

The Surging Relevance of Human Error in Pharmaceutical Manufacturing Sectors

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Abstract: A fundamental aspect of human behaviour is human error. The phrase "Human Error" is frequently used in the pharmaceutical industry. It comes from the idea of "Quality and Safety" in the manufacturing process. In the SISPQ sector, human error has grown to be a significant problem, and because regulatory bodies are present, there is a high demand for human error research. Human error is being reduced at all levels through quality efforts. The relevance of human error in the pharmaceutical industry cannot be ignored due to persistent challenges. Professionals in the pharmaceutical industry are concerned about the rising number of incidents linked to human error and take all reasonable precautions to prevent them in the relevant sector. Through a thorough review of the literature, this research paper aims to examine the relevance and significance of human error within the pharmaceutical industry.

Keywords: Good Manufacturing Practices, SISPQ, Human error, Training, Human factor, Pharmaceutical industry, Compliance

1. Introduction

The term "human error" came into existence as a result of brainstorming that followed accidents caused by human beings. There were many instances reported where human beings were held responsible for certain deviations or disasters that could have been avoided otherwise through proper initiatives and approaches.

The list of such disasters ranges from big to small including Fukushima Nuclear Plant Disaster, the Deepwater Horizon Oil Spill, the Space Shuttle Columbia Disaster, etc., which deserve special mention (MESSER, 2016).

The word error is often associated with individual mistakes, e. g., realising one's mistakes implies that a person has done something wrong (ARMITAGE, 2009). As cited by Hansen (2006), Erwin mentioned pilot error as the reason for 72% of Navy and Marine Corps flight mishaps recorded between 1995 and 1999, whereas Green and Senders mentioned human error as the sole cause for 57% of road accidents and a contributing factor for more than 90% of accidents.

Accidents mostly take place on straight roads instead of at bends or intersections, concluding the fact that human error is the major factor causing road accidents rather than environmental factors. (Arora et al., 2013) Various sorts of statistical data were made available from time to time that explored the role of human error in regulating accidents. Hansen (2006) stated that human error accounts for 30% to nearly 100% of accidents. According to Wood and Banks (1993 as cited by Liginlal et al., 2009) said the most common reason for data breaches in the firms analysed was determined to be human error. In computer science and other more technical fields, an error is used in connection with the failure of systems but in other fields, the word still has

pejorative connotations for the individuals involved (ARMITAGE, 2009).

Human error has become one of the greatest risks to the success of the pharmaceutical business, which triggers a loss of £23.9 million each year in the UK due to a misunderstanding of the job role, as per an IDC survey (Clarke, 2009). Organizations frequently deviate from established processes due to misunderstandings (Gauvin et al., 2018). Deviations in the pharmaceutical industry have always proved to be a costly affair as they impact the productivity of the supply chain profusely. The average deviation in the pharma and biotech industry normally costs from \$25, 000 to \$55, 000, and even the top deviation can reach \$1, 000, 000 per deviation if product loss is involved (Benson, 2021). The human error proved to be a multimillion - dollar mistake at one of the manufacturing plants for the COVID - 19 vaccine (Lowe, 2022). Shares of Emergent BioSolutions plunged by more than 37% after the company was forced by the federal government to cancel a \$628 million contract after botching COVID - 19 vaccine doses, and the company forwent \$180 million due to it (Jr, 2021). Human error ruined up to 15 million Johnson and Johnson doses and that refers to poorly trained lab workers (Spencer, 2021).

Issues related to human error that caused loss of resources engaged the industry leaders to consider human error seriously in controlling accidents across domains. Various ongoing investigations and other human error - related issues may cause product delays in the market, preventing patients from receiving timely medications and costing the pharmaceutical and biotech industries revenue (Benson, 2021). As a result, human error has emerged as an important point of discussion in the pharmaceutical manufacturing sector across the globe.

