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Role Of Managing Tools For Identification And Reduction Of Human Errors In Pharmaceutical Industry.

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Abstract

Human error can be defined as "the failure of a planned action to achieve the desired result". The GMPs explicitly state in CFR 211.22 that "the quality control unit has ... the authority to review production records and to ensure that no errors have occurred or, in the event of errors, to be totally investigated." Let's analyze this statement. If FDA expects the errors to be fully investigated, it is safe to assume that the time error is NOT the cause. That is why it needs to be totally investigated, which is why the cause of the human error is determined. To achieve this goal, we need to understand how we can improve the way we deal with these situations. This article reviews accurately how we can accurately identify human errors, determine whether deviations or inconsistencies require CAPA, and begin using tools and processes for improving the performance of your organization.

Keywords: GMP, CRF, CAPA, error, Reduction, and Management.

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INTRODUCTION

A human error is often defined as "the failure of a planned action to achieve the desired result". According to Irish Medicines boards "Human errors are often cited as the main cause of high-level problems that have led to the mass recall." Its report suggests that about 25 percent of all quality issues like deviations, lab error, complaints, and testing problems — is caused by human error. Including -Failure to follow proper procedures -Using technical documentation to support batch release that does not accurately reflect the contents of the sales permit-Poorline clear, resulting in rogues being left in the repair line-Failed to make a difference following their approval. And labels are attributed to human error and that quality defects are often caused by a human error without scientific evidence [1-11].

Human behaviour is complex and just like equipment, product, and process it needs to be analyzed in depth.

About Human Errors

- Human Errors are a basic part of human nature.
- Human Errors will occur if humans are fragment of a production process.
- Human Errors are always unplanned (if not it must be assumed obstruct!)
- Human Errors can be reduced but not totally avoided (some business think they can)
- Human Errors are the manifestation but not the root origin.
- Human Errors are forced by the conditions of the situation.

Types of Human Error

- **Ignoring Safety:** It happens because when an employee feels comfortable with his or her job or lacks common sense, employees often ignore even basic safety measures. Ignoring the safety agreements used often leads to work accidents that could have been completely avoided.
- **Messing Around:** Meeting together at work can help improve morale, but if it leads to noisy play it can be a serious safety hazard. Playing with horses both physically and verbally can be equally dangerous and can lead to personal injury, product, and mechanical damage, and/or conflicts with co-workers.
- **Tiredness:** When an employee is tired to safely complete their essential job responsibility, the chance of a workplace accident arises significantly. Exhausted employees will often ignore the basic safety protocols, fall asleep on the job, and even operate heavy machinery while drowsy. If this occurs regularly, it could warrant a human error investigation.
- **Working Speed:** An employee who is in a hurry to do his or her job to meet the requirements or to complete the work so that they can travel without having to miss out on important information. Proper equipment and operating equipment, safety rules, and production chains can all be areas that a fast worker can take into account.
- **Poor Training:** Personal error is not limited to employees, and sometimes employers are to blame for an accident at work. When a supervisor accelerates the training of employees or omits all-important training topics, occupational accidents can be unavoidable.

How to reduce human errors: Human errors have a detrimental effect on the quality of the pharmaceutical product. About 80% of product quality errors occur as a result of human error. Human errors are found when deviations occur in the process. Many cause of deviation from human errors due to not suitable communication or failure to following procedure written as below.

Following are some solutions to minimize the human errors.

Identify the Error Reduction Moments: The area where a human error can occur must be recognize in the manufacturing and quality control. It should be identified individually for the equipment, documentation and systems where improvement can be done.

Redesign Procedures: Make the necessary changes to standard operating systems and formats that are long and difficult to track for users. Procedures should be short and clearly marked. Try to keep the

formats and forms as short as possible and easy to complete. Write clear instructions for filling in where there is a possibility of human error. Delete sections in processes and formats that do not work.

Improve Supervision: Instructions to employees and pharmacists should be given at all stages of production by management. Before starting a specific task, instructions must be given to the supervisor. Managers should be down and not in the office.

Improve Supervision: Instructions to the workers and pharmacists should be given at every stage of manufacturing by the supervisors. Before starting a specific job working instructions should be given by the supervisor. Supervisors should be on the floor not in the office.

Job Assignment: Performance of the individual personnel should be monitored by supervisor and job should be assigned according to their capabilities. It shall give the better result and chances of human errors shall also be reduced. Every time you assign a job, find the person who fits best to the job for its successful completion.

Training: On job training is necessary to all workers for all critical activities. Training should include all possible human errors and related question that may occur during the process.

