



Glossary of Validation Acronyms	
IQ	Installation Qualification – Documented evidence that the equipment has been installed per the manufacturer’s requirements. Often coupled with an OQ.
OQ	Operation Qualification - Documented evidence that the equipment operates per the manufacturer’s specifications and includes maintenance requirements. Often coupled with an IQ.
I/OQ	Installation/Operation Qualification - A compilation of the IQ and OQ, often performed simultaneously on a recently installed piece of equipment. Also written as IQ/OQ.
PQ	Process Qualification – Documented evidence that a process will provide predictable results. This is often a challenge of a given range of process parameters.
PPQ	Product Performance Qualification – Documented evidence when employing specifically defined operational and manufacturing criteria that a product can be manufactured repeatedly and reliably using a qualified process. This qualification is typically performed over multiple production lots under a variety of conditions, such as day/night shifts and/or including tear down and set up of the process.
DOE	Design of Experiments – An engineering and statistical tool used to identify critical process parameters, their acceptable ranges and their interaction with other process parameters.
FMEA	Failure Mode and Effects Analysis – A documented analysis developed by a cross-functional team to identify and rank potential failure modes of a process/product based upon the severity, rate of occurrence and detectability of the identified failure modes.
MSV	Manufacturing Software Validation – Documented evidence that the process specific software used to perform a task (or multiple tasks) will provide predictable results.
Gage R&R	Gage Reliability and Repeatability – A documented blind test performed on a gage using multiple inspectors and samples to determine the inherent variability in the measuring technique.
TMV	Test Method Validation – A validation of an inspection method for a particular application. The TMV may include multiple gage R&Rs or reference to them.
DMR	Device Master Record – A document that summarizes all documentation relating to the device, production process, packaging and labeling specifications, quality assurance and maintenance procedures and methods.
DHR	Device History Record – The complete record of all production lots of a particular item. It can also be the combination of all information of multiple components making a device or package. In the case of a single component where the entire production was made in one production lot, DHR may be synonymous with Lot History Record.
LHR	Lot History Record – The compilation of documentation of a particular production lot. The LHR may include documentation of the processes (the job router), the material certifications, the certification of outside processes, the finishing certifications and the lot inspection records, including in-process and final inspections and any other quality assurance documents pertinent to that particular lot.
cGMP	(Current) Good Manufacturing Practices – The guidelines of the FDA.
FDA	Food and Drug Administration of the United States of America – A governing body that certifies NNI’s quality system to Federal Register Quality System Register 21 CFR Part 820.
ISO	International Organization of Standards – A governing body that certifies NNI’s quality system to ISO 13485:2003 and ISO 9001:2008.
GHTF	Global Harmonization Task Force – A conglomeration of industry leaders that aid in interpretation and implementation of the various governing body’s requirements.