Accidents due to human error vary from industry to industry along with their criticality. Human error has been shown to reduce productivity. As a result, the pharmaceutical industry across the globe is working to reduce human error - related incidents through various affirmative actions. The human error approach enhances the safety of people, products, processes, and performance. The acquired knowledge is used to enhance the awareness of stakeholders through training and development. Many disasters and catastrophes would have been prevented if the human resources in charge could have done the right thing (MESSER, 2016).

The consequences of human error in pharmaceutical companies are vast. Pharmaceutical companies take this as an opportunity to improve the situation by exercising better control to keep human error at bay. Therefore, based on the above we can infer that there is a need to proactively reduce human error. It can identify the root cause of accidents in manufacturing sectors and de-risk the overall system.

There is also a need to understand the reasons for accidents and reduce losses at the earliest possible time. Thus, this paper investigates the significance of human error in the pharmaceutical industry by reviewing the relevant literature.

2. Review of Literature

2.1 Human Error

Human error is an unsuitable or unwanted human decision or behaviour that reduces or has the potential to reduce, effectiveness, safety, or system performance (McCormick et al., 1987). It is defined as an identifiable human action that is seen retrospectively as the cause of an unwanted concept (Erik, 2005).

Human error is used to explain the result or consequence of human action, the contributing factor of an accident, deliberate deviations, and the actual action taken by a human being, and it is defined as the characteristics of human beings that include unintentional deviations from what is correct, right, or true (Hansen, 2006). A popular definition of human error is when a planned action does not result in the expected result (Khoja et al., 2017).

Human error occurs when several types of committed or omitted human actions appear to be linked retrospectively to undesirable consequences, although undesirable consequences do not essentially imply the occurrence of human error. Throughout the twentieth century, the dominant viewpoint on human error in many U. S. industries was to attribute negative outcomes to the people whose actions were most closely associated with these events (Sharit, 2006).

In problem management, out of the multiple causes of problems across any given environment, application, or platform, human error is one of the most frustrating causes, specifically one that has a large impact number (Handley, 2022).

Human error is classified in many ways. However, human error, classified into approaches of person and system, is

crucial for corrective action. The person approach focuses on the errors of individuals, accusing them of forgetfulness, inattentiveness, or moral weakness, whereas the system approach focuses on the conditions under which people work and attempts to build defences to avoid errors or mitigate their effects (Reason, 2000).

2.2 Consequences of Human Error

The consequences of human error in the pharmaceutical industry are severe. Human error is costly to pharmaceutical manufacturing, and pharma prioritizes reducing human error in manufacturing to improve quality (Lowe, 2022).

Quality issues due to human error impact the productivity of pharmaceutical companies. Human error leads to issues that delay the production schedule and make customers suffer, which intensify during emergencies like pandemics. Human errors play a role in almost every quality issue, equipment shutdown, or accident in industrial and manufacturing facilities (Deeksha Ramananda Pai et al., 2016).

McFadden et al. (2004) stated that medical errors are the eighth leading cause of death in the United States, referring to the Institute of Medicine's (2000) report, which claimed medical errors are behind 98,000 injuries and about 98,000 deaths annually. Human errors were identified as one of the most frequently cited causes of medical errors and adverse events. Based on this, it can be argued that just as medical errors have serious consequences, human process errors in the pharmaceutical industry prove costly to the quality of service and delivery. They may impact the quality and safety of drugs. This has the potential to lead to adverse events for end users. They are also to be treated seriously, as human-led deviations impact productivity.

Pharmaceutical manufacturing industries are governed by stringent Good Manufacturing Practices (GMP) to ensure quality output. Even with GMP in place, the occurrence of human error - related incidents cannot be ruled out, and even today across the globe, most pharmaceutical companies face compliance challenges due to human error.

Pharmaceutical industries depend on quality compliance. Non-compliance may happen at any particular step of the workflow. There may be many causes for non-compliance, and human error might be one of them. Non-compliance may pose a risk to end users and put industries under regulatory pressure.

Making medicines is a delicate process. In pharmaceutical operations, non-compliance of any type is required to be logged into the system, and investigations to find the root cause are to be done.

