contribute significantly to the occurrence of errors during operations [4, 5].

A common cause of errors is physical or mental exhaustion from long operational shifts or nighttime work. Fatigue can severely impair workers' attention and decision-making capacity [6]. An illustrative example is the aviation industry, where studies show a substantial proportion of pilots faced with serious sleep issues and health problems such as daytime sleepiness, unintended naps, and constant fatigue [7]. Sleep deprivation critically impacts physiological functions, including immune suppression due to reduced cell production [8]. Excessive productivity demands can push workers to disregard safety protocols to meet targets [9]. Dejours [10] noted, “The organization of work exerts a specific action on humans, impacting their psyche.” Stress experienced by workers often results from their perceived inability to handle workplace pressures.

Rasmussen [11] observed that most severe industrial accidents were not the result of independent human errors but rather systematic behavioral shifts in organizations toward accidents, driven by cost-effectiveness pressures in competitive environments.

Distraction, whether caused by personal worries or chaotic work environments, is another major contributor to lapses and operational mistakes. It is particularly concerning as it can seem trivial, such as paying attention to a loud noise, but it be simultaneously dangerous. Statistics indicate that distraction accounts for 80% of all accidents and 65% of near misses among drivers [12]. Outside of traffic contexts, distraction can lead to severe workplace accidents. Ensuring full concentration on critical tasks is vital in situations where distraction is unacceptable [13].

Untrained workers are more prone to mistakes. Regular retraining is critical to maintain technical competence [14]. Approximately 80% of industrial accidents stem from human errors, such as judgment mistakes, inattentiveness, or ignorance of safety procedures [15]. Therefore, investing in adequate training is essential to mitigate risks associated with human error. Companies with robust, regular training programs tend to see significant reductions in workplace accidents and incidents [16]. Araujo [17] emphasized that training should not be confused with simple courses transmitting new information; instead, it should foster

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individuals' continuous development within the organization, supported by a learning-focused culture.

Overconfidence bias leads individuals to prioritize their knowledge over others' input. Skilled professionals may underestimate risks and overlook safety procedures, increasing the likelihood of errors [18]. Overconfidence is a common pitfall leading to severe accidents across contexts, including workplaces, construction, manufacturing, and transportation sectors [19]. In recreational activities, such as adventure sports, overconfidence similarly increases risks [20].

Organizations with poor safety cultures see higher rates of incidents. Establishing a business culture centered on safety is critical [21]. Safety climate manifestation of organizational culture encompassing attitudes, perceptions, and behaviors toward norms, values, and safety practices is integral to safety performance in organizations [22]. Companies with strong safety cultures tend to foster psychologically positive environments, where employees feel secure expressing concerns and contributing to safety improvements [23].

Communication failures between teams or managers and workers can lead to misunderstandings and errors [24]. Differentiating communication from information is essential. Information refers to the content of a message, while communication involves the process of circulating and understanding this information [25]. Miscommunication, rather than the absence of information, often causes workplace incidents. Inadequate communication was identified as a primary source of errors in complex systems [26]. For instance, failure to communicate changes in safety procedures or operational conditions can lead to severe accidents.

Ergonomics, which adapts work to fit employees, plays a crucial role in reducing human deficiencies in industrial environments. Designing systems, equipment, and workplaces considering human capabilities and limitations aims to minimize errors and enhance operational safety and efficiency. Ergonomic interventions, such as workstation redesign and installing ergonomically designed equipment, are associated with significant reductions in workplace accidents and injuries [16].

Work-related accidents or occupational diseases claim approximately 2.78 million lives annually [27]. This underscores the importance of rigorous safety procedures and adequate training. As highlighted, human error remains a primary cause of industrial accidents, exacerbated by inadequate supervision, insufficient training, and risky behaviors [28]. Promoting a safety culture and implementing effective safety management systems are crucial to mitigating risks tied to human errors [29]. In healthcare, human errors contribute significantly to adverse events, underscoring the need to address poor communication, lack of teamwork, and excessive workloads [30].

Material damage from workplace errors imposes substantial costs, including repairs, equipment replacement, and operational interruptions [31]. Human errors are a significant source of such damage, emphasizing the need for preventive measures and regular maintenance. Workplace material damages in the United States cost billions of dollars annually

[32]. Environmental impact is also critical, as errors can lead to toxic spills, water and soil contamination, and other forms of pollution [33].

