Summary - Documentation Example for Continuous Quality Verification

Continuous Quality Verification (CQV) is an alternative approach to process validation. Documentation for a process may include some or all of the content described here, depending on the nature of the process. Other documentation may also be needed to support a CQV approach.

The process: A granulated drug product mixture is dried using a fluid bed dryer. Air is passed through the mixture to remove moisture, providing a mixture for compression into tablets.

Process Understanding documentation for this process includes a brief description of a process to dry a granulated drug product mixture, such as that described below.
The product is dried with a fluid bed dryer, which uses a through-the-bed flow pattern with air passing through a distribution plate and into the drying chamber, where it lifts the granular product and maintains the granules in a fluidized state. This bed of granulate particles displays fluid-like properties like that of a liquid. This fluidization provides intimate contact between particles and the warm (about 40 ^{o}C) air stream, providing an efficient means of transferring moisture away from the product particles.

While air flow, and temperature are considered potential critical process parameters (CPPs) for this operation, monitoring with NIR provides superior control and permits relaxation of time and temperature limits. Air flow and drying temperature must still be controlled within reasonable limits to reduce process variability in terms of the time needed for the drying operation. However, continuous monitoring with NIR, while not itself an operating parameter, is identified as the critical process control necessary to insure consistently meeting the product's moisture CQA.

A plan should be established for the analysis of process trends. This plan should include a recommendation for the appropriate frequency for evaluation of process trends and what data should be reviewed.

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