For any sort of non-compliance in the Good Manufacturing Practices (GMP) environment, the scope of human error is taken into consideration for any sort of involvement. Human error investigations focus on realistic corrective and preventive action (CAPA).

Pharmaceutical industries are known for their quality output, so any sort of non-compliance is taken seriously.

Non-compliance may even trigger regulatory action, and pharmaceutical manufacturing companies would incur a loss for the same. Monitoring and controlling human error-related non-compliances has become a bigger challenge for the pharmaceutical industry across the globe. In the pharmaceutical industry, it is observed that the approach to human error is not limited to safety. Although safety and effectiveness typically go hand in hand, human reliability assessment may also be thought of as a method of "Continuous Improvement," ensuring that human operators (and their managers) are capable of both. (Kirwan, 2008)

Human factors are being prioritised to improve quality. As quality is the main foundation for the pharmaceutical business, the inclusion of human error in deviations from pharmaceutical events strengthens the core value of quality enhancement in the said sector. Research on human error in the pharmaceutical sector got attention, and gradually human error was prioritized to be considered seriously as part of quality assurance. Quality Assurance has the final authority to approve incidents and investigations logged in pharmaceutical manufacturing plants.

Human error is responsible for more than 80% of process deviations in the pharmaceutical industry and related manufacturing industries (Collazo, 2020).

Human error in the pharmaceutical manufacturing sector becomes significant as errors originating from humans cause a loss of productivity. Human error is the most discussed topic in the pharmaceutical sector, as many incidents due to human error are recorded in the industry.

And hence, the pharmaceutical industries are more engaged with human error-related issues, which optimises the training needed for public awareness in the overall control of human errors.

With prevailing deviations ascribed to human error assessed at 50% within the biopharma industry [an internal BioPhorum Operations Group (BPOG) member survey], the core importance and practical value of integrating human performance (HuP) principles are noticeable (Wilson et al., 2015). According to Cott (1994, as cited by Patel et al., 2002) said crucial tasks which require the conversion of knowledge into a suitable course of real action, like the reading of pharmaceutical labels, are the most prone to human error.

The primary reason for quality defect problems that have resulted in batch recalls, according to Irish Medicines Boards, is commonly described as human error (Khoja et al., 2017).

According to the analysis of the Irish Medicines Board, human error is responsible for almost 25% of all quality faults, including deviations, laboratory errors, complaints, and inspection concerns (Khoja et al., 2017).

Literature is not only limited to the consequences of human error but also highlights the importance of human factors in regulating human error.

2.3 Good Manufacturing Practices

To flourish the pharmaceutical manufacturing sector, the pharmaceutical industry's operational requirements must be focused on Good Manufacturing Practices (GMP). GMP compliance is required for any pharmaceutical industry unit that conducts operations.

According to the World Health Organization (WHO), Good Manufacturing Practices (GMP, also referred to as 'cGMP' or 'Current Good Manufacturing Practice') is the feature of quality assurance that ensures that medicinal products are constantly produced and controlled to the quality standards suitable to their intended use and as needed by the product specification.

GMP outlines requirements of quality measures for both production and quality control. It ensures that processes essential for production and testing are clearly defined, validated, reviewed, and documented and that the personnel, premises, and materials are appropriate for the production of pharmaceuticals and biologicals, including vaccines. GMP also contains legal components for accommodating responsibilities for distribution, contract manufacturing and testing, and responses to product defects and complaints. Specific GMP requirements required for classes of products like sterile pharmaceuticals or biological medicinal products are available in a series of annexes to the general GMP requirements (Good Manufacturing Practices, n. d.).

"Human factors address what people are being asked to do (the work and its characteristics), who is doing it (the people and their competence), and where they are working (the organisation and its attributes)" (humanfactors101, 2016).

Pharmaceutical industries are known for their quality. GMP guidelines state the need for competent employees to perform the assigned roles.

According to Stracke (2019), if a good performer is placed in a bad system, the system will always win, and technical experts must have relevant education and experience on human factors and human performance principles to improve human performance.