The systemic reduction of human errors involves continuous employee training, developing standardized operational procedures, and reducing human intervention through technology. An organizational culture prioritizing safety and quality, fostering open communication, and encouraging error reporting is essential. Methodologies like Failure Modes and Effects Analysis (FMEA) can help identify and mitigate potential human error sources before they impact quality [34].

Human Errors in the Pharmaceutical Industry: Regulation and Impacts

Human errors can lead to severe mistakes during the manufacturing process, compromising drug quality and endangering patient health. These errors are among the primary causes of incidents and quality issues in the pharmaceutical industry [35]. Process automation reduces the risk of errors and decreases dependency on human intervention [36]. Continuous and rigorous employee training ensures that all staff remain updated on the best safety practices and standard operating procedures [37]. Additionally, implementing robust monitoring and quality control systems facilitates the early identification and correction of errors before they impact production [38].

These errors may lead to various problems, such as threats to patient safety, including adverse reactions or poor treatment efficacy. Companies face repercussions such as lawsuits, loss of consumer trust, and product recalls [2]. These additional costs can harm a company financially, as well as its reputation and relationships with clients and investors. Human errors can also result in legal and insurance costs, as companies may incur fines, lawsuits, and increased insurance premiums [9].

In Brazil, the safety, quality, and efficacy of pharmaceutical products are guaranteed by regulations established by the National Health Surveillance Agency [39]. The industry must adhere to these guidelines to ensure that medications are safe for consumption and effective for their intended treatments. ANVISA plays a crucial role in protecting public health by preventing the sale of products that do not meet established standards [40].

A comprehensive public health protection system is created through regulations, including Good Manufacturing Practices (GMP) and Good Distribution and Storage Practices (GDP). Compliance with these rules safeguards consumers and enhances confidence in Brazilian pharmaceutical products, facilitating their acceptance in domestic and international markets [41].

All aspects of the manufacturing process, from the procurement of raw materials to the packaging and distribution of finished products, are covered by these practices. To ensure that medicines are reliable and consistent across production batches, strict adherence to GMP is necessary. These practices ensure compliance with national and international laws and protect public health by preventing contamination, errors, and variations in pharmaceutical products. Numerous studies and reports highlight the role of GMP in the pharmaceutical industry. Adhering to GMP is essential for maintaining the integrity of pharmaceutical products and

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protecting consumer health [42]. Companies that rigorously follow these practices reduce the risk of recalls and other quality issues that could damage their reputation and financial stability. Furthermore, GMP helps the pharmaceutical industry become more sustainable and competitive by increasing operational efficiency and optimizing production processes.

Effective implementation of GMP ensures that medications meet consumer expectations regarding quality and safety while also fulfilling regulatory requirements [43].

MATERIALS AND METHODS

This research employed an exploratory methodology based on interviews. "This type of research seeks to deepen understanding of the subject through the evaluation of real cases and conducting open dialogues to identify successful outcomes and challenges" (44, 45). To achieve this goal, the method used in this study was a multi-case approach based on the analysis of real-life events [46]. Participants in the interviews were given the opportunity to freely express opinions and describe their experiences, revealing key points for the successful development of the research [47].

Data Collection

Data was collected through interviews based on semi-structured questionnaires, supported by the critical incident technique. Semi-structured interviews are ideal for exploring the complexity of social and behavioral phenomena [48]. while the critical incident technique enables the data collected to be analyzed to identify behaviors and patterns that occur most frequently. This technique explicitly highlights outcomes—positive or negative—aligned with specific objectives [46].

To refine the questionnaire, a pilot interview was conducted with a professional meeting the research requirements. This helped anticipate difficulties in obtaining information, identify improvement points, and optimize the process dynamics. The interviews were conducted online using Microsoft TEAMS, involving all selected participants, and lasted an average of 71.4 minutes. Throughout the process, the proposed themes were addressed, alongside opportunities for open exploration of interviewees' experiences, fostering rich discussions of actions taken and the intersection between theory and practice.

The selection process for interviewees aimed to produce a convenient sample of seven professionals with diverse profiles and perspectives. All had experience in the pharmaceutical industry and were engaged in activities related to the challenges of addressing human errors in production processes. The selection criteria included:

- Professional experience: Over 10 years in pharmaceutical production processes.
- Experience in quality deviation management.
- Experience with national and multinational companies.
- Expertise in GMP (Good Manufacturing Practices) concepts.
- Experience in people management.

