White Paper

Process Validation Is Vital To Success

Process validation plays a critical role in ensuring medical devices and other products for various industries meet stringent regulatory and quality requirements. Process validation goes beyond compliance; it helps reduce costs and scrap, improve quality and consistency, shorten time-to-market and increase customer satisfaction. Working with an experienced plastic injection molder that is well versed in process validation, like Manar, Inc., is vital to the success of your product.

WHAT IS PROCESS VALIDATION?

The purpose of process validation is to provide documented evidence that a manufacturing process is properly defined, controlled and capable of consistently producing a product or part to specification prior to beginning production runs. A process that has been subjected to rigorous scrutiny can virtually guarantee the end result. It is especially important if predetermined requirements of the product can only be assured by destructive testing.

COMPLEXITIES

Medical device and other manufacturers are obligated to establish and maintain procedures for monitoring and controlling parameters for validated processes. This can be conducted in numerous ways due to significant variations in manufacturing complexities, production volumes and costs.

DESIGN VALIDATION

Design validation ensures that the product or part meets user needs and intended uses, a responsibility that falls on the device owner. In contrast, process validation focuses on the consistent and reliable production of the device or component.

BENEFITS OF PROCESS VALIDATION

- Meet stringent regulatory requirements
- Risk mitigation
- Improve quality and consistency
- Reduce costs
- Minimize scrap
- Shorten time to market
- Improve customer satisfaction

+1 812-526-2891| sales@manarinc.com | manarinc.com

White Paper

Process Validation Is Vital To Success

Following design validation, there are three phases of process validation — IQ, OQ and PQ — to ensure that every new or modified process meets rigorous standards for quality and reliability.

INSTALLATION QUALIFICATION (IQ)

The initial qualification of critical manufacturing equipment, molds and measurement tools.

- Verification of installation and calibration certificates.
- Documentation of setup, utility connections and environmental conditions.
- First Article Inspection: Initial inspection of parts for dimensional accuracy and visual standards.

OPERATIONAL QUALIFICATION (OQ)

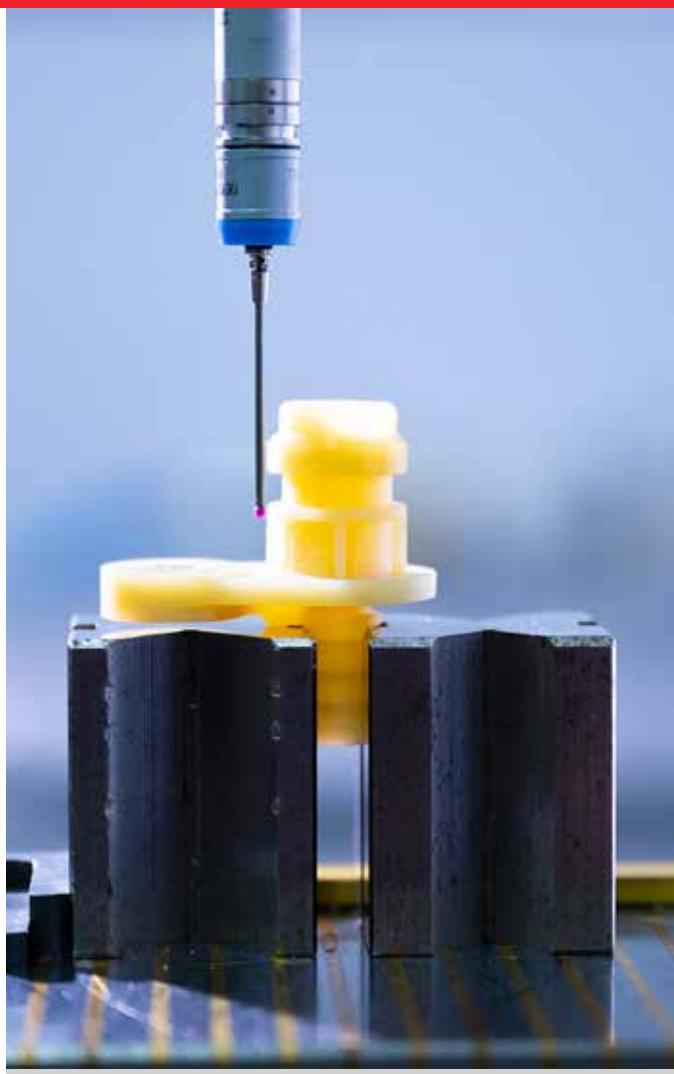
OQ validates that equipment operates consistently across predefined ranges. It involves short production runs at both high and low process setpoints to simulate worst-case scenarios.

- **Window Studies:** Capability analysis across various parameters.
- **Gauge Repeatability and Reproducibility:** Ensuring the measurement system is accurate.
- **Capability Index (Cpk) Requirements:** Minimum of 1.00 Cpk to confirm reliable operations.

PERFORMANCE QUALIFICATION (PQ)

PQ ensures that the process consistently produces quality products under actual production conditions. This phase involves multiple long production runs, testing for variations in materials, operators and machines.

- Three production runs at nominal settings to confirm repeatability.
- Multiple machines, material lots and operators to simulate real-world variability.
- Final Capability Analysis: Cpk of at least 1.33 required to pass validation.
- Visual requirements per print or other relevant specifications are also verified.



ISO 13485 REQUIRES

"The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement."

+1 812-526-2891| sales@manarinc.com | manarinc.com

White Paper

Process Validation Is Vital To Success

Documentation of validation activities and results are reviewed and approved by the manufacturer and the customer. The date of final approval signifies that production can officially begin.

Process validation is essential for delivering safe, high-quality products to the market. With a proven track record and expertise in scientific molding, Manar, Inc. helps clients meet regulatory requirements while minimizing risks and improving efficiency. Our employee-owners blend plastic injection molding expertise, flexibility, innovation and advanced technology to steer your business and products to success. Choose Manar as your partner for process validation and manufacturing — because compliance is just the beginning.

LET'S VALIDATE YOUR SUCCESS

Manar, Inc. is committed to delivering high-quality plastic components and assemblies with precision and speed. Whether you're launching a new medical device or improving existing products, Manar's team is ready to help you achieve your goals with robust process validation protocols.

ILLUMINATING YOUR JOURNEY. A SAFER PATH.

By choosing Manar as your manufacturing partner, you benefit from:

- **Extensive Industry Experience:** We support medical, automotive, electronics and other industries.
- **Scientific Molding Expertise:** Every process is optimized for precision and reliability.
- **Customer-Centric Approach:** We collaborate closely with your team, offering tailored solutions to meet your needs.
- **Advanced Quality** Management: Compliance with ISO 9001:2015, ISO 13485:2016 and IATF 16949:2016.

+1 812-526-2891| sales@manarinc.com | manarinc.com