Pharmaceutical manufacturers need to ensure their products have higher safety and quality. Any deviation from standard operating procedures must be investigated to find the root cause. If any sort of human error is noted along with the root cause, investigation needs to be continued with feasible corrective and preventive actions.

The pharmaceutical industry is implementing stringent GMP from time to time as per regulatory needs and establishing a validated Quality Management System (QMS) to log and investigate incidents.

Hales & Pronovost (2006) stated that error management is significant for industries like product manufacturing, in which minor errors during the development or manufacturing process could compromise the requirements of customers, increase the manufacturing cost, and also add to the stringent quality control requirements of pharmaceutical and medical device manufacturing.

Thus, the issues related to human error and investigation processes related to human error become significantly important in the pharma sector as productivity loss due to human errors in the said industry has become a pain point and industries need to educate people in controlling incidence due to human error.

The primary goal of GMP is to protect the product from contamination and cross - contamination, particularly from human plant workers (Plumb, 2005). The USFDA issued warning letters to many pharmaceutical companies for non - compliance with GMP norms. In many cases, such non - compliances are triggered due to human error - related issues. Food and Drug Administration (FDA) inspections and guidelines have focused on ensuring current good manufacturing practices (cGMPs) in the pharmaceutical industries (Wilson et al., 2015).

2.4 Causes of human error

Human error is caused by numerous factors. Any deviation logged into a system needs to be properly investigated to identify the root cause. Human error - related deviations are more prevalent in certain industries, including pharmaceutical manufacturing units.

Three common causes of human error are distractions, anxiety, and lack of sleep. Distractions limit the focus of the workers on the task, which leads to accidents, and individuals need to deal with various types of distractions at the workplace effectively. Anxiety or stress causes a variety of problems in both personal and professional lives. Stress leads to a negative environment for the team and improvised individual mental work, which leads to accidents. A lack of sleep can cause cognitive issues, carried on by fatigue, and individuals who are deprived of proper sleep won't think clearly or quickly (Admin, 2020). Stress and fatigue can lead to human error, resulting in more mistakes in judgement and a reduction of compliance and proficiency (Hales & Pronovost, 2006).

Human error is caused by problems with human - machine interaction, stressful workplaces, and other situational factors (Liginlal et al., 2009).

Human error is usually resulted due to poor design (Munot, 2017). Another viewpoint on human error focuses on design flaws, which are also frequently mentioned in the literature. When something goes wrong, users are blamed by designers, but in a way, designers are blaming their designs (Munot, 2017).

Apart from design, work procedures also have a significant role in human error. According to research by Peter (as cited by Siahaan, 2016), out of many reasons, the human error also results from errors in the design and the work procedure. The common sense understanding that it is impossible to design a plant that is completely "human - error - free" strengthens the importance of the function ascribed to human factors (Cacciabue & Vella, 2010). McCormick et al. (1987) emphasised finding out how much human error contributes to accidents relative to other contributing factors

There are numerous reasons for the occurrence of human errors, counting inadequate lighting in the work area, insufficient training or skill of the manpower involved, poor equipment design, high noise levels, an inadequate work layout, improper tools, and poorly written equipment maintenance and operating procedures (Dhillon & Liu, 2006). Errors in planning or decision - making result in mistakes (Liginlal et al., 2009).

From the point of view of human resources management, the origin of human error lies in the selection process and personnel training (Siahaan, 2016). Michaelides - Mateou and Mateou (2010 as cited by Dekkar, 2011) said there has been a surge in the criminalization of human error in the fields of aviation and healthcare.

Many companies still deal with human error according to the "blame" principle, which appeals to the fear of the individual (Khoja et al., 2017). Blaming has become a daily talk on the shop floor which needs to be stopped. The blame perspective only leads to employees having less confidence in raising issues that can lead to errors, which in turn leads to management being less aware of system weaknesses that ultimately lead to more errors (Khoja et al., 2017).

