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How to Maintain the Qualification Status of Your Equipment

The life cycle of an equipment begins with initial qualification and ends with decommissioning. Once a qualification status has been achieved, it must be guaranteed over the entire life cycle until the equipment is decommissioned. This is ensured by regular calibration, maintenance, effective change management and periodic review.

Since Annex 15 of the EU GMP Guide does not provide detailed requirements for measures to check and, if necessary, restore the qualification status, each company should regulate how it deals with this issue, e.g. in a validation master plan or in a standard operating procedure (SOP).

Periodic Review

According to Annex 15, Section 4.1, it should be evaluated at an appropriate frequency (periodically) whether the equipment remains in a qualified condition. This examination can take the form of a review. On the one hand, such a review is a good preparation for requalification, but it can also be used to check the qualification status with regard to upcoming audits or inspections. Furthermore, the review is a good means of checking the quality assurance systems. The most important contents of a periodic review are:

Calibration

The review checks whether the calibration has been performed regularly according to the specified calibration interval. Special attention must be paid to whether warning and/or tolerance limits have been exceeded or whether trends can be detected. If necessary, changes to the calibration interval or the warning or tolerance limits are derived from this review.

Maintenance

The reports of maintenance and repairs are reviewed and evaluated with regard to possible effects in relation to the qualification status. Maintenance must have been carried out regularly according to the defined maintenance type. Attention must be paid to trends, e.g. frequent occurrence of certain defects. If necessary, changes to the maintenance interval are derived from this review.

Logbook

The documentation of the logbook is checked with regard to technical problems and trends. Observed technical deficiencies must have led to adequate measures in the past.

Deviations

The deviation reports on the operation of the equipment are evaluated with regard to defect trends. A possible influence of the occurred deviations on the qualification status is evaluated. The aim is to identify systematic defects.

Changes

Whereas major changes usually result directly in requalification measures as part of the change procedure, this can often be dispensed with in the case of so-called minor changes (e.g. in the case of replacement of components of the same type as part of maintenance activities). Nevertheless, the sum of multiple minor changes over time can have a significant influence on the overall system. During revision, series of minor changes that have not led to requalification are evaluated in their entirety with regard to their influence on the qualification status.

Risk analysis

The risk analysis is discussed again and revised if necessary. This is done by the qualification team on the basis of the operational experience gained since the time of initial qualification and on the basis of the knowledge gained during the review.

Qualification documents

It is checked whether the existing qualification documents meet the current requirements (internal/external regulatory requirements, state of science and technology). It is also checked to what extent the working range (range of process parameters) within which the equipment is currently used may have changed. A possibly revised risk analysis must be covered by the existing qualification, if necessary test plans must be newly created and processed.

Technical documentation

As part of the life cycle concept, documents must always be kept up to date. This includes, for example, flow diagrams and specifications.

Business continuity

In the case of critical processes, it must be ensured in accordance with Annex 11 of the EU GMP Guide that the processes are adequately fail-safe. Regular checks must be carried out to ensure that fail-safety is guaranteed in accordance with the criticality of the process.

The reviews conducted and their results are documented and evaluated in the review summary report. The overall assessment may conclude with the following results:

- The equipment is still in a qualified condition. A requalification is not necessary.
- The equipment can continue to be operated. The deviations identified have been assessed and remedied or are being worked through via deviation management.
- The equipment is placed in qualification quarantine until the identified deviations/defects have been remediated. For this purpose, the defects are classified in terms of their criticality as critical, major or minor. The order of

correcting the defects is to be derived from this listing.

Periodic requalification

According to Annex 15, Section 4.2, it may be necessary to perform a periodic requalification. The time interval and the criteria leading to requalification shall be documented. It must also be taken into account that minor changes occur over time.

This procedure is often used when minor changes are frequently made, to show that the equipment is still qualified. This can be useful for air conditioning systems, for example. For systems that are subject to an aging process, such as refrigerators, regular temperature mapping can be useful to show that seals and cooling medium do not promote drift in the cooling results. This temperature mapping corresponds to a requalification.

The text is a translated and edited excerpt from the online knowledge portal GMP:KnowHow Equipment Qualification which is available in German language.

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