Table 1 presents the interviewees, along with the respective dates, duration of each interview, and a summary of their backgrounds.

Table 01: Information from research work interviews

	Current Position/Company	Education	Years of Experience	Date	Duration
"A"	Production Manager / Multinational A	Pharmacist / Biochemist	25 years	07/08/24	95 min
"B"	Production Manager / Multinational B	Pharmacist	34 years	07/08/24	68 min
"C"	Factory Manager / National Company C	Pharmacist	24 years	08/08/24	75 min
"D"	Plant Director / Multinational D	Pharmacist	22 years	09/08/24	72 min
"E"	Production Supervisor / Multinational B	Pharmacist	14 years	10/08/24	64 min
"F"	Production Supervisor / National Company E	Pharmacist	15 years	10/08/24	59 min
"G"	Production Supervisor / National Company F	Pharmacist	15 years	12/08/24	67min

Data Analysis

For data analysis, the initial data was coded to examine the emerging concepts identified in each interview. This stage plays a key role in identifying patterns and correlations to obtain qualitative data [49]. After examining the data, the items were categorized to understand how they connect. This step is crucial for organizing the data and understanding how the identified topics align with existing literature [50]. Next, a thematic analysis was conducted as a tool to identify the most recurring themes based on the collected data. Understanding data trends and existing patterns is vital for clarity and guiding the exploratory research process [51]. Finally, the data was interpreted, and the themes were organized using a mind mapping tool, which was the final step in the data analysis process, always aligned and discussed with existing literature. Data interpretation serves to provide significant insights for the research project [52]. The mind mapping technique helped visualize, understand, correlate, and emphasize the importance of the themes raised during the interviews and their results. The mind map was generated using the CHATGPT version 4 application.

Characterization of Cases

The research included national and multinational companies of small, medium, and large sizes to reach a heterogeneous audience with a diverse range of realities, aiming to enrich the research work.

Table 02: Information about the industries in which the interviewees work

Code	Company Type	Number of Employees in Brazil	Number of Employees Worldwide
"A"	Medium-sized Multinational	180	6,400
"B"	Small-sized Multinational	160	6,500
"C"	Large National Company	5,100	—
"D"	Small-sized Multinational	175	1,900
"E"	Large National Company	7,000	—

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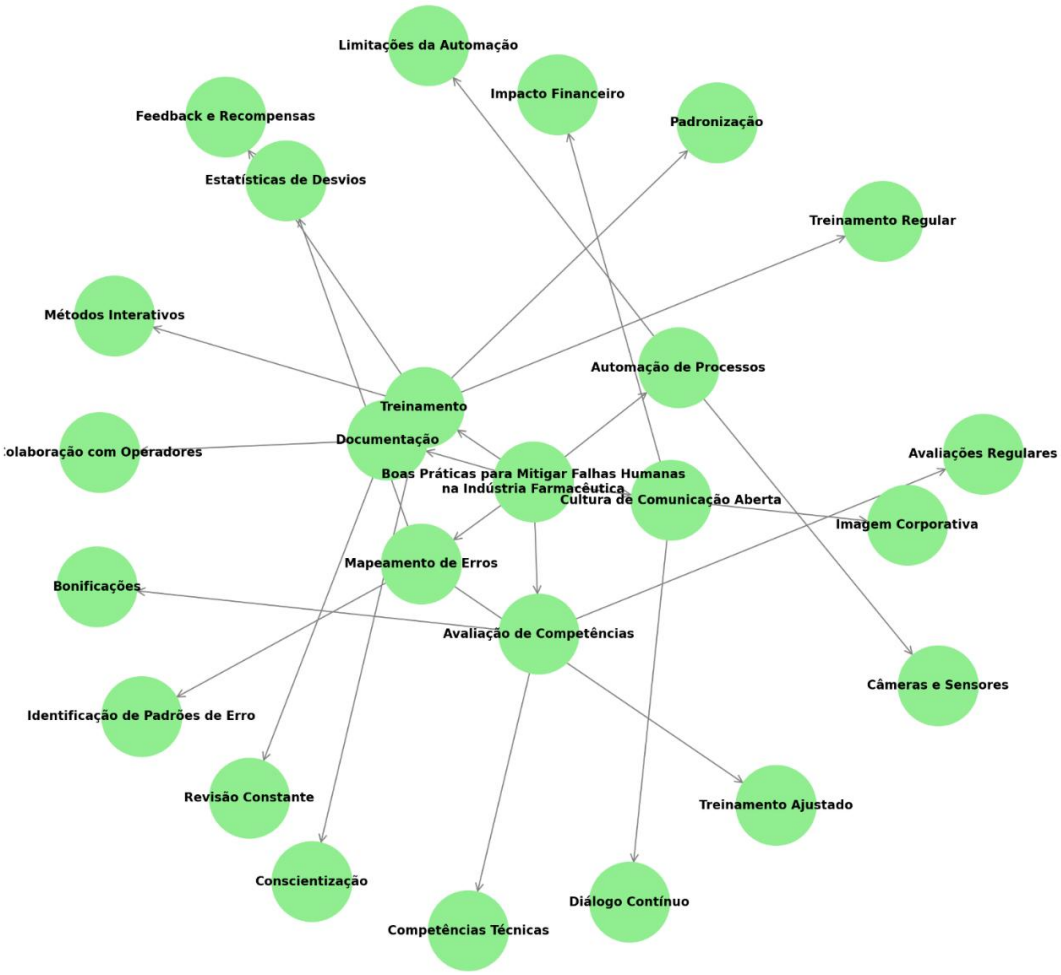
"F"	Medium-sized National Company	2,700	—