Blaming any person for human error won't fix the problem, as the same mistake is likely to be repeated by someone else (Munot, 2017). Accident prevention depends on employees' responsibility as well as a safe workplace (Admin, 2020).

2.5 Context of Indian Pharma Industry and human error

The pharmaceutical industry has grown significantly worldwide in recent years and the entire global pharmaceutical market was valued at 1.48 trillion dollars in 2022 (Mikulic, 2021). The group of emerging markets, which includes India, have emerged as the second - largest market for medicines after the United States (Mikulic, 2021).

In India, pharma exports have observed a growth of 103 percent since 2013 - 14, from Rs.90, 415 crores in 2013 - 14 to Rs.1, 83, 422 crores in 2021 - 22, which shows that the exports grew by almost \$10 billion in eight years. (IPHEX to Turbocharge Indian Pharma Industry, 2022)

As per the annual report 2020-21 of the Department of Pharmaceuticals of the Government of India, Indian Pharmaceutical Industries ranks third in production volume globally. In 2020-21, India recorded a CAGR of 9.43% with total pharma exports of USD 24.35 billion versus total pharma imports of USD 6.66 billion. The report also specified that, until the end of September 2021, India generated a trade surplus of USD 7.22 billion. The industry is mainly comprised of generic drugs, OTC medicines, bulk drugs, vaccines, contract research and manufacturing, biosimilars, and biologics, and it achieved the highest number of United States Food and Drug Administration (USFDA) compliant Pharma plants outside of the USA. This industry contributes about 8% to the global API industry and 20% to the global generic supply, with 60, 000 diverse generic brands covering 60 therapeutic categories. Access to

affordable HIV treatment in India was one of the greatest success stories in medicine, which enables India, on a similar line, to provide low - cost vaccines in the world.

The share of pharmaceuticals and drugs from India in global exports is 5.92%, with a 73.31% share of the total exports contributed by formulations and biologicals, followed by bulk drugs and drug intermediates with exports of USD 4437.64 million (India's Pharma Exports Grow by 103% since 2013 - 14, 2022).

The top five pharmaceutical export destinations for India are the United States, the United Kingdom, South Africa, Russia, and Nigeria, with approximately 55 percent of pharma exports going to highly regulated markets (India's Pharma Exports Grow by 103% since 2013 - 14, 2022).

The extraordinary export growth in 2020–21 was achieved despite frequent lockdowns, global supply chain disruptions, and the depressed manufacturing sector, and the Indian pharma industry significantly fought against the COVID pandemic and established itself as a reliable and dependent partner in dealing with a global health crisis (India's Pharma Exports Grow by 103% since 2013 - 14, 2022). India developed COVID vaccines with indigenous technology in the shortest recorded time, on par with highly developed countries like America and the EU (India's Pharma Exports Grow by 103% since 2013 - 14, 2022). According to the Ministry of Health, India has supplied over 23.9 million doses of Covid vaccine to 101 countries (IPHEX to Boost Indian Pharma Industry, 2022). The annual report 2020–21 of the Department of Pharmaceuticals of the Government of India previously mentioned that due to the low price and high quality, Indian medicines are preferred worldwide, thereby rightfully making the country the "pharmacy of the world".

The Indian pharmaceutical industry is growing at a high pace because of its high quality and affordability. The pharmaceutical sector in India is expanding the opportunity to serve global needs. Access to affordable HIV treatment in India was one of the greatest success stories in medicine, which enables India, on a similar line, to provide low - cost vaccines in the world (Annual report Department of Pharmaceuticals, GOI, 2020–21).

To improve quality, pharma also needs to prioritize reducing and eliminating human error in manufacturing. Human error problems existed before the pandemic but were exasperated by amplified demand and subsequent shortages (Lowe, 2022).

