Validation: IQ, OQ, PQ

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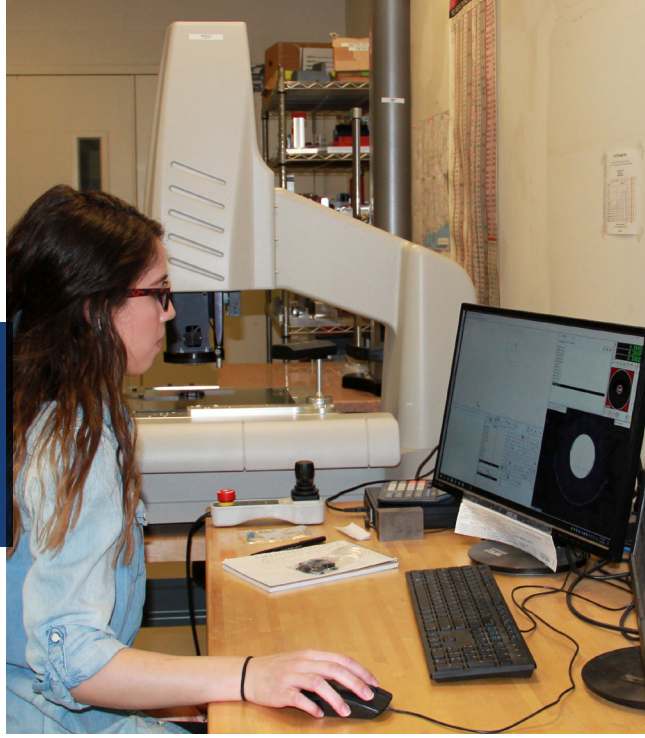

Programming and utilizing Micro-Vu measurement system for quality assurance

All products and processes need validation when verification cannot be identified in the process output by monitoring or measuring. These types of validations are performed to reduce production costs and ensure regulatory requirements are met.

Installation Qualification, Operation Qualification and Performance Qualification (IQ, OQ, PQ) are requirement-based methods that facilitate the validation of a process before it is placed within a target environment. In the medical community, the primary regulatory body is the FDA which requires all medical device manufacturers perform a detailed IQ, OQ, PQ validation to fully verify each process.

IQ validation ensures that the facility and all equipment used to manufacture, measure and test the product is installed, maintained and calibrated as required. Additionally, this validation provides the opportunity to benchmark specific installation and process conditions over the life of the molding program. For example, if a process is not yielding the same dimensional stability after multiple runs, the problem could be attributed to water flow, different styles of nozzles or tips, or the use of different equipment. These deviations can contribute to process and dimensional variation as well as part instability. Documenting the initial installation settings allows for quick identification of the root cause of rejects.

OQ validation verifies key performance components of a product or process without taking into consideration the cumulative effects introduced within the environment during testing. Through the use of analytical processes, statistical/ dimensional evaluations, and engineering studies, this validation can establish the appropriate operating limits of varied process parameters to meet requirements of the end product.

A Process Failure Mode Effects Analysis (PFMEA) is a tool used to identify the potential failures in the process from procurement of material to shipment of product. Each potential failure is assigned a Risk Priority Number (RPN) which assists the molder to narrow in on the problem areas of the process. In addition to the high-risk variables, a molder will also use the specifications of the materials, molding press characteristics, and part geometry to choose the process parameters to vary during OQ validation.

An OQ protocol outlines what will be tested throughout the run - including the number of samples. After completing gate freeze and viscosity studies, the different combinations of those pre-determined parameters are tested in a Design of Experiment (DOE) and the parts are delivered to the Quality Department assuming all cosmetics are acceptable.

A complete First Article Inspection (FAI) is an essential piece to OQ validation and determines whether all aspects of the tool are correct. A capability study is also essential and performed on all customer-identified critical to functional dimensions. A common target Cpk is 1.33 to ensure the process yields repeatable parts from setup to setup and is centered within the print specification limits. If it is determined that parts do not meet a Cpk of 1.33 or better, the molder may choose to re-execute OQ validation by narrowing the process parameters or revise the print specifications to account for the actual results of the molded parts.

PQ validation demonstrates that the process is stable and dimensionally capable and the molded part meets the customer's expectations. Typically, PQ is accomplished by running the defined process through three separate runs. These runs are a simulation of three separate production runs with a shutdown period between each run. If the PQ is unsuccessful and the molded part does not meet customer expectations, the root cause needs to be evaluated and the two parties must work together to define and accept a resolution.

Validation is a method of establishing documented evidence that proves a high degree of assurance that the manufacturing process will consistently yield a product of pre-determined quality. The business approach that integrates validation touches many areas of a company. At PTA Plastics, our commitment to the process is essential to success.

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