Case study #1

In this case study, the materials present inside the device for sterilizing, holding and transferring stoppers, this organization having six hopper devices. Following use, the hopper use for manufacturing is sent by personnel in technical service department for cleaning and preparation. For this, the hopper is taken from an interlock area that separates technical services from the aseptic filling area (a transfer from an ISO class 7 to an ISO class 8 clean room [operational states]). Once in the technical services area two filters, stainless clamps, triclover seals, stainless 'T' piece and tray are removed from each hopper. The hopper and its parts are then rinsed manually using Water for Injection Bulk (WFI). The components are placed inside the hopper and dried inside a drying oven.

This process is shown in figures 1 and 2.

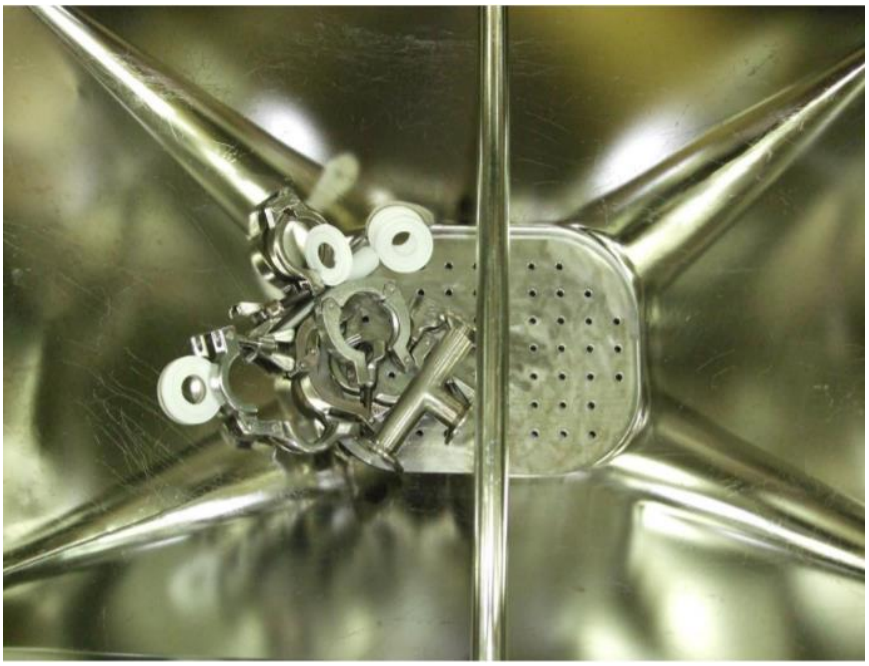

Figure 1: After cleaning the components are left in the hopper during drying.

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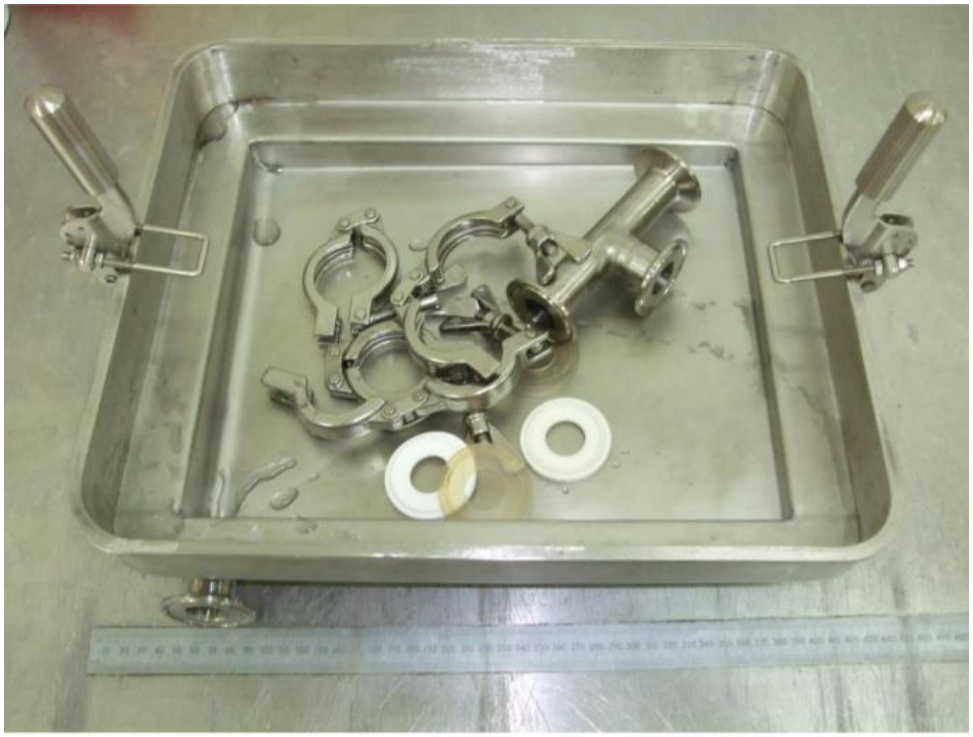

Figure 2: The hopper tray is washed and placed back into the hopper during drying.

