

instances, for example, orphan drug or low volume products, an interim PV report may be acceptable. The following list summarizes conditions that should be satisfied or reviewed for suitability, prior to release of such batches for commercial use:

- If a Prospective Validation approach is used, the manufacturing process validation is complete and a summary validation report has been approved. For Concurrent validation, an interim report should be approved.
- 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.
- Processing of the batches must have met all site GMP requirements.
- The qualification status of supporting systems (utilities, facilities, etc.) used to manufacture the pre-validation batches has been assessed in terms of their suitability.

Qualification of Systems used to manufacture the pre-validation batches should be completed prior to the release of pre-validation batches for commercial use. Exceptions to this must be approved.

- The batches were prepared according to pre-approved, documented work instructions by trained personnel. For Drug Product, pre-validation batch manufacturing is typically conducted using a pre-approved protocol, detailing the purpose of the activity. For APIs, an approved Master Record is sufficient.
- The batches were manufactured according to a process that is supported by the PV. Any changes in process, supporting systems (e.g. equipment, facilities, utilities), or scale between the pre-validation batch (es) and the subsequent validation batches should be minor. A discussion of any such changes and their impact should be documented when considering a demo batch for commercial release.
- There were no significant deviations during the preparation of the pre-validation batches that affect product quality and that were related to the process. Deviations that occur during the manufacturing of pre-validation batches shall be evaluated for their impact on the validation exercise.
- All critical parameters identified and monitored during PV were also monitored during the manufacture of these pre-validation batches and were within approved limits.