DETERMINATION OF THE CALIBRATION INTERVAL OF QUALITY CONTROL EQUIPMENT

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Introduction

For the production of effective and safe medicines, it is necessary to comply with the rules of Good Manufacturing Practices (GMP). Equipment calibration is an essential requirement for GMP maintenance. Calibration consists of a set of verification and adjustment operations to certify that the equipment works within its limits of precision and accuracy [1].

The correct adjustment of the calibration interval allows the equipment to be used according to its operational performance, avoiding wear, damage and underutilization In addition, it also allows the optimization of expenses with calibration services [2].

The objective of this work is to apply calibration interval adjustment methods to determine the periodicity of calibration of Quality Control equipment in a Pharmaceutical Industry.

Material and Methods

The Quality Control equipment that could be calibrated was identified and their respective calibration certificates were collected. After this step, the A1 calibration interval determination method was applied. This method is based for its development on the current calibration status of the equipment. In this study, the sampling used comprises the calibration certificates for the period 2018-2021, thus the current calibration status corresponds to the results available in the calibration certificates for the year 2021.

The purpose of method A1 is to verify if the deviations presented in the calibration tests are within the established tolerance limit. According to this method, the equipment can increase the current calibration interval by 10%, if the instrument presents deviations within the tolerance, or the calibration interval can be reduced by 45%, if the instrument is out of tolerance [3,4]. The tolerance limit for each equipment was obtained from the current metrological standard for each class/type of equipment (mass, pressure, temperature). The error of each equipment was calculated through the average of the trend values found in the calibration tests. After applying the A1 method, the A2, A3 and Shumacker methods will be applied.

The results obtained in the application of these methods will be compared and will be used to determine the new calibration intervals of the equipment.

Results and Discussion

The 42 Quality Control equipment that could be calibrated were identified. The calibration certificates for these equipment, for the period 2018-2021, were collected in the technical quality documentation files and separated by equipment and year to facilitate subsequent analyses. Of these 42 quality control equipment listed for carrying out this work, 36 present the calibration certificate for the year 2021. The partial results of the application of the A1 method in 10 of the 42 equipment showed that these equipment can have the calibration interval increased by 10 % over the current range. Thus, these equipments can have their calibration frequency changed from 365 days to 401 days. The 10 pieces of equipment used to start the application of the A1 method were chosen because they are equipment that is widely used in the Quality Control laboratory and of great importance for carrying out the analyses.

Conclusion

The partial results obtained in the application of the A1 method demonstrated that the calibration intervals of the 10 equipments can be optimized. The A1 method will be applied to the equipment remaining and upon completion the A2, A3 and Sumacher methods will be applied. The results obtained will be compared and a new calibration frequency will be defined for each of the Quality Control equipment.

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