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Smart Deviation Management – Vision or Reality?

by Felix Tobias Kern, PhD and Liwa Schneider

The GMP-compliant and timely management of deviations is very often addressed in audits. One reason for this is that deviations reveal gaps in the defined quality systems or indicate that they have not been set up correctly.

The regulatory requirements for deviations present themselves like a patchwork quilt. In Chapter 1 of the EU GMP Guidelines, we find both the requirement for **complete recording** and **investigation of the deviation**, as well as the **resulting corrective and preventive actions (CAPA)** and the **verification of the effectiveness** of these actions. In addition, the Code of Federal Regulation (21 CFR 211.192) contains the requirement to produce the **complete batch reference** of the deviation, as well as the preparation of a **written record (conclusion)**. The ICH Q10 Guideline additionally requires a systematic **root cause analysis**.

The most important tasks of a systematic deviation management can therefore be summarised as follows:

- Complete documentation of the deviation and the investigation
- Systematic root cause analysis
- Determination of corrective and preventive actions (CAPA) including success control
- Complete batch reference
- Risk assessment of the deviation
- Written record (conclusion)

From experience, 90 - 95% of the deviations occurring in a manufacturing plant are of low or no risk (minor category) and for a large percentage the points listed above are already known when the deviation is reported.

A technical defect of a piece of equipment due to wear can be listed as an example. Due to the permanent use of a production equipment, a breakage on the surface in contact with the product cannot be completely avoided despite intensive control before batch production. This usually results in a minor cosmetic defect on the surface of the final product with no risk to the patient. Since the occurrence of this deviation is known, the cause, the necessary CAPA measures, and the batch reference of the deviation are also already known. This can already be included in the deviation notification.

The question now is: What is the need for the detailed description of the investigation? Everything that is necessary for the summary and for the risk assessment is already listed in the deviation notification.

In an electronic deviation management system, an investigation would mean opening an additional interface in which the cause, CAPA action, etc. would have to be detailed again. In a paper-based deviation management system it would mean that pages of

paper have to be filled in additionally, although everything is already known.

Another issue is the burden on human resources. The deviation notification is first checked by a QA function, such as a QA manager, and then the associated investigation is opened. The investigation is then prepared by a manager, such as a production manager or a person delegated by him, and forwarded again to the QA function, which again has to check the investigation before writing its own assessment and forwarding this to the QP for review and approval. This means that up to 3 people are involved in the investigation, even though everything is already listed in the deviation notification.

A **smart approach** would be to define a few questions that already need to be clarified in detail by the deviation notification. Examples:

- Is the cause known?
- Have CAPA measures already been implemented and are they sufficient?
- Is the batch reference known?
- Is there no risk for the batches or/and for the continuation of the process?
- Has the deviation already been considered in the context of a risk management and has it been classified as acceptable?

If these questions have already been clarified, it is possible that the QA function itself already writes the summary and closes the deviation without investigation. It is not necessary to include the QP as an approval function. He or she will review it during the final release.

Summary:

With this smart deviation management approach described above, it is possible to close a high percentage of deviations directly after reporting (time requirement approx. 30 - 60 minutes) and fewer personnel resources have to be used. Thus, a company can focus more on the critical deviations and is not burdened with unnecessary documentation.

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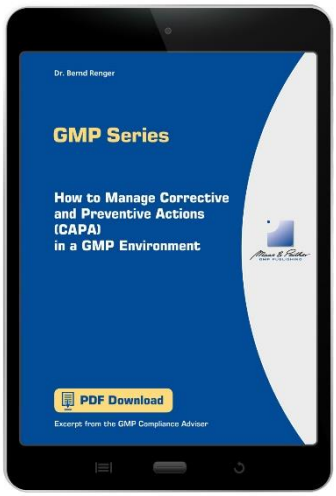

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