LOGFILE Feature 34/2020

Inadequate Handling of Deviations: The Cause "Human Error"

Shortened excerpt from the GMP Compliance Adviser, Chapter 21.C Frequent deficiencies in GMP inspections, their recurring pitfalls and how to avoid them

by Lea Joos

The deficiency

In the case of the deviation inspected, it was found that the batch number, which had to be manually transferred to the product before production started, was not correctly transferred to the product. The cause was found to be a "human error" in the manual transfer of the batch number during the root cause analysis. An evaluation of possible technical or organizational causes for the "human error" was missing. The evaluation was also missing for the third deviation of this type in the last three months.

(Ref.: EU GMP Guide Part I No. 1.4 xiv)

That was the problem

The faulty transfer of the batch number before the start of production was attributed to the human factor without a more detailed analysis of the cause. Due to the manual transfer, the cause "human error" was obvious: an employee had obviously transferred the batch number incorrectly.

However, according to EU GMP Guide Part I No. 1.4 xiv, the so-called "human error" should be handled very carefully and should only be recorded as the cause if other technical, process-related, system-related or organisational causes could be excluded.

The extent to which the transfer error was due to other causes of a technical or organisational nature was not verified by the company in the present case. The "correctness" of the assumed cause was not checked even after the third deviation of this type within the last three months. For each of these deviations, the human error was found to be the cause. As a preventive measure, the employee concerned was given follow-up training.

At the latest, however, a recurrence of a deviation should lead to a questioning of an initially identified cause. If one employee makes the same mistake again and again or several employees make the same mistake, the causes may actually lie in the process or in the process flow.

This is the most common pitfall

For the practical implementation of the root cause analysis, the instructions of the companies often do not contain very many specifications - except that the "most probable" cause must be identified. Subjectively, the most probable cause can sometimes be found very quickly – often it is the "human error". However, such "snapshots" are initially only subjective assumptions - even if they usually do not come from one person alone. They must be further questioned, checked and verified.

To avoid this error

There are several methods that can be used to analyze the cause of a deviation. However, it does not always require "elaborate" diagrams to penetrate to the necessary depth within the framework of a root cause analysis.

When analysing the causes, imagine that you have an inquisitive child next to you who keeps bugging you with the question "why?":

- Child: "Why did the employee transfer the batch number incorrectly?"
- You: "Because the employee could hardly recognize the batch number on the instruction document."
- Child: "Why could the employee hardly recognize the batch number on the instruction document?"
- You: "Because the instruction document can only be on the side table at the time of transfer and is therefore relatively far away from the employee."
- Child: "Why is the document so far away?"
- You: "Because the instruction documents cannot be placed on the work table for reasons of hygiene."
- With this "child's play" questioning method, you can get closer to the actual cause relatively easily, as shown once again in Figure 1:

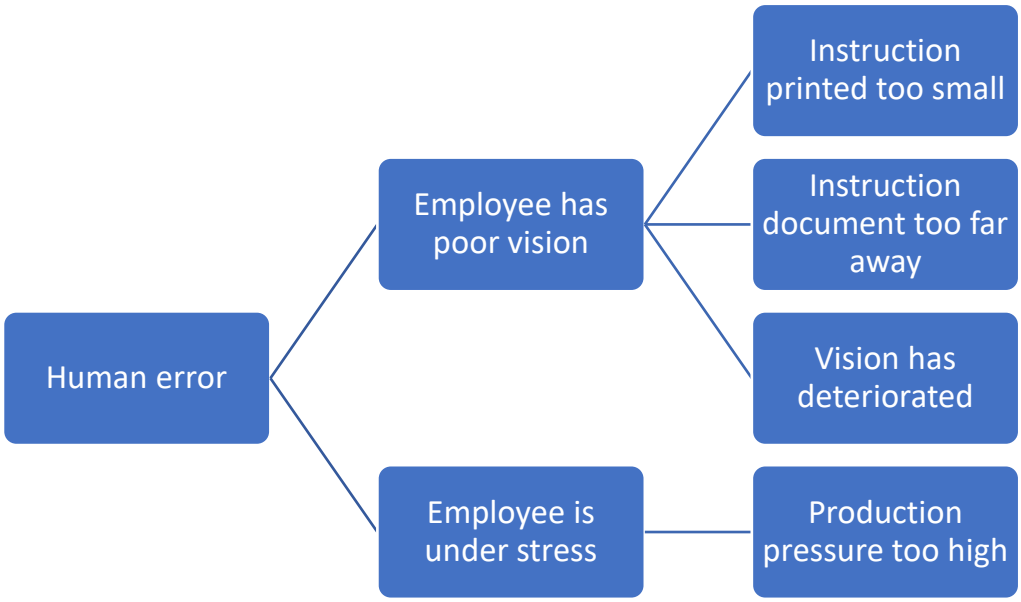

Figure 1 "Child's play" cause analysis using "why" questions. Each connecting stroke stands for a "why" question.

After the fifth "why?" you may be very annoyed by your child's counterpart, but you are much closer to identifying the most likely cause: you may have noticed that the deviation could have been caused by an unfavorable work routine. But even this is still a guess and has to be verified by checking, depending on the type and severity of the deviation. In this case, the possibilities of such verification are limited, since only the employees can be questioned or the effectiveness of previous corrective and preventive measures can be verified

For the processing of deviations it is important that both parts of the root cause analysis are included:

- Detailed root cause analysis and
- Testing the hypothesis of the presumed cause.

Only when you have found the most likely cause of the deviation can you take effective action. Using the example of the transfer of the wrong batch number, this means: only if you find out that the wrong transfer of the batch number is caused by the fact that the instruction document is too far away from the transferring employee, you can reorganize the workflow and place the instruction document in a different, more visible location to make it easier for employees to transfer the batch number manually.

If you generally assume the "human error" as the most probable cause and derive the employee's retraining from this, he or another employee will make the mistake again. The same is true if you identify a wrong cause: if you come to the conclusion during the root cause analysis that the employees' vision is impaired and you advise the employees to see an ophthalmologist, the error will probably occur again as long as the specification document is too far away and cannot be seen easily.

Conclusion:

In order to avoid a recurrence of a deviation according to EU GMP Guide Part I No. 1.4, it is necessary to identify the actual cause and to eliminate the cause with the correct measures.

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