During the diligent interview process, it was possible to understand the reality of industries regarding process automation. For instance, Company "E" is fully aligned with what we call Industry 4.0, but even with this advanced setup, it still experiences examples of human errors in production. On the other hand, we have examples such as Companies "A" and "B," which, despite being multinational corporations, have a lower level of automation. As a result, some controls are manual through procedures. These two companies show a lower operational failure rate in their processes, but at the same time, they are more constrained and less productive.

DISCUSSIONS & RESULTS

According to the results of the research, it was possible to outline six main topics identified as best practices in the pharmaceutical industry. The best practices listed were training, error mapping, documentation, process automation, competency evaluation, and an open communication culture. Below is Graph 01, the mind map created based on the interviews.



Graph 01: Mind map based on interviews conducted
Created by Chat GPT 4o in the original language of the research

Training

Operational training was mentioned in all the interviews, seen as an essential tool to reduce human errors in the pharmaceutical industry. The literature also reinforces this view, highlighting the importance not only of the quantity of training but also the quality and, most importantly, the assessment of its effectiveness. All interviewees agreed that a well-trained employee is a safer and more efficient employee. To achieve this, the way training is viewed within companies needs to change, being seen as an investment in the team rather than a waste of time (Interviewees A, B, C, and D). According to Interviewee A, training should be carefully planned with a future-focused approach. Interviewee D added that this plan needs to be continuously evolving. Training must, of course, meet regulatory requirements, but more importantly, it should be an integral part of the company culture, especially in leadership and operations (Interviewee E).

It is not enough just to train; everyone must understand the impact of an error, whether financial, patient safety-related, or in terms of the company's reputation (Interviewee E). Another important point is the format of the training. More dynamic and interactive methodologies are seen as far more effective than simple presentations or readings followed by tests (Interviewees A and D). The instructor's dynamism is essential to motivate and engage the team, and friendly competitions can increase interest and learning (Interviewee F). Furthermore, it is important to encourage the team to participate actively in training, with constant feedback and individual goals. This can increase commitment and adherence to the process (Interviewee A). However, this training-focused mentality must start with leadership and then spread throughout the company, aligning everyone's objectives (Interviewee D). Finally, frequency and dedication to training are essential. It must be incorporated into the factory's routine with dedicated hours (Interviewee E). The biggest challenge is balancing training with daily demands, but it is a critical point for ensuring best practices.

Error Mapping

Error mapping is viewed as an essential practice in the pharmaceutical industry, as it allows for identifying patterns, deviation statistics, and the need for adjustments in training. All interviewees agree on the importance of a robust investigation process to map errors. Several tools, such as the Ishikawa diagram and the 5 Whys, are used to identify the root causes of problems. Understanding why failures occur is the first step to mitigating them. Mapping errors by operator is a productive strategy for addressing operational failures. Sometimes, unexpected difficulties are identified, such as issues with filling out documents due to a lack of basic knowledge (Interviewee D).

