

HUMAN DRUG CGMP NOTES

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Has FDA established a required number of runs to be performed during Operational Qualification (OQ) testing? If a firm qualifies one type and model of equipment, can it be used in a different process without additional qualification?

Reference: [21 CFR 211.100](#), Written procedures; deviations; May 1987, [Guideline on General Principles of Process Validation](#)

Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ), along with other similar terms, are commonly used in the pharmaceutical industry to discuss the generally accepted concept that a firm should *qualify* equipment and systems as part of *validating* a manufacturing process. The FDA Guideline on General Principles of Process Validation does not use the term Operational Qualification. It defines Installation Qualification as establishing confidence that process equipment and ancillary systems are capable of consistently operating within established limits and tolerances. This includes IQ and OQ. The FDA Guideline also defines Process Performance Qualification as establishing confidence that the process is effective and reproducible.

The guideline states that "*it is important that equipment qualification simulate actual production conditions, including those which are 'worst case' situations,*" and that "*tests and challenges should be repeated a sufficient number of times to assure reliable and meaningful results.*"

Regarding the first question, the often-cited "three consecutive batch" recommendation is intended for process validation rather than for equipment qualification. FDA has not recommended any specific number of "runs" for equipment qualification, but expects multiple tests to simulate actual operating ranges and to establish consistency.

As to the second question, FDA expects Installation Qualification on each piece of equipment to document that it is installed correctly and operates consistently according to

established limits and tolerances. Operational Qualification should also be performed for each different use of the equipment or system to document the suitability for that use, but would not be required for additional pieces of the same type/model of equipment when used in the same process. Process Performance Qualification would also not be required for each piece of the same type/model of equipment used in the same process, provided installation qualification has been performed.