Summary - Release for Commercial Use of Drug Product Validation Batches

Batches of product manufactured prior to completion of PV activities may be released for commercial use following verification of acceptable results for all tests, verification that the acceptance criteria have been satisfied, the critical process parameters, ranges and materials used are the same as the proposed commercial manufacturing process and fulfilment of other site requirements for product release as necessary. Release for commercial use will require satisfactory completion of the validation study for that process, ensuring that the recommendations described in this bulletin are met for these pre-validation batches.

Product batches manufactured prior to completion of PV activities may include Demonstration (demo) batches, sometimes called 'proof of concept' batches, pre-validation batches, or engineering batches. These are typically manufactured for the purpose of examining a new process or a process with a significant planned change that requires revalidation, to insure that the process operations are understood and work as planned before beginning production of validation batches.

The process used must be within processing conditions allowed by the approved product registration, unless the validation activities include, or are as a direct result of changes to registered processing conditions. The requirements for Product Change Management system should be followed. Once registration approval has been received, the recommendations of this guidance can apply to the new manufacturing process.

The scope of a validation project can vary in many ways. The decision to approve and release product batches prepared for the validation study should be made only after review of relevant data and verification that the required acceptance criteria have been met. Depending on organization of validation protocol(s) prepared for a process, there may be different points in the production process where evaluation of data and verification of meeting acceptance criteria are needed.

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