By stratifying these errors, it is possible to develop an effective action plan that directly addresses the root cause. The purpose of this mapping is not to expose individual failures but to support the development of each employee (Interviewee G). Statistical analysis of the deviations found helps focus on critical areas and processes needing more attention. These data not only show where failures are most frequent but also guide the creation of effective action plans (Interviewee C). Identifying the causes of human errors allows for properly addressing the issue and developing preventive strategies (Interviewees A and B). When this analysis is not conducted correctly, the team's efforts can be wasted, and problem resolution becomes much more labor-intensive. Customizing training is often necessary based on detected errors

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(Interviewee A). Often, the approach to training or documentation needs adjustment (Interviewee C). Understanding how the team learns best is a constant challenge, but it can become a leadership differentiator, especially when there is openness to change and persistence (Interviewees E and G). Customizing training is a valuable tool to mitigate human errors in the production process (Interviewee B). This practice strengthens continuous improvement and the development of better-skilled teams.

Documentation

Standardizing documents, such as production orders, is one of the biggest challenges for some industries. According to Interviewee C, when documents have the same format and layout, it makes operators' work easier, reducing human errors and improving training. A clear and consistent document creates a positive memory for the operator, allowing for greater accuracy in filling out forms. Creating clear and suitable documentation for operations, while also meeting legal requirements, is an ongoing task. Standardizing these documents prevents confusion for both those filling them out and those reviewing them (Interviewee D). Including operators in the document creation process brings significant benefits. When adjustments are made based on worker feedback, there is more engagement, and the certainty that the document meets the operational reality (Interviewee B). The person performing the task is often the best to suggest improvements to the process. Many companies fail by not involving their operators, creating documents that often do not reflect the work reality (Interviewee G). This involvement strengthens the revision process, resulting in more effective and applicable documents in daily production.

Automation

Automation in the pharmaceutical industry is often seen as the ideal solution to avoid human errors, but this view is not entirely correct. During the interviews, different levels of automation were discussed, and it became clear that, in many cases, human presence is still essential, especially in more complex decision-making. Although technologies such as cameras and sensors offer great benefits, it is important to understand that automation also has its limitations when it comes to eliminating human errors. According to Interviewee F, technological advances have enabled nearly total automation, using artificial intelligence and sensors that virtually eliminate the need for human interference. Even so, human intervention can still significantly impact the process. In some cases, overconfidence in systems or unrestricted access to controls can lead to failures that would otherwise be avoidable. A clear example is when the system detects a failure, but the operator, for some reason, decides to continue the process, causing a deviation. The great challenge in the pharmaceutical industry is finding the balance between automation and human intervention. Automation brings more reliability and precision to the production process but still requires careful monitoring to ensure everything works correctly. The use of robots and digital systems is seen to increase efficiency and reduce errors, but as Interviewees A and B pointed out, it is essential to define how far automation can go and how it should be validated and controlled. This ensures that the production process stays within quality and safety standards. In the end, automation is a powerful ally, but it does not eliminate the risk of human errors. The real challenge is combining the best of technology with human expertise to minimize mistakes and ensure a safer, more efficient process.

Competency Evaluation

The competency evaluation of operators is crucial for minimizing human errors in the pharmaceutical industry. Understanding employees' behavior and knowledge allows for the development of effective action plans to address issues during production. For this, it is essential to have a structured evaluation process that includes not only tests but also effectiveness measurements and bonuses, increasing employee engagement. Operators' training should focus on both technical and behavioral skills, considering that many important aspects are often overlooked. Understanding the team's behavioral profile and how each employee handles different situations is vital for proper task allocation. For example, a dynamic person may struggle with tasks requiring analysis and concentration.

Therefore, aligning these characteristics to create a cohesive team is a challenge. Regular performance evaluations and clear goals are recommended practices that contribute to mitigating human errors. Integrating this process into the daily routine is a cultural shift that must be addressed. Evaluations should not be merely formal but effective, using theoretical and practical tests, as well as 360° evaluations that consider not only those performing the tasks but also those defining the procedures. A clearly defined bonus system is essential for the continuous development of employee competencies. The use of rewards and penalties, when applied correctly, can be an effective tool in reducing errors. However, the financial impact of these actions can be an obstacle to implementation. It is crucial to demonstrate that avoiding errors results in significant benefits, such as cost savings and an improved company image.