2.6 How can human errors be reduced

Humans being the most unpredictable variables, we should be caring and thoughtful in our designs that expect or necessitate human interaction, and when human errors happen, we need the time to talk, reflect, and analyse holistically to prevent human errors (Handley, 2022). Situational awareness (SA) may reduce the risk of human error, which is developed in teams by empowering all involved to speak without fear of retribution at all times (Hellyer, 2020). According to a study by Brenman et al. (as

cited by Hellyer, 2020), both distraction and intense concentration can impair situational awareness, so operators should take a break if they are hungry, angry, late, lonely, tired, or any of the other listed HALT conditions, and operators should be prepared to stop, look, assess, and manage (SLAM) their needs at any time.

As per the Health and Safety Commission Annual Report of 1988–1989, human error, which acts as a major contributory factor in 90% of industrial accidents, can be intensely prevented by management action through controlling hardware as well as the human performance factor (TAN et al., 1991). The reduction of the likelihood of errors produced from human - related sources and a clear focus on minimising their effect on manufacturing help create a safe, dynamic working environment at pharmaceutical companies (Korol & Zavadskiy, 2020).

Endsley and Robertson (2000) recommended the development of training programmes to improve situation awareness in aircraft maintenance at the individual and team levels as part of discussing the role of situation awareness in error prevention. For the employees to get a comprehensive awareness of the defined procedures, the employer must provide ongoing training (Konstantinos et al., 2011). Training people to work effectively in groups is inexpensive, but it has resulted in significant improvements in human performance (Reason, 1995).

According to a study by Manwaring et al. (as cited by Dhillon & Liu, 2006), the implementation of improved training along with other factors is needed to ensure safety. Human error must be seen as an integral feature of any socio - technical system (Cacciabue & Vella, 2010). On a similar line Dhillon & Liu (2006) also referred to the study of Shepherd and Kraus where the need to develop pre - training job aids was mentioned to address human factor issues.

Human error can be reduced and safety increased in military teams operating in the maritime environment by implementing a non - technical skills (NTS) training program (Campaniço Cavaleiro et al., 2020). Training programmes are viewed as an effective and beneficial technique around the world to make sure that all employees are prepared to carry out their job responsibilities and to meet any problems thrown at them (Deeksha Ramananda Pai et al., 2016). Proper training improves the performance of all employees, who should be taught that they are better suited to comply with cGMPs through training (Wilson et al., 2015).

Varied industries, including product manufacturing, where safety and precision are dominant inaccurate service delivery, have come to heavily rely on checklists to minimise human error (Hales & Pronovost, 2006). Speaking of human error and accident management (HEAM) makes sense to encompass the whole range of potential scenarios and interactions that could involve humans and machines (Cacciabue & Vella, 2010). To deal with human errors, an open reporting and learning culture is fostered by the individual, the leaders, and the organisation (Bodmann et al., 2016).

Through the extensive literature review, it is noted that pharmaceutical manufacturing plants employ personnel in compliance with the set requirements of education, training, and experience as per the job role concerned. Employees are qualified through a proper training system and released for activities.

Although a large proportion of incidents reported in the pharmaceutical industry are caused by human error, whether directly or indirectly it is earlier explained that the term "human error" is not familiar in the recognised GMP guidelines, where the term error is mainly used generally to highlight the issue.

Guidelines state the responsibilities of personnel working in pharmaceutical companies in a stringent sense so that product quality is enhanced under GMP environments.

There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in - process materials, packaging material, labelling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated (Federal Register:: Request Access, n. d.)

An appropriate level of root cause analysis should be applied during the investigation of deviations, suspected product defects, and other problems (EudraLex the Rules Governing Medicinal Products in the European Union Volume 4 EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use Chapter 1 Pharmaceutical Quality System, n. d.).

Pharmaceutical companies ensure the proper functioning of their quality management systems by complying with regulatory guidelines in every process, including deviation handling and the way forward. An investigation of deviations was carried out to determine the root cause, including the human error factor as well as other contributions. The significant contribution of human error is the result of opportunity rather than excessive carelessness, ignorance, or recklessness (Reason, 1995).

Employees' weaknesses and strengths are required to bridge knowledge gaps and minimise the risk of human error (Clarke, 2009). In the pharmaceutical industry, various types of checklists are issued to ensure the activity is done as per the guidelines which in turn reduces chances of human error.

