Summary - Process Validation for Drug Products and Medical Devices

This GMP guideline provides guidance in the validation of manufacturing process for drug products and medical devices.

Critical Process Parameters -rationale for defining the critical parameters of a process should be documented, including Probable Adverse Consequences to be expected when critical process parameter ranges are not met.

Brief description of product, including product name, dosage form, and strength where applicable; critical processing steps to be evaluated and critical parameters to be monitored; specifications);

- The number of consecutive successful validation batches/lots needed to show consistent control of the process.

- Equivalency to existing drug products (where applicable) by comparison to previously produced batches/lots (commercial, development, or biobatches).

- Requirements to conduct homogeneity and hold time studies, if applicable;

Critical process parameters and operating ranges, including justification for these (e.g., one-time studies on validation batches/lots using portable equipment, measuring equipment).

Representative samples should be drawn after critical process steps (e.g., freeze
- Number of specific drug product strengths;
- Number of drug product batch/lot sizes involved;
- Critical quality attributes;
- Critical process parameters; and
- Batch/lot size effects on equipment or processing capability.

Consistency should be demonstrated among the results of validation batches/lots. development or carried out in conjunction with process validation batches/lots and documentation describing changes to the protocol;
- Test results;
- Review of critical process parameters from batch/lot production records; development, or biobatches), where applicable;
- Batch/lot processing and packaging records;
- Process control charts;
- Change control records (e.g., process equipment, facilities, and utilities);
- Process performance (e.g., capability studies); and

Major Changes - examples of major changes to an established process that require
- Changes in the acceptable range of a critical process parameter or a planned shift impact product quality;
- Fundamental change to manufacturing process or technology

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