Open Communication Culture

Open communication between leadership and the operational team is one of the biggest challenges faced by companies. While it seems simple, creating an environment where employees feel comfortable discussing incidents without fear of exposing the truth is crucial for mitigating human errors. According to Interviewee E, the lack of complete information during deviation investigations makes resolution more complex, increasing the likelihood of identifying the wrong causes. Clearly communicating the financial impacts of deviations can foster a sense of belonging and engagement among employees, encouraging them to prevent future occurrences.

Furthermore, the corporate image and the losses that may affect the company and its employees are critical. Interviewee F emphasizes that clear communication is essential for understanding and resolving issues resulting from failures. Financial impacts range from minor to severe, possibly even leading to the company's closure. Interviewee C highlights the importance of informing employees about the consequences of deviations, promoting a sense of responsibility for their actions. It is vital that this communication does not create a fearful environment but rather a space for mature discussion, as suggested by Interviewee D. Involving employees in raising awareness about the company's image and its societal impact is an effective strategy to increase engagement. In the pharmaceutical sector, where reputation is crucial, a good image is essential for commercial success. Promoting constant, open dialogues for problem-solving is seen as good practice by Interviewees F and G. An environment where employees are afraid to speak up can increase human errors, making it even more urgent to address these issues collaboratively between operations and leadership. These strategies

discussed in the interviews are fundamental to reducing human errors in pharmaceutical production.

Relationships Between the Best Practices Identified in the Interviews

The mind map generated was an important tool for identifying the relationships between the raised items and understanding how they are interconnected. This played a key role in the research conclusions. In Table 03, we can observe each of the best practices with their respective descriptions and how they relate to one another. It is interesting to note that each one has a unique relationship with the others, yet it is evident that they complement each other, providing meaning to the actions and needs identified in the industry.

Table 03 - Relationship between good practices raised in the interviews

Item	Description	Relationships
Training	Trains operators and promotes cultural change, increasing awareness and reducing errors.	• Error Mapping (focus on critical areas) • Documentation (explaining new procedures) • Competency Evaluation (impact of training) • Open Communication Culture (to provide continuous feedback)
Error Mapping	Identifies failure patterns, guides training and documentation revision, and customizes interventions.	• Training (to adjust critical areas) • Documentation (revision based on errors) • Competency Evaluation (to align skills with needs)
Documentation	Clear and standardized documentation reduces confusion in production processes, especially in complex and automated operations.	• Training (for clear guidelines) • Error Mapping (based on feedback) • Automation (to ensure operators follow procedures correctly in automated processes)
Process Automation	Automation reduces human intervention but requires trained operators to set up and monitor systems correctly.	• Documentation (for clear instructions on interacting with automated systems) • Competency Evaluation (to ensure operators have technical skills for automation)
Competency Evaluation	Continuous evaluation of operators ensures they have the necessary skills, preventing failures.	• Training (for constant skill updates) • Automation (to ensure mastery of technologies) • Error Mapping (to adjust focus of evaluations)
Open Communication Culture	Promotes engagement and understanding of operators about the impact of their actions, encouraging continuous improvements and reducing errors.	• Relates to all other practices, as communication is essential for training, error feedback, documentation review, and automation implementation.

Priority Ranking Based on the Interviews

Based on the impact of the practices described in the research, a priority ranking for implementing best practices in the industry was developed. This ranking helps to understand

the necessary actions versus the expected outcomes, which is crucial when considering where and how to begin the implementation of these best practices. This ranking reflects the approach presented in the interviews, where training and error mapping are the central pillars for mitigating human errors. Documentation, evaluation, and communication support the process, while automation complements the system, but does not replace it.

The ranking created allowed us to identify which items should be prioritized based on the companies' realities, always considering the time and investment required and the expected results for each one. In Table 04, we can observe the priority ranking along with the rationale for these definitions.

Table 04: Priority Ranking of Best Practices Based on Interview Findings

Ranking	Best Practice	Reason for Priority
1	Training	Training is viewed as the foundation for reducing human errors. Well-trained employees ensure safer and more efficient operations. It is essential for instilling the necessary skills and culture.
2	Error Mapping	Error mapping allows identification of failure patterns, guiding necessary adjustments in training and operations. It supports continuous improvement and is key to targeted actions.
3	Documentation	Clear and standardized documentation ensures that operators follow consistent processes, reducing confusion and errors. This is crucial in complex operations, especially with automation.
4	Competency Evaluation	Regular competency evaluation ensures that operators maintain necessary skills and adapt to evolving processes, preventing human errors. It complements training and automation.
5	Open Communication Culture	Open communication fosters engagement and understanding of the impact of actions, promoting continuous improvement and reducing errors. It ensures that feedback loops are constructive and transparent.
6	Process Automation	Automation complements the system by reducing human intervention but requires skilled operators to monitor and intervene when necessary. While beneficial, automation cannot replace the need for skilled human oversight.