Where human error is suspected or identified as the cause, this should be justified by having taken care to ensure that process, procedural - , or system - based errors or problems have not been overlooked, if present (EudraLex the Rules Governing Medicinal Products in the European Union Volume 4 EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use Chapter 1 Pharmaceutical Quality System, n. d.).

Regulatory guidelines assist Quality Control Units in making decisions to qualify a drug for use.

The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company (Federal Register:: Request Access, n. d.).

A quality management system ensures proper corrective and preventive actions to control deviations and helps educate personnel to close gaps, including human error.

Appropriate corrective actions and/or preventative actions (CAPAs) should be identified and taken in response to investigations. The effectiveness of such actions should be monitored and assessed in line with quality risk management principles (EudraLex the Rules Governing Medicinal Products in the European Union Volume 4 EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use Chapter 1 Pharmaceutical Quality System, n. d.).

"To comply with this regulatory requirement, a human error investigation programme can now be perceived as a non - negotiable GMP requirement, but bear in mind that the spirit of the regulation is not referring only to the investigation process, but the actual results" (Admin, 2018).

Essam Eissa & Hamed (2019) said that in the pharmaceutical industry, under GXP operations, for any established processes, the system must be under control and yield reproducible and predictable product quality. Errors in procedures may be caused by human limits or by inadequate procedures that need to be changed (Helmreich, 2000).

Whereas with a system in place, even if gaps are observed and industries face product quality challenges, written procedures are available, and standard operating procedures (SOPs) are continually updated as per regulatory and in - house requirements. Review of documents in pharmaceutical industries is handled profusely through the document management system (DMS). The documentation lifecycle strengthens the ALCOA+ requirements for data integrity. ALCOA+ ensures an effective data management system.

The FDA labelled the acronym ALCOA, as attributable, legible, contemporaneous, original, and accurate (Rattan, 2017).

Human errors are also significant factors in almost every quality problem, equipment shutdown, or accident in industrial and manufacturing facilities. Thus, this article also explores the need for GMP training and its application to comply with GMP requirements. The first prerequisite for the production of pharmaceuticals complies with the law regulating GMP requirements (Konstantinos et al., 2011).

Pharmaceutical companies work with integrity to ensure product quality. Quality drives better productivity. Quality policies, SOPs, and regulatory guidelines always reinforce quality output.

"Everyone involved has to understand that there is no productivity without the best quality. This includes the need to improve operational performance in general, including a culture change toward human performance (HuP) principles (Wilson et al., 2015). The goal of human reliability

assessment (HRA) is to foresee how human performance and error may affect risk (Kirwan, 2008). In addition to cultural considerations, clear, straightforward, and accurate procedures are requirements for preventing human errors (Bodmann et al., 2016).

"Training" was mentioned in 10 of the 71 warning letters, according to the Gold Sheet (Deeksha Ramananda Pai et al., 2016). In all cases, error avoidance depends on users receiving regular training to increase both their knowledge and their expertise (Liginlal et al., 2009). Pharmaceutical sciences researchers with an educated and training mindset are always in a competitive advantage in the pharmaceutical industry (Bjerrum, 2011).

Pharmaceutical companies' quality policies are extremely important because they play a key role in aligning employees with the importance of quality and serve as a cornerstone to enlighten the quality principle among employees. Proficiency errors point to the need for technical education, whereas communication and decision mistakes demand team education (Helmreich, 2000).

Incidents or deviations in pharmaceutical manufacturing plants are investigated to find out the root cause of the incidents and their impact on quality.

"Rather than focus on the person, we need to explore the task, tools, and operating environment. This means that human error becomes a starting point for investigation, not the root cause" (Wilson et al., 2015). Programmes for operators must be rigorous, repeated, and intended to push them beyond their comfort zones (Liginlal et al., 2009). In the pharmaceutical sector, a larger sample size, a longer time frame, and demographic factors must be involved to evaluate the impact of training (Aydogdu, 2012) along with a clear definition of human error with defined mitigation measures (Hansen, 2006) for extensive control of human error in the pharmaceutical manufacturing sectors.