The investigation into how the error occurred was subject to an analysis of Risk Influencing Factors. Such an analysis is integral to the Error Risk Reduction Process. The exercise identified the following:

Process Risk Influencing Factors

- There was no formal procedure for removing the hopper and for washing and drying the parts. This meant that informal procedures were used. Therefore, the reliability of the process and the consistency of the application were not guaranteed.
- People use their own sequence. This has been shown to create ambiguity, especially when work is given among employees during shift shifts.
- The process was not the same. Here people adapted to the basic method in order to obtain the desired effect in their own way. Specific outcomes of outcome and consistency assurance were shown to depend on who performed the task.
- There was also a risk of people working in 'autopilot' when work became 'second nature'. The result of this was that a little caution fails to detect something wrong unless it strongly contradicts what is expected.

Information Risk Influencing Factors

- It was found that there was an incorrect level of detail in the texts. This meant that very little information that led to thinking was used to fill the gaps.
- The command was not visible in the workplace, which led to memory dependence.
- Which staff members do unspecified work which means that some actions are not taken by anyone.

The obvious correction here was to add the appropriate level of data to the record for processing the relevant collection and General Procedure. Managers need to make sure the instructions are visible. Importantly, clear written instructions reduce memory dependence.

Good Practice Risk Influencing Factors

In the review, some examples of best practice have been found to accompany the implementation of a formal process to ensure that the hopper is tested before autoclaving. The previous practice was that the hopper test, to make sure it was empty, was not officially performed. It was agreed that the importance of visual assessment needed to be strengthened. A revised procedure was required to ensure compliance with the procedural steps, including documentary proof of check. This has the added benefit of preventing misunderstandings when a task is assigned. Managers are also committed to ensuring that all team members are informed of the impact of misconduct.

Case study #2

In this case study a new tablet product is manufactured from few mounts, containing a potent drug. The tablet was a small round tablet having few milligrams of potent active drug. The production run properly but, after several mounts, the compressing area reported several instances of broken punches during tablet compressing. Tablet punches were never broke in past manufacturing of this product. Manufacturing personnel reported that the dried granulation had too many fines and required extreme compressing forces to compress acceptable tablets. High compression force resulted in broken punches.

The manufacturing process in this case study involved manual personnel error. These manual errors occurred due to several factors such as wrong data put into the compression machine or by some manual error in weighing, mixing and some other factors.

Figure 1: Compression machine handling

The manufacturing process for the product having following steps:

- Firstly weighing of all excipients and APIs
- Potent drug and excipients were mixed and added to granulation equipment.
- Granulation started with binder solution.
- Dried granulation was sized using an impact mill combination.
- Granules, disintegrant, and lubricants were combined in a blender and mixed for 15 minutes.
- Then tablets were compressed on a rotary compressing machine.

After several mounts of successful manufacturing tablet compressing abruptly became extremely difficult. The tablet compression required much higher compressing force and slower compressing speed to compress acceptable tablets. Due to higher forces of compression punches were broken. These problems occurred unexpectedly after a period of successful processing.

Corrective And Preventive Actions

- Procedure-related errors
- Human factor engineering related error

- Training-related error
- Supervision-related error
- Communications-related error
- Individual error

Human error which affect production and its solution

- Due to improper mixing of granules
- Due to correct amount of excipients are not used
- Speed and pressure as per SOP
- Personnel and hygiene

Figure 2: Production of tablet

Solution

Due to improper mixing of granules: Proper mixing of powders is done with speed and time which is mentioned in SOP. This error can be done because of lack of personnel knowledge and experience or by excessive moisture present in granules.

Due to incorrect amount of excipient: Due to excessive amount of binder in material causes brittleness of tablet. Some time inaccurate amount of glident reduces flow property of granules.

Speed and pressure as per SOP: Some time workers put wrong value in manufacturing machines and these wrong input causes many defects in production if punching speed is fast then if cause fracture of punches and if pressure is more, it break the tablet and less pressure cause incomplete compression of tablet.

Personnel and hygiene: Persons works in industry are well qualified and trained. TO prevent the contamination personnel follow all disinfection process. And cleaning of equipment must be noticed. The storage area and walkways should be cemented to minimize the risk of spreading impurities.

CONCLUSION

Human error reduction through effective research and application of the learning model, SOP Implementation, Production of high-quality pharmaceutical products, and Aid Industry to implement restrictions from Moving Beyond Retraining as FDA Response (RIFs) good and acceptable.

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