CONCLUSIONS

The objective of this research was to identify the best practices for mitigating human errors in the pharmaceutical industry. The exploratory research technique was chosen, utilizing a semi-structured questionnaire as the basis for the interviews. In total, seven interviews were conducted with industry specialists, creating an open-dialogue environment that allowed each interviewee to share their experiences. For data treatment, a collection and analysis method was employed, resulting in the creation of a mind map. This tool facilitated understanding and the connections between the discussed topics. Six best practices were identified that can be applied in the industry: Training, Error Mapping, Documentation, Competency Evaluation, Open Communication Culture, and Automation. The research revealed that the implementation of these best practices varies according to the size of the company and may have different relevance for each organization. One point emphasized in all the interviews was the importance of training to mitigate human errors, which is closely linked to process standardization and

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documentation revision. Dynamic training with competitions, frequent sessions to reinforce best practices, and the use of rewards to encourage participation were some techniques suggested that could contribute to the success of mitigating human errors. Competency evaluation also stood out during the research as it was defined as a fundamental process to ensure that employees have the necessary technical and behavioral skills to operate. This evaluation plays a vital role in the industrial context, helping to determine whether people are in the right positions and what training is needed for the development of both the individual and the operator team.

Automation was mentioned by some interviewees as a critical element for mitigating human errors in the manufacturing process. However, contrary to what many believe, automation is not a one-size-fits-all solution for reducing errors. Although it is assumed that more automated processes lead to fewer human interventions and, thus, fewer errors, the research showed that even companies with high levels of automation experience operational errors due to human failures. This is because, in many cases, systems are set up to allow human intervention for approving or reviewing a process that, through automation, should have been rejected. This intervention leads to failure.

Each of the best identified practices has a "class" related to its subdivision or topic within that theme. In Table 5, a detailed breakdown of each subtopic is presented, summarizing the actions to be identified and implemented in the industry.

Table 05: Best practices for mitigating human error in the pharmaceutical industry

Item	Class	Details
Training	Awareness	Focus on cultural change and valuing the impact of errors.
	Playful Methods	Dynamic training with competitions to maintain motivation.
	Frequency	Frequent training sessions to reinforce best practices.
	Feedback and Rewards	Use of incentives to encourage participation.
Error Mapping	Pattern Identification	Assessment of common errors by operator.
	Deviation Statistics	Data collection to focus on critical areas.
	Training Adjustment	Customization of training based on identified errors.
Documentation	Continuous Review	Ongoing improvement of procedural clarity.
	Standardization	Use of fixed base documents to avoid confusion.
	Collaboration with Operators	Adjustments based on workers' feedback regarding documentation difficulties.
Process Automation	Cameras and Sensors	Implementation of technology to detect errors and automatic rejections.
	Automation Limitations	Automation reduces but does not completely eliminate human errors.
Competency Evaluation	Technical Skills	Focus on equipping operators with appropriate technical skills (e.g., process knowledge).

	Regular Evaluation	Measurement of individual performance and goal setting.
	Incentives	Use of rewards and penalties (e.g., performance bonuses).
Open Communication Culture	Financial Impact	Highlight the economic impact of errors for operators.
	Corporate Image	Engage workers in preserving the company's image.
	Ongoing Dialogue	Regular discussions about errors and how to avoid them.

Another point observed during the research was that at no point was fatigue or exhaustion of operators listed as a cause of human error in the pharmaceutical industry, which contrasts with many previous studies that consider this factor significant. This discrepancy arises because, in most cases, the pharmaceutical industry demands less physical effort from its employees compared to sectors such as steel production or mechanics. Additionally, aspects related to ergonomics, health, and workplace safety are highly prioritized in the pharmaceutical industry, making these themes even more relevant.

Some avenues for further study include deeper exploration of topics such as training, open communication culture, and competency evaluation. These areas could be investigated in more detail to identify opportunities and best practices across various fields. These are some of the suggestions for future research on the best practices in the pharmaceutical industry. This certainly opens a broad field for further research, offering diverse perspectives.

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