Training is always taken into consideration to update employees on various aspects of GMP and daily activities. It helps employees stay alert and reduces the chance of human - led deviations.

3. Results and Discussions

From the above discussion of human error through a relevant literature review, ample studies support how human error has gained significance in pharmaceutical industries. Human error, which began in other industries and prompted a focus on safety features, has redefined the SISPQ elements as part of human intervention in pharmaceutical manufacturing set up under the GMP environment. The presence of human error has become significant with the growing importance of quality in the pharmaceutical industry. Any factor influencing quality in pharmaceutical manufacturing industries is identified and prioritised and human error is not an exception. Human errors are becoming increasingly important in the pharmaceutical industry due to their influence on SISPQ elements. Human errors impact the productivity and reputation of pharmaceutical companies.

Currently, across the world, the competition in pharmaceutical industries is mainly dependent on quality, whereas human error is considered a potential risk to quality. The presence of human error hinders productivity on the shop floor and often triggers batch rejection or destruction or delay in the schedule. Logging of human error in any function needs to be handled through a quality management system, which needs a proper investigation to eliminate the root cause of the error. Not only time but other resources are also compromised to accommodate the investigation of human error. Literature review support that the reduction of human error is necessary for better pharmaceutical output. This paper also investigated the context of Indian pharmaceutical manufacturing concerning human error, noting that the Indian pharmaceutical manufacturing industry is in a high growth phase and any disruptions in productivity due to any reason including human errors are detrimental to the said industry. Many studies have already been conducted that relate human error to loss of quality and productivity in pharma industries.

Human error as a whole, as well as any other contributing factors, must be taken seriously to ensure SISPQ elements in the pharmaceutical industry. A better approach to dealing with human error is critical for any pharmaceutical manufacturer. To sustain the growth curve of the pharma industry, manufacturers along with regulatory bodies are always concerned with the right quality. Control of human error in the right context is always profitable for any organisation. Human error in the pharmaceutical manufacturing sector is very significant and relevant in today's world.

Through the above literature review, the significance of human error in pharmaceutical manufacturing industries is well accepted. The pharmaceutical industry is always guided by GMP to ensure SISPQ elements at all levels of manufacturing. But even with so many stringent processes, non - compliance often resulted due to human error in the system. Human error impacts quality in pharmaceutical industries and hampers productivity. Through quality management systems (QMS), pharma manufacturers are interested to find out the root cause of human errors to control them.

Continual training and various awareness programmes are mandatory in pharmaceutical industries to strengthen GMP compliance in the industry. Adherence to regulatory guidelines and an established quality management system safeguards the SISPQ elements of the industry. The Indian pharmaceutical manufacturing sector is growing. Quality issues or productivity delays due to human error need to be controlled. Productivity loss caused by human error not only reduces a company's competitive advantage but also impacts the overall system.

The literature review establishes the significance of human error in pharmaceutical manufacturing and also uplifts the need of controlling human error in the said sector holistically for the betterment of the pharma world.

4. Conclusion

Due to regulatory guidelines, human error investigation has become a routine practice in the pharmaceutical industry. With the growing market, pharmaceutical companies are facing market challenges. Any batch loss caused by human error reduces a company's competitive advantage. Investigation and subsequent awareness through training will control deviations caused by human error. Hence, continuous training to educate people can reduce human errors and helps to establish a good quality management system.

Pharmaceutical industries stand on the pillar of SISPQ and a consistent approach to strengthening SISPQ not only enhances the standards upholding safety, integrity, strength, purity, and quality but also echoed the significance of control of human errors in the said industry on priority. With time, the importance of human error and its effective control has penetrated the quality consciousness of the pharmaceutical manufacturing industries and established the need to investigate human error to find out the root cause and mitigate the risk to the maximum extent. Thus, human error has become significant and surging relevant in a Good Manufacturing Practice